Rehabilitation Reference Manual
Tab Index

Table of Contents 1

Section One: General Information
Introduction 2
Principles of Documentation 3

Section Two: Comprehensive Outpatient Rehabilitation Facilities (CORFs)
Introduction to Comprehensive Outpatient Rehabilitation Facility Survey 4
State Operations Manual Excerpts Pertaining to CORFs 5
CORF Survey Process 6
Forms for CORF Survey 7
References for CORF Survey 8
CORF Survey Deficiency Documentation 9

Section Three: Outpatient Therapy Facilities (OPTs)
Introduction to Outpatient Therapy Facility Survey 10
State Operations Manual Excerpts Pertaining to OPTs 11
OPT Survey Process 12
Forms for OPT Survey 13
References for OPT Survey 14
OPT Survey Deficiency Documentation 15

Section Four: Inpatient Rehabilitation Facilities (IRFs)
Introduction to Inpatient Rehabilitation Facility Survey 16
State Operations Manual Excerpts Pertaining to IRFs 17
IRF Survey Process 18
Basic Hospital Surveyor Training Modules: IRFs 19
Forms for IRF Survey 20
References for IRF Survey 21
IRF Survey Documentation 22

Section Five: Critical Access Hospital Rehabilitation Distinct Part Units (CAH DPUs)
Introduction to Critical Access Hospital Rehabilitation Distinct Part Units 23
State Operations Manual Excerpts Pertaining to CAH Rehabilitation DPUs 24
CAH Rehabilitation DPU Survey Process 25
Forms for CAH Rehabilitation DPU Survey 26
References for CAH Rehabilitation DPU Survey 27
Survey Documentation for CAH DPUs 28

Rehabilitation Reference Manual

Authors:

Captain Georgia A. Johnson, MA, OTR/L
Centers for Medicare & Medicaid Services
Centers for Medicaid & State Operations
Survey & Certification Group
Division of Continuing Care Providers
Central Office

Ginger Odle, PT, MS
Centers for Medicare & Medicaid Services
Division of Survey & Certification
Dallas Regional Office

Patricia Farren, PT, MPH
Centers for Medicare & Medicaid Services
Northeast Consortium Division of Survey & Certification
Boston Regional Office

Issued November 2005

Copyright Warning

Training materials produced by the Centers for Medicare & Medicaid Services (CMS) are considered to be in the public domain, except where specific copyrighted works have been incorporated into the material with permission from the copyright holder. Such permission allows CMS to use the material only within the full context of the manual. These materials may include audiovisual materials (photos, slides, films, videos, computer-generated images, illustrations, graphics, audio recordings) and text materials, such as direct quotes or entire reprints. With respect to such copyrighted works, reproducing them is prohibited without permission from the copyright holder.

Foreward

This manual represents a collaborative effort among members of State agencies, Regional Offices and Central Office. We hope you will find the updated materials to be useful whether you are conducting surveys, answering questions from providers or communicating with one another.

This is just the first step in our efforts to provide resource/training materials that can be used in the office, on a survey or at home. We realize that you may have many questions regarding some of the updated material. We have established an email site for questions and answers: Rehabilitation_Mailbox@cms.hhs.gov. Alternatively, you can call Georgia Johnson at 410-786-6859.

We've included Question & Answer sections for the various rehabilitation providers. These questions reflect many of those that are received at both Regional Offices and/or Central Office.

We plan to update the manual on a yearly basis. We realize that there may be materials that we didn't include in this reference manual. In November, 2005, we will begin Phase II of the rehabilitation training program. We hope to develop cost-effective training tools for issues related to rehabilitation providers.

We welcome your comments and suggestions regarding this manual, and we also welcome your suggestions for material you would like to have covered in Phase II.

We hope that you will find the *Rehabilitation Reference Manual* to be helpful in your daily activities, and we look forward to expanding into other rehabilitation training venues.

Acknowledgements

The *Rehabilitation Reference Manual* is a collaborative effort among CMS Central Office, Regional Offices and State agencies. It is designed to enhance the survey process for State surveyors as well as provide updated information regarding rehabilitation provider types for Regional Office personnel. The hardcover copy can be used as a reference tool in offices, and the CD-ROM can be utilized during the survey while the surveyor is onsite.

We acknowledge the following individuals who contributed their valuable time and talents to this project, without which, this manual would still be only an idea.

Initial Development and Design

Patricia Farren, PT, MPH
Centers for Medicare & Medicaid Services
Northeast Consortium Division of Survey & Certification
Boston Regional Office

Captain Georgia A. Johnson, MA, OTR/L
Centers for Medicare & Medicaid Services
Centers for Medicaid & State Operations
Survey & Certification Group
Division of Continuing Care Providers
Central Office

Ginger Odle, PT, MS
Centers for Medicare & Medicaid Services
Division of Survey & Certification
Dallas Regional Office

Debra Reynolds, MA
Instructional Designer & Technical Editor
Remtech Services, Inc. division of CIBER

Carol Zafiratos, MBA, PT, ATC
Director, Health Care Section
Office of Regulatory Services
Georgia Department of Human Resources

Level Two Reviewers

Kenneth Allison
Centers for Medicare & Medicaid Services
Division of Medicaid & State Operations
Denver Regional Office

Lesa Boom
Department of Public Health and Environment
Colorado State Survey Agency

Gina Brown
Centers for Medicare & Medicaid Services
Division of Medicaid & State Operations
San Francisco Regional Office

Cathy Davenport
Centers for Medicare & Medicaid Services
Division of Medicaid & State Operations
Survey & Certification Branch
Denver Regional Office

Captain Marjorie E. Eddinger, RN, MS, CLNC, CNA
Centers for Medicare & Medicaid Services
Centers for Medicaid & State Operations
Survey & Certification Group
Division of Continuing Care Providers
Central Office

Patricia Farren, PT, MPH
Centers for Medicare & Medicaid Services
Northeast Consortium Division of Survey & Certification
Boston Regional Office

Michelle Griffin, RN, JD
Centers for Medicare & Medicaid Services
Division of Survey & Certification
San Francisco Regional Office

Barbara Hansen
Centers for Medicare & Medicaid Services
Survey & Certification Group
Seattle Regional Office

Marialice Hawkins, OTR/L
Los Angeles County Department of Health Services
Nursing Home Licensing
California Health Facilities Inspection Division

Ron Ho
Centers for Medicare & Medicaid Services
Division of Medicaid & State Operations
San Francisco Regional Office

Craig Jimerfield
Texas Department of State Health Services
Health Facility Compliance
San Antonio Group

Captain Georgia A. Johnson, MA, OTR/L
Centers for Medicare & Medicaid Services
Centers for Medicaid & State Operations
Survey & Certification Group
Division of Continuing Care Providers
Central Office

Kim Kalil
Centers for Medicare & Medicaid Services
Western Consortium
Survey & Certification Branch
Denver Regional Office

Catherine (Kate) Mitchell
Centers for Medicare & Medicaid Services
Survey & Certification Group
Seattle Regional Office

Lynette Mitchell
Centers for Medicare & Medicaid Services
Survey & Certification Group
Seattle Regional Office

Ginger Odle, MS, PT
Centers for Medicare & Medicaid Services
Division of Survey & Certification
Dallas Regional Office

Debra Reynolds, MA
Instructional Designer & Technical Editor
Remtech Services, Inc. division of CIBER

Kari Roosenberg, OTR/L, CHT
California Department of Health Services
Licensing and Certification Program
San Diego North District Office

Maelin Yee, OTR/L
California Department of Health Services
Licensing and Certification Program
Headquarters

Carol Zafiratos, MBA, PT, ATC
Director, Health Care Section
Office of Regulatory Services
Georgia Department of Human Resources

Rehabilitation Reference Manual

Tab 1: Table of Contents

Table of Contents

Tab

Table of Contents 1

Section One: General Information

Introduction 2
- 2.1 Using the Reference Manual
- 2.2 Comparison Table
- 2.3 Survey Highlights
- 2.4 Abbreviations and Acronyms
- 2.5 General Online Resources
- 2.6 Coverage Issues

Principles of Documentation 3
- 3.1 *State Operations Manual* Exhibit 7A, *Principles of Documentation*

Section Two: Comprehensive Outpatient Rehabilitation Facilities (CORFs)

Introduction to Comprehensive Outpatient Rehabilitation Facility Survey 4
- 4.1 Introductory Comments
- 4.2 Skills Checklist: CORFs

State Operations Manual Excerpts Pertaining to CORFs 5
- 5.1 Appendix K (Draft)
- 5.2 Sections 2360–2366
- 5.3 Section 3224

CORF Survey Process 6
- 6.1 CORF Survey Process
- 6.2 Q&A

Form for CORF Survey
- 7.1 Form CMS-360 7

References for CORF Survey 8
- 8.1 *Code of Federal Regulations*
  - 42 CFR 410.100–105
  - 42 CFR 485.50–74
- 8.2 Survey & Certification Memoranda
- 8.3 Social Security Act, Section 1861(cc)
- 8.4 *Medicare Benefit Policy Manual,* Chapter 12
- 8.5 CMS Program Memorandum Transmittal AB-02-183 (2002)
- 8.6 Other Print and Online References

CORF Survey Deficiency Documentation 9
9.1 Examples
9.2 Survey Tool: CORFs

Section Three: Outpatient Therapy Facilities (OPTs)

Introduction to Outpatient Therapy Facility Survey 10
10.1 Introductory Comments
10.2 Skills Checklist: OPTs

State Operations Manual Excerpts Pertaining to OPTs 11
11.1 Appendix E (Draft)
11.2 Sections 2290–2306 (Draft)

OPT Survey Process 12
12.1 OPT Survey Process
12.2 Q&A

Forms for OPT Survey 13
13.1 Form CMS-1893
13.2 Form CMS-381

References for OPT Survey 14
14.1 *Code of Federal Regulations*
42 CFR 410.59–62
42 CFR 485.701–729
14.2 *Federal Register*
14.3 Survey & Certification Memoranda
Review of Plans of Care
Aquatic Therapy
OPT Extension Locations
Updates to the SOM
14.4 Social Security Act, Sections 1861(g) and (p)
14.5 *Medicare Benefit Policy Manual,* Chapter 15
14.6 Other Print and Online References

OPT Survey Deficiency Documentation 15
15.1 Example
15.2 Survey Tool: OPT

Section Four: Inpatient Rehabilitation Facilities (IRFs)

Introduction to Inpatient Rehabilitation Facility Survey 16
16.1 Introductory Comments
16.2 Medical Conditions That Count Towards the 75% Rule
16.3 Skills Checklist: IRFs

State Operations Manual Excerpts Pertaining to IRFs 17
17.1 Excerpts from Appendix A
17.2 Sections 3100–3112

IRF Survey Process 18
18.1 IRF Survey Process
18.2 Q&A

Basic Hospital Surveyor Training Modules: IRFs 19
19.1 42 CFR 482.56, Rehabilitation Services
19.2 PPS Exclusions: Hospitals and Units

Forms for IRF Survey 20
20.1 Form CMS-437A
20.2 Form CMS-437B
20.3 Exhibit 126
20.4 Exhibit 127

References for IRF Survey 21
21.1 *Code of Federal Regulations*
42 CFR 412.20–30
42 CFR 412.600–632
42 CFR 482 Subparts A–D
21.2 *Federal Register*
66 Fed. Reg. 56681–7 (2001)
21.3 Survey & Certification Memoranda
21.4 Social Security Act, Section 1886(j)
21.5 Setting the ODIE System Switch to Receive Data for IRFs
21.6 *Inpatient Rehabilitation Facility – Patient Assessment Instrument*
21.7 Chronic Care Policy Group Memorandum
21.8 Other Print and Online References

IRF Survey Documentation 22
22.1 Examples
22.2 Survey Tool: IRFs

Section Five: Critical Access Hospital Rehabilitation Distinct Part Units (CAH DPUs)

Introduction to Critical Access Hospital Rehabilitation Distinct Part Units 23
23.1 Introductory Comments
23.2 Skills Checklist: CAH DPUs

State Operations Manual Excerpts Pertaining to CAH Rehabilitation DPUs 24
24.1 Appendix W

CAH Rehabilitation DPU Survey Process 25
25.1 CAH Rehabilitation DPU Survey Process
25.2 Q&A

Forms for CAH Rehabilitation DPU Survey 26
26.1 Form CMS-437A

References for CAH Rehabilitation DPU Survey 27
27.1 *Code of Federal Regulations*
42 CFR 410.28
42 CFR 412.25, 29, 30, 600–632
42 CFR 482 Subparts A–D
42 CFR 485.618(d), 647
42 CFR 488.26
42 CFR 489.10(d)
27.2 *Federal Register*
69 Fed. Reg. 28330–1 (2001)
69 Fed. Reg. 49214-222, 49272
27.3 Survey & Certification Memoranda
27.4 Social Security Act, Section 1820(c)(2)(E)
27.5 Medicare Modernization Act, Section 405(g)(1)
27.6 *Inpatient Rehabilitation Facility – Patient Assessment Instrument*
27.7 Other Print and Online References

Survey Documentation for CAH DPUs 28
28.1 Examples
28.2 Survey Tools: CAH DPUs

Rehabilitation Reference Manual

Tab 2: Introduction

2.1 Using the Reference Manual

2.2 Comparison Table

2.3 Survey Highlights

2.4 Abbreviations and Acronyms

2.5 General Online Resources

2.6 Coverage Issues

2.1 Using the Reference Manual

2.1 Using the Reference Manual

The CMS Rehabilitation Reference Manual is intended as a digest of information pertinent to rehabilitation.

CMS provides the manual on CD-ROM to enhance utility and portability. A hypertext table of contents permits the user to access the portion of interest without having to navigate file directories. The user may also browse the file directories. When a document is open in Acrobat Reader, the user may search the contents of a file for a word or phrase.

2.2 Comparison Table

2.2 Comparison Table

	CORF	OPT	IRF	CAH Rehab DPU
Definition	A comprehensive outpatient rehabilitation facility is established and operated ***exclusively*** for the purpose of providing diagnostic, therapeutic and restorative services to outpatients for the rehabilitation of injured, disabled or sick persons, at a single fixed location, by or under the supervision of a physician, and must provide at a minimum, the following services: CORF physician services, physical therapy and social or psychological services.	A rehabilitation agency provides an integrated interdisciplinary rehabilitation program designed to upgrade the physical functioning of disabled individuals by bringing specialized rehabilitation staff together to perform as a team and provide at a minimum the following services: physical therapy or speech-language pathology services and social or vocational adjustment services.	Inpatient rehabilitation facilities are free-standing rehabilitation hospitals and distinct rehabilitation units of acute care hospitals that are excluded from the acute care hospital IPPS. To qualify for such exclusion, rehabilitation facilities must meet two conditions. First, Medicare patients must receive intensive therapy (generally at least three hours per day). Second, 75 percent of each facility's patients must have one of 13 specified medical conditions.	A CAH rehabilitation DPU is a 10-bed distinct part unit which is excluded from the CAH payment system. To qualify as an excluded inpatient rehabilitation unit, the DPU must meet the CoPs in §485.647. In addition, the DPU must meet all exclusion criteria in §412.25, §412.29 and §412.30. Furthermore, the DPU must be in compliance with the Hospital CoPs in §482. The rehabilitation DPU is not held to the 96-hour length of stay that applies to the CAH.
Formal Survey Process?	Yes	Yes	Yes	Yes
SSA References	§1861(cc)(2)	§1861(p), §1861(g)	§1886(j)	§1820(c)(2)(E)
MMA References				§405(g)(1)

	CORF	**OPT**	**IRF**	**CAH Rehab DPU**
SOM References	Appendix K Sections 2360–2366	Appendix E Sections 2290–2306	Appendix A Section 3100	Appendix W Section 3100
CFR References	42 CFR: §410.100–105 §485.50–74	42 CFR: §410.59–62 §485.701–729	42 CFR: §412.20–30 §412.600–632 Subpart P §482 Subparts A–D	42 CFR: §485.647 §412.25, .29, & .30 §412.600–632 Subpart P §482 Subparts A–D §485.618(d), 647 §488.26 §489.10(d)
Federal Register		FR 63, 211, 58868–9	FR 66, 208, 56681–7	FR 69, 154, 49214-222, 49272
HCFA, CMS S&C Letters	S&C 05-45: Updates to *SOM* for OPTs and CORFs	HCFA memo of 9/20/2000: Aquatic Therapy S&C 05-45: Updates to *SOM* for OPTs and CORFs		S&C 04-48: Implementation of CAH DPUs
CMS Program Memoranda			Chronic Care Policy Group Memo Enforcement of IRF Classification Criteria	
Key Survey Forms	CMS-360	CMS-1893 CMS-381	CMS-437A CMS-437B	CMS-437A
Background Forms	CMS-855 CMS-359 CMS-1561	Copies of service provider contracts, if any CMS-855 CMS-1856 CMS-1561	IRF-PAI	IRF-PAI
Services Provided under Arrangement	Facility contracts	Agency contracts		

	CORF	OPT	IRF	CAH Rehab DPU
Infection Control	Individual or group	Committee		
Location	Fixed site and offsite PT/OT/SLP	Primary and extension sites		

2.3 Survey Highlights

2.3 Survey Highlights

Comprehensive Outpatient Rehabilitation Facilities (CORFs) The Act 1861(cc) & 42 CFR 485.50.ff	Clinics/Rehabilitation Agencies & Public Health Clinics Providing Outpatient Therapy (OPTs) The Act 1861(p), 1861(g) & 42 CFR 485.701.ff	Inpatient Rehabilitation Facilities (IRFs) The Act 1886(j) & 42 CFR 412.20–412.30 Rehab Units of Acute Care Hospitals, Rehab Hospitals and CAH Rehab DPUs
Services		
• Must provide, at a minimum, CORF physician services, physical therapy and social or psychological services as part of a comprehensive, coordinated, skilled rehabilitation program. • CORF cannot specialize in single service provision (e.g., hyperbaric oxygen, infusion therapy must not be the primary or the only service provided).	• Must provide at a minimum, physical therapy/speech-language pathology services and social or vocational adjustment services.	• Inpatient rehabilitation services provided to patients able to tolerate three hours of intensive rehabilitation daily (three hours is a general guideline).
Physician Requirement		
• Must have participated for at least a year in a residency program that provides training in the medical management of patients needing orthopedics, neurology, neurosurgery, rheumatology, physical medicine, etc. • Specialization in pulmonary medicine does not, by itself, satisfy the requirements for rehabilitation training.	• Must be in the facility for a sufficient amount of time to: – Provide medical direction – Establish POT when applicable – Establish/implement pt. care policies – Participate in POT reviews, case conferences, pt. assessments, reassessments & U.R.	• Rehab hospitals must have a full-time director of rehabilitation (MD/DO), and his/her hours cannot be substituted for by a Physician Assistant. Rehab units must have a part-time director of rehabilitation. Hospital policies dictate the number of hours a full- or part-time person is employed and should be applied consistently to all employees.

Comprehensive Outpatient Rehabilitation Facilities (CORFs) The Act 1861(cc) & 42 CFR 485.50.ff	Clinics/Rehabilitation Agencies & Public Health Clinics Providing Outpatient Therapy (OPTs) The Act 1861(p), 1861(g) & 42 CFR 485.701.ff	Inpatient Rehabilitation Facilities (IRFs) The Act 1886(j) & 42 CFR 412.20–412.30 Rehab Units of Acute Care Hospitals, Rehab Hospitals and CAH Rehab DPUs
Location		
• Must provide all services at a single fixed location. Exception: OT/PT/SLP that may also be provided at off-site locations. • The CORF is responsible for supervision and oversight of all off-site locations. • The CORF is responsible for assuring that staff at off-site locations are familiar with disaster plans and have practiced disaster plans & drills.	• Rehab agencies may provide therapy services at extension locations. The agencies must report projected extension locations to the SA. Some extension locations are many miles. • Some rehab services are provided at community facilities (i.e., community pools, etc.). • When a community facility is used to provide therapy, the facility must be closed to the public for the hours that patients are present. Review written policies regarding the handling of emergencies in community facilities.	• IRFs can have satellite locations but must report satellite locations to the SA.
Patient Population Characteristics		
		• 75% Rule—This rule has been changed effective July 2004. Originally, 75% of an IRF's population would require intensive rehab services for treatment of one or more conditions listed in §410.30 to be excluded from Medicare Hospital PPS. The current rate is 50% and will change incrementally until July 2007,

Comprehensive Outpatient Rehabilitation Facilities (CORFs) The Act 1861(cc) & 42 CFR 485.50.ff	Clinics/Rehabilitation Agencies & Public Health Clinics Providing Outpatient Therapy (OPTs) The Act 1861(p), 1861(g) & 42 CFR 485.701.ff	Inpatient Rehabilitation Facilities (IRFs) The Act 1886(j) & 42 CFR 412.20–412.30 Rehab Units of Acute Care Hospitals, Rehab Hospitals and CAH Rehab DPUs
		at which time it will return to 75%. The number of qualifying medical conditions has increased from 10 to 13. The medical conditions are listed on Forms CMS-437A and CMS-437B.
Infection Control		
• Reviewed by individual or group.	• Reviewed by committee.	
Plans of Care		
• Must be reviewed every 60 days. • Physician must sign and certify that POT is being followed and the patient is making progress.	• Must be reviewed 60 days after the initial review and every 30 days thereafter. • Physician must sign and certify that POT is being followed and the patient is making progress.	
Survey Preparation		
• Use Appendix K and Section 2360.	• Use Appendix E and Section 2290.	• Use Appendix A and the Rehab Module.
Forms		
• CMS-360—Survey Report Form.	• CMS-1893—Survey Report Form.	• CMS-437A and CMS-437B must be completed by surveyors on the initial survey. The SA is responsible for

Comprehensive Outpatient Rehabilitation Facilities (CORFs) The Act 1861(cc) & 42 CFR 485.50.ff	Clinics/Rehabilitation Agencies & Public Health Clinics Providing Outpatient Therapy (OPTs) The Act 1861(p), 1861(g) & 42 CFR 485.701.ff	Inpatient Rehabilitation Facilities (IRFs) The Act 1886(j) & 42 CFR 412.20–412.30 Rehab Units of Acute Care Hospitals, Rehab Hospitals and CAH Rehab DPUs
		annually verifying the Medical Director requirement. After the initial survey visit, an onsite visit is not required to verify the Medical Director requirement. This requirement may be verified through appropriate documentation from the facility. The FI verifies annually that the facility is meeting the "75% rule." The provider can attest to meeting the other requirements listed on Form CMS-437A or -437B.

2.4 Abbreviations and Acronyms

2.4 Commonly Used Acronyms and Abbreviations

A

ADL	activities of daily living
ADON	assistant director of nursing
ADR	adverse drug reaction
AIA	American Institute of Architects
AIS	automated information systems
ALJ	Administrative Law Judge
ALOS	average length of stay
AOA	American Osteopathic Association
AORN	Association of Operating Room Nurses
AOTA	American Occupational Therapy Association
APC	ambulatory payment classification
APIC	Association for Professionals in Infection Control and Epidemiology
APRN	advanced practice registered nurse
APTA	American Physical Therapy Association
ASC	ambulatory surgery center *or* ambulatory surgical center
ASHA	American Speech-Language-Hearing Association
ASPEN	Automated Survey Processing Environment

B

BBP	bloodborne pathogen
BP	blood pressure

C

CAH	critical access hospital
CAHEA	Committee on Allied Health Education and Accreditation
CARF	Commission on Accreditation of Rehabilitation Facilities
CASPER	Certification And Survey Provider Enhanced Reporting
CCMO	Consortium Contractor Management Officers
CDC	Centers for Disease Control and Prevention
CEO	chief executive officer
CFR	Code of Federal Regulations
CIM	Coverage Issues Manual
CIRP	Comprehensive Inpatient Rehabilitation Program
CLIA	Clinical Laboratory Improvement Amendment *or* Clinical Laboratory Improvement Act
CM	case manager
CMHC	community mental health center
CMM	Center for Medicare Management
CMP	competitive medical plan
CMS	Centers for Medicare & Medicaid Services
CMSO	Centers for Medicaid and State Operations
CNA	certified nursing assistant
CNS	community nursing service

CO	Central Office
COP	Condition of Participation
CORF	comprehensive outpatient rehabilitation facility
COTA	certified occupational therapy assistant
CPT	Current Procedural Terminology
CR	clinical record *or* change request
CRNA	certified registered nurse anesthetist
CRP	comprehensive rehabilitation program
CS	coordination of services
CV	curriculum vitae

D

DA	delegation of authority
DAB	Departmental Appeals Board
DCCP	Division of Continuing Care Providers
DDLD	Division of Data Liaison and Distribution
DES	diethylstilbestrol
DHS	designated health services
DME	durable medical equipment
DNR	do not resuscitate
DOB	date of birth
DOJ	Department of Justice
DON	director of nursing
DP	disaster procedures *or* disaster preparedness
DPL	disaster plan
DPU	distinct part unit
DRG	diagnostic related group
DRI	Dietary Reference Intake
DSH	disproportionate share hospital
DST	drills & staff training

E

ED	emergency department
ELOS	estimated length of stay
EMS	emergency medical service
EMT	emergency medical technician
EPA	Environmental Protection Agency
ER	emergency room
ES	electrical stimulation
ESRD	end stage renal disease

F

FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
FI	fiscal intermediary
FIM	functional independence measure

FQHC	Federally qualified health center
FR	Federal regulation or Federal Register

G

GAO	Government Accountability Office
GB	governing body and administration
GCS	Glasgow Coma Score

H

H & P	history and physical exam
HBO	hyperbaric oxygen
HBV	hepatitis B virus
HCFA	Health Care Financing Administration
HCPCS	Healthcare Common Procedure Coding System
HCPP	health care prepayment plan
HHA	home health agency
HHC	home health care
HHS	Health and Human Services
HIC	health insurance claim
HIPAA	Health Insurance Portability and Accountability Act
HIV	human immunodeficiency virus
HMO	health maintenance organization

I

IBP	Institutional Budget Plan
IC	intensive care *or* infection control
ICD-9-CM	International Classification of Diseases, Ninth Revision, Clinical Modification
ICF/MR	intermediate care facility for those with mental retardation
ICU	intensive care unit
IDTF	individual diagnostic treatment facility
IJ	Immediate Jeopardy
IPF	inpatient psychiatric facility
IPPS	inpatient prospective payment system
IRF	inpatient rehabilitation facility
IRF-PAI	Inpatient Rehabilitation Facility Patient Assessment Instrument (data set used by IRFs)
IRM	Information Resource Management
IV	intravenous

J

JCAHO	Joint Commission on Accreditation of Healthcare Organizations

K

L

LCD	local coverage determination
LICSW	licensed independent clinical social worker

LPN	licensed practical nurse
LSC	Life Safety Code
LTC	long term care
LTCH	long term care hospital

M

MCM	Medicare Carriers Manual
MCMG	Medical Communications Management Group
MCO	managed care operation *or* managed care organization
MD	doctor of medicine
MD/DO	medial doctor/doctor of osteopathy
MDH	Medicare-dependent hospital
MDS	Minimum Data Set (data set used by SNFs)
MEPG	maintenance of equipment, physical location & grounds
MI	mental illness
MMA	Medicare Medication Act *or* Medicare Modernization Act
MPFS	Medicare Physician Fee Schedule
MPFSDB	Medicare Physician Fee Schedule Database
MR	mental retardation
MS	multiple sclerosis
MSA	Medicaid State agency *or* Metropolitan Statistical Area
MSN	Medicare Summary Notice
MSW	Master of Social Work degree
MVA	motor vehicle accident

N

NARA	National Archives and Records Administration
NCD	national coverage determination
NECMA	New England County Metropolitan Area
NFPA	National Fire Protection Association *or* National Fire Protection Amendment
NIST	National Institute for Standards and Technology
NMES	neuromuscular electrical stimulation
NP	nurse practitioner
NPI	national provider identifier
NPP	nonphysician practitioner

O

OASIS	Outcome and Assessment Information Set (data set used by HHAs)
OB	obstetrics
OBRA	Omnibus Budget Reconciliation Act
OCSQ	Office of Clinical Standards and Quality
ODIE	Online Data Input and Entry
OGC	Office of General Council
OIG	Office of Inspector General
OL	Office of Legislation
OMB	Office of Management and Budget

OPO	organ procurement organization
OPT	Provider of Outpatient Physical Therapy or Outpatient Speech Language Pathology (OPT/OSP) services *or* outpatient physical therapy *or* outpatient therapy providers
OPTN	Organ Procurement and Transplantation Network
OR	operating room
ORF	outpatient rehabilitation facility
OSCAR	Online Survey, Certification and Reporting system
OSHA	Occupational Safety & Health Administration
OSP	outpatient speech pathology
OT	occupational therapist *or* occupational therapy
OTA	occupational therapy assistant
OTIP	occupational therapist in independent practice
OTPP	occupational therapist in private practice
OTR/L	occupational therapist registered/licensed

P

PA	patient assessment *or* physician's assistant
PAI	patient assessment instrument
PCP	Patient Care Plan *or* Patient Care Policy
PE	physical environment *or* program evaluation
PHS	Public Health Service
PI	physician involvement
PIN	personal identification number
PIP	periodic interim payments
PM	program memorandum
POC	Plan of Correction
POD	Principles of Documentation
POS	place of service
POT	Plan of Treatment
PPS	prospective payment system
PRN	as necessary
PRO	peer review organization
ProPAC	Prospective Payment Assessment Commission (Task Force)
PRTF	psychiatric residential treatment facility
PS	physician services *or* provision of services
PT	physical therapist *or* physical therapy
PTA	physical therapy assistance *or* physical therapy assistant
PTIP	physical therapist in independent practice
PTPP	physical therapist in private practice

Q

Q & A	Questions and Answers
QA	quality assurance
QAPI	quality assurance and program improvement
QI	quality indicator
QIES	Quality Improvement and Evaluation System

QIO	quality improvement organization
QOC	quality of care

R

RAI	resident assessment instrument
RAS	remote access service
RDA	Recommended Dietary Allowance
RHC	rural health center *or* rural health claim *or* rural health clinic
RN	registered nurse
RNHCI	religious nonmedical health care institution
RO	Regional Office
RP	rehabilitation program
RPCH	rural primary care hospital
RT	respiratory therapist

S

S & C	Survey & Certification
SA	State agency
SCG	Survey & Certification Group
SCH	sole community hospital
SCP	safety and comfort of patients
SE	sanitary environment
SLP	speech-language pathologist
SMA	State Medicaid agency
SNF	skilled nursing facility
SNF/NF	skilled nursing facility/nursing facility
SOD	statement of deficiencies
SOM	*State Operations Manual*
SOR	system of records
SPA	State Plan Amendment
SSN	Social Security number
ST	speech therapy *or* surgical technologist

T

TB	tuberculosis
TEFRA	Tax Equity & Fiscal Responsibility Act of 1982
TENS	transcutaneous electrical nerve stimulation
TPA	third party administrators

U

UPIN	unique provider identification number
UR	utilization review
URP	utilization review plan

V

W

X

Y

Z

2.5 General Online Resources

2.5 General Online Resources

CMS Quarterly Provider Update

http://www.cms.hhs.gov/providerupdate/whatsnew.asp

HIPAA

https://www.cms.hhs.gov/hipaa/hipaa2/regulations/privacy/finalrule/default.asp

Occupational Therapy

American Occupational Therapy Association: www.AOTA.org
- Topics of interest accessible to members:
  - AOTA Governance
  - Education Resources
  - Evidence-Based Practice Resources
  - Issues and Advocacy
  - Licensure
  - OTA Area
  - Practice and Ethics
  - Reimbursement

National Board for Certification in Occupational Therapy: http://nbcot.org

Nursing

National Council of State Boards of Nursing: http://www.ncsbn.org

Physical Therapy

American Physical Therapy Association: www.APTA.org
- Topics of interest (some topics may require organizational membership):
  - Continuing Education
  - Medicare
  - Practice Management
  - Reimbursement

Respiratory Therapy

American Association for Respiratory Care: http://aarc.org

Speech-Language Pathology and Audiology

American Speech and Hearing Association: www.AHSA.org
- Topics of interest (some topics may require organizational membership):
  - Legislation and Advocacy
  - Ethics: Documentation and Issues

Credentialing
Continuing Education

Social Work

American Board of Examiners in Clinical Social Work: http://www.abecsw.org
Association of Social Work Boards: http://www.aswb.org
Clinical Social Work Federation: http://www.cswf.org

2.6 Coverage Issues

2.6 Coverage Issues

Aquatic therapy

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Care Financing Administration

MEMORANDUM

DATE: **September 20, 2000**

FROM: Steven A. Pelovitz
Director
Survey and Certification Group

SUBJECT: Aquatic Therapy

TO: Walter Kummer
Associate Regional Administrator
Division of Medicaid and State Operations
Region V

The purpose of this memorandum is to clarify the provision of aquatic therapy by outpatient therapy providers at the request of Robert Anderson of your office. Aquatic therapy is considered a "therapeutic procedure" as listed in the Current Procedure Terminology (CPT) manual. It is not a modality. Medicare will reimburse the aquatic therapy procedure under CPT code 97113.

"Procedures" are defined as a manner of effecting change through the application of clinical skills and/or services that attempt to improve function. This can be achieved through exercise or training and must include active interaction between therapist and beneficiary. "Modalities" are defined as any physical agent applied to produce therapeutic changes to biologic tissue and include, but are not limited to, thermal, acoustic, light, mechanical, or electric energy.

An outpatient therapy (OPT) provider can contract with a local pool to offer aquatic therapy under the following conditions: a qualified therapist must be present and providing treatment to the beneficiary; the pool must be closed to the public during the therapy times and the pool must meet any health and safety criteria established by the local health department.

The OPT provider should have written policies governing the OPT services provided (including aquatic therapy). Aquatic therapy should have a doctor's order and be indicated on the plan of care. If aquatic therapy is provided under arrangement, the services are to be furnished in accordance with the terms of a written contract, including the identification of the qualified professional providing the service.

Please share this information with the States in your region.

Page 2 – Walter Kummer, ARA, DMSO, Region V

If you have additional questions, you may contact Georgia Johnson of my staff at (410) 786-6859.

/s/

Steven A. Pelovitz

cc: ARAs: RO I-IV
RO VI-X

policy to establish two annual per-beneficiary limits of $1,500. There will be (1) an annual per-beneficiary limit for all outpatient physical therapy services excluding hospital outpatient therapy services furnished to an outpatient or an inpatient who is not in a covered Part A stay and, (2) an annual per beneficiary limit for all outpatient occupational therapy services excluding hospital outpatient therapy services furnished to an outpatient or an inpatient who is not in a covered Part A stay. As stated previously, outpatient physical therapy services include speech-language pathology services. A provider of outpatient rehabilitation services with a provider agreement under section 1866 of the Act, as well as physicians, PTIPs and OTIPs, will be allowed to collect payment from a beneficiary for therapy services after the $1,500 limit is reached. This is consistent with current policy allowing PTIPs and OTIPs to collect payment from a beneficiary for therapy services in excess of the current $900 limit.

Required Congressional Report on Financial Limitation

We note that a report to the Congress is due from the Secretary no later than January 1, 2001. This report must include recommendations on the establishment of a revised coverage policy of outpatient physical therapy services, including speech-language pathology services and outpatient occupational therapy services. The revised policy must be based on a classification of individuals by diagnosis category and prior use of services in both inpatient and outpatient settings. The report should include recommendations on how such durational limits by diagnostic category could be implemented in a budget-neutral manner.

Comment: It was recommended by a commenter for the report to the Congress that, in addition to basing a revised policy on classification by diagnosis category and prior use of services, an individual's functional status should be a component of any system that purports to address a patient's need for rehabilitation.

Response: As we develop the report to the Congress, we will consider the feasibility of the recommendation.

4. Qualified Therapists

Section 1861(p) includes services furnished an individual by a physical therapist who meets licensing and other standards prescribed by the Secretary if the services meet the conditions relating to health and safety the Secretary finds necessary. The services must be furnished in the therapist's office or the individual's home. By regulation, we have defined therapists meeting the conditions for coverage of services under this provision as physical therapists in independent practice. The conditions for coverage are set forth in part 486, subpart D (Conditions for coverage: Outpatient Physical Therapy Services Furnished by Physical Therapists in Independent Practice) and require that the services be provided by a therapist in independent practice under § 410.60. Under § 410.60, a therapist in independent practice is one who:

- Engages in the practice of therapy on a regular basis.
- Furnishes services on his or her own responsibility without the administrative and professional control of an employer.
- Maintains at his or her own expense office space and equipment.
- Furnishes services only in the office or patient's home.
- Treats individuals who are his or her own patients and collects fees or other compensation for the services.

Under § 486.151 (Conditions for coverage: Supervision), all therapy services must be furnished under the direct supervision of a qualified therapist in independent practice. In other words, the therapist in independent practice must be on the premises whenever services are provided to Medicare beneficiaries, including services provided by a licensed physical therapist. This long-standing requirement has been controversial with therapists in independent practice. For example, a therapist in independent practice cannot have more than one office open for services at the same time since he or she could not be on both premises at once.

We are revising our policy to replace the existing "Conditions for Coverage: Outpatient Physical Therapy Services Furnished by Physical Therapists in Independent Practice" (part 486, subpart D), which requires survey and certification, with a simplified criteria for physical therapists in private practice that would use a carrier enrollment process. The impetus for this change comes from congressional statements associated with the fiscal year 1997 appropriations process. Statements in both the House and Senate committee reports accompanying HCFA's fiscal year 1997 appropriations addressed the issue of requiring that the certified physical or occupational therapist in independent practice directly supervise all services performed by his or her employees, even if those employees are fully-licensed therapists. The House committee report urged that we modify the regulations so that the certified therapist need not be on premises to supervise other licensed therapists. The Senate urged us to review this concern and recommend regulatory or instructional changes.

We are redefining those therapists who are qualified under section 1861(p) of the Act. That is, we would discontinue the focus of the regulation on their "independent" status (which is not statutory) and recognize therapists in private practice who are employed by others and, therefore, do not meet our current "independent" criteria. This would be consistent with health and safety concerns and would conform to normal private sector practice standards. The following new requirements replace the current ones for qualified therapists:

- The term "independent" is dropped and the benefit would be for an individual physical therapist or occupational therapist in private practice.

Private practice includes an "individual" whose practice is in an unincorporated solo practice, unincorporated partnership, or unincorporated group practice. Private practice also includes an "individual" who is practicing therapy as an employee of one of the above or of a professional corporation or other incorporated therapy practice. However, private practice does not include individuals when they are working as employees of a provider. A provider as defined in § 400.202 includes a hospital, CAH, SNF, HHA, hospice, CORF, CMHC, or an organization qualified under part 485, subpart H (Conditions of Participation for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services), as a clinic, rehabilitation agency, or public health agency.

- In implementing the statutory requirement that services be furnished to an individual in the therapist's office, or in the individual's home, "in his office" is defined as the location(s) where the practice is operated, in the State(s) where the therapist (and practice, if applicable) is legally authorized to furnish services, during the hours that the therapist engages in practice at that location.

A therapist in private practice must maintain a private office, if services always are furnished in patients' homes. However, if services are furnished in private practice office space, that space would have to be owned, leased, or

rented by the practice and used for the exclusive purpose of operating the practice. For example, because of the statutory restriction on the site of services, a therapist in private practice cannot furnish covered services in an SNF. Therefore, if a therapist wished to locate his or her private office on site at a nursing facility, special care would need to be taken. The private office space could not be part of the Medicare-participating SNF's space, and the therapist's services could be furnished only within that private office space. Neither the therapist nor any assistants or aides who help furnish services could be employed by the SNF during the same hours that they are working in the private practice. Another example where special attention would be needed is space that generally serves other purposes and is only used by a therapy practice during limited hours. For example, a therapist in private practice may furnish aquatic therapy in a community center pool on Wednesday mornings. The practice would have to rent or lease the pool for those hours, and the use of the pool during that time would have to be restricted to the therapist's patients, in order to recognize the pool as part of the therapist's own private office during those hours.

In describing other services that are specifically limited to the patient's home, the statute uses qualifying language. For example, the durable medical equipment definition in section 1861(n) of the Act refers to a patient's home as "including an institution used as his home other than an institution that meets the requirements of subsection (e)(1) of this section or section 1819(a)(1)." This definition of home is codified under our regulations at § 410.38(b). The same definition always has been used in the Medicare Carriers Manual for purposes of covering therapists' services in a patient's home. We are continuing the current practice and are adopting the definition formally in this regulation.

- Assistants and aides have to be personally supervised by the therapist and employed directly by the therapist, by the partnership or group to which the therapist belongs, or by the same private practice that employs the therapist. Personal supervision requires that the therapist be in the room during the performance of the service. Levels of supervision are defined in § 410.32 of our regulations.
- The therapist must be licensed or otherwise legally authorized to engage in private practice. We understand that all States license or certify physical therapists, so no alternative personnel qualifications need to be specified.
- Each therapist enrolls "as an individual" with the carrier.

There would be no survey and no certification by HCFA. The Medicare carrier would verify that the qualifications proposed in §§ 410.59(c)(1) or 410.60(c)(1) of our regulations are met. All applicants for new enrollment would become subject to these new rules and procedures upon the effective date of the final rule. For transition purposes, we intend that independent therapists who are certified and enrolled at that time would be "grandfathered" temporarily and would become subject to the new enrollment rules and procedures at the time of their next regular periodic reenrollment.

These changes would address the concern that current rules require each independent therapist to personally supervise services performed by any other licensed therapists that he or she employs. Under our proposal, each individual therapist in a practice could qualify to separately enroll, and enrolled therapists would not be required for purposes of Medicare to be supervised by their employer. These changes also address the concern that current rules prohibit an independent therapist from being employed by any entity. Under our proposal, a variety of employment situations would be permitted.

These new requirements are established in a revised § 410.60(c) for physical therapists. To date, the statutory requirements for coverage of outpatient occupational therapy services have not been codified. We are codifying these requirements by establishing a new § 410.59 for outpatient occupational therapy services. The regulations section for outpatient occupational therapy parallels the § 410.60 requirements for outpatient physical therapy, as revised in this final rule. We are also making conforming changes in § 410.61 to include occupational therapy.

Therapists in private practice do not participate in the Medicare program in the same way that "providers of services" do. Though they must be approved as meeting certain requirements, unlike "providers of services," they do not execute a formal provider agreement with the Secretary as described in 42 CFR part 489 (Provider Agreements and Supplier Approval). Like physicians, they do have the option of accepting a beneficiary's assignment of his or her claim for Medicare Part B benefits and of becoming a Medicare-participating supplier that agrees to accept assignment in all cases.

Comment: One commenter strongly supports the carrier enrollment process for physical therapists instead of the existing conditions of coverage. However, the commenter wanted operational issues addressed such as a specification that payments will be made under the practice or corporation's tax ID number for services furnished by physical therapists in private practice who are employees of other practices or corporations. This is the same payment system used by a physician group practice, and the treating therapist's Medicare number or license number would be included on the bill. In addition, the commenter urged that the same process be used for the carrier enrollment process as for the current physician enrollment. Another commenter supported the changes for OTPPs; however, assuming that payment is made to the individual, the commenter inquired as to whether group numbers would be assigned so that payment could be issued to the group under the tax identification number of the business entity.

Response: We will use the same enrollment and billing process as is currently used for individual physicians and physician group practices. This process is delineated at section 1030.7 of the Medicare Carriers Manual, HCFA Pub. 14–Part 4. We note that payment is not made on the basis of the corporate or group practice tax identification number. This number is just one of the data elements that can be related to the Medicare individual and/or group billing number.

Comment: A commenter recommended that direct supervision of assistants and aides be required instead of personal supervision. The commenter provided that direct supervision would be consistent with state laws, the supervision requirements for nonphysician personnel performing services in a physician's office, and with the supervision requirements for aides and assistants of PTIPs.

Another commenter agreed that personal supervision over therapy aides by a qualified occupational therapist or qualified occupational therapy assistant is appropriate. However, the commenter strongly disagreed with the proposal to require personal supervision over occupational therapy assistants and instead urged the adoption of a policy for practicing occupational therapists whereby occupational therapy assistants can perform covered services under the general supervision (that is, initial direction and periodic inspection) of a qualified occupational therapist. In

Hyperbaric oxygen

Program Memorandum Intermediaries/Carriers

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal AB-02-183 **Date: DECEMBER 27, 2002**

CHANGE REQUEST 2388

SUBJECT: Coverage of Hyperbaric Oxygen (HBO) Therapy for the Treatment of Diabetic Wounds of the Lower Extremities

This Program Memorandum (PM) summarizes the revision to §35-10 of the Coverage Issues Manual (CIM) regarding Hyperbaric Oxygen (HBO) Therapy. Please refer to this section of the CIM for complete information regarding this policy.

Conditions of Coverage

Hyperbaric oxygen therapy is a modality in which the entire body is exposed to oxygen under increased atmospheric pressure. Effective April 1, 2003, a National Coverage Decision expanded the use of Hyperbaric Oxygen (HBO) therapy to include coverage for the treatment of diabetic wounds of the lower extremities in patients who meet the following criteria:

(1) Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes; (ICD-9-CM diagnosis 250.7, 250.8, 707, 707.1, 707.10, 707.12, 707.13, 707.14, and 707.19).
(2) Patient has a wound classified as Wagner grade III or higher; and
(3) Patient has failed an adequate course of standard wound therapy.

The use of HBO therapy will be covered as adjunctive therapy only after there are no measurable signs of healing for at least 30 days of treatment with standard wound therapy and must be used in addition to standard wound care. Standard wound care in patients with diabetic wounds includes: assessment of a patient's vascular status and correction of any vascular problems in the affected limb if possible, optimization of nutritional status, optimization of glucose control, debridement by any means to remove devitalized tissue, maintenance of clean, moist bed of granulation tissue with appropriate moist dressings, appropriate off-loading, and necessary treatment to resolve any infection that might be present. Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days. Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO treatment is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

This PM also clarifies that CMS has concluded that special supervision and credentialing requirements should not be imposed on physicians who perform HBO therapy. You may not impose a higher level of supervision than direct supervision as is required for all "incident to" therapies. CMS encourages physicians who perform HBO therapy to obtain adequate training in the use of HBO therapy and in advanced cardiac life support.

NOTE: Topical application of oxygen does not meet the definition of HBO therapy as stated above. Also, its clinical efficacy had not been established. Therefore, no Medicare reimbursement may be made for the topical application of oxygen.

CMS-Pub. 60AB

2

Billing Requirements for Intermediaries

Follow the general bill review instructions in §3604 of the Medicare Intermediary Manual, Part 3. Claims for HBO therapy should be submitted on Form HCFA-1450 or its electronic equivalent.

Applicable Bill Types

The applicable bill types are 11X, 13X and 85X.

HCPCS Coding

- 99183 – Physician attendance and supervision of hyperbaric oxygen therapy, per session.
- C1300 – Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval.

NOTE: Code C1300 is not available for use other than in a hospital outpatient department. In skilled nursing facilities (SNFs), HBO therapy is part of the SNF PPS payment for beneficiaries in covered Part A stays.

For hospital inpatients and critical access hospitals (CAHs) not electing Method I, HBO therapy is reported under revenue code 940 without any HCPCS code. For inpatient services, show ICD-9-CM procedure code 93.59 in FL 80 and 81.

For CAHs electing Method I, HBO therapy is reported under revenue code 940 along with HCPCS code 99183.

Payment Requirements for Intermediaries

Payment is as follows:

Intermediary payment is allowed for HBO therapy for diabetic wounds of the lower extremities when performed as a physician service in a hospital outpatient setting and for inpatients. Payment is allowed for claims with valid diagnostic ICD-9 codes as shown above with dates of service on or after April 1, 2003. Those claims with invalid codes should be denied as not medically necessary.

For hospitals, payment will be based upon the Ambulatory Payment Classification (APC) or the inpatient Diagnosis Related Group (DRG). Deductible and coinsurance apply.

Carrier Billing Requirements

The following HCPCS Code applies:

- 99183 - Physician attendance and supervision of hyperbaric oxygen therapy, per session

Claims Requirements

Follow the general instruction for preparing claims in §2010, Purpose of Health Insurance Claim Form CMS-1500, Medicare Carriers Manual (MCM) Part 4, Chapter 2. Claims for this service should be submitted on health insurance claim Form CMS-1500 or electronic equivalent. Claims should be processed in accordance with §4020, Review of Health Insurance Claim Form CMS-1500, of Part 3, Chapter IV of the Medicare Carriers Manual.

Payment Requirements

Payment and pricing information will be on the April update of the Medicare Physician Fee Schedule Database (MPFSDB). Pay for this service on the basis of the MPFSDB. Deductible and coinsurance apply. Claims from physicians or other practitioners where assignment was not taken are subject to the Medicare limiting charge (refer to MCM Part 3, chapter VII, §7555 for more information).

Medicare Summary Notices (MSNs)

Use the following MSN Messages where appropriate:

In situations, where the claim is being denied on the basis that the condition does not meet our coverage requirements, use one of the following MSN Messages:

"Medicare does not pay for this item or service for this condition." (MSN Message16.48)

The Spanish version of the MSN message should read:

"Medicare no paga por este articulo o servicio para esta afeccion."

OR "This service is not covered prior to April 1, 2003." (MSN Message 16.51)

The Spanish version of the MSN message should read:

" Esta servicio no se cubre antes del 1 de abril de 2003."

In situations where, upon medical review of the claim based upon the above utilization policy, you determine that the service is not medically necessary, use the following MSN message, 15.4.

"The information provided does not support the need for this service or item."

The Spanish version of the MSN message should read:

" La informacion proporcionada no confirma la necesidad para este servicio o articulo."

Remittance Advice Notices – Use appropriate existing remittance advice and reason codes at the line level to express the specific reason if you deny payment for HBO therapy for the treatment of diabetic wounds of lower extremities. If denying services as furnished before April 1, 2003, use existing ANSI X 12-835 claim adjustment reason code 26 "Expenses incurred prior to coverage" at the line level.

Provider Education – You must notify providers of this information through your next scheduled bulletin and on your website within two weeks.

The *effective date* for this PM is April 1, 2003.

The *implementation date* for this PM is April 1, 2003.

These instructions should be implemented within your current operating budget.

This PM may be discarded after April 1, 2004.

If you have any questions, contact the appropriate regional office.

Rehabilitation Reference Manual

Tab 3: *Principles of Documentation*

3.1 *SOM* Exhibit 7A, *Principles of Documentation*

3.1 *SOM* Exhibit 7A, *Principles of Documentation*

EXHIBIT 7A

PRINCIPLES OF DOCUMENTATION

NOTE: Principles of Documentation are merely guidance for surveyors and do not impose obligations on either providers or surveyors for the suggestions contained in them.

Table of Contents

Introduction

Definitions

Legal Aspects of the Statement of Deficiencies

Overview

- Principle #1 - Entity Compliance and Noncompliance
- Principle #2 - Using Plain Language
- Principle #3 - Components of a Deficiency Citation
  - A - Regulatory Reference
  - B - Deficient Practice Statement
  - C - Relevant Facts and Findings
- Principle #4 - Relevance of Onsite Correction of Findings
- Principle #5 - Interpretive Guidelines
- Principle #6 - Citation of State or Local Code Violations
- Principle #7 - Cross-References
- Principle #8 - Condition of Participation Deficiencies

Principle #1 - Entity Compliance and Noncompliance

- Exhibit 1-1 - Effective Documentation for Principle #1
- Exhibit 1-2 - Effective CMS-2567L Documentation for Nursing Homes With an A level finding

Principle #2 - Using Plain Language

Principle #3 - Components of a Deficiency Citation

- Regulatory Reference
- Requirements
- Deficient Practice Statement
  - Exhibit 3-2 - Effective Documentation of Deficient Practice Statement
- Extent

Identifiers
Sources of the Evidence
Observations
Exhibit 3-3 - Effective Documentation of Observation-Based Findings
Interviews
Exhibit 3-4 - Effective Documentation of Interview Based on Findings
Review of Records and Other Documents
Exhibit 3-5 - Effective Documentation of Record Review-Based Findings
Exhibit 3-6 - Effective Documentation of Record Reviews
Exhibit 3-7 - Effective Documentation of Principle #3
Outcomes
Exhibit 3-8 - Effective Documentation of Deficient Practice Statement
Findings
Facts
Exhibit 3-9 - Documentation of Facts
Organization of Findings
Exhibit 3-10 - Effective Documentation of Two Deficient Practice Statement and Their Findings
Principle #4 - Relevance of Onsite Correction of Findings
Exhibit 4-1 - Effective Documentation for Principle #4
Correction of Immediate Jeopardy (IJ) During Survey
Exhibit 4-2 - Effective Documentation for Correction of IJ during Survey-Principle #4
Principle #5 - Interpretive Guidelines
Exhibit 5-1 - Interpretive Guidelines
Exhibit 5-2 - Effective Documentation for Principle #5
Principle #6 - Citation of State or Local Code Violations
Exhibit 6-1 - Effective Documentation for Principle #6
Exhibit 6-2 - Effective Documentation for Principle #6
Principle #7 - Cross-References
Principle #8 - COP Deficiencies
Exhibit 8-1 - Effective Documentation for Principle #8
Conclusion

Appendix A - Components to be Documented in A Deficiency Citation

Introduction

This appendix provides guidance on how to structure a deficiency statement on the Form CMS-2567 after all the necessary information and evidence have been gathered. These guidelines include a general discussion of the legal aspects of the Statements of Deficiencies and identify and explain the principles considered in the citation of deficiencies to be documented on the Form CMS-2567. The principles are generic and apply to the documentation of survey results regardless of the particular program (Medicare, Medicaid or the Clinical Laboratory Improvement Amendments) or the particular provider or supplier type.

This guide does not replace or supersede the law, regulations, or State Operations Manual (SOM). Rather, this appendix is intended to provide guidance for documenting citations. Therefore, this appendix does not create additional substantive or procedural requirements that must be present to sustain a valid citation.

The CMS-2567 is the record of the survey where the survey team documents and justifies its determination of compliance and informs the provider or supplier of its state of compliance with the requirements for participation in the Federal programs. This information will serve as the basis for the facility to analyze its deficient practices or system failures and to develop plans of correction. The CMS-2567 may also document deficient practices identified by means other than an onsite survey, e.g., a review of compliance with the requirements to transmit comprehensive assessments to the State Agency.

Each principle is discussed in depth and includes an example of that principle. Each example is identified as being effective and is included to illustrate a particular documentation principle and may not represent a complete citation. In each case, there may be other language that may be as effective. The adequacy of any citation can be evaluated only in the context of the particular type and source of evidence, the extent and consequence of deficiency, and other relevant factors.

Definitions

Listed below are definitions that will be used throughout these materials.

COP - an abbreviation that commonly refers to a " condition of participation." COP also is used throughout this manual to refer to a "condition for coverage" relevant to suppliers. The Conditions of Participation are requirements with which an entity must comply in order to participate in the programs.

Deficiency Citation - an entry made on the Form CMS-2567 that includes: (1) the alpha prefix and data tag number, (2) the Code of Federal Regulations (CFR), or Life Safety

Code (LSC) reference, (3) the language from that reference which pinpoints the aspect(s) of the requirement with which the entity failed to comply, (4) an explicit statement that the requirement was "NOT MET" and (5) the evidence (the deficient entity practice statement and relevant individual findings or facts) to support the decision of noncompliance (see Exhibit 0-1).

Deficient Practice - the action(s), error(s), or lack of action on the part of the entity relative to a requirement (and to the extent possible, the resulting outcome). ("practice" and "entity practice" are used interchangeably throughout this manual.)

Deficient Practice Statement - a statement at the beginning of the evidence that sets out why the entity was not in compliance with a regulation.

Entity - a generic term used to describe providers and suppliers under the Social Security Act or laboratories that participate in the CLIA program.

Evidence - an integral part of the citation that begins with a description of the deficient entity practice and identifies the relevant individual findings and facts that substantiate the failure of the entity to comply with the regulation.

Extent of deficient practice - the prevalence or frequency of a deficient entity practice.

Finding - a generic term used to describe each discrete item of information observed or discovered during the survey about practices of an entity relative to the specific requirement being cited as being not met.

Fact - an event known to have actually happened. A truth known by actual experience or observation.

Forms CMS-2567/CMS-2567L Statement of Deficiencies and Plan of Correction - the official document on which citations are recorded (see Appendix A).

Outcome - a result/consequence of entity practices (e.g., development of avoidable pressure sore/ulcer; reaction due to receipt of blood of wrong blood type.).

Recipient - one who receives services (a patient, resident or a client) from an entity regardless of whether or not that person is eligible for, or is receiving, Medicare or Medicaid.

Requirement - any structure, process or outcome that is required by the law, regulations, or the Life Safety Code (LSC).

S/S - In the LTC survey, symbol accompanied by a unique letter (A through L) that illustrates the effect of the noncompliance on the nursing home resident (severity) and the number of residents actually or potentially affected (scope) by the provider's

noncompliance. The symbol with the letter assigned to the noncompliance appears under the tag number on the Form CMS-2567L for nursing homes. (See Appendix P).

Universe - the total number of individuals, records, observations, objects, related to the entity practice or recipients at risk as a result of a deficient practice. Used as the denominator when determining the extent of a deficient practice.

Appendix P - Guidance to Surveyors - Long-Term Care Facilities

Appendix Q - Guidelines for Determining Immediate and Serious Threat to Patient Health and Safety

Legal Aspects of the Statement of Deficiencies

The survey and certification of an entity that participates in Medicare, Medicaid or the Clinical Laboratory Improvement Amendments (CLIA) of the Public Health Service Act, is a process that must adhere to legal requirements. These programs are administered under extensive laws, regulations, operation manuals and other guidelines. Surveys and the documentation from surveys become an important part of subsequent legal proceedings arising out of the certification process.

This section is a brief overview of the legal aspects of surveying and the importance of surveyor documentation to the decision making and appeals process. It is not intended to provide complete and detailed information on the mechanics of the process. Please refer to the State Operations Manual (SOM) for more detailed information.

The survey process determines, and the documentation records, the compliance or noncompliance of providers, suppliers, and CLIA laboratories. The surveyor provides the reasons justifying any resulting enforcement action and the record on which to defend that action in the appeals process. Consistent and accurate documentation is imperative in the entire certification process as it forms the basis for the record and the certification decision. Moreover, the documentation may also be reviewed in any subsequent appeal, i.e., reconsideration, hearing before an Administrative Law Judge (ALJ) of the Departmental Appeals Board (DAB), review by the Board's Appellate Division, and judicial review.

A certification of compliance or noncompliance with the applicable requirements by the State agency or the Federal Government is an official finding and determines whether or not the provider or supplier may participate in the Medicare or Medicaid program or whether a laboratory is issued a certificate to operate under CLIA. It also determines whether any of these entities are subject to other sanctions. The decision-making process and subsequent certifications are based on the documentation of the survey in the Statement of Deficiencies (Form CMS-2567), as well as, other documentation such as surveyor worksheets or notes.

A prospective provider, supplier or clinical laboratory may request a reconsideration of a

determination that it does not qualify to participate in the Medicare/Medicaid program. A formal reconsideration is a thorough, independent review of the prior decision and the entire body of evidence. If the reconsideration determination upholds the initial decision, the entity may request an evidentiary hearing before an ALJ.

If an entity is determined to no longer meet the requirements and is subject to termination or alternate remedies/sanctions, the actual or projected termination or remedy may be appealed through an evidentiary hearing before an ALJ. If a laboratory's certificate is subject to limitation, suspension, revocation, or is actually limited, suspended, or revoked, the actual or projected limitation, suspension or revocation may be appealed through an evidentiary hearing before an ALJ. During a hearing, the government has the responsibility to show why a provider or supplier should be terminated or be subject to alternate remedies, and/or a laboratory's certificate should be limited, suspended or revoked.

The evidence must provide the underlying reason, basis or rationale for the findings of noncompliance with the regulatory requirement(s). Such a hearing is an adversarial proceeding. At the hearing, witnesses testify for both the entity and for CMS, and are subject to cross-examination. The primary evidence is the Form CMS-2567, and any other documentation used to make the determination of survey results (e.g., worksheets, narratives, etc.). The ALJ relies on the testimony of witnesses and the documentation from the survey in making a decision. All documentation used at the hearing becomes part of the public record. The ALJ issues a written decision as to whether or not the entity should be found in compliance with the requirements of the program. The ALJ is usually not a health professional, therefore, it is important that the surveyor present the findings in plain language. For this reason, the Form CMS-2567 does not contain technical jargon or abbreviations that would not be readily understood by a lay person.

If either CMS or the entity is dissatisfied with an ALJ decision or dismissal, it may file a request for review to the DAB Appellate Division. The DAB considers the evidence introduced at the ALJ hearing to determine whether the ALJ's decision had a sound factual basis. An entity dissatisfied with the DAB decision has the right to seek judicial review, CMS does not. The survey documentation again becomes an important document of the proceedings. The review by the Court is limited to the record of the proceedings before the ALJ and the DAB's Appellate Division.

Documentation on the Form CMS-2567 remains the key element in the record to support a determination to certify compliance or noncompliance with applicable requirements and, if necessary, to defend the determination before the public, during the appeals process, or in court. The documentation of each and every survey should be treated as if it will be subject to close scrutiny. The determination of compliance, as well as noncompliance must be based on objective, factual observations and not vague conclusions. A judge will usually rely on surveyor judgment if the documentation is thorough and comprehensive.

If, during the course of the survey, information/evidence involving recipient outcomes is discovered, surveyors should make every effort to relate the deficiencies to the effect on the recipient and recipient's care. Citations must relate to the statutory or regulatory requirements.

In addition, a clear and comprehensive Statement of Deficiencies is necessary to provide the entity with the information necessary to analyze its problems, define appropriate corrective action and come into compliance with the requirements.

Overview

Listed immediately below for easy reference are the principles considered in the development and completion of the Form CMS-2567. Following this listing, each principle is explained in detail in a separate section.

Principle #1 - Entity Compliance and Noncompliance

When an entity complies with the requirements applicable to the survey conducted, the Form CMS-2567 should consist of an explicit statement that the entity is in compliance. If an entity does not comply with one or more applicable requirements, the Form CMS-2567 includes corresponding citations of noncompliance.

Principle #2 - Using Plain Language

The deficiency citation is written clearly, objectively and in a manner that is easily understood. The deficiency citation does not include consultation, advice, comments or direction aimed at the surveyed entity.

Principle #3 - Components of a Deficiency Citation

A deficiency citation consists of (A) a regulatory reference, (B) a deficient practice statement and (C) relevant findings.

A - Regulatory Reference

A Regulatory Reference includes the following components:

1. A survey data tag number,
2. The CFR or LSC reference,
3. The language from that reference which specifies the aspect(s) of the requirement with which the entity was noncompliant.
4. An explicit statement that the requirement was "NOT MET."

B - Deficient Practice Statement

The statement of deficient practice is one component of the evidence. It includes:

1. The specific action(s),error(s), or lack of action (deficient practice),
2. Outcome(s) relative to the deficient practice, when possible
3. A description of the extent of the deficient practice or the number of deficient cases relative to the total number of such cases,
4. The identifier of the individuals or situations referenced in the extent of the deficient practice, and
5. The source(s) of the information through which the evidence was obtained.

C - Relevant Facts and Findings

The facts and findings relevant to the deficient practice, answer the questions: who, what, where, when, and how. They illustrate the entity's noncompliance with the requirement or regulation.

Principle #4 - Relevance of Onsite Correction of Findings

If, during the survey, the entity corrects the situation that resulted in the deficiency, a determination of "NOT MET" must be documented on the Form CMS-2567. The entity may indicate its correction in the right-hand column of the Form CMS-2567. If, during the survey, the entity initiates corrective actions that abate a finding of immediate jeopardy, follow the guidance described in Appendix Q.

Principle #5 - Interpretive Guidelines

The deficiency citation explains how the entity fails to comply with the regulatory requirements, not how it fails to comply with the guidelines for the interpretation of those requirements.

Principle #6 - Citation of State or Local Code Violations

The entity's failure to comply with State or local laws or regulations is not documented in the Form CMS-2567 except when the Federal regulation requires compliance with State or local laws. When the authority having jurisdiction for that State or local law has made a decision of noncompliance and has effectuated an adverse action that has been sustained through the hearing process (such as removal of the license to operate), the Form CMS-2567 should note that the entity no longer has a license.

Principle #7 - Cross-References

The cross-referencing of requirements is an acceptable form of documentation on the Form CMS-2567 only when it is applicable and provides additional strength to the linked citations. Cross-referencing is most effective when the linked citations have a direct cause and effect relationship to the deficient practices described in both citations. In all instances, the linked citation must contain sufficient evidence to demonstrate noncompliance for the referenced regulation at the linked site.

Principle #8 - Condition of Participation Deficiencies

The COP citation includes deficient practice statements and findings to support the determination of noncompliance with a condition level requirement. The findings may be incorporated either by cross references to those requirements which must be corrected to find the COP in compliance or by narrative description of the individual findings.

Principle #1 - Entity Compliance and Noncompliance

When an entity complies with the requirements applicable to the survey conducted, the Form CMS-2567 should consist of an explicit statement that the entity is in compliance for that particular survey. If an entity does not comply with one or more applicable requirements, the Form CMS-2567 includes corresponding citations of noncompliance. The statutes and implementing regulations are the legal authority for determining an entity's compliance with Federal requirements for participation or coverage in Medicare, Medicaid, and CLIA.

The Form CMS-2567 is the official document that communicates the determination of compliance or noncompliance with the Federal requirements. Also, it is the form that an entity uses to submit a plan to achieve compliance. It is an official record and is available to the public on request.

Exhibit 1-1 illustrates how to give official notice to the provider or any other interested parties of the compliance status of the entity when the surveyor has identified no deficiencies. The specific requirements with which the entity must comply, as contained in Title 42 of the Code of Federal Regulations (CFR), are included.

Exhibit 1-1 - Effective Documentation for Principle #1

Tag	Summary Statement of Deficiencies
G 000	The [Name] Home Health Agency is in compliance with 42 CFR Part 848, Requirements for Home Health Agencies.

If a nursing home has no deficiencies identified at the time of the survey, the entry on the Form CMS-2567 would read that the NH is in compliance with 42 CFR Part 483, "Requirements for Long Term Care Facilities."

For SNF/NF, if the provider's noncompliance is isolated and does not pose a risk of more than minimal harm (S/S=A), the deficiency is documented on the "A" Form - "Statement of Isolated Deficiencies Which Cause No Harm With Only A Potential For Minimal Harm for SNFs and NFs." (See Appendix Q?) In addition, the documentation on the Form CMS-2567L would state the SNF/NF is in substantial compliance.

Exhibit 1-2 - Effective CMS-2567L Documentation for Nursing Homes With an A level finding

Tag	Summary Statement of Deficiencies
F 000	The [Name] Nursing Home is in substantial compliance with 42 CFR Part 483 Requirements for Long Term Care Facilities

If a nursing home is in substantial compliance but has deficiencies, other than the Isolated Deficiencies which Cause No Harm with Only A Potential For Minimal Harm (S/S=B, C), the deficiencies are documented on the Form CMS-2567L and no additional language regarding substantial compliance is entered on the Form CMS-2567L.

NOTE: The remainder of the principles of documentation address how to document citations, that is, situations in which the entity has been found not to comply with one or more requirements.

Principle #2 - Using Plain Language

The deficiency citation is written clearly, objectively and in a manner that is easily understood. Each deficiency citation relates to a requirement within the CFR or the LSC. The deficiency citation should contain only the evidence to support the determination of noncompliance. Exclude the use of consultation, advice, comments or directions aimed at the surveyed entity. The deficiency citation should contain only the evidence to support the determination of noncompliance.

Inclusion of extraneous comments or consultative remarks in citations may lead to confusion. The entity surveyed and the public may not be able to distinguish between what the survey team would like to see and what is legitimate evidence of noncompliance. To decrease confusion, documentation in the Form CMS-2567 contains only the citation and evidence to support the determination on noncompliance. Extraneous information that is not relevant to demonstrating noncompliance with the specific requirement should be avoided.

An example of an extraneous remark would be: When documenting a deficient practice of failure to complete a care plan, a comment regarding the Resident's lack of knowledge regarding her Medicaid benefits is included. The Resident's knowledge regarding her Medicaid benefits has no relevance to the deficient practice regarding the care plan and only confuses the reader.

The language used to write a deficiency citation should be as clear as possible. Many styles of writing are acceptable, and style is a matter of individual preference; however, surveyors should not use slang, unfamiliar terms and phrases.

Best practice is to:

- Put all relevant facts in chronological order.
- Keep sentences short.
- Use simple sentence structure.
- Use the active voice (e.g. "The DON reprimanded the CNA" not "the CNA was reprimanded by the DON.").
- Avoid undefined abbreviations, initials and technical jargon.
- Write in layman's terms.
- Write to inform, not impress.
- Avoid unnecessary words.
- Avoid vague terminology (such as, seems, appears, did not always).
- Avoid words that imply or state conclusions without including the facts to support them (e.g., "only," "just," "unsatisfactory," "unnecessary," or "inadequate").
- Ensure the accuracy of quoted material.

According to "Strunk and White," When you become hopelessly mired in a sentence, it is best to start fresh; do not try to fight your way through against the terrible odds of syntax. Usually what is wrong is that the construction has become too involved at some point; the sentence needs to be broken apart and replaced by two or more shorter sentences."

Principle #3 - Components of a Deficiency Citation

A deficiency citation consists of (a) a regulatory reference, (b) a statement of deficient practice, and (c) relevant findings. (For SNFs and NFs, the scope and severity decision is documented in the left column under the survey data tag number.). Since all relevant information demonstrating noncompliance have been provided in the deficiency citation, conclusion or summary remarks at the end of the deficiency citation are not necessary and should be avoided.

This principle addresses **all** of the components of a complete citation.

Regulatory Reference

When the entity's practice violates a regulation or requirement, determine the regulation that the entity may have violated. Examine the language of the regulation under which a deficiency could be cited. Determine if the requirement addresses the entity's policies and procedures, actions, or inaction.

A regulatory reference is composed of: (1) a survey data tag number, (2) the CFR or LSC reference, (3) the language from that reference which specifies the aspect(s) of the requirement with which the entity was noncompliant, and (4) an explicit statement that the requirement was "NOT MET."

Regardless of the computer software used to produce the Form CMS-2567, essential components of the citation: survey data tag, CFR or LSC reference, language of the requirement for that reference, and an explicit statement that the requirement was not met are generated automatically on the Form CMS-2567. Each handwritten citation should include all of those components. The deficient entity practice statement and the relevant findings then follow these components.

If the approved CMS software program for documenting deficiencies does not capture the language of the requirement being cited at a particular data tag or the specific regulatory/statutory requirement, incorporate the language for the specific aspect of the requirement being cited as being deficient.

Federal certification requirements are located at Title 42 of the Code of Federal Regulations (CFR) or in the Life Safety Code. [1] (LSC) The requirements are further coded into a series of alpha numeric data tags (e.g., F201, A53, G156, etc.) that allow essential survey information to be retrieved and analyzed to determine trends and patterns of noncompliance. The numerical order of survey data tags approximates the order of the requirements within the CFR or LSC [1].

Tag	Summary Statement of Deficiencies
F 174 S/S (A-L)	42 CFR 483.10 (k) The resident has the right to have reasonable access to the use of a telephone where calls can be made without being overheard. This requirement is NOT MET as evidenced by:

Requirements

Federal requirements for participation or coverage can be categorized as follows:

- **Structure - requirements** that specify the initial conditions that must be present for an entity to be certified to participate and that, in general, are expected to remain as is unless there is a need for major renovation, reorganization or expansion of services. Some examples of structure requirements include:

  The agency has by-laws that **or** Each bedroom measures

- **Process - requirements** that specify the ongoing manner in which an entity must operate. They do not allow the entity discretion to vary from what is specified. Examples of process requirements include:

  The plan of care must be reviewed by **or** The physical examination is conducted on an annual basis

[1] If a LSC chapter references another chapter or NFPA reference document, the referenced chapter or document should also be cited. For instance, 1985 Life Safety Code, 13-3.5.1: Sprinkler systems shall be in accordance with Chapter 7.7-7.1: Sprinkler systems shall comply with NFPA 13, Sprinkler systems… 4-4.1: Buildings shall be sprinkled throughout the premises.

- **Outcome - requirements** that specify the results that must be obtained or events that must occur or not occur following an act. Generally, these requirements are stated in terms of the recipient's response to receipt of needed services or conditions that must result from, or are prevented by, implementing one or more processes. Example of outcome requirements include:

  The facility must ensure that a resident maintains acceptable parameters of....

  F-314: Based on the comprehensive assessment of a resident, the facility must ensure that a resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates they are unavoidable.

The findings document the outcomes that occurred or failed to occur or failure to assist the individual(s) to achieve optimal improvement in overall functioning or to prevent avoidable regression or loss of function. The citation documents sufficient facts to illustrate the level of harm that has occurred or may occur.

Deficient Practice Statement

The statement of deficient practice must be written in terms specific enough to allow a reasonably knowledgeable person to understand the aspect(s) of the requirement that is (are) not met. They are also used to identify the levels of scope and severity of the deficiency. It includes what the entity did or did not do which caused the noncompliance.

The statement of deficient practice must not repeat the regulation, but should state what the facility did that was wrong or failed to do, to let the reader know what to look for in the findings. The statement of deficient practice presents the specific action(s), error(s), or lack of action(s) relative to the requirement.

The evidence for a citation begins with a statement of deficient practice that summarizes the issues that led to the determination that the entity was not in compliance with that requirement and contains all the objective findings. The statement of deficient entity practice includes: (1) the specific action(s), error(s), lack of action (deficient practice); (2) when possible, resultant outcome(s) relative to the deficient practice; (3) a description of the extent of the deficient practice or the number of deficient cases relative to the total number of such cases; (4) the code of the individuals or situations referenced in the extent of the practice; and (5) reference to the source(s) of the information through which the evidence was obtained.

Some certification requirements state multiple expectations at a single survey data tag. The entity must maintain compliance with each facet of the requirement in order to continue participation. The failure to comply with only one expectation may be sufficient evidence for a citation of the entire requirement. The deficient practice must be described

in concise clear terms so that the entity can determine which part of the regulation it has NOT MET. The deficient practice statement should be organized and presented in a logical manner and should relate to each part of the regulation with which the entity failed to comply.

Exhibit 3-2 - Effective Documentation of Deficient Practice Statement

Tag	Summary Statement of Deficiencies
F 455	42 CFR 483.70 (c)(1) The facility must provide sufficient space and equipment in dining, health services, recreation, and program areas to enable staff to provide residents with needed services as required by these standards and as identified in each resident's plan of care. This requirement was NOT MET as evidenced by: Based on observation, record review and staff interviews, the facility failed to provide a space and the equipment required for physical therapy services for 4 of 10 sampled residents (4, 6, 7, and 10) who needed mat exercises, ambulation in parallel bars, and weight training to improve their physical functioning. Findings include:

Extent

Extent is the prevalence or frequency of a deficient practice and is a numerical quantification of the deficient practice. The extent is expressed in a numerical format by identifying the number of deficient cases within the total number of relevant cases or universe. For example, 4 of 6 residents observed during lunch. The universe may be all of the recipients provided care and services by an entity, if the failed practice affects all the recipients, e.g., when a hospital does not provide adequate maintenance of the fire alarm system. When the failed practice does not affect all the recipients of care and services provided by an entity, the surveyor must attempt to determine the relevant universe or the total number of recipients who could be affected by the failed practice. For instance: The ESRD center does not provide adequate monitoring of anti-coagulant therapy. Only those patients on anti-coagulant therapy would be affected by the deficient practice. Therefore, the universe would be the total number of patients with orders for anti-coagulants.

The surveyor then determines the number of individuals within the sample or expanded sample on anti-coagulant therapy who were harmed or could be harmed by the failed practice. Did the ESRD center fail to monitor all of those patients on anti-coagulant therapy? If not, how many were not monitored? The total number of patients affected by the failed practice divided by the total number of patients that could have been affected

by the failed practice provides a numerical quantification in percent of the extent of the failed practice.

The extent of deficient practice will depend upon whether:

1. The requirement related to all cases or individuals served by the entity;

2. Surveyors had knowledge of all cases to which the requirement applied;

3. The requirement related to a subset of all the cases or individuals served by the entity or only a sample of applicable situations or cases;

4. The deficient practice was determined through only random opportunities for discovery.

> Based on observation, the facility failed to maintain appropriate lighting standards for 7 of 12 emergency exits and failed to test pressure back flows on 2 of 2 water lines. In this example, there are 3 separate expressions of extent: the deficient practice created a potential hazard/impact on the entire recipient population, there were 12 exits and the lighting was insufficient at 7 of those 12, and 2 of 2 water lines were deficient.

- Knowledge of all cases or situations

When the deficiency is based on knowledge obtained about all applicable cases or situations, both this total and the number of cases/situations that evidenced deficiency should be recorded within the body of the citation. The following phrases illustrate a variety of acceptable measures:

> In an interview with the pharmacist at 2:00 p.m. on 5/29/XX he stated that of 98 residents at the facility for whom Haldol had been prescribed, 74 had individual program plans that had not been developed with the participation of…
>
> The hospital's pharmacy committee minutes dated 01/11/XX confirmed that of the 86 patients to whom medications are administered, 45 (approximately 53%) were identified as being unable to...
>
> Nineteen of the 20 residential living units were observed to need the following repairs:
>
> Each of the 5 seclusion rooms used by the facility

- Sample of applicable situations

  When the requirement is not applicable to all of the cases or individuals served by an entity, the extent would be developed by using only the cases or individuals with a negative outcome as a result of the deficient practice divided by the total number of cases or individuals in the sample that could have been impacted by the deficient practice. The extent of deficiency should be reported in numeric, quantified terms. For example:

  Review of records for 10 of the 60 patients who received transfusions between 7/10/XX and 9/30/XX revealed that the facility failed to monitor the vital signs for 6 of the 10 patients...

  Records for 2 of the 4 surgical patients in the recovery room at 9 AM on 1/7/XX and 3 of the additional 9 records reviewed of patients having had surgery between 12/28/XX and 1/6/XX revealed that no history and physical had been documented or dictated.

  Based on record review, and patient and staff interviews, the facility failed to complete an incident and accident report for 1 of 8 sampled patients (#6) reviewed and failed to analyze incident reports for health/safety hazards for 16 of 16 incidents reviewed.

  Based on observation, interview and record review, the facility failed to respond to residents' requests for assistance in a manner that maintained or enhanced their dignity for 5 of 9 sample residents (#5, 9, 12, 18, 24).

  Resident Assessments of 5 residents in the sample of 10 had not been evaluated by...

  For 22 of 50 clients in the sample who have current restraint programs authorized, 19 were...

- Random opportunities for discovery

When the deficiency is based on random opportunities for discovery of the problem, all of the applicable cases or situations may not be known. Surveyors may quantify their observation but may not be able to reference a total number of cases or situations that apply. Even though this procedure does not yield as precise a measure as has been discussed above, the report of measure is valid, particularly when serious outcomes of the deficiency have been observed and reported.

For example:

  In 3 of 4 random observations, the facility failed to honor the resident's requested preference for an alternate meal choice (RS #1, 2, 3).

Based on record review, interview and patient observation, the staff did not recognize and failed to assess the patient for the signs and symptoms of possible fecal impaction.

During the tour of Ward J-7 on XX/XX/XX at 10:00 am, three CNAs were observed addressing residents about their incontinent and personal hygiene in the solarium using extremely loud voices that could be heard down the hall. (RS #1, 2, 3, 4).

Based on observation, on XX/XX/XX the integrity of firewalls located between 1-East and 1-West was breached by a hole measuring 5 inches…

During tour on unit on XX/XX/XX at 2:15 p.m., RS #1 was observed to be mechanically restrained to his bed in locked leather cuffs while he was asleep…

Identifiers

An individual's name must not appear in the Form CMS-2567. The identity of the recipients of deficient practice or any persons, including surveyors, who will be referred to in the report, must remain confidential. They are included in the report by indicating their identifiers, which can be letters, numbers, or a combination or both. These identifiers also appear in the statement of deficient practice and in the findings.

When the person referred to in the report is an entity staff member, the person(s) may be addressed by their position, discipline, or job title, or be assigned an identifier.

Identification of each case found to be deficient provides the entity with information necessary to evaluate the context of the problem. When the evidence refers to individual recipients, the statement of deficient entity practice should reference by identifiers.

The coding system used to indicate the recipients should be decipherable by the entity, and retrievable by the RO or SA. Whenever possible, if a revisit or follow-up survey finds noncompliance for the same individual as in the standard survey, reassign the same identifier code. If it is not possible to use the same identifier, use a different set of numbers for revisits so that in the event of a hearing, the same identifier is not used for two different recipients. Every effort should be made to protect a recipient's privacy especially regarding information gathered during an in-depth interview. Do not identify recipients or family members without their permission. If the interviewee does not wish the entity to know the source of the information provided to you, that information may be recorded on the Form CMS-2567 without an identifier. The CMS-2567 would state, 'During a confidential interview...." However, the interviewee must be told that there is no guarantee this information will remain confidential as a court may require that confidential information be disclosed. If the interviewee's identity is not disclosed to the

entity, the Form CMS-2567 must contain sufficient information for the entity to correct the deficient practice, and to contest the deficiency, if it desires.

When the deficient entity practice references personnel files or staff training, a separate coding system should be developed to identify the staff affected by the deficient entity practice without using their names.

When random observations or recipients/cases/records beyond the original sample(s) are included in a citation, an identifier should be given to the individual so that the entity may evaluate the extent of the problem or patterns and correct the deficient entity practice.

For example:

> During dining observations in an ICFs/MR, 4 non-sample random clients are observed who were not given an opportunity for incidental training during their dining experience.

After further investigation focused on the identified concern, if a citation is developed, these randomly observed clients need to be assigned an identifier so that the entity may address the deficient practice in its POC.

Examples of identifiers include:

> Sample Recipient identifiers:...for 3 of the 5 clients in the sample (Clients 2340, 5496, and 0429). Staff identifiers: (Title or Position) Based on interview with the ADON responsible for infection control, the entity failed **OR** Staff Identifier Coding System: 7 of 10 CNAs did not receive the 12 hours of in service training (So, 2, 3, 4, 7, 9, 10). Confidential Interview Identifier: Based on record review, the ESRD (entity) failed to allow patient participation in the development of the long term care plan for 4 of 10 patients (#2, 4, 5, 10). In addition a confidential interview revealed...

Sources of the Evidence

The source of evidence is the manner through which the evidence was obtained. Sources of evidence may include: observation, interview, and record review. They contain specific information regarding the who, what, when, where, and how of the events(s) or situation(s) that contributed to the deficiency. It is best to utilize supporting evidence obtained from more than one source of evidence.

The sources of evidence are presented in the statement of deficient practice and are described in detail in the findings portion of the Form CMS-2567 report.

Each statement of deficient practice identifies the source(s) through which the evidence was obtained, that is, from observation, interview, or reviews of records or other documents. Sources identified in the entity practice statement must be represented in the findings. The findings describe the specifics regarding the sources.

For example:

> What was learned from the source; the date, time, and location of the observations; the date and time of the interviews; titles of the interviewed persons and the types and dates of records/documents used in the identification of the deficient practices.

Do not identify the recipients or families when using information from the interview. Use a generic term to identify the person who has been interviewed, e.g., a family member, or a resident. Identify by title those staff who were interviewed. If more than one of the same type is interviewed, then the number of staff should be identified.

Observations

Observation is the process by which a surveyor gathers information in accordance with the requirements, based on input obtained from the five senses. It is what the surveyor sees, hears, touches, smells or tastes during the survey that evidences an entity's deficiency. It must answer the who, what, where, when, and how questions. A surveyor may observe if the actions or outcomes described in a clinical or administrative record actually occur in the daily operation of the entity. Actions or outcomes that are described in a clinical or administrative record and observed are also recorded as an observation.

The surveyor must note the specific date and time the observations were made and describe the observation.

Detailed documentation of observations of deficient practice assists the provider in identifying when and where the deficient practice occurred. Time includes the number of observations in which the deficient practice was observed and, as appropriate, the duration of each observation. For example, a series of observations that identify the failure to deliver service from 4:00 P.M. to 6:00 P.M., may help the entity to identify staffing or supervisory concerns, such as, inadequate supervision or sufficient staffing on a particular shift. Terms such as "throughout the survey," " during observation on the second day of the survey," etc. are vague, too general and should be avoided. Exhibit 3-3 illustrates an appropriate manner to document the evidence that was obtained through observation.

Exhibit 3-3 - Effective Documentation of Observation-Based Findings

Tag	Summary Statement of Deficiencies
K 021	NFPA 101 STANDARD: LIFE SAFETY CODE STANDARD Doors in fire separation walls, hazardous area exposure, horizontal exits, or smoke partitions may be held open only by devices arranged to automatically close all such doors by zone or throughout the facility upon activation of: (a) The required manual alarm system and (b) Local smoke detectors designed to detect smoke passing through the opening or a required smoke detection system and (c) The automatic sprinkler system, if installed. 13-2.11.5 Based on observations, the facility used a door wedge (an unapproved Device) to hold open 1 of the 9 entry doors included in the facility's fire Safety system. Findings include On facility tour between 2:30 and 3:30PM on xx/xx/xx, a door wedge was Observed at the foot of the West entry door holding the door open. The Door was being held in an open position and could not automatically close in case of fire.

Interviews

The interview process largely consists of talking to individuals (e.g., patients, clients, residents, family, visitors, staff, physicians, ombudsman) to collect information in accordance with requirements about the entity practices. Information obtained through interviews can provide evidence to support a deficiency.

For example:

Surveyors talk with recipients to determine whether the entity fulfills the commitments it has made in records; staff are interviewed to determine their knowledge of the needs of the recipient and of entity polices and procedures. To the greatest extent possible, the surveyor verifies the information obtained from interview through observation or record review. In the absence of other objective validation of information, information may also be confirmed/verified through multiple interview sources.

Exhibit 3-4 - Effective Documentation of Interview Based on Findings

Tag	Summary of Statement of Deficiencies
F 252	42 CFR 483.15 (h)(1) The facility must provide a safe, clean, comfortable and homelike environment, allowing the resident to use his or her personal belongings to the extent possible. This requirement was NOT MET as evidenced by: Based on observation and interview, the facility failed to provide a homelike environment for 2 of 15 sampled residents (#5, #6) whose rooms lacked individual decorations and any personal belongings. Findings include: 1. Observations made during the tour at 10 AM on xx/xx/xx, noted that Resident 5's room was barren of any individualized decorations and personal belongings. During an interview on XX/XX/XX at 3:00 p.m., Resident #5 stated, "I miss my pictures; they are all I have left. I want them with me but no one will get them for me. I want my own toiletries too!" 2. At 10 AM on xx/xx/xx, Resident #6's room was observed to be barren of any individualized decorations and personal belongings. During an interview on XX/XX/XX at 11:00 a.m., a family member of Resident #6 stated, "My (Resident #6) would like to have a rocking chair. I asked the nurse if I could bring it in and she said she would check on it and let me know. This was about three weeks ago and she has not yet told me if it was acceptable or not." During an interview with the director of nursing (DON) on XX/XX/XX at 1:00 p.m., the DON revealed that the facility was aware of the residents' requests for personal belongings but had tried to discourage displays of any personal items to reduce theft in the facility.

Review of Records and Other Documents

Evidence discovered during review of the entity's documentation is discussed with the staff to determine if additional documentation or other information exists. Record or document review is the process through which administrative (e.g., statements of policy and procedure, committee minutes, injury/incident reports) and clinical (e.g., comprehensive assessments and evaluations, consultations, laboratory reports, plans of care, progress notes) documents are read and analyzed. Through review of recipients' clinical records, surveyors determine the needs of individuals and the extent to which the

entity has addressed those needs. Through review of administrative documents, surveyors assess the entity's compliance with requirements for the maintenance and use of those documents.

When using information obtained through record review, identify the record that contained the information. If the deficiency results from a lack of documentation, make sure the documentation is requested from the staff member who might or who should know where the documentation can be found.

Obtain copies of the records, which show the deficient practice to prove the deficiency, and to show after-the-fact changes that may be made by the entity.

If the regulation requires a policy on specific issues, ascertain that the policy fails to address the necessary issues before determining it is deficient.

Examples of documenting information from records and some of the additional investigation necessary, include:

> Patient Y's medical record contained a urinalysis report dated XX/XX/XX for urine which was sent to a laboratory on XX/XX/XX. The report indicated the sample had been contaminated and recommended that a new sample be submitted. The record did not indicate that another specimen had been sent and the staff on XX/XX/XX were unable to determine if any had been sent.
>
> The medical record did not contain the results of the urinalysis for the sample sent to the lab on XX/XX/XX. Staff were unable to locate the report and reported upon inquiry of the lab that the results had not been sent to the facility.
>
> The initial Minimum Data Set (MDS), dated XX/XX/XX, documented that a resident was readmitted from home on XX/XX/XX with a reddened area. The nurses notes dated XX/XX/XX, documented a "reddened area to left ankle."

Exhibit 3-5 - Effective Documentation of Record Review-Based Findings

Tag	Summary Statement of Deficiencies
V 321	405.2137(b)(4)STANDARD: PATIENT CARE PLAN The care plan for patients whose medical conditions has not stabilized is reviewed at least monthly by the professional patient care team described in paragraph (b)(2) of this section. For patients whose condition has become stabilized, the care plan is reviewed every 6 months. The care plan is revised as necessary to insure that it provides for the patient's ongoing needs. This STANDARD is NOT MET as evidenced by: Based on record review, the provider failed to address changes in therapies on the Patient Care Plan (PCP) for 2 of 7 patients (#1, #4). 1. Review of the admission progress note dated 4/10/XX showed that Patient #1 started receiving peritoneal dialysis (in the home) on 4/1/XX. Per the 10/2/XX Social Services note, Patient #1 was switched (at the request of the patient) from peritoneal to hemodialysis (in the dialysis center) on 9/11/XX. Review of the most current PCP dated 12/2/XX revealed that this change in treatment modality was not addressed in the PCP. 2. Patient #4 started hemodialysis (in the dialysis center) on 2/11//xx per the admission assessment. The 9/8/XX Physicians Progress note indicated that Patient #4 received a transplanted kidney on 4/5/XX, but restarted hemodialysis again on 8/1/XX after the transplant was rejected. Review of the PCP dated 12/2/XX revealed that the patient's changes in status were not addressed in the PCP.

Exhibit 3-6 - Effective Documentation of Record Reviews

Tag	Summary Statement of Deficiencies
F 225 S/S	42 CFR 483.13 (c)(2) The facility must ensure that all alleged violations involving mistreatment, neglect or abuse, including injuries of unknown source and misappropriation of resident property are reported immediately to the administrator of the facility and to other officials in accordance with State law through established procedures (including to the State survey and certification agency). This requirement was NOT MET as evidenced by: Based upon staff interview, review of medical records, and review of the policy and procedure manual, facility staff did not report to the administrator bruising of unknown origin for 2 residents in the sample of 20 (#15, 24). The findings include: 1. A record entry dated XX/XX/XX, for resident #24 noted that staff had observed bruises on the resident's genitals and inner thigh. During an interview at 1:00 p.m. on XX/XX/XX, the Director of Nurses stated that the Administrator had been ill for 2 months around that time and she had been acting Administrator. She said, "Staff did not report the bruises to me ...I have not investigated for the cause of the bruises." 2. A record entry, dated XX/XX/XX, for resident #15 noted that staff had discovered that the bridge of the resident's nose was very bruised and no indications of a possible cause were noted. An interview with the charge nurse on the south wing on XX/XX/XX at 10:00 a.m. confirmed that no one knew how the bruise occurred. The injury of unknown origin had not been reported to the administrator and had not been investigated. 3. Review of the policy and procedure manual on XX/XX/XX, did not provide evidence that the facility had established procedures in the manual that specify how allegations of abuse or injuries of unknown origin were to be reported. During interview on XX/XX/XX at 3:00 p.m., the administration confirmed that the facility had no current policy or procedure directing staff regarding when to report possible abuse or injuries of unknown origin.

The following are examples of complete citations that comply with the Principles of Documentation.

Exhibit 3-7 - This example reports the evidence in a way that the entity can understand that the requirement was not met and how the survey team determined that the requirement was not met. The facts are stated clearly, the deficient practice is apparent, and there is no extraneous information within the citation that might cause confusion. All of the components of a complete citation are included.

Exhibit 3-7 - Effective Documentation of Principle #3

Tag	Summary Statement of Deficiencies
L 210	418.94 (a)Standard: Supervision A registered nurse visits the home site at least every two weeks when aide services are being provided, and the visit includes an assessment of the aide services. This STANDARD is NOT MET as evidenced by: Based on review of 4 of 12 medical records (#5, 3, 9, 12) and interviews in 2 of 4 home visits (#5, 12), it was determined that the registered nurse visit did not include an assessment of whether the aide provided grooming services (shampoo and shower) to the patients. The findings include: 1. Review of medical records for Patient #5 revealed that: between 10/20/XX to 12/20/XX, the records did not contain documentation that any of the registered nurse visits to the home site included an assessment of the aide services. The son of Patient #5 said, during an interview on 12/28/XX, "The aide never shampoos my Mom's hair and the nurse said that she is supposed to be doing that." During an interview at 10 a.m. on 12/29 with the nurse caring for the patient, the nurse acknowledged that the family member had mentioned the shampoos, the plan of care did indicate the patient was to receive shampoos, but she had not followed up with the aide about not doing them, nor had she verified what was reflected on the aide assignment sheet or what the aide had recorded. 2. Review of medical records for Patient #12 revealed that: between 10/28/XX to 12/28/XX, the records did not contain documentation that any of the registered nurse visits to the home site included an assessment of the aide services. The family member of Patient #12 said, during an interview on 12/28/XX, "The aide did not give (my family member) a shower; instead the aide gave (my family member) a very quick bath in bed. I don't know why but the aide always comes late and leaves early."

Tag	Summary Statement of Deficiencies
	3. The same lack of documentation regarding registered nurse visits to the home site to assess aide services was found in medical records for Patients #3 for review period 03/10/XX to 05/07/XX; and #9 for review period 02/11/XX to 03/29/XX.

Each of the three sources may not be necessary to confirm a deficiency. Regardless of the particular avenue(s) through which information about an entity's compliance with requirements is gathered, the Principles of Documentation statement should include how the information was obtained.

Outcomes

To the extent possible, especially where described or anticipated in the requirement(s), the deficient practice indicates outcome(s). The statement of findings describes the specific results and consequences of the entity's deficient practice for the individual cases reported. Negative outcomes include deterioration, failure to improve or maintain, etc. Although no negative outcome may be evident from the deficient practice, a failure to comply with a requirement is a deficiency. Many requirements are not outcome oriented. An example of outcome requirements includes:

A resident who enters the facility without pressure sores does not develop pressure sores.

Exhibit 3-8 - Effective Documentation of Deficient Practice Statement

Tag	Summary Statement of Deficiencies
F 314	42 CFR 483.25 (c) Based on a comprehensive assessment of a resident, the facility must ensure that (1) a resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable: and This requirement was NOT MET as evidenced by: "Based on observation, staff interview, and record review, the facility failed to provide services to prevent the development of a pressure ulcer, to promote healing and to adhere to infection control measures (universal precautions) designed to prevent cross contamination resulting in the development of an avoidable Stage III pressure ulcer for 1 of 3 sample residents (R#2) with pressure sores. Resident #2 experienced ongoing pain, infection and was unable to continue activities of daily living." Findings include:

This example reports the evidence in a way that the entity can understand that the requirement was not met and how the survey team determined that the requirement was not met. The statement identifies the extent of the deficient entity practice, includes identifiers for the individuals affected by the deficient entity practice, identifies the sources from which the information was obtained, and clearly states the outcomes of the deficient entity practice.

Findings

Findings support or illustrate an entity's noncompliance with a requirement. Cite only findings attributable to the entity. Each statement of deficient practice is followed by the specific findings (**who, what, where, when, how)** that illustrate the entity's noncompliance for each case/issue referenced in the deficient practice statement. The facts are presented in a concise and logical sequence. The findings include the outcomes, descriptions of actions/situations, identifiers, and sources. Any evidence that supports a finding and affects the deficiency determination must be incorporated into the deficiency citation.

When details for a number of individual examples have been described to illustrate a particular deficient practice, a final entry may describe additional similar findings and identifiers to demonstrate the magnitude of the problem.

Facts

A fact is an actual occurrence, something known to exist or have happened. The findings are facts that allow the entity to compare what it did or failed to do, against what is required. The findings support the deficient practice statement. For example, if residents #1, 3, 5, and 7, are discussed in the deficient practice statement, the findings are the facts to support the noncompliance for residents #1, #3, #5,and #7.Without the presence of facts, the evidence can be construed to mean that an assumption was made, rather than a known conclusion about the entity's practice.

Failure to include pertinent facts may prevent the entity from discovering what contributed to the deficient practice. For example, there may be many reasons for the failure of a patient to receive a needed treatment, such as: the patient was not scheduled for a treatment; the staff had not been trained regarding how to provide the treatment; trained staff were not available to provide the treatment; trained staff were available but forgot to provide the treatment; proper authorization for treatment was not provided; or, the patient refused the treatment.

Identification of the pertinent facts gives the entity the means to examine the failure to comply, in light of the specific circumstances or contexts, which the failure occurred.

When writing a deficiency citation, try to provide answers to basic questions - Who?, What?, When?, Where?, and How?. Based on the nature of the deficiency, it may be

impossible or inappropriate to answer each question. However, this approach facilitates inclusion of the pertinent facts. Deficiency citations identify:

How the deficiency was determined, and how the evidence relates to the requirement;

What entity practice was noncompliant;

Who were the residents or staff involved;

Where the deficient practice occurred, e.g., specific locations in the entity or documents; and

When (e.g., for how long) the problem occurred. Include the number of observations and the duration of the observations. Include the specific dates or time period for the noncompliance. The findings also include documentation of verification or request for additional information through interviews with facility staff.

Exhibit 3-9 - The statement of the findings in this example illustrates how the relevant facts answer the basic questions of who, what, when, where and how.

Exhibit 3-9 - Documentation of Facts

Tag	Summary Statement of Deficiencies
F 369	F369 42 CFR 483.35(g)) The facility must provide special eating equipment and utensils for residents who need them. This requirement is NOT MET as evidenced by: Based on record review, observation and interview "HOW" the facility failed to provide adaptive fork and spoon "WHAT" for a resident (R#7) who was assessed to need these items. "WHO" The findings include: 1. The care plan, dated XX/XX/XX for Resident #7 "HOW" indicated that R#7, who has suffered from a recent "WHAT" stroke, needed adaptive utensils to eat meals independently. 2. R#7 was observed in the dining room during "HOW" and "WHERE" breakfast on XX/XX/XX and XX/XX/XX, "WHEN" lunch on XX/XX/XX and XX/XX/XX, and "WHEN" dinner on XX/XX/XX "WHEN"

Tag	Summary Statement of Deficiencies	
	struggling to eat, using a regular fork and spoon, and most of the food was falling off the utensils	"WHAT"
	The resident ate only about 25 percent of each meal	"WHAT"
	3. During an interview with the nurse aide on XX/XX/XX at 12:00 p.m., the nurse aide stated, "For a few days R#7 was given special utensils, but I don't know what happened to them	"HOW"
	I haven't seen them for a week or so."	"WHEN"
	4.R#7 said during an interview on XX/XX/XX at 12:25 p.m. "My right hand just doesn't work like it used to since I had this stroke. I was never good at using my left hand, I don't understand	"HOW"
	why they stopped giving me the special fork and spoon, I guess they just want me to eat with regular silverware."	"WHAT"

Organization of Findings

The findings should be organized in a chronological and logical order. Grouping related findings and facts under applicable statements of the deficient practice statement assists the entity in focusing on the development of plans to correct its deficient practices rather that on correction of the findings. The organization of the findings should clearly convey to the reader the sequential order of events that resulted in a citation. For example, situations or cases are presented in a logical sequence to show individual deterioration over time or date.

When setting forth a series of facts and events, start by setting out the relevant background facts (e.g., "Resident #1 was at risk for weight loss as set forth in the MDS dated XX/XX/XX.") Then, if possible, set out the events in chronological order.
The following example, Exhibit 3-10 illustrates a citation from the home health requirements. The citation is written based on two separate requirements contained in the language of the requirement. It includes two statements of deficient practice and organizes the relevant findings/facts under those statements.

Exhibit 3-10 - Effective Documentation of Two Deficient Practice Statement and Their Findings

Tag	Summary Statement of Deficiencies
G 108	42 CFR 484.10(c)(1)STANDARD:RIGHT TO BE INFORMED AND PARTICIPATE IN PLANNING CARE AND TREATMENT The patient has the right to be informed, in advance about the care to be furnished, and of any changes in the care to be furnished. The HHA must advise the patient in advance of the disciplines that will furnish care, and the frequency of the visits proposed to be furnished. The HHA must advise the patient in advance of any change in the plan of care before the change is made. This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the agency failed to inform 2 of 12 patients (#3 and #9) reviewed about changes of the frequency of care to be furnished, and the facility failed to inform 2 of 12 patients (#7 and #10) in advance of changes to the plan of care. The findings include: Changes in Frequency of Care: 1. Patient #3 began receiving services on 10/15/XX due to a fractured hip. These services were to include physical therapy (PT) three times a week for 8 weeks for gait and balance training to restore ambulation ability. The PT note, dated 11/1/XX, states, "Increase in case load prohibits three sessions a week of treatment. Frequency to be once a week for reminder of treatment." Observation during the 12/7/XX home visit revealed that the patient is not ambulating. Interview on 12/7/XX during the home visit with Patient #3 indicates that the patient was not informed of the change of frequency of the PT services. Telephone interview with the physical therapist on 12/7/XX confirms that this patient is not ambulating due to the decreased frequency of treatment and that the patient was not informed of the change of frequency. 2. Patient #9 began receiving services on 9/10/XX due to a stiff shoulder....

	Changes in Plan of Care 1. Patient #7 began receiving services on 11/20/XX. The plan of care dated 11/23/XX, indicated that services were to include skilled nursing services for wound care and home health aide assistance for activities of daily living. On 11/28/XX, the nurse's note states: "care plan revised as the home health aide can do wound care. Sufficient healing has occurred so that skilled services are not indicated. Wound needs to be cleansed during bathing." Observation on the 12/8/XX home visit indicated that the wound was healed. Interview with Patient #7 indicated that the patient wondered about the whereabouts of the nurse who used to come to clean the wound. She had not seen her in a long time. Interview with the nurse indicated that as the person was progressing well, there was no need to inform her about the change in the plan of care. 2. Patient #10 was admitted for service on 11/13/XX.The plan of care, dated 11/13/XX, identified an occupational therapy (OT) consultation to determine if environmental modifications to the home were indicated. An OT note of 11/17/XX states: "Consultation not indicated." No additional information was recorded. Interview with Patient #10 on 12/8/XX indicates that he was satisfied with the services received, but, "I hope that the person who is supposed to help with the arrangement of the house gets here soon. It is difficult for me to get around here." Interview with the Director of Services on 12/8/XX confirmed that the person was not informed of the changes to the plan of care."

Principle #4 - Relevance of Onsite Correction of Findings

If, during the survey, a deficiency is found, but the entity corrects the situation as soon as they become aware, a determination of "NOT MET" must be documented on the Form CMS-2567. The entity may indicate its correction in the right-hand column of the Form CMS-2567. If, during the survey, the entity initiates corrective actions that abate a finding of immediate jeopardy, follow the guidance described in Appendix Q. The entity may indicate its correction in the right-hand column of the Form CMS-2567.

If an entity demonstrates practices that cause it to be out of compliance, there may be a system failure. The findings used as part of the evidence illustrate the result of that failure; the findings are not the cause of it. Mere correction of the findings reported to the entity prior to the exit conference would not necessarily assure that the cause of the finding had been addressed. The entity, not the survey team must ascertain the cause and correct the systems failure that caused the deficient entity practice.

Exhibit 4-1 demonstrates how to document a deficient practice even though the entity may have addressed the effects of the practice during the survey.

Exhibit 4-1 - Effective Documentation for Principle #4

Tag	Summary Statement of Deficiencies
G 145	483.14(g)Standard Coordination of patient services A written summary report for each patient is sent to the attending physician at least every 62 days. This standard is NOT MET as evidenced by; Based on record review and staff interview, it was determined the home health agency failed to ensure a written summary report which included a compilation of pertinent factors of patient's clinical progress had been sent to the physicians' office for 2 of 2 sampled patients (#4, and 5) who required a 62 day summary. Findings include: 1. Patient #4 was admitted for home health services on XX/XX/XX. The plans of care for the certification periods XX/XX/XX to XX/XX/XX and XX/XX/XX to XX/XX/XX included goals which stated "Patient will experience stable cardiopulmonary status as evidenced by clear lung sounds, no chest pain, SaO2 (saturation of arterial blood) greater than or equal to 92%." Summary reports addressing the patients progress or lack of progress were not available as part of the Patient's clinical record. 2. Patient #5 was admitted for home health services on XX/XX/XX with the diagnosis of pressure ulcer and congestive heart failure. The plan of care for them certification period XX/XX/XX to XX/XX/XX included goals that stated " Patient will have pressure ulcer healed with no sign or symptoms in 10 weeks." The summary report addressing the status of the patient's wound was not available as part of the clinical record. Staff interview on XX/XX/XX confirmed the HHA had not sent written summary reports to the physicians, until after the surveyor inquiry when summary reports were then completed and faxed to the physician during the survey.

Correction of Immediate Jeopardy (IJ) During Survey

Exhibit 4-2 documents noncompliance with a participation requirement that resulted in a situation of immediate jeopardy. The CMS-2567 includes the facility's actions to remove the immediate jeopardy while the survey team was onsite; however, as stated above, mere correction of the findings does not assure that necessary corrections, at the systems level, have taken place. Follow the directions for immediate jeopardy located in Appendix Q of the State Operations Manual.

Exhibit 4-2 - Effective Documentation for Correction of IJ during Survey-Principle #4

Tag	Summary Statement of Deficiencies
F 223 S/S = J	42 CFR 483.13(b)Requirement Abuse…The resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion. The requirement is NOT MET as evidenced by: Based on staff interviews and record review, the facility failed to prevent 1 of 21 sample residents (#5) from being assaulted by staff and failed to report the assault to the appropriate authorities in a timely manner and failed to take actions to prevent further such incidents to residents resulting in immediate jeopardy. Findings include: Interviews with 3 CNAs A, B, C, on duty on 7/10/XX, indicated that they observed a certified nursing assistant (CNA)(E-1) "throw" a resident (R#5)to the ground during a picnic at the facility on 5/26/XX. The CNA, who observed R#5 becoming agitated, went to the resident to bring him back into the facility. When the resident became "uncooperative and irritated" and refused to go into the building, the CNA gave the resident a "bear hug." The resident fell to the ground at which time the CNA dragged the resident by the back of his shirt into the facility, a distance of approximately 30 - 40 feet. Nurses notes on 6/1/XX state that the resident had abrasions on the lower lumbar and upper left thoracic regions, but was not able to say how he got them. During an interview with the facility administrator on 7/11/XX, the administrator said, "I was not aware of the incident until 6/1/XX when a staff member asked for medication to put on [resident #5's[cuts. I notified the health department on 6/1/XX." The administrator acknowledged he did not remove the CNA from providing resident care until questioned by the surveyor on 7/11/XX.

	The administrator was notified of the immediate jeopardy at 2:00 p.m. on 7/11/XX. At 3:00 p.m. the administrator notified the survey team that the involved CNA had been removed from duty and that the CNA would be fired.

Principle #5 - Interpretive Guidelines

The deficiency citation demonstrates how the entity fails to comply with the regulatory requirements, not how it fails to comply with the guidelines for the interpretation of those requirements. Various appendices to the SOM contain "Interpretive Guidelines" or "Guidance to Surveyors." These Guidelines were designed to assist surveyors to develop a better understanding of the requirements, to apply these requirements in a consistent manner across entities, and to suggest pathways for inquiry.

Although surveyors must use the information contained in Guidelines, they must be cautious in their use. Guidelines do not replace or supersede the law or regulation, and therefore, may not be used as the basis for a citation. However, they do contain authoritative interpretations and clarifications of statutory and regulatory requirements. Interpretive guidelines can include professionally recognized standards and assist surveyors in making determinations about an entity's compliance with requirements. When an entity is found to violate a requirement because of its connection to a professionally recognized standard, the surveyor must indicate such on the Form CMS-2567.

Surveyors should carefully consider how the practices of the entity relate to the illustrations within the Interpretive Guidelines, and then compare the entity's practice to the specific language and requirement of the regulation before determining that a deficiency exists.

Exhibit 5-1 - Interpretive Guidelines

Regulation	Guidance To Surveyors
42 CFR 483.35 (h)(2) "Sanitary Conditions." The facility must (2) store, prepare, distribute, and serve food under sanitary conditions; and	Hot foods which are potentially hazardous should leave the kitchen (or steam table) above 140 degrees Fahrenheit, and cold foods at or below 41 degrees Fahrenheit, etc... Referenced guidance 1999 FDA Food Code.

Exhibit 5-2 illustrates how material in Interpretive Guidelines can be used to support the citation. The critical factor is whether or not the evidence relates directly to the language and requirement within the regulation.

Exhibit 5-2 - Effective Documentation for Principle #5

Tag	Summary Statement of Deficiencies
W 214	42 CFR 483.440 (c)(3)(iii) The comprehensive functional assessment must identify the client's specific developmental and behavioral management needs. This Standard is NOT MET as evidenced by: Based on observations, staff interview, and record review, the facility failed to include in the comprehensive functional assessment, the client's cognitive ability for 2 of the 4 clients in the home (#2, #3). The findings include: Review of Client #3's medical records, dated between XX/XX/XX and XX/XX/XX, revealed 11 evaluations conducted by the professional staff. None of the evaluations specified any deficits that may have contributed to his diagnosis or his reported developmental level of functioning. Observations on XX/XX/XX and XX/XX/XX confirmed that...In an interview on XX/XX/XX, LPN1 said, "I am unclear about the client's identified strengths."

Principle #6 - Citation of State or Local Code Violations

The entity's failure to comply with State or local laws or regulations is not documented in the Form CMS-2567 except when the Federal regulation requires compliance with State or local laws. When the authority having jurisdiction for that State or local law has made a decision of noncompliance and has effectuated an adverse action that has been sustained through the hearing process (such as removal of the license to operate), the Form CMS-2567 should note that the entity no longer has a license.

Federal certification requirements are uniform throughout the United States. However, States and localities may have additional requirements that the entity must meet in order to continue to operate within those jurisdictions. Some licensing requirements may be more stringent or prescriptive than Federal requirements. Licensure surveys are conducted to determine an entity's compliance with specific State or local laws and regulations. Entities that do not meet the State or local requirements for licensure may not be certified for participation in the Medicare/Medicaid programs.

In the event of a difference in the stringency of a Federal certification requirement and a corresponding State or local (e.g., licensing) requirement, the entity is to comply with the

more stringent of the two. However, when enforcement of the more stringent requirement comes from an authority other than the Federal requirement, the evidence may be recorded on the Form CMS-2567 only in the manner prescribed by CMS.

Failure of the entity to meet State or local requirements is recorded on the Form CMS-2567 at a Federal data tag for one of two reasons:

1. The language of the Federal regulation explicitly requires compliance with State or local laws and codes. Deficiency citations made under these requirements should include a reference to the particular State or local code with which the entity is noncompliant. This insures that there is legal authority to describe any conditions or practices described as deficient. Surveyors always should review their findings relative to the specific Federal requirement to determine if and when an entity's failure to achieve compliance with a licensure requirement is sufficient evidence to cite noncompliance with a Federal certification requirement.

Exhibit 6-1 is consistent with Principle #6. The entity's practice of using LPNs to conduct the health status review was deficient specifically relative to the requirement; or

Exhibit 6-1 - Effective Documentation for Principle #6

Tag	Summary Statement of Deficiencies
W 345	42 CFR 483460(d) The facility must utilize registered nurses as appropriate and required by State law to perform the health services specified in this section. This STANDARD was NOT MET as evidenced by: Based on record review, the facility for the period between 7/1/XX and 9/30/XX, utilized Licensed Practical Nurses (LPNs) to review the health status of residents for 4 of 10 sampled records (2, 6, 12, 19).Section 76543 of the Code of Professional Health Practices (State Requirement) requires that this function be performed only by Registered Nurse (RNs).

2. The authority having jurisdiction has made a determination of noncompliance with State or local law, has taken and sustained an adverse action (See Exhibit 6-2.). An adverse action is any procedure taken by a State Agency that goes beyond the approval of a plan of correction, such as, fines, ban on admissions, loss of license, etc. The authority having jurisdiction is the person or persons who have the authority to make a final determination of noncompliance and are responsible for signing the correspondence notifying the facility of the adverse action. A final determination means the determination has not been appealed or is no longer being appealed by the entity.

Exhibit 6-2 - Effective Documentation for Principle #6

Tag	Summary Statement of Deficiencies
F 492	42CFR483.75(b) Compliance with Federal, State, and local laws and professional standards. The facility must operate and provide services in compliance with all applicable Federal, State and local laws, regulations, and codes, and with accepted professional standards and principles that apply to professionals providing services in such a facility. This requirement is NOT MET as evidenced by: Based on evidence in the attached notice of determination of noncompliance, the entity did not meet (state or local) Law #XXX. An adverse action was taken against the entity by (the authority having jurisdiction.) See attached.

Principle #7 - Cross-References

The cross-referencing of requirements is an acceptable form of documentation on the Form CMS-2567 only when it is applicable and provides additional strength to the linked citations. Descriptive evidence (facts and findings) from one citation may be linked into the evidence for a citation at another requirement. The evidence being linked into that requirement must support the determination of noncompliance with that requirement. Each citation must contain all components described in this document independent of the additional information being linked into that citation. Cross-referencing is most effective when the linked citations have a direct cause and effect relationship to the deficient practices described in both citations. In all instances, each citation must contain sufficient evidence to demonstrate noncompliance for the referenced regulation. Additional guidance for cross-referencing for COP level citations is provided in POD #8.

Tag	Summary Statement of Defciencies
G 170	G170 42 CFR 484.30 Skilled Nursing Services The HHA furnishes skilled nursing services in accordance with the plan of care. This requirement is NOT MET as evidenced by: Staff interview and review of seven clinical records requiring RN skilled services revealed that the RN did not comprehensively assess the patients or furnish the frequency of visits required by the Plan of Care for 4 of the 7 patients (H3 H5, H6, H7). See G174 for additional information regarding patients H3, H5, and H7.

	1. Review of H3's clinical record indicated physician orders for twice daily RN visits from 10/01 to 10/08/XX to administer IV antibiotics, assess the stats of and perform a dressing change to the Stage 3 ulcer of the left heel. The aide sheet for 10/04 reflected that the aide had changed the heel dressing that a.m. The record shows two LPN visits and an evening dressing change by the LPN on 10/04 but does not contain information of an RN visit, assessment or dressing change on 10/04/XX. Interview at 10:30 a.m. on 11/10/XX with supervising nurse confirmed that on 10/04/XX an aide had performed the a.m. dressing change on H3's Stage 3 pressure ulcer of the heel. The supervising nurse reported that although the RN was ill and had not made the planned a.m. or p.m. visits that day, the agency's LPN had performed the visits and supervised the aide. 2. Review of H5's clinical record indicated that the Plan of Care for H5 required RN visits from 4 to 5 times the week of 10/07/XX and 3 times a week for 3 weeks beginning 10/4/XX to assess the patient's response to changes in the medication to control her angina and blood pressure. The RN visited only 3 times (10/07, 10/08 and 10/10) during the week of 10/07 and limited her assessment to checking breath sounds and blood pressure. The RN did not evaluate for signs and symptoms or complications of either hypo or hypertension or for compliance with dietary restrictions or known side effects which accompany the use of calcium channel blockers. 3. Review of H6's clinical record indicated the RN did not visit H6 twice daily as required by the Plan of Care to monitor the institution of sliding scale insulin for the newly diagnosed brittle diabetic. The Plan of Care required twice daily visits from --- to ---. The actual visit frequency was ---.

Tag	Summary Statement of Deficiencies
G 170	G170 42 CFR 484.30 (Cont.) 4. Review of H7's clinical record indicated the RN did not assess, record, and report to the physician the change in the status of the suture line of the hip wound on 10/21/XX.The Plan of Care required RN visits 5 times a week for 1 week then 3-5 times a week for 2 weeks or until the wound healed to change the dressing and assess the character of the post operative wound. The therapist's progress notes from the therapy visit on 10/21 at 10 a.m. (3 hours prior to the RN visit) reflect that the patient complained to the therapist of burning and dampness at the suture line.

Principle #8 - COP Deficiencies

The evidence for the citation of noncompliance with a Condition of Participation explains how the extent or severity of deficient practices justifies a conclusion of noncompliance at the COP level. The COP citation includes a statement(s) of deficient entity practice(s) and findings to support the determination of noncompliance with a condition level requirement. The findings may be incorporated either by cross references to those requirements which must be corrected to find the COP in compliance or by narrative description of the individual findings. The COP citation includes ONLY those requirements that must be corrected to achieve compliance with the COP.

The determination that an entity is not in compliance with an applicable COP is one of the most serious decisions the RO or SA can make. The decision as to whether there is compliance with a particular COP depends upon the manner and degree to which the entity satisfies the various requirements and standards within each COP. If a COP is determined to be deficient, the Form CMS-2567 should identify the specific practices that must be corrected before the entity can be found to be in compliance. If these practices refer to requirements specified at Standards or other subsidiary requirements, the deficient practices and individual findings would be cited at the relevant requirements. The findings under these subsidiary requirements may be referenced under the COP citation.

For certain provider and supplier types, a COP may stand alone at a single survey data tag without accompanying standards or other requirements. The text of the particular COP may have multiple components. Based on the evaluation of the evidence, an entity can be cited at a COP level even if it violates only one component of multi-component regulations.

> For example, in the Ambulatory Surgery Center program, 42 CFR 416.43 Condition for Coverage Evaluation of Quality (tag Q 9) has multiple requirements:
> (1) conduct an ongoing , comprehensive self-assessment of the quality of care provided, (2) include active participation of the medical staff, (3) include review of the medical necessity of the procedures performed and appropriateness of care, (4)

use the findings, when appropriate, in the revision of the center policies and (5) use the findings, when appropriate, in the consideration of clinical privileges.

There may be entity practices relevant to standards that are deficient, yet not essential for a determination of compliance with the COP. Most likely it is because the nature of these practices, individually or collectively, does not justify a conclusion of noncompliance and warrant an adverse action. Such requirements are not referenced at the COP citation. They are included at the appropriate tag number and corresponding CFR reference in the Form CMS-2567.

Exhibit 8-1 - Effective Documentation for Principle #8

Tag	Summary Statement of Deficiencies
Q 003	416.41 Condition Governing Body and Management The ambulatory surgical center must have a governing body, that assumes full responsibility for determining, implementing and monitoring policies governing the centers total operation and for ensuring that these policies are administered so as to provide quality health care in a safe environment. When services are provided through a contract with an outside resource, the center must assure that these services are provided in a safe and effective manner. This Condition is NOT MET as evidenced by: Based on staff interview and review of administrative records, policies and procedures, and infection control and quality assurance documentation, it was determined that the ambulatory surgery center's governing body failed to assume full responsibility for determining, implementing and monitoring policies governing the center's total operation. The governing body failed to ensure that practitioners had been appointed to the medical staff and had been granted privileges to practice at the ASC (refer to Q19, Q20, Q21, and Q22), failed to ensure that a comprehensive quality assurance program was in place (refer to Q9); failed to ensure that an effective infection control program had been established (refer to Q14). The cumulative effect of these systemic problems resulted in the surgery center's inability to ensure the provision of quality health care in a safe environment.

Conclusion

All requirements are binding. The structures, processes and outcomes required by the regulations are necessary for the entity to provide quality care, prevent negative outcomes, and facilitate positive outcomes. Failure of the entity to provide any of the

required services or to meet required conditions constitutes evidence of noncompliance regardless of the presence of outcomes. The purpose of these Principles of Documentation is to provide structure and consistency to the construction of a citation.

Correctly documenting the "Statement of Deficiencies and Plan of Correction" (Form CMS-2567) is the key to the success of the survey and certification process. Effective documentation of the survey signals the provision or denial of financial participation in the Medicare/Medicaid program, as well as the provision of or lack of quality care in health care settings.

Keep in mind that one of the roles of the surveyor is to ensure that quality health care is provided by those entities participating in the Medicare/Medicaid program. It is the surveyor's knowledge of the regulations and how to interpret and apply these regulations in a consistent manner during the survey that will produce a clear description of the entity's deficient practice. When the deficient practices are resolved by the entity, quality of care and quality of life can be a reality in health care settings.

Appendix A - Components to be Documented in A Deficiency Citation

COMPONENTS TO BE DOCUMENTED IN A DEFICIENCY CITATION

Data Tag				
In CFR/LSC/CLIA order				
CFR/LSC/CLIA Reference				
CFR/LSC/CLIA Requirement				
Statement that requirement is "Not Met"				
Evidence: Each Statement of deficient practice with corresponding findings (repeat each practice)	**YES(Y)**	**NO (N)**	N/A	
Extent of deficient practice				
Identifiers (confidential)				
Description of violation of regulation				
Source of evidence				
State/local code reference, if applicable				
Findings/Facts:				
Who				
What				
When				
Where				
How				
Outcome				
Observations: date, time, location				
Record/document reviews: date(s), record type				
Sequential organization of facts				
Is the Deficiency Citation…	**Yes**	**No**	N/A	
Applicable to requirement cited?				
Written in plain language?				
Free of extraneous remarks and advice				

Rehabilitation Reference Manual

Tab 4: Introduction to Comprehensive Outpatient Rehabilitation Facility Survey

4.1 Introductory Comments

4.2 Skills Checklist: CORFs

4.1 Introductory Comments

4.1 Introductory Comments

Section Two of the Reference Manual includes copies of *State Operations Manual* Appendix K and section 2360 that have been updated to 1) provide clearer guidelines for survey using the comprehensive outpatient rehabilitation facility (CORF) regulations and 2) streamline the survey process. The CORF tags have been included in the interpretive guidelines and the expectations CMS has for CORF services have been more clearly defined.

In many States, therapy services are available through CORFs. CORFs are different from other types of Medicare-certified outpatient therapy providers in that, in addition to physical therapy, regulations require that they offer psychological or social services and the services of a physician who specializes in rehabilitation medicine (the treatment of individuals with disabling conditions and diseases, designed to yield improvement in function, level of independence and quality of life). Required CORF services must be provided at a single, fixed location; however, physical, occupational and speech-language pathology services can be provided offsite from the CORF. CORFs are also unique in their authority to provide a variety of nontherapy services, such as respiratory therapy treatment or nursing care, if medically necessary in the context of a patient's rehabilitation therapy treatment plan.

CORFs must be able to provide the required core services and additional services as detailed in the patient's Plan of Treatment. It is not acceptable for the CORF to provide noncore services only. In the past few years it has become apparent that while most CORFs are complying with the regulations in 42 CFR 485.50 regarding the furnishing of required services, a few CORFs specialize in nontherapy services and are not providing the three required core services (physical therapy, psychological or social services, and the services of a physician who specializes in rehabilitation medicine).

CORFs may hire individual providers of rehabilitation services directly or provide services under an arrangement (the CORF may establish contracts with individual providers of rehabilitation services). Such contracts must indicate the hours per week that the provider works. As the CORF must provide physical therapy, social or psychological services and physician CORF services, those providers' hours should match the hours the CORF is in operation.

4.2 Skills Checklist: CORFs

4.2 Skills Checklist: CORFs

The following list summarizes the skills and knowledge necessary for successful survey. The surveyor should be able to:

- ☐ Describe the three core services that a Comprehensive Outpatient Rehabilitation Facility (CORF) must provide.
- ☐ Describe the difference between a CORF and an outpatient physical therapy (OPT) practice.
- ☐ Describe the purpose of the survey tour and what to look for during the tour.
- ☐ Define the types of physicians that meet the qualifications specified for the facility physician.
- ☐ Determine whether the patient care policies meet the Federal standard.
- ☐ Describe what services are required to meet the definition of a comprehensive rehabilitation program.
- ☐ Determine whether the facility physician is spending sufficient time in the facility to meet the intent of regulations.
- ☐ Describe appropriate means of assessing clients for and referring clients to social/psychological services.
- ☐ Determine whether professionals are qualified to provide therapy services, nursing services, etc.
- ☐ Describe the differences in scope of practice for registered therapists (physical therapist [PT]/occupational therapist [OT]), assistant-level therapists (physical therapy assistant [PTA]/certified occupational therapy assistant [COTA]) and rehabilitation aides.
- ☐ Determine what constitutes appropriate supervision of supportive personnel (assistants and aides).
- ☐ Determine when CORF services may be provided off the premises of the CORF.
- ☐ Explain the special considerations that apply if services are being provided off the CORF's premises.
- ☐ Describe what information must be in a client's medical record.
- ☐ Determine how many client records should be reviewed.
- ☐ Describe various pieces of equipment that might be on the premises and their use and maintenance.

- ☐ Describe how to determine if equipment is being properly maintained and calibrated.
- ☐ Determine what the utilization review process involves and whether or not the facility's program meets the requirement.
- ☐ Describe the CORF survey process.

Rehabilitation Reference Manual

Tab 5: *State Operations Manual* Excerpts Pertaining to CORFs

5.1 Appendix K

5.2 Sections 2360–2366

5.3 Section 3224

5.1 Appendix K

5.1

This document is a replica of the official record copy maintained by the Issuances and Records Management Group.

State Operations Manual

Appendix K - Guidance to Surveyors: Comprehensive Outpatient Rehabilitation Facilities

---

Table of Contents

(Rev. 16, 01-10-06)

INDEX-

§485.51 Definition

§485.54 Condition *of Participation*: Compliance With State and Local Laws

§485.54(a) Standard: Licensure of Facility

§485.54(b) Standard: Licensure of Personnel

§485.56 Condition *of Participation*: Governing Body and Administration

§485.56(a) Standards: Disclosure of Ownership

§485.56(b) Standard: Administrator

§485.56(c) Standard: Group of Professional Personnel

§485.56(d) Standard: Institutional Budget Plan

§485.56(e) Standard: Patient Care Policies

§485.56(f) Standard: Delegation of Authority

§485.58 Condition *of Participation*: Comprehensive Rehabilitation Program

§485.58(a) Standard: Physician Services

§485.58(b) Standard: Plan of treatment

§485.58(c) Standard: Coordination of Services

§485.58(d) Standard: Provision of Services

§485.58(e) Standard: Scope and Site of Services

§485.58(f) Standard: Patient Assessment

§485.60 Condition *of Participation*: Clinical Records

§485.60(a) Standard: Content

§485.60(b) Standard: Protection of Clinical Record Information

§485.60(c) Standard: Retention and Preservation

§485.62 Condition *of Participation*: Physical Environment

§485.62(a) Standard: Safety and Comfort of Patients
§485.62(b) Standard: Sanitary Environment
§485.62(c) Standard: Maintenance of Equipment, Physical Location and Grounds
§485.62(d) Standard: Access for the Physically Impaired
§485.64 Condition *of Participation*: Disaster Procedures
§485.64(a) Standard: Disaster Plan
§485.66 Condition *of Participation*: Utilization Review Plan
§485.66(a) Standard: Utilization Review Committee
§485.66(b) Standard: Utilization Review Plan
General Comments

Explanation of Conditions of Participation for

Comprehensive Outpatient Rehabilitation Facilities

42 CFR 485.51 Definition of a CORF

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

*A CORF is established and operated **exclusively for** the purpose of **providing diagnostic, therapeutic, and restorative services** to outpatients **for** the **rehabilitation of injured, disabled, or sick persons**, at a single fixed location, by or under the supervision of a physician **and meets all the requirements of Subpart B**—Conditions of Participation: Comprehensive Outpatient Rehabilitation Facilities.*

I-501

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.54 Condition *of Participation*: Compliance With State and Local Laws

The facility and all personnel who provide services must be in compliance with applicable State and local laws and regulations.

A - General

In order to assure that the Comprehensive Outpatient Rehabilitation Facilities (CORF) and staff furnishing services are in possession of current licenses as required by State and local laws, licenses should be available for review.

If the facility has not met local and State building, fire and safety codes or doesn't have the appropriate licenses, the facility should be refused admission into the program or termination proceedings should be initiated, whichever is appropriate.

Review the licenses to assure the licenses are current and are applicable to the State in which the provider is providing services.

B - Major Sources of Information

1. State and local laws governing health care; building, fire and safety codes;
2. Applicable State and local licenses and organization personnel records containing up-to-date information; and
3. Written policies pertaining to communicable and reportable diseases, conforming to applicable State and local laws.

I-502

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.54(a) Standard: Licensure of Facility

If State or local law provides for licensing, the facility must be currently licensed or approved as meeting the standards established for licensure.

The facility must meet all building, fire and safety codes where these are required for licensure before a facility would be eligible for certification. Ascertain that all State and local licenses, permits and approvals that govern the facility's operation are current and valid.

If the proper authorization(s) has not been granted, or has been temporarily revoked or suspended, the facility should be found in noncompliance with this standard.

If a facility has been issued a provisional license, permit or approval, determine whether the limitation(s) prevents the facility from complying with the conditions of participation.

Document the reason for this issuance including the limitation(s) imposed on the facility's operation.

Facilities exempt from State licensure, must be approved by the State as meeting the standards established for licensure. Examples of exempted facilities may include facilities that operate on a Federal reservation under agreement with the Department of Health and Human Services and facilities operated by a State, city or county health department.

I-503

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.54(b) Standard: Licensure of Personnel

Personnel that provide service must be licensed, certified, or registered in accordance with applicable State and local laws.

Personnel providing services at the CORF must be licensed**,** registered or *certified* when licensure, registration or *certification* is applicable. This includes employees, independent contractors and individuals from organizations with which the CORF has an arrangement to provide services.

Review policies and procedures regarding the CORF's verification of qualified personnel.

Verify licensure or registration of personnel by reviewing a central State listing or other evidence such as wallet size identification cards.

I-505

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.56 Condition *of Participation*: Governing Body and Administration

The facility must have a governing body that assumes full legal responsibility for establishing and implementing policies regarding the management and operation of the facility.

A - General

The CORF must have a governing body which is responsible for its policies and operation, and which appoints an individual to act as the facility administrator. A group of professional personnel must develop and review policies that govern the CORF services.

The governing body is the Board of Directors or Trustees of a corporation or the owner(s), in the case of a proprietary agency, or others who assume legal responsibility for the facility. While there are no requirements that the governing body follow a prescribed meeting schedule, there should be evidence that the governing body takes an active role in the overall operation of the CORF. This includes the development and review of the institutional budget plan, and knowledge of and concurrence with all patient care and major operational policies, *utilization review and quality improvement activities.*

B - Major Sources of Information

- Articles of incorporation, bylaws, policy statements, etc.
- Minutes of governing body, staff and patient care policy meetings.
- Organization chart showing administrative framework
- Personnel records -- job descriptions and personnel qualifications
- Institutional budget plan
- Management contracts
- Patient care policies
- Clinical records
- *Utilization Review/Quality Improvement Reports*

Assess the effectiveness and adequacy of the governing body's management and operation of the facility by reviewing documentation of the governing body's activities. This documentation should include minutes of the governing body, policy statements, bylaws and delegations of authority.

I-506

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.56(a) Standard: Disclosure of Ownership

The facility must comply with the provisions at 42 CFR Part 420, Subpart C that require health care providers and fiscal agents to disclose certain information about ownership and control.

The facility must disclose certain information about its ownership and control in complying with 42 CFR Part 420, Subpart C. Fiscal Intermediaries will review and verify the information provided on the Form CMS—855A (Application for Health Care Providers that will Bill Medicare Fiscal Intermediaries), prior to the state's survey of a new CORF or when a CORF makes a change (e.g., change of ownership (CHOW) or change of address).

Review ownership documents for signature and completeness.

I-507, I-508, I-509, I-510, I-511

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.56(b) Standard: Administrator

The governing body must appoint an administrator who:

(1) Is responsible for the overall management of the facility under the authority delegated by the governing body;

(2) Implements and enforces the facility's policies and procedures;

(3) Designates, in writing, an individual who, in the absence of the administrator, acts on behalf of the administrator; and

(4) Retains professional and administrative responsibility for all personnel providing facility services.

The qualifications of an administrator may vary among facilities, i.e., some administrators may be health professionals while others may be business managers. The administrator's

basic responsibility regardless of the field of expertise is to assure that services are rendered in accordance with CORF policies and that there is efficient utilization of resources and coordination of services. The administrator should have a thorough working knowledge of the overall operation of the facility, including the scope of services provided, policies governing these services, budgetary and fiscal matters and the utilization and qualification of personnel.

Discussion with the administrator will assist in determining depth of facility knowledge.

An administrator, especially of a large facility, generally functions on a full-time basis. However, a small facility may have a part-time administrator, e.g., one who also provides services as one of the professional personnel.

Determine if services are being provided in accordance with facility policies, that policies are current and reflect an acceptable standard of care, that care is coordinated among the professional staff and that there is efficient use of resources. If system problems are identified in any of these areas, consider a citation under governing body.

Facility policies must designate in writing an individual who acts on behalf of the administrator during a period of absence.

Review facility policies to ensure the facility has named an individual who will serve as administrator in the administrator's absence.

I-512, I-513, I-514

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.56(c) Standard: Group of Professional Personnel

The facility must have a group of professional personnel associated with the facility that:

(1) Develops and periodically reviews policies to govern the services provided by the facility; and

(2) Consists of at least one physician and one professional representing each of the services provided by the facility.

The group of professional personnel serves a very specific facility function, that is, to make certain that policies relating to patient care are realistic and best meet the needs of the facility and patients alike. Effective facility operation is dependent, in part, on workable policies especially those relating to: limitation of service capability, criteria for patient admission, etc. These policies must be developed and periodically reviewed by the group of professional personnel. The facility should be able to show that the group of professional personnel is carrying out its policy formulation and review function. The group must consist of at least one physician and one professional representing each of the

services provided by the facility. The names of all group members must be available and evidence must confirm their participation in policy development and review.

All or part of the group of professional personnel, or a group of similar composition, can serve as the facility's utilization review committee. Although a similarly comprised group not associated with the facility can perform the utilization review function, it cannot develop and periodically review the facility's policies

Review facility policies and/or procedures or other documentation that reflects this function is being carried out (i.e., minutes of meetings, etc).

I-515, I-516, I-517

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.56(d) Standard: Institutional Budget Plan

The facility must have an institutional budget plan that meets the following conditions:

(1) It is prepared, under the direction of the governing body, by a committee consisting of representatives of the governing body and the administrative staff;

(2) It provides for:

(i) An annual operating budget prepared according to generally accepted accounting principles;

(ii) A three year capital expenditure plan if expenditures in excess of $100,000 are anticipated, for that period, for the acquisition of land; the improvement of land, buildings and equipment; and the replacement, modernization, and expansion of buildings and equipment; and

(iii) Annual review and updating by the governing body.

In reviewing the facility's institutional budget plan, there must be evidence the plan has been prepared under the direction of the governing body (a committee composed of at least one member of the governing body and at least one member of the administrative staff). The CORF may have a 3-year capital expenditure plan if expenditures, in excess of $100,000 are anticipated for that period of time (i.e., acquisition or improvement of land, replacement or modernization of equipment, buildings, etc.).

Review the Institutional Budget Plan for evidence that the governing body annually reviews and updates the institutional budget plan. If the administrator states that there is no capital expenditure plan because no capital expenditure in excess of $100,000 is anticipated, note on the Survey Report Form CMS -360.

I-518, I-519, I-520, I-521, I-522, I-523, I-524, I-525, I-526, I-527, I-528

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.56(e) Standard: Patient Care Policies

The facility must have written care policies that govern the services it furnishes. The patient care policies must include the following:

(1) A description of the services the facility furnishes through employees and those furnished under arrangements;

(2) Rules for and personnel responsibilities in handling medical emergencies;

(3) Rules for the storage, handling, and administration of drugs and biologicals;

(4) Criteria for patient admission, continuing care, and discharge;

(5) Procedures for preparing and maintaining clinical records on all patients;

(6) A procedure for explaining to the patient's family the extent and purpose of the services to be provided;

(7) A procedure to assist the referring physician in locating another level of care for patients whose treatment has terminated and who are discharged;

(8) A requirement that patients accepted by the facility must be under the care of a physician;

(9) A requirement that there be a plan of care established by a physician for each patient; and

(10) A procedure to ensure that the group of professional personnel reviews and takes appropriate action on recommendations from the utilization review committee regarding patient care policies.

These policies comprise the basic operating framework of the CORF and are critical to its effective operation. All policies must be in writing and documentation must verify the input of the group of professional personnel in policy development and review. The policies should be current, compatible with the CORF's provision of services and be responsive to the needs of the patients.

Copies of all patient care policies should be reviewed.

In brief, patient care policies must reflect the following:

All services rendered by the CORF including those which are rendered by employees or by others furnished under an arrangement;

A description of personnel tasks during medical emergencies and specific responsibilities, where assigned;

The types of drugs and biologicals usually kept on the premises, their use, their manner of storage, who has access to these materials and a procedure for periodic review to determine the expiration date *of the drugs and biologicals*.

All criteria governing patient admission, continuing care and discharge. These criteria should coincide with professional staffing and must be as specific as possible. Factors governing admission may include geographic areas, ambulatory status of patients, specific diagnoses, patient ability to carry through on a home program, etc. Criteria developed for discharge may follow along the lines of specific levels of progress (attainment of goals), need for higher level of care etc;

The manner in which clinical record documentation is to be prepared and maintained. At a minimum, policies should state that all personnel performing services (i.e., those defined in the conditions of participation) must *authenticate* any entry they place in the patient's clinical record regardless of whether such personnel are employees of the facility or others. Clinical records must be maintained so that easy access is afforded all CORF personnel.

The policy must require that documentation in the clinical records be sufficient to support reasons for admission, care and treatment and discharge/transfer status;

A procedure for explaining a patient's treatment program to the patient and to the patient's family. In most cases this procedure would include a discussion of the diagnosis (es), the type and reasons for treatment, the treatment goal and the type of home program, where applicable, which will be developed. In general, unless the referring physician specifically notes that certain information is not to be revealed to the patient or family, the treatment program is to be discussed in detail and procedures are to be in effect for continuing discussions as they are warranted;

A policy that requires all patients to be under the care of a physician and that a plan of treatment for each patient must be in effect;

A procedure to assist the referring physician in locating another level of care for patients whose treatment has terminated and who are discharged; and

A procedure to ensure that the group of professional personnel reviews and takes appropriate action on recommendations from the utilization review committee regarding patient care policies.

Review clinical records and utilization review committee minutes, to determine if policies have been developed for all aspects of care. Interview members of the professional staff to determine if they have a working knowledge of the policies.

I-529, I-530, I-531

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.56 (f) Standard: Delegation of Authority

The responsibility for overall administration, management and operation must be retained by the facility itself and not delegated to others:

(1) The facility may enter into a contract for purposes of assistance in financial management and may delegate to others the following and similar services:

(i) Bookkeeping;

(ii) Assistance in the development of an operating budget;

(iii) Purchase of supplies in bulk form; and

(iv) The preparation of financial instruments.

(2) When the services listed in paragraph (f)(1) of this section are delegated, a contract must be in effect and:

(i) May not be a term of more than 5 years;

(ii) Must be subject to termination within 60 days of written notice by either party;

(iii) Must contain a clause requiring renegotiation of any provision that CMS finds to be in contravention to any new, revised, or amended Federal regulation or law;

(iv) Must state that only the facility may bill the Medicare program; and

(v) May not include clauses that state or imply that the contractor has power and authority to act on behalf of the facility, or clauses that give the contractor rights, duties, discretions, or responsibilities that enable it to dictate the administration, management, or operations of the facility.

A CORF may obtain assistance in financial management and delegate certain services, including bookkeeping, billing procedure and accounting system development, budget development, supply purchasing, and financial statement preparation. Where a CORF

does obtain services from another entity, the CORF must have a contract for a term of not more than 5 years in effect. Such a contract must provide a 60 day right of termination, permit renegotiation of any term which CMS determines as contravening a Federal law or regulation, and not permit the contractor to act on behalf of the facility or to bill the Medicare program.

Review CORF contracts for adherence to this Standard.

I-532

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.58 Condition *of Participation*: Comprehensive Rehabilitation Program

The facility must provide a coordinated rehabilitation program that includes, at a minimum, physicians' services, physical therapy services and social or psychological services. The services must be furnished by personnel that meet the qualifications set forth in §485.70 and must be consistent with the plan of treatment and the results of comprehensive patient assessments.

A – General

CORFs must provide a coordinated, comprehensive, skilled rehabilitation program. In this instance, comprehensive means a broad array of services that must include, at a minimum, the following three "core" services: Physician services (rendered by a physician and defined in Standard (a): Physician Services of this appendix), physical therapy services and social work or psychological services.

Coordinated means the rehabilitation plan of treatment is developed, periodically reviewed and modified as appropriate by the interdisciplinary treatment team members providing the rehabilitative care to the patient. Progress notes should reflect on-going communication and collaboration *among* the individual's treatment team members, the individual being served and members of the individual's family/support system, as appropriate. *Review progress notes and other medical record entries for examples of on-going communication.*

Skilled rehabilitation program is defined as services requiring the skills of qualified professional personnel who have the expertise necessary to identify and treat the individual's functional, psychological, social and medical needs, such as a physical therapist, occupational therapist, social worker or psychologist. The skilled rehabilitation services provided must be designed to minimize impairment, reduce activity limitation or lessen participation restrictions.

Review medical record for examples of patient progress toward attaining rehabilitation goals set in plan of treatment. Maintenance therapy programs are not considered

reasonable and necessary by Medicare. A therapist can develop a maintenance program for the patient to follow at home—this does not require the ongoing skills of a therapist.

Review a listing of the facility's CORF services to determine whether the required three ("core") services: physician services, physical therapy and social or psychological services are furnished. Review medical records for indication that patients are receiving the "core" CORF services and optional CORF services as indicated in the plan of treatment.

In addition, the CORF may provide any or all of the following optional CORF services: Occupational therapy, speech-language pathology, respiratory therapy, prosthetic and orthotic devices, nursing, drugs and biologicals, *DME and a single home visit, and be reimbursed for those services, only if they are part of a comprehensive, coordinated, skilled rehabilitation program.* Nursing services, specified in the plan of treatment and any other nursing services necessary for the attainment of the rehabilitation goals, are provided by or under the supervision of a professional registered nurse. The services must be furnished by nursing personnel who meet the qualifications set in §485.70. The services must be consistent with the plan of treatment.

Verify the CORF is providing the three "core" CORF services.

Ascertain, by record review and staff interview, whether the CORF is providing an individualized comprehensive, coordinated, skilled rehabilitation services program. The program should be directed at optimizing function and promoting interventions to increase the function of the persons served.

NOTE: *Physician diagnostic and therapeutic services (e.g., evaluation and management services that are furnished to an individual patient) are not physician services covered under the CORF outpatient therapy benefit. When a physician personally performs these services, they are billable to the Part B carrier. Hyperbaric oxygen (HBO) services are considered physician therapeutic services and are not CORF services.*

As always, the services provided must be considered reasonable and medically necessary.

B - Major Sources of Information

Assimilation of information from patient care policies, plans of treatment, clinical records and staff interviews is necessary to obtain a clear picture of the CORF's operations (i.e., is the CORF following the intent of the regulations and providing a comprehensive rehabilitation program or is it primarily specializing in a particular type of the treatment (i.e., HBO, psychiatric nursing, infusion therapy)?

1. Policies and Procedures: Determine whether the CORF offers a comprehensive, integrated rehabilitation treatment approach. *Review policies and procedures, organizational charts and medical records for evidence of interdisciplinary treatment team meetings.*

2. Review organization chart showing administrative facility framework.

I-533, I-534

§485.58(a) Standard: Physician Services

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

(1) A facility physician must be present in the facility for a sufficient time to:

(i) Provide, in accordance with accepted principles of medical practice, medical direction, medical care services and consultation;

(ii) Establish the plan of treatment in cases where a plan has not been established by the referring physician;

(ii) Assist in establishing and implementing the facility's patient care policies; and

(iv) Participate in plan of treatment reviews, patient case review conferences, comprehensive patient assessment and reassessments and utilization reviews.

(2) The facility must provide for emergency physician services during the facility operation hours.

Written documentation must indicate that a physician(s), (who meets the qualifications in the conditions of participation regulation at §485.70(a))**,** performs the required *CORF* physician services. Participation for at least one year in a residency program that provides training in the medical management of patients needing services such as orthopedics, neurology, neurosurgery, rheumatology, *physical medicine*, etc., meets the definition of facility physician. *Specialization in pulmonary medicine does not by itself satisfy the requirements for rehabilitation training. A facility physician who does not have specialized training in one of the approved rehabilitation disciplines may satisfy the qualification requirements through at least one year of work experience providing medical management services in a rehabilitation setting. Such services must include developing plans of treatment, participation in patient case review conferences, and establishing patient care policies for rehabilitation patients.* While it is preferable for this experience to have been full-time, part-time experience is acceptable. However, part-time experience should have been on a continuing weekly basis. The degree of time spent must confirm that required functions were accomplished.

Review physician hours.

Documentation must verify this training or experience. It might consist of a résumé, certificates of training or letters acknowledging completion of training or experience.

Review available material to verify compliance with physician qualification requirements at §485.70.

The facility physician may be associated with the facility on either a part-time or full-time basis. If part-time, it is important to determine that the physician is effectively performing required responsibilities. Review the activities of the group of professional personnel, utilization review process, patient records and reports of case review conferences to ascertain the extent of physician participation in patient care activities. The extent of physician participation can be determined, in part, by the type and volume of patients, scope of services and need for consultation and medical care services. Normally, greater physician participation will be required in a facility where the patients have multiple chronic disabilities, require several services, and require frequent changes in the plan of care than in a facility where the patients have acute disabilities.

Generally, a facility physician may refer patients to the facility. CORFs may have a physician(s) providing physician services at the facility on a part-time basis and this physician(s) may have an office practice distinct from the CORF. In such cases this physician(s) may establish the CORF plan of treatment when referring patients to the CORF. If the referring physician has not established a plan of treatment, a facility physician is responsible for establishing a plan of treatment.

CORF physician services are administrative in nature: consultation with and medical supervision of non-physician staff, establishment and review of the plan of treatment, and other medical and facility administration activities. **Diagnostic and therapeutic services are not CORF physician services.**

(§410.100 clearly defines the types of services the professional staff may provide in a CORF).

A facility physician need not perform emergency physician services. Rather, these services may be provided by another physician(s) or by paramedics with hospital emergency room back-up, or through other arrangements that ensures prompt delivery of emergency services.

These mechanisms must be in writing, readily available and familiar to all staff. Emergency services must be available during the total operating hours of the CORF.

I-535, I-536, I-537, I-538, I-540

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.58(b) Standard: Plan of treatment

For each patient, a physician must establish a plan of treatment before the facility initiates treatment. The plan of treatment must meet the following requirements:

(1) It must delineate anticipated goals and specify the type, amount, frequency and duration of services to be provided and indicates the diagnosis and anticipated rehabilitation goals;

(2) It must be promptly evaluated after changes in the patient's condition and revised when necessary;

(3) It must, if appropriate, be developed in consultation with the facility physician and the appropriate facility professional personnel;

(4) It must be reviewed at least every 60 days ***(the 60 day period begins with the first day of skilled rehabilitation therapy)*** *by a facility physician who, when appropriate, consults with the professional personnel providing services. The results of this review must be communicated to the patient's referring physician for concurrence before treatment is continued or discontinued; and*

(5) It must be revised if the comprehensive reassessment of the patient's condition indicates the need for revision.

Every patient must have a plan of treatment established, either by the facility physician, the referring physician or both in collaboration *prior to the facility commencing treatment*. Usually, a plan of treatment is written; however, it is acceptable in certain circumstances for a verbal order and plan to be telephoned to the CORF by the referring physician. The time, date, referring physician's name and contents of the verbal order must be documented and signed by the person receiving the order, and countersigned by the referring physician as soon as possible. Specific information relative to *type, amount, frequency and duration of services as well as anticipated goals, should routinely be incorporated with the physician referral.* The plan of treatment must include all of the services needed by the patient that meet the definition of CORF services. (CORF services are: physician; physical therapy; occupational therapy; speech-language pathology; respiratory; prosthetic; orthotic; social; psychological; nursing; drugs and biologicals; and supplies, appliances and equipment). For example, if a patient is in need of social services, physical therapy and speech-language pathology, all three services must be included in the CORF plan of treatment. *The plan of treatment must, if appropriate, be developed in consultation with the facility physician and the appropriate facility professional personnel.*

After treatment has begun, any change in the plan of treatment should be supported in the patient's clinical record by dated documentation signed by either the facility physician or by the referring physician. Any change in the patient's condition must be accompanied by a *revised plan of treatment.*

A facility physician must perform a 60 day review of the plan of treatment to *determine if the plan is being followed and whether or not the patient is making progress in attaining the established goals.* However, the referring physician should always be given the opportunity to have continued input into the patient's treatment program.

In this regard, CORF staff must communicate either verbally or in writing the results of the 60-day review to the referring physician. Verbal communication should be by either a facility physician or one of the professional personnel carrying out the plan of treatment. The referring physician's verbal concurrence for revision of the plan of treatment should be documented in the patient's clinical record by the individual communicating with the referring physician. This documentation should include the date and the subject matter discussed. The referring physician's response should be incorporated into the patient's clinical record.

I-541, I-542, I-543, I-544, I-545

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.58(c) Standard: Coordination of Services

The facility must designate, in writing, a qualified professional to ensure that professional personnel coordinate their related activities and exchange information about each patient under their care. Mechanisms to assist in the coordination of services must include:

(1) Providing to all personnel associated with the facility, a schedule indicating the frequency and type of services provided at the facility;

(2) A procedure for communicating to all patient care personnel pertinent information concerning significant changes in the patient's status;

(3) Periodic clinical record entries, noting at least the patient's status in relationship to goal attainment; and

(4) Scheduling patient case review conferences for purposes of determining appropriateness of treatment, when indicated by the results of the initial comprehensive patient assessment, reassessment(s), the recommendation of the facility physician (or other physician who established the plan of treatment), or upon recommendation of one of the professionals providing services.

Patients receive maximum benefit from an *individualized* comprehensive, *coordinated, skilled* rehabilitation outpatient program when services are provided in a coordinated manner. In most CORFs, a multi-disciplinary team of professional personnel provides several rehabilitation services to patients. The team may include full-time and part-time employees as well as *contract* employees functioning on either a full-time or part-time basis. It is, therefore, important that the facility take steps to assure that services are provided in an efficient, effective and coordinated manner. The facility must designate in writing one professional to oversee the coordination *of CORF services* that the facility has developed. This responsibility can be performed concurrently with the assigned

person's normal professional duties. *All personnel providing services at the CORF should receive a schedule of the frequency and type of services provided at the CORF.*

Review CORF policies/procedures to ensure the CORF provides in-service education regarding the importance of coordinating patient services. Evidence may also appear in the medical record in assessments, progress notes, interdisciplinary treatment team meetings, discharge planning meetings, etc. Verify that the individual identified as the coordinator is qualified to perform this function.

Frequency of clinical record entries may range from a brief entry in a patient's clinical record each day the patient receives treatment, to entries of longer intervals. The facility must establish some procedure detailing the frequency of clinical record documentation. Since this documentation may be used as one of the factors in determining the outcome of the 60-day plan of treatment review, entries should appear frequently enough during each 60-day period to provide an adequate picture of *coordination of the* care being given and the patient's status relative to established goals.

The frequency, format, and criteria for patient case review conferences may vary among facilities. These conferences generally will be convened to determine the appropriateness of continuing treatment, changing a plan of treatment, or to coordinate treatment activities. Conferences may routinely be scheduled for each patient after the patient has been undergoing treatment for a specified period of time or has had a specified number of treatments; or conferences may be scheduled only for patients who are not meeting anticipated goals, who need a different level of care, or who are receiving an intensive multi-service rehabilitation program. There must be a written policy regarding patient case review conferences, and it should be adhered to. There should be a formal procedure to familiarize all personnel treating the patient with the results of the CORF's coordination of service activity.

Review past patient case review conference documentation and interview personnel regarding its utilization. In reviewing case conference documentation, look for evidence that the CORF has the three "core" services available.

I-546, I-547, I-548, I-549, I-550, I-551, I-552

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.58(d) Standard: Provision of Services

(1) All patients must be referred to the facility by a physician who provides the following information to the facility before treatment is initiated:

(i) The patient's significant medical history;

(ii) Current medical findings;

(ii) Diagnosis(es) and contraindications to any treatment modality;

(iv) Rehabilitation goals, if determined.

(2) Services may be provided by facility employees or by others under arrangements made by the facility;

(3) The facility must have on its premises the necessary equipment to implement the plan of treatment and sufficient space to allow adequate care;

(4) The services must be furnished by personnel that meet the qualifications of § 485.70 and the number of qualified personnel must be adequate for the volume and diversity of services offered. Personnel that do not meet the qualifications specified in § 485.70 may be used by the facility in assisting qualified staff. When a qualified individual is assisted by these personnel, the qualified individual must be on the premises, and must instruct these personnel in appropriate patient care service techniques and retain responsibility for their activities;

(5) A qualified professional must initiate and coordinate the appropriate portions of the plan of treatment, monitor the patient's progress, and recommend changes in the plan, if necessary;

(6) A qualified professional representing each service made available at the facility must be either on the premises of the facility or must be available through direct telecommunication for consultation and assistance during the facility's operating hours. At least one qualified professional must be on the premises during the facility's operating hours; and

(7) All services must be provided consistent with accepted professional standards and practice.

All CORF patients must be referred by a physician. The referral should contain the patient's medical history, current medical findings, diagnosis, contraindications to any treatment modality and rehabilitation goals, if determined. Current medical findings and a complete and appropriate medical history do not always accompany a physician's referral. In such cases, a qualified professional or a facility physician should obtain this information from the patient and obtain additional necessary information through follow-up with the referring physician.

Review medical records to ensure the CORF patients have a referral and the information listed above.

CORF services may be provided by employees or by others under arrangements, i.e., individuals from an organization that has a contract with the facility to provide services,

and individuals that contract directly with the CORF. A CORF need not expressly employ professional personnel under an arrangement exclusively for a CORF. Personnel may be associated with other organizations while they are associated with the CORF, but must be available during operating hours. For example, a principal(s) of a skilled nursing facility (SNF) may also own a CORF and share personnel between these two providers. This is permissible and satisfies compliance with regulations when these personnel are able to **perform** exclusively for each provider, **respectively,** in carrying out **specific** responsibilities. This is especially important because each CORF is a separate identifiable provider and must independently meet the conditions of participation.

Review contracts the CORF has for providing services under arrangement. The CORF has the administrative responsibility for the services provided to its patient.

Ascertain that the CORF has the equipment and personnel necessary to adequately and effectively provide the services *as defined in the plan of treatment.* Review medical records to determine specific equipment requirements from the plans of treatment, and verify the presence of such equipment.

A facility need not own all of the equipment required for implementing the plan of treatment. It is permissible to rent or lease necessary equipment on an as needed basis. *The CORF must demonstrate that all required equipment will be readily procured, obtained and available on the premises when providing treatment services to the patients. The CORF cannot share equipment with any other entity during its hours of operation. Ensure equipment levels are sufficient to treat patients.*

Adequacy of staffing levels of qualified professionals and other staff should be based upon the types of patients treated and the frequency, duration and complexity of treatment required, rather than general staff to patient ratios.

When *non-professional* personnel other than those that are noted in the personnel qualification section of the conditions of participation (see §485.70) are used to assist qualified professionals, their duties, responsibilities and qualifications should appear in the facility's policies and be consistent with accepted standards and practices. Appropriately qualified personnel must instruct all *non-professional* personnel in specific patient care techniques.

The form and extent of any instruction provided to non-professional personnel must be appropriate to that person's assigned responsibilities, education, experience and types of patients treated. The appropriately qualified professional must be on the premises, and supervise the care given when non-professional personnel are utilized. Verify this through a review of the treatment and staffing schedule. For example, when non-professional personnel are used in conjunction with the furnishing of physical therapy services, a person meeting the qualification requirements of §485.70 (formerly §488.70) must be on the premises.

Qualified professional personnel may initiate changes that need to be made concerning the implementation of the plan of treatment. Assistant-level personnel (as defined in §485.70 and *§484.4*) must not initiate such changes without the approval of the appropriately qualified professional. *Qualified personnel must be available for duty on the CORF's*

*premises as **needed for consultation and/or assistance** or must be able to be contacted by telephone.*

Consultation and assistance cannot be provided to non-professional personnel by phone as they require on the premises supervision.

At least one qualified professional must be on the facility's premises during its hours of operation.

It may not be unusual to find that, in a CORF that furnishes a broad array of rehabilitation services, several types of professionals are furnishing particular aspects of care. For example, registered nurses with special training in respiratory care or physical therapists may furnish respiratory therapy services.

The CORF is responsible for ensuring that a practitioner furnishing a particular service is qualified to do so under State law and does so within accepted professional standards and practices. Carefully review the qualifications of a professional providing more than one CORF service. Determine the scope of the particular service.

Verify that the practitioner is qualified to provide the service, and that it is provided pursuant to State law and accepted professional standards and practices.

I-553

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.58(e) Standard: Scope and Site of Services

(1) Basic requirements: the facility must provide all the CORF services required in the plan of treatment and, except as provided in paragraph (e)(2) of this section, must provide the services on its premises;

(2) Exceptions: physical therapy, occupational therapy and speech pathology services furnished away from the premises of the CORF may be covered as CORF services if Medicare payment is not otherwise made for these services. In addition, a single home visit is covered if there is need to evaluate the potential impact of the home environment on the rehabilitation goals. The home evaluation is not covered as a routine service for all CORF patients. It is covered only if, in establishing or carrying out the plan of treatment, there is a clear indication that the home environment might adversely affect the patient's rehabilitation. Coverage is limited to the services of one professional either physical or occupational therapist, (whose services are covered by the CORF benefit) who is selected by the CORF.

In general, all services must be furnished on the premises of the CORF. The only exceptions are the home evaluation visit. The provision allowing offsite therapy services does not

permit the CORF to establish extension locations and all records must be maintained on the premises of the CORF. The purpose of the home visit is to evaluate the home environment in relation to the patient's established treatment goals. The home visit evaluation may include assessing the need for modifying the physical and/or social environment to maximize the patient's functional capability. The home, for purposes of this home evaluation visit, is the patient's legal residence. The visit may take place anytime between the implementation of the plan of treatment and the discharge of the patient. A patient who is periodically discharged and admitted for a chronic but stable problem would not normally receive more than one home evaluation visit, even though the patient may be receiving more than one service.

Ask the CORF if therapy services are provided off-site and if so, which services are provided. Even though the CORF patients can be treated in off-site locations by therapists, the CORF is ultimately responsible for the coordinated, comprehensive rehabilitation program for each patient. All appropriate CoPs apply to the services provided at off-site locations.

Review clinical records.

Notes in the patient's clinical record should indicate when the visit was made, who made it, its purpose and the results of the evaluation.

Also, the CORF must provide all the CORF services required in the plan of treatment. Since personnel may provide these services under arrangements, there should be minimal difficulty in obtaining personnel to provide services regardless of the infrequency of demand for the service. The unavailability of a service forces the patient to seek the service at another location. This is contrary to one of the purposes of the CORF legislation, i.e., to remedy the situation where beneficiaries needing several rehabilitation services are required to seek them at more than one location.

NOTE: When completing the CORF Survey Report Form (CMS-360) do not mark standard 485.58(e) (tag number 1-553) "no" if the CORF provides physical therapy, occupational therapy or speech pathology services offsite. We will revise the CMS-360 to include this offsite provision when it is reprinted.

I-554, I-555, I-556

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.58(f) Standard: Patient Assessment

Each qualified professional involved in the patient's care, as specified in the plan of treatment, must—(1) carry out an initial patient assessment; and (2) In order to identify whether or not the current plan of treatment is appropriate, perform a patient reassessment after significant changes in the patient's status.

Each qualified individual, providing services to a patient, must conduct an initial patient assessment with periodic reassessment of the patient to determine whether the patient is meeting rehabilitation goals and to update the plan of treatment. Because the reassessment usually consists of the same evaluative mechanisms (e.g., test procedures, measurements, professional observations and subjective information from patient) used in the initial assessment to obtain indicators of the patient's status, the patient's status at different points in time can be compared. Since a reassessment must be performed when significant changes in the patient's condition are noted, such a comparison is useful to determine whether the current plan of treatment is appropriate. In contrast to the information obtained in a reassessment, periodic entries in the clinical record as required in §485.58(c)(3) usually contain information such as a patient's reaction to treatment, general condition of patient, significant changes in patient's status and/or changes in the intensity of treatment. These entries provide in chronological order a picture of the patient's progress in relation to the care being given.

Verify that each patient is assessed by each qualified professional personnel involved in the patient's care prior to the implementation of the plan of treatment. *During a review of the clinical records c*ompare the date the plan of treatment was established to the date of the initial assessment by the appropriate professional defined in §485.70. *If* the plan of treatment specifies several rehabilitation services, the professional personnel responsible for initiating the plan may be unable to complete their respective assessments on the same day. For example, the physical therapist may complete an assessment of the patient and initiate the physical therapy service portion of the plan before the speech pathologist assesses the patient. *However, if the physician ordered all therapies to assess and begin treatment upon receipt of the plan of care, it is reasonable to expect all assessments be completed in the first week of receiving the plan of treatment.*

Review the clinical records for availability of an initial assessment and re-assessments as appropriate.

I-557, I-558

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.58(g) Standard: Laboratory services

(1) If the facility provides its own laboratory services, the services must meet the applicable requirements for laboratories specified in part 493 of this chapter;

(2) If the facility chooses to refer specimens for laboratory testing, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the requirements of Part 493 of this chapter.

A CORF may either conduct its own laboratory services or refer specimens to another laboratory. Either laboratory must meet the applicable requirements at 42 CFR §493. The laboratory must meet any and all State requirements for certification or licensure.

Review certification/licensure if the CORF offers laboratory services.

I-559

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.60 Condition *of Participation*: Clinical Records

The facility must maintain clinical records on all patients in accordance with accepted professional standards and practice. The clinical records must be completely, promptly, systematically organized to facilitate retrieval and compilation of information.

A - General

The clinical record serves as a basis for documentation of care rendered to the patient and communication between all personnel furnishing services. Determine whether the content of the clinical record presents a total, or at a minimum, an adequate picture of the care being given.

B - Major Sources of Information

- Active and closed clinical records; and
- Policies regarding protection and retention of clinical records.

I-560, I-561, I-562, I-563, I-564, I-565, I-566, I-567

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.60(a) Standard: Content

Each clinical record must contain sufficient information to identify the patient clearly and to justify the diagnosis and treatment. Entries in the clinical record must be made as frequently as is necessary to insure effective treatment, and must be signed by personnel providing services. All entries made by assistant level personnel must be countersigned by the corresponding professional. Documentation on each patient must be consolidated into one clinical record that must contain:

(1) The initial assessment and subsequent reassessments of the patient's needs;

(2) Current plan of treatment;

(3) Identification data and consent or authorization forms;

(4) Pertinent medical history, past and present;

(5) A report of pertinent physical examinations if any;

(6) Progress notes or other documentation that reflect patient reaction to treatment, tests, or injury, or the need to change the established plan of treatment; and

(7) Upon discharge, a discharge summary including patient status relative to goal achievement, prognosis, and future treatment considerations.

All medical records must be maintained according to accepted professional standards of practice. The medical records must be readily available to staff and surveyors.

Examine a substantial number of both active and closed clinical records and ascertain that the required material is included. If any of the material required in this standard (§485.60(a) is absent from the clinical records, review additional records to determine the prevalence of such omissions. Record the number of records reviewed and the number and types of deficiencies observed. In determining the number of records to be reviewed, be guided by the size of the CORF's patient caseload. The larger the caseload, the larger the review sample should be.

Each patient's record should contain a summary of each patient's case review conference, where appropriate, and indicate the purpose and recommendation resulting from the conference. All reports generated as a result of any meetings concerning patient care issues should be dated, signed and made a part of the record.

Ascertain that periodic progress notes are entered in the clinical records at intervals commensurate with the type and frequency of treatment. These notes are to address the progress of the patient in attaining stated plan of treatment goals. Some facilities may require a brief entry in the clinical record each day the patient receives a treatment while other facilities may require routine progress reports at longer intervals. Ascertain the time interval between progress reports. Determine whether the time interval is impeding coordination and communication in patient care activities. Regardless of the frequency of progress notes, the notes should record the patient's status in relation to the stated treatment goals.

A discharge summary should include the date and reason for discharge, a brief summary of the patient's current status and, where applicable, details regarding referral of the patient to another level of care.

All information appearing in the clinical record must be dated, appropriately signed and promptly incorporated in the record. *Regulations require that entries written by therapy assistants be countersigned even though some state practice acts may not require this. All entries in the clinical record must be legible.*

A physician must certify that CORF services are required because the individual needs skilled rehabilitation services. The treatment plan must include a diagnosis and must address rehabilitation goals associated with that particular diagnosis. Throughout the course of rehabilitation treatment, the medical records must indicate the ongoing services provided by a physical therapist, social worker or psychologist.

Verify the medical records contain signed and dated certifications and re-certifications.

I-568

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.60(b) Standard: Protection of Clinical Record Information

The facility must safeguard clinical record information against loss, destruction, or unauthorized use. The facility must have procedures that govern the use and removal of records and the conditions for release of information. The facility must obtain the patient's written consent before releasing information not required by law.

*Verify that a*ctive and closed clinical records are stored where they are protected from fire and unauthorized use.

Review the CORFs written procedures governing the use of records which specify to whom the records or copies of records may be provided, the use to which the material may be put and the circumstances describing the return of such material. *Also, review the medical records to determine that written patient consent is present to allow the release of all material not authorized by law.*

I-569

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.60(c) Standard: Retention and Preservation

The facility must retain clinical record information for 5 years after patient discharge and must make provision for the maintenance of such records in the event that it is no longer able to treat patients.

The facility must provide for the maintenance of clinical records in cases where the CORF ceases to function.

Review the CORF's policy for the preservation and retention of clinical records and verify that applicable State laws or regulations are met.

I-570

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.62 Condition *of Participation*: Physical Environment

The facility must provide a physical environment that protects the health and safety of patients, personnel, and the public.

A - General

A CORF must provide a physical environment that protects the health and safety of the staff, patients and public.

B - **Major Sources of Information**

1. Applicable State and local laws;
2. Inspection reports of State and local building and fire authorities; and
3. Organization policies and procedures regarding maintenance of equipment, buildings and grounds.

I-571, I-572, I-573, I-574, I-575, I-576, I-577, I-578

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

485.62(a) Standard: Safety and Comfort of Patients

The physical premises of the facility and those areas of its surrounding physical structure that are used by the patients (including at least all stairwells, corridors and passageways) must meet the following requirements:

(1) Applicable Federal, State, and local building, fire and safety codes must be met;

(2) Fire extinguishers musts be easily accessible and fire regulations must be prominently posted;

(3) A fire alarm system with local (in-house) capability must be functional, and where power is generated by electricity, an alternate power source, with automatic triggering must be present;

(4) Lights, supported by an emergency power source, must be placed at exits;

(5) A sufficient number of staff to evacuate patients during a disaster must be on the premises of the facility whenever patients are being treated;

(6) Lighting must be sufficient to carry out services safely; room temperature must be maintained at comfortable levels; and ventilation through windows, mechanical means, or a combination of both must be provided; and

(7) Safe and sufficient space must be available for the scope of services offered.

Review available reports of State and local personnel responsible for enforcement of building, fire and safety codes and verify that the CORF is in compliance with applicable codes.

All areas occupied or accessible to the facility for use during emergency or non-emergency activity, including corridors and stairways, are to be protected by easily accessible fire extinguishers. Lights, supported by an emergency power source, must be placed at exits. Where there is a CORF established on the premises of another health entity, also survey those areas which are common to both, i.e., corridors, stairways, storage areas, etc.

The fire alarm system must be adequate to alert personnel in time for safe evacuation of the building. The system should consist of either a manual (pull type) fire alarm system with or without automatic fire department response, or an automatic detection system along with an audible manual alarm. Any system should have the capacity for manual activation that triggers an audible in-house alarm which alerts personnel, patients and the public to the present danger and need for action. Where the alarm system is activated by a disruption of the electrical system or in other ways dependent on it, an emergency power source with automatic triggering, e.g., battery or auxiliary generator, must be available to serve as a backup. In the absence of State or local requirements, the above systems are to be approved by the State Fire Marshall's Office.

Verify the availability of fire extinguishers and fire alarms.

The number of staff necessary to evacuate patients during an emergency depends largely on the number and types of patients scheduled to be on the premises at any one time. A patient population consisting largely of patients dependent on assistive devices for ambulating (e.g., canes, crutches and walkers), wheelchair bound patients and other patients who would need assistance from CORF personnel for a quick, safe evacuation, would require the presence of more staff than a patient population which is not dependent on ambulatory assistive devices.

Obbserve the number of staff and the types of patients to determine the efficiency of an evacuation in case of an emergency.

An emergency power source must be supplied, e.g., by battery or auxiliary generator, to assure adequate lighting during emergency operation within the treatment areas or those passageways, stairwells and exits (as noted above) accessible to the CORF. In cases of

power outage, the emergency power source should respond either automatically or require only minimal activation effort.

Verify that the temperature and ventilation is maintained at a comfortable level.

I-579, I-580, I-581, I-582, I-583

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.62(b) Standard: Sanitary Environment

The facility must maintain a sanitary environment and establish a program to identify, investigate, prevent, and control the cause of patient infections:

(1) The facility must establish written policies and procedures designed to control and prevent infection in the facility and to investigate and identify possible causes of infection;

(2) The facility must monitor the infection control program to ensure that the staff implement the policies and procedures and that the policies and procedures are consistent with current practices in the field;

(3) The facility must make available at all times a quantity of laundered linen adequate for proper care and comfort of patients. Linens must be handled, stored, and processed in a manner that prevents the spread of infection; and

(4) Provisions must be in effect that the facility's premises are maintained free of rodent and insect infestation.

*Verify that t*he facility maintains a sanitary environment and has established a program to identify, investigate, prevent and control the cause of patient infections.

Review the written policies and procedures regarding infection control and maintenance of a sanitary environment.

Verify that they are sufficient in light of the volume and types of patients and services provided, and that there is consistency with current practices of infection control.

Identify the individual or group responsible for establishing, implementing and monitoring the policies and procedures. The facility must monitor the infection control program to ensure that policies and procedures are being complied with and are consistent with currently accepted practices, if applicable. Pay particular attention to the policies, procedures and reports concerning the care and debridement of wounds, and the cleaning and disinfection of equipment such as whirlpools and paraffin baths and respiratory therapy equipment.

Verify the general sanitation, cleanliness and orderliness of the premises and verify that clean and soiled linen is handled in an orderly and sanitary manner that will prevent the spread of infection. There must be an adequate supply of fresh linen (sheets, towels, pillowcases) which must be stored and processed separate from soiled linen. Soiled linen must be processed and stored in an area away from patients, personnel and the public.

Review the CORF policies and procedures regarding preventive maintenance and infection control to determine if they are compatible with the scope of services, the type of equipment used and type of patients accepted for treatment.

I-584, I-585, I-586

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.62(c) Standard: Maintenance of Equipment, Physical Location and Grounds

The facility must establish a written preventive maintenance program to ensure that:

(1) All equipment is properly maintained and equipment needing periodic calibration is calibrated consistent with the manufacturer's recommendations; and

(2) The interior of the facility, the exterior of the physical structure housing the facility, and the exterior walkways and parking areas are clean and orderly and maintained free of any defects that are a hazard to patients, personnel, and the public.

CORF personnel should inspect all equipment *as per the manufacturer's directions* or more frequently depending on equipment condition and its frequency of use. Written procedures regarding the preventive maintenance program must include the following: equipment to be inspected, a brief statement concerning the general inspection process and frequency of inspection for each piece of equipment. For all electrically powered patient care equipment, appropriate manufacturer's operating and maintenance information must be on file.

Review this information and ascertain what specific manufacturer's recommendations, if any, are made for equipment calibration checks, periodic maintenance procedures, etc. Then, through copies of service repair statements or other documentation, determine whether such recommendations were followed.

The facility must be free of hazards to the health and safety of patients, personnel and the public, e.g., broken window and door panes, obstruction of passageways and dangerous floor surfaces, and any hazardous exterior walkways or parking areas. Hazards are to be brought to the attention of CORF personnel.

I-587, I-588, I-589, I590, I-591, I-592

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.62(d) Standard: Access for the Physically Impaired

The facility must ensure the following:

(1) Doorways, stairwells, corridors, and passageways used by patients are:

(i) Of adequate width to allow for easy movement of all patients (including those on stretchers or in wheelchairs); and

(ii) In the case of stairwells, equipped with firmly attached handrails on at least one side.

(2) At least one toilet facility is accessible and constructed to allow utilization by ambulatory and non-ambulatory individuals;

(3) At least one entrance is usable by individuals in wheelchairs;

(4) In multi-story buildings, elevators are accessible to and usable by the physically impaired on the level that they use to enter the building and all levels normally used by the patients of the facility;

(5) Parking spaces are large enough and close enough to the facility to allow safe access by the physically impaired.

The CORF must ensure the exits and entrances are wide enough to allow for easy movement of all patients whether they are ambulatory, in a wheelchair or on a stretcher and that the exits and entrances are not blocked with furniture or equipment. For patients who use a stairwell, rails must be firmly attached on one wall. A wheelchair entrance must be equipped with a suitable ramp if needed.

Inspect the premises to verify whether the facility ensures safe access and adequate space to maneuver in waiting areas, treatment areas and toilet facilities for all physically impaired patients including those on stretchers or in wheelchairs. *Verify* that at least one toilet facility can be used by ambulatory and nonambulatory patients, that is, grab bars are provided, elevated toilets seats are available, etc. *If the CORF is in a multi-story building at least one elevator is available and functioning for the physically impaired who are entering or leaving the premises as well as to all patient areas that are part of the CORF.*

I-593

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.64 Condition *of Participation*: Disaster Procedures

The facility must have written policies and procedures that specifically define the handling of patients, personnel, records, and the public during disasters. All personnel associated with the facility must be knowledgeable with respect to these procedures, be trained in their application, and be assigned specific responsibilities.

A - General

A well-developed disaster plan is to be documented and posted in areas accessible for continuing personnel review and where the public can see it.

B - Major Sources of Information

- Disaster plan; and
- Documentation as to ongoing training sessions and dates of disaster drills

---

I-594, I-595, I-596, I-597, I-598

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.64(a) Standard: Disaster Plan

The facility's written disaster plan must be developed and maintained with assistance of qualified fire, safety, and other appropriate experts. The plan must include:

(1) Procedures for prompt transfer of casualties and records;

(2) Procedures for notifying community emergency personnel (for example, fire department, ambulance, etc.);

(3) Instructions regarding the location and use of alarm systems and signals and fire fighting equipment; and

(4) Specification of evacuation routes and procedures for leaving the facility.

The disaster plan should document the assignment of responsibilities to CORF personnel providing services to the CORF, evacuation routes, and procedures for the transfer of records and casualties. In addition, the plan should include procedures for notifying community emergency personnel, procedures for leaving the facility and instructions regarding the location and use of alarms and fire fighting equipment.

Review the disaster plan to determine if the plan documents all of the above procedures and instructions. *If CORF employees are working at off-site locations, it is incumbent upon the*

CORF to ensure those employees have been trained and are knowledgeable regarding disaster plans, evacuation routes for those locations, etc. Surveyors should interview staff to determine whether the CORF has provided training in the off-site locations.

I-599, I-600 - I-601

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.64(b) Standard: Drills and Staff Training

(1) The facility must provide ongoing training and drills for all personnel associated with the facility in all aspects of disaster preparedness; and

(2) All new personnel must be oriented and assigned specific responsibilities regarding the facility's disaster plan within 2 weeks of their first workday.

Every CORF must provide ongoing training and drills for all personnel associated with the facility in all aspects of disaster preparedness. Larger, more complex CORFs would most likely provide ongoing training more frequently than smaller CORFs. *All new employees must be oriented and assigned specific responsibilities as part of the disaster plan within 2 weeks of their first workday. This includes all employees who provide services to the CORF under an arrangement.* The date of training and names of those persons taking part are to be documented.

Review the CORF's written Disaster Plan. *Verify* that all personnel have been instructed and trained in their responsibilities and that all new personnel are properly trained within 2 weeks of their first workday. Interview the staff to ensure that they are familiar with the plan as well as being familiar with their role in the plan.

I-602

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.66 Condition *of Participation*: Utilization Review Plan

The facility must have in effect a written utilization review plan that is implemented at least each quarter, to assess the necessity of services and promotes the most efficient use of services provide by the facility.

A - General

(I-602) Each facility must have in effect, a written utilization review plan. An established utilization review plan serves to indicate how well policies are functioning, how effective treatment regimens have been, and how well the CORF has adapted its particular program to selected patients.

B - **Major Sources of Information**

- Clinical records; and
- Written utilization plan

I-603

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.66(a) Standard: Utilization Review Committee

The utilization review committee, consisting of the group of professional personnel specified in §485.56(c), a committee of this group, or a group of similar composition, comprised by professional personnel not associated with the facility must carry out the utilization review plan.

The Utilization Review (UR) Committee must meet at least quarterly. *The composition of this committee should be written into the utilization review plan and should be representative of the professional personnel that provide services in the CORF. A facility physician or non-CORF physician must be a member of the UR committee.*

I-604, I-605, I-606, I-607

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.66(b)Standard: Utilization Review Plan

The utilization review plan must contain written procedures for evaluating:

(1) Admissions, continued care, and discharges using, at a minimum, the criteria established in the patient care policies;

(2) The applicability of the plan of treatment to established goals; and

(3) The adequacy of clinical records with regard to:

(i) Assessing the quality of services provided;

(ii) Determining whether the facility's policies and clinical practices are compatible and promote appropriate and efficient utilization of services.

The plan should contain specific procedures and standards necessary to assess the effectiveness and efficiency of the services provided. The number of cases selected for

review should be representative of the types of patients treated at the CORF and the types of services provided. The frequency of reviews should be outlined in the plan.

Reports and outcomes of evaluations should be reflected in the minutes of the utilization review committee. Those minutes should also indicate the extent to which the CORF program, policies and practices are being followed. *Review the minutes of the utilization review committee to determine if the plan is being followed.*

Results of utilization review activities should be made available to all professional personnel. Identify whether the results of the review prompted recommendations concerning CORF policies and practices and whether the recommendations were communicated to the administrator and governing body and the group of professional personnel (if different from the utilization review committee).

GENERAL COMMENTS:

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

A CORF may be established on the premises of another health entity irrespective of whether this entity is already certified under Medicare as a provider or supplier of services. For example, a CORF may be established on the premises of a skilled nursing facility (SNF) and the SNF's owner(s) may either have legal responsibility for both the SNF and the CORF, or merely rent space within the SNF to the CORF's owner(s). In either situation, the CORF must be certified separately and be functionally and operationally independent. The regulatory definition of a CORF precludes the CORF, and another entity from mixing functions and operations in a common space during concurrent or overlapping hours of operation.

In the same manner as space may be shared, equipment may also be shared. All common equipment must be available (on the premises of the CORF) during the CORF's hours of operation and not, at that time, be utilized by the other entity for any purpose.

The CORFs must be surveyed pursuant to the CORF conditions of participation and all standards must be surveyed independent of any findings resulting from the completed survey of the other entity. That is, although there may have been no deficiencies noted during the survey of the other entity, this fact must not influence any determination with respect to the survey pursuant to the CORF conditions of participation.

5.2 Sections 2360–2366

This document is a replica of the official record copy maintained by the Issuances and Records Management Group.

Comprehensive Outpatient Rehabilitation Facilities (CORFs)

2360 - CORF - Citations and Description

(Rev. 1, 05-21-04)

The statutory basis for CORFs is §1861(cc) of the Social Security Act (the Act). This was amended by §4078 of OBRA 1987 to allow CORFs to provide physical therapy, occupational therapy, and speech pathology services off-site. The CoPs are found in 42 CFR 485, Subpart B. Appendix K contains surveyor and interpretive guidelines.

A CORF is a facility established and operated at a single fixed location exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients by or under the supervision of a physician (See §2364). With the exception of financial management contracts, the responsibility for overall administration, management, and operation must be exercised by the CORF itself and not delegated to others. Financial management contracts may not be for more than five years as governed by 42 CFR 485.56(f) (formerly 42 CFR 488.56(f)).

2362 - Scope and Site of Services

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The CORF provides a broad array of services that must include, at a minimum, the following three core services: physician services, physical therapy services and social work or psychological services.

With the exception of physical therapy, occupational therapy, and speech-language pathology services, all CORF services must be provided on the CORF premises. However, one visit to the patient's home is allowed to evaluate the home environment in relation to the patient's established treatment plan. Physical therapy, occupational therapy, and speech pathology services may be provided off the CORF premises (including a patient's home). *The CORF is responsible for the implementation and supervision of any therapy services that are provided at an off-site location. All appropriate CoPs apply to the services provided at off-site locations.*

Covered CORF services are those that would be covered as inpatient hospital services if furnished in a hospital. Covered items or services must be reasonable and medically necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member. A service furnished as part of a maintenance program involving repetitive activities not requiring the skilled services of nurses or therapists would not be covered. *A CORF may be reimbursed for optional CORF services if they are part of a comprehensive, coordinated, skilled rehabilitation program. (Optional CORF services are: Occupational therapy, speech-language pathology, respiratory therapy, prosthetic and orthotic devices, nursing, drugs and biologicals, DME and a single home visit).*

2364 - CORF'S Relationship With Other Providers or Suppliers

(Rev. 1, 05-21-04)

A CORF may be owned by, or affiliated with, a legal entity operating as another type of Medicare provider. The requirement for functional and operational independence does not require separate incorporation. Coordination between such entities in relation to personnel, equipment, and facilities is permissible if it is undertaken in accordance with §2364. The requirement for functional and operational independence is to assure that any entity seeking approval as a CORF meets the requirements for such approval and that the costs of different Medicare providers are clearly identified, segregated, and attributed to the proper provider.

When certifying a CORF, it is important to understand the relationship of space, equipment, and employees shared with other providers and suppliers.

2364A - Shared Space With Another Provider or Supplier

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

A CORF may be established on the premises of another health entity even though the other entity is currently approved under Medicare as a provider or supplier of services. For example, a SNF owner may rent space within the SNF to the CORF. The CORF must be functionally and operationally independent from the SNF (see §2360).

A CORF may not share a common space with the other entity unless the CORF is able to fully function without interruption during its scheduled hours of operation. Use of the CORF space by another, or host entity, during CORF hours of operation is not allowed. For example, one room in a suite used by an OPT/OSP provider and owned by the OPT/OSP provider or another party may function as a CORF location. However, although the CORF is located on the premises of the OPT/OSP provider, this space is not to be used for OPT/OSP purposes during the operating hours of the CORF. *The CORF must make provisions to secure medical records from unauthorized use.*

2364B - Sharing of Equipment

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

Equipment may be shared in the same manner as space. All common equipment must be available on the premises of the CORF during hours of operation and not used at the same time by the other entity for any purpose.

A CORF need not own all of the equipment required for implementing a plan of treatment, but it must demonstrate that all required equipment can be readily procured when needed *and be available in the facility when providing treatment services to the patients.*

2364C - Employee Sharing

(Rev. 1, 05-21-04)

CORF employees or others may provide CORF services under arrangements with the CORF. It is not required that professional personnel be employed only by the CORF or function under arrangements exclusively for the CORF. However, CORF personnel also associated with another organization must be available during CORF operating hours.

2366 - Conversion of OPT/OSP to CORF

(Rev. 1, 05-21-04)

An OPT/OSP primary location may convert to a CORF if it meets the CORF CoPs. Normally, the OPT/OSP provider will relinquish its OPT/OSP site unless it shares space with the CORF. To share space, an identifiable part of the OPT/OSP at the site must be set aside exclusively for the operation of the CORF and treatment of CORF patients during CORF hours of operation.

5.3 Section 3224

This document is a replica of the official record copy maintained by the Issuances and Records Management Group.

3224 - Addition of Sites to an Existing Provider

(Rev. 1, 05-21-04)

It is inherent in the provider certification process that a provider give notification to CMS of its proposal to expand its service area by adding a branch, satellite or extension location. The Medicare statute and applicable regulations are implicit that the proposed expanded service area meet the Conditions of Participation the same as the primary location that has signed the provider agreement or that has been assigned a provider number or both. In the absence of notification, CMS has no way of determining whether the requirements critical to health and safety are met at the expanded location. For example, a hospice's request for satellite location may be denied because it cannot demonstrate how the hospice will assume administrative and supervisory responsibility for the services provided at the expansion site. Moreover, there is no basis for a provider to bill Medicare for services provided by a site which has not been determined to meet applicable requirements of participation.

When an expansion request is received, before making a determination the RO considers the following:

- Whether the proposal meets Medicare statutory and regulatory requirements. For example, in the case of an HHA, does the proposed branch meet the definition of a branch office at 42 CFR 484.2. If it is possible to make a decision based on the provider's description of how it intends to operate, an onsite survey may not be necessary.

- If the proposal complies with State and local laws related to the particular type of provider/supplier; and

- Whether Medicare reimbursement is affected by the proposal. For example, a hospital states that is has purchased a physicians' clinic that is now a part of the hospital. In such a case, input from the Division of Medicare and the fiscal intermediary will likely be necessary. While CMS does not dictate to a provider how it should operate its business, the provider does have to comply with Medicare requirements. Whenever an entity can meet the requirements of two different categories; e.g., subunit and independent home health agency, it is generally CMS' policy to designate the category for which there is the least potential to increase Medicare costs. If a proposed branch is in an area that would receive a different payment rate than the parent HHA, it could be found to be in a different geographic area and determined not to be a branch.

Although legal authority exists for conducting a survey, a survey may not be necessary because the provider furnishes the RO with sufficient information to make a determination about its proposed expansion either at the time of its initial request or subsequently. If the RO believes a survey is required, but the SA is unable to conduct a survey within a reasonable period of time, the RO may take one of the following actions:

- Make a determination based on the expansion information provided by the provider and inform the provider of the decision; and

- Inform the provider that a survey will be necessary and that it should not bill Medicare for services provided at the proposed expansion location until the survey is conducted and a determination is made.

In the absence of notification of an expansion, CMS has the authority to deny bills for services furnished at the expanded site. When notification is received of a proposed expansion, the RO should inform the provider of whether the expanded site meets applicable requirements. The fiscal intermediary should be notified of the RO's decision.

Rehabilitation Reference Manual

Tab 6:
CORF Survey Process

6.1 CORF Survey Process

6.2 Q&A

6.1 CORF Survey Process

Survey Protocol for Comprehensive Outpatient Rehabilitation Facilities (CORF)

Definition of CORF

A CORF is a comprehensive rehabilitation facility which is "established and operated at a single fixed location, exclusively for the purposes of providing diagnostic and restorative services to outpatients by or under the supervision of a physician." (42 CFR §485.51)

Scope and Site of Services

As defined in the *State Operations Manual (SOM)*: a CORF must provide, *at a minimum*, physician's services, physical therapy, social or psychological services.

Services furnished as part of a maintenance program not requiring the skilled services of nurses or therapists are not covered.

With the exception of physical therapy (PT), occupational therapy (OT) and speech therapy (ST), all CORF services must be provided on the CORF premises. For example, the CORF may provide PT, OT and/or ST services at an assisted living center that is not located on the same premises as the CORF. However, the CORF cannot provide any other services at that assisted living center. In addition, if OT and/or ST are provided offsite, those services must also be provided at the primary CORF site.

Conditions of Participation (CoPs) for CORFs are found in 42 CFR Part 48 subpart B. Appendix K of the *State Operations Manual* contains interpretive guidelines.

References:

- 42 CFR 485.50–74, Conditions of Participation: Comprehensive Outpatient Rehabilitation Facilities.
- *State Operations Manual (SOM)*, Appendix K, Interpretive Guidelines for Comprehensive Outpatient Rehabilitation Facilities.
- *State Operations Manual (SOM)* 2360–2366, Additional certification information regarding CORFs.
- *State Operations Manual (SOM)* 2008.A. Initial certification information, including the description of a "fully operational" provider.

Survey Protocol

Task 1: Offsite Preparation
Task 2: Entrance Conference
Task 3: Tour
Task 4: Clinical Review
Task 5: Review of Administration
Task 6: Compliance Determination
Task 7: Exit Conference
Task 8: Documentation of Findings

Task One: Offsite Preparation

The general objective of offsite preparation is to analyze various sources of available information in order to identify potential concerns before conducting the survey.

Information sources for offsite preparation:

- Documentation submitted by a provider requesting certification: Provider Enrollment Form (Form CMS-855), Request to Establish Eligibility (Form CMS-359), Health Insurance Benefits Agreement (Form CMS-1561) and any other information the provider may have submitted.
- Information about offsite locations (i.e., other sites where the CORF is providing PT, OT and/or ST services).
- Prior survey Statements of Deficiencies (for recertification surveys).
- Appendix K of the *State Operations Manual (SOM)*.
- Form CMS-360 Survey Report for CORF Surveyors should be familiar with this form, which contains the Conditions of Participation for CORFs.
- Written agreement between States if the CORF has offsite locations in more than one State. The written agreement should specify which State agency is responsible for surveying which location.

Prior to conducting the survey, surveyors should be familiar with the CoPs and the interpretive guidelines for CORFs. They should review any previous Statements of Deficiencies to look for potential areas of weakness in the provision of care at the CORF.

In addition, the surveyor must know what services *must* be provided (physician services, PT and social or psychological services). Surveyors must also know what the role of the physician is in the CORF setting.

Task Two: Entrance Conference

Once onsite, the surveyor must meet briefly with the administrator of the CORF. A lengthy meeting may delay Task 3, the Initial Tour, and disrupt the gathering of evidence. The

purpose of this meeting is to announce the survey to the provider, explain the survey process to the administrator and gather information from the administrator. A lengthy meeting may delay Task 3, the Initial Tour, and disrupt the gathering of evidence. If the administrator is not on the premises, meet with the administrator-designee.

During this meeting with the administrator, the surveyor should ask what services are being provided at the CORF. Be sure that, at a minimum, the CORF is providing physician services, physical therapy and social or psychological services. In addition, ask the administrator about any other services the CORF may be providing (e.g., nursing services, occupational therapy, speech therapy, respiratory therapy).

PT, OT and ST services may be provided offsite, so the surveyor should request a written listing of all sites where the CORF is providing services. If any service (PT, OT, ST) is provided offsite, that service must also be provided at the primary site. During the initial meeting with the administrator, ask what services are being provided offsite and then verify that those services are also being provided at the primary site.

If any of the offsite facilities are in another State, request a copy of the written agreement between the two State agencies that specifies which State agencies are responsible for surveying which sites.

Request documentation from the administrator including:

- Personnel files.
- Policy and procedure manuals.
- Client census.
- Staff schedules.
- Disaster plans.
- Any contracts that the CORF may have in effect (i.e., contracts with therapists to provide services under arrangements, contracts for housekeeping/linen services, contracts for pick up of biohazardous waste, etc.).
- Copies of infection control policies and procedures.
- A copy of the preventative maintenance program and the utilization review plan.

Task Three: Tour

Following the entrance conference with the administrator, request a tour of the facility. Pay attention to the following during the tour:

A. Observe interactions between CORF staff and clients:
   - Are clients treated with dignity and respect?
   - Are there provisions made to maintain client privacy during treatment, such as privacy curtains and screens?

B. Observe the equipment in the treatment areas:
   - Is there enough space and equipment for the services being provided?
   - Are treatment tables clean and free of dust?
   - Is equipment in proper working order?

- If there are inspection stickers on pieces of equipment, such as a hydrocollator machine or an electrical stimulation machine, check the stickers to ensure that equipment is being properly inspected and calibrated.
- Is equipment clean and free of dust?

C. Observe the general condition of the space:
- Are client records left open, strewn about the room?
- Is there proper lighting?
- How is the ventilation?
- Is there any evidence of pests or rodents?
- Are there potentially hazardous materials left in patient care areas?

D. Observe the location of fire extinguishers, posting of the evacuation plan in case of fire/emergency, lights at exits.

E. Observe accessibility of the facility:
- Are doorways and corridors used by clients of adequate width to allow for easy movement of all clients, including those clients who utilize wheelchairs?
- Is there at least one toilet facility that is handicapped accessible?
- If the building has multiple levels, is there an elevator for those clients who require it?
- Are there parking spaces located close enough to the facility to allow safe access by the physically impaired?
- Is there at least one entrance that is accessible to those clients who utilize wheelchairs?
- Do stairwells have at least one firmly attached handrail?

F. Observe linen:
- Is there enough linen and is the linen in good condition?
- Is the linen handled and stored in a manner that prevents the spread of infection?

G. Observe staff infection control practices:
- Are staff washing their hands appropriately?
- Is there protective equipment, such as gloves, masks and gowns available to staff (if necessary)?
- Is equipment such as whirlpools, ultrasound machines and treatment plinths being properly disinfected?

H. If applicable, observe the storage, handling and administration of any drugs and biologicals.

Task Four: Clinical Review

CoP: Comprehensive Rehabilitation Program (I532). The CORF must provide a coordinated rehabilitation program that includes, at a minimum:
- Physician services.
- Physical therapy.
- Social or psychological services.

The services must be provided by qualified personnel and must be consistent with the Plan of Care. The surveyor should review a listing of CORF services to ensure that the three required services are being provided.

- Standard: physician services (I533). The facility physician must be present in the facility for a sufficient time to:
  - Provide medical direction and consultation.
  - Establish the plan of treatment in cases where a plan has not been established by a referring physician.
  - Assist in developing and implementing the CORF's patient care policies.
  - Participate in plan of care reviews, patient care conferences and utilization review (I534).

In addition, the CORF must provide for emergency physician services during the CORF's operating hours. Verify that the CORF has made arrangements for emergency medical services and that staff are familiar with these arrangements (I535).

The surveyor must verify that the physician meets the qualifications as set forth in 42 CFR 485.70—Personnel qualifications. This may be accomplished by reviewing a resume, certificates of training and/or letters acknowledging completion of training or experience.

Review the activities of the group of professional personnel, utilization review meetings, patient records and reports of case review conferences to assist in determining whether the physician is spending sufficient time in the facility.

Diagnostic and therapeutic services furnished by the physician are *not* CORF services.

- Standard: plan of treatment (I536). For each client, the physician must establish the plan of treatment. The plan of treatment must:
  - Specify anticipated goals (I537).
  - Specify the type of services and the frequency and duration of those services (I537).
  - Be promptly evaluated following any changes in the client's condition and revised as indicated (I538).
  - If applicable, be developed in consultation with the facility physician and the appropriate facility personnel (I539).
  - Be reviewed at least every 60 days by a facility physician, who, when appropriate, consults with the professional providing the service. The results of this review must be communicated to the client's referring physician before treatment is continued or discontinued (I540).
  - Be revised if the comprehensive reassessment of the client's status or the results of the client case review indicate the need for revision (I541).

If clients require social and/or psychological services, those services must be included in the Plan of Care. When reviewing clinical records of those clients receiving social and/or psychological services, surveyors must ensure that CORF staff are not relying on client self-

referral. In other words, if social and/or psychological services are included in the plan of care, the client must be evaluated by an appropriate professional.

- Standard: coordination of services (I542). The facility must designate, in writing, a qualified professional to ensure that patient care is coordinated. The surveyor should ensure that mechanisms are in place to ensure coordination of services. Those mechanisms should include:
  - A schedule, distributed to all personnel associated with the facility, that indicates the type and frequency of the services provided at the facility (I543).
  - A procedure for communicating to all client care personnel any pertinent information concerning significant changes in client's status (I544).
  - Periodic clinical entries noting the client's status in relation to rehabilitation goals (I545).
  - Indications of client case review conferences to determine appropriateness of treatment, upon any recommendations of the facility physician (or other physician who established the plan of care) or upon recommendation of one of the professionals providing services (I546).

The frequency, format and criteria for client review conferences may vary. In general, these conferences will be held to determine if further treatment is appropriate, if there are changes to the plan of care or if the client requires a different level of care. Surveyors must make sure that there is a written policy regarding client case review conferences and that the policy is being adhered to. The surveyor should interview the professional that has been designated to coordinate services. In addition, surveyors should review documentation from previous case review conferences and should also interview CORF personnel regarding their knowledge of how the case review conference process works.

- Standard: provision of services (I547). All clients must be referred to the CORF by a physician, who provides the following information (I548):
  - The client's significant medical history.
  - Any current medical findings.
  - Diagnosis(es) and any contraindications to treatment modalities. For example, clients with a diagnosis of cancer should not receive ultrasound treatments.
  - Rehabilitation goals, if determined.

In some cases, the client may not come to the CORF for his/her first treatment session with current medical findings and/or a complete medical history. In this situation, a qualified professional or a facility physician should obtain this information from the client. If necessary, the CORF staff should follow up with the referring physician to obtain any other information.

CORF services may be provided by facility employees or by others under arrangements made by the facility (I549). For example, an owner of a CORF may also own a skilled nursing facility (SNF). Staff may be shared between these two providers. However, the CORF and the staff providing care in the CORF must meet all of the CoPs for CORFs.

The CORF must have on its premises the necessary equipment and sufficient space to carry out the plan of treatment (I550). Surveyors should review some plans of treatment and verify that the necessary equipment is on the premises. For example, if the plan of treatment calls for electrical stimulation, verify that there is an electrical stimulation machine on the premises.

Services must be provided by qualified personnel as detailed in 42 CFR 485.70. In addition, there must be an adequate number of staff for the diversity and the volume of clients treated. It is permissible to use supportive personnel, such as rehabilitation aides, to assist the qualified staff of the CORF. However, if rehabilitation aides are used, the qualified personnel must be *on the premises* and must instruct the supportive personnel in appropriate care. The surveyor should be familiar with the various levels of professional personnel and the scope of practice of each level. Each State has practice acts which govern the scope of practice of professionals. State practice acts for physical therapy can be obtained at www.apta.org. For occupational therapy and speech/language pathology, State practice acts can be obtained through State government web sites.

In addition, if supportive personnel are assisting the professional in providing care, the surveyor should ask to review some type of "competency checklist" to ensure that the supportive personnel have been trained in various techniques and that their level of competency has been evaluated. In addition, surveyors should interview the supportive personnel and ensure that they have, in fact, been trained.

If supportive personnel are being utilized, the surveyor should talk to staff (all levels) to ascertain how supervision is being provided to the supportive personnel. When supportive staff are used, the *qualified professional still maintains responsibility* for the services provided by the supportive personnel.

A qualified professional must initiate and coordinate the appropriate portions of the plan of treatment, monitor the client's progress and recommend any necessary changes to the plan of treatment (I552). Assistant level personnel (PTA, COTA) *must not* initiate any changes to the client's plan of care without approval of the appropriately qualified professional (PT, OT).

A qualified professional representing each service available at the facility must be either on the premises of the CORF or available through direct telecommunication for consultation and assistance during the CORF's hours of operation. At least one qualified professional must be on the CORF's premises during the hours of operation (I553). If services (PT, OT, SLP) are being provided offsite, the surveyor should verify that the professionals are readily available to provide consultation and/or assistance. The surveyor may want to call CORF staff to verify that they are, in fact, available.

All services must be provided in accordance with acceptable standards of practice (I554):

- Standard: scope and site of services (I555). The facility must provide all the CORF services as required in the client's plan of treatment on the premises of the CORF. There are two exceptions to this regulation:

  - One visit may be made to the client's home to evaluate the potential impact of the home environment on the rehabilitation goals.
  - Physical therapy, occupational therapy and speech/language pathology services may be provided offsite.

Surveyors should review documentation that indicates when a home visit was made, who conducted the home evaluation and what the results of that evaluation were. Since the purpose of the home evaluation is to assess the need for possible modifications to the environment to maximize the client's functional ability, assistant-level personnel or rehabilitation aides should not conduct home evaluations.

If the CORF is providing PT, OT or SLP services offsite, *all records* must be maintained on the premises of the CORF. Surveyors should ask to review records of clients receiving services offsite to ensure that clinical documentation is maintained on the premises of the CORF.

- Standard: patient assessment (I556). Each qualified professional involved in the client's plan of care and specified in the plan of care must:
  - Carry out an initial client assessment (I557).
  - Perform reassessments after significant changes in the client's status in order to identify whether the current plan of treatment is appropriate (I558).

Review patient care files. From the list provided by the administrator, randomly select at least 10 or 10% of the patients who have received or are receiving one or more of the required services during the past year. Select some of the files of patients whose care was observed. Select some closed records. Keep in mind that many State practice acts address documentation requirements.

Surveyors should review records and determine whether there are time lapses between the initial evaluation and the initiation of treatment. If there are significant time delays, this may be due to a lack of coordination of services (I542).

Task Five: Review of Administration

A. CoP: Compliance with State and Local Laws (I501). The facility and all personnel who provide services must be in compliance with applicable State and local laws.
   - Standard: licensure of facility (I502). If State or local law requires it, the facility must be licensed (in the case of a recertification survey) or must meet the standards for State licensure (in the case of an initial survey).
   - Standard: licensure of personnel (I503). All personnel providing services at the CORF must be licensed, certified or registered in accordance with State or local laws.

Review evidence such as State registries or wallet-sized licenses to verify that all therapists (PT, OT, ST and/or respiratory therapists), the physician(s), any nursing staff, the social worker(s) and/or psychologist(s) are all *licensed in the State in which they are practicing*. This is especially important to review when the CORF provides services in more than one State.

B. CoP: Governing Body and Administration (I505). The facility must have a governing body that assumes full legal responsibility for establishing and implementing policies regarding the management and operation of the CORF.

The surveyor should interview the administrator to determine who is on the governing body and to ensure that the governing body assumes responsibility for the management and operation of the CORF.

While there is no requirement that the governing body follows prescribed meeting schedules, it should be evident to the surveyor that the governing body takes an active role in the overall operation of the CORF.

- Standard: disclosure of ownership (I506). Surveyor should review disclosure of ownership information provided by the administrator.
- Standard: administrator (I507). There are no requirements for the qualifications of the administrator. In some cases, the administrator may have a clinical background, while in other cases the administrator may have a business management background. Regardless of the administrator's area of expertise, the administrator's responsibility is to ensure that services are rendered in accordance with the CORF's policies and that there is effective utilization of resources.
  - The administrator must be appointed by the governing body. The surveyor should review governing body meeting minutes to determine that the governing body has appointed the administrator.
  - The administrator is responsible for the overall management of the facility (I508).
  - The administrator is responsible for implementing and enforcing the facility's policies and procedures (I509).
  - The administrator must designate *in writing* an individual to act as administrator in the case of his/her temporary absence (I510). The surveyor should determine the individual designated to act in the case of the absence of the administrator and verify that this person has been designated in writing.
  - The administrator retains professional and administrative responsibility for all personnel providing facility services (I511).
- Standard: group of professional personnel (I512). The facility must have a group of professional personnel associated with the facility.
  - The group of professional personnel must develop and periodically review policies governing the services provided by the facility (I513).
  - The group of professional personnel must consist of at least one physician and one professional representing each of the services provided by the CORF (I514).
  - The surveyor should confirm that the group of professional personnel exists. Names of the group members should be available and there must be evidence that those individuals have participated in the development and periodic review of policies and procedures.
  - There is no specific requirement as to how often policies and procedures must be reviewed. However, if the surveyor determines during the course of the survey that written policies and procedures are not being followed or are ineffective, the CORF would be considered "out of compliance" with this standard.

- Standard: institutional budget plan (I515). The CORF must have a budget plan that meets the following criteria:
  - The budget must be prepared under the direction of the governing body by a committee consisting of representatives from the governing body and representatives from the administrative staff of the CORF (I516).
  - The budget must provide for an annual operating budget that has been prepared according to generally accepted accounting principles (I517).
  - There must be a three-year capital expenditure plan *if* expenditures in excess of $100,000 are anticipated for the acquisition of land or the improvement of land, buildings or equipment (I517).

There must be evidence that the budget has been reviewed and updated annually by the governing body (I517).

In reviewing the budget, surveyors must only confirm that the budget exists and meets the previously mentioned criteria; surveyors *do not* need to review the budget for substance.

- Standard: patient care policies (I518). The CORF must have written policies that govern every service it furnishes. The patient care policies must include the following:
  - A description of the services that the CORF provides through employees and those services furnished under arrangements (I519).
  - Rules for personnel responsibilities during a medical emergency (I520).
  - Rules for the storage, handling and administration of drugs and biologicals (I521).
  - Criteria for client admission, continuation of care and discharge. Criteria for admission may include such things as diagnosis, ambulatory status of clients, geographic areas, etc. Criteria for discharge may include such things as attainment of goals, refusal to participate in treatment, need for higher level of care, etc. (I522).
  - Procedures pertaining to clinical records (I523). At a minimum, policy must state that all entries into the clinical record must be signed.
  - A procedure for explaining to the client and/or the client's family the extent and purpose of the services being provided (I524).
  - A procedure to assist the referring physician in locating another level of care for clients who have been discharged (I525).
  - A requirement that any client accepted for CORF services be under the care of a physician (I526).
  - A requirement that each client have a plan of care established by a physician (I527).
  - A procedure to ensure that the group of professional personnel reviews and takes appropriate action on recommendations from the utilization review committee regarding patient care policies (I528).

Patient care policies are the basic foundation of the operation of the CORF. Therefore, all patient care policies should be reviewed during the survey. Surveyors should verify that all policies are in writing and that the group of professional personnel provided input into the development and review of the policies. Surveyors should interview members of the group of professional personnel to determine if they have a working knowledge of the policies.

- Standard: delegation of authority (I529). The responsibility for overall administration, management and operation of the CORF must be retained by the facility itself and not delegated to others. For example, the CORF *may not* designate a person who works for another entity to act as administrator of the CORF.

The CORF *may* enter into a contract with another entity to provide services such as bookkeeping, billing and accounting services, purchasing of supplies in bulk form, assistance in developing a budget and preparing financial statements. If such contracts exist, the surveyor must ensure that the term of the contract is not more than five years and the contract must be subject to termination within 60 days of notice by either party. In addition, the contract must contain a clause requiring renegotiation of any provision that CMS finds to be in contravention to any new, revised or amended Federal regulation or law. Finally, the contract may not include any clauses that allow the contractor to act on behalf of the CORF and/or enable the contractor to dictate administration, management or operation of the CORF.

C. CoP: Clinical Records (I559). The facility must maintain clinical records on all clients in accordance with accepted professional standards. The records must be complete, promptly and accurately documented, readily accessible and systematically organized.
   - Standard: content (I560). The clinical records must contain enough information to identify the client clearly and to justify the diagnosis and treatment. All entries *must be signed by the personnel providing services*. All entries made by assistant-level personnel must be countersigned by the qualified professional. The clinical record must contain:
     - The initial assessment and any reassessments of the client (I561).
     - The current plan of treatment (I562).
     - Identification data and consent forms (I563).
     - Pertinent medical history (I564).
     - Progress notes or documentation that reflects client reaction to treatment, tests, etc. (I566).
     - Upon discharge, a discharge summary that includes client's status in relation to his/her rehabilitation goal and any recommendations for further treatment (I567).

For an initial certification survey, surveyors should review at least 10 active and closed records of those clients who have received one or more of the required CORF services (PT, physician services, social/ psychological services). For a recertification survey, the surveyors should review 10% of active and closed records.

If required material is missing from clinical records, surveyors should review additional clinical records to determine the prevalence of such omissions.

Each client's record should contain summaries of any client case conference reviews. The summary should indicate the reason for the case conference review and the outcome/recommendations from the review.

The surveyor will ensure that there are periodic progress notes in the clinical records. The notes should indicate the client's reaction to treatment and progress toward rehabilitation goals.

For closed records, there should be a discharge summary that includes the date of and reason for discharge, a brief summary of the client's status and, if applicable, any recommendations for further care.

All information in the clinical record must be *signed and dated.*

- Standard: protection of clinical record information (I568). The facility must ensure that clinical records are protected from loss, destruction or unauthorized use. The CORF must have procedures that govern the use and removal of records and the conditions for the release of information. The CORF must obtain the client's written consent prior to releasing information. The surveyor should ensure that active and closed records are stored in a manner that ensures protection from damage and unauthorized use. Determine that there is written consent from the client before any information is released.
- Standard: retention and preservation (I569). The CORF must maintain clinical record information for five years after the client has been discharged and must make provisions for the maintenance of clinical records in the event that the CORF goes out of business.

D. CoP: Physical Environment (I570). The facility must provide a physical environment that protects the health and safety of clients, staff and the public.

Surveyors should examine the building and make sure that it meets State and local building, fire and safety codes.

A CORF may be established on the premises of another health entity, such as a skilled nursing facility (SNF). However, the CORF must be certified separately from the SNF and must be operationally independent from the SNF. If the CORF is located in another health entity, the surveyor must ensure that space is not used by the other entity during the CORF's hours of operation.

Equipment can be shared between the two entities. However, all common equipment must be available on the CORF's premises during the CORF's hours of operation.

When a CORF is housed in another health entity, surveyors must survey the CORF utilizing the CORF Conditions of Participation, independent of any other findings resulting from the survey of the other entity. That is, even though a survey was conducted at a SNF which houses a CORF and there were no deficiencies cited, that fact should have no bearing on the CORF survey.

- Standard: safety and comfort of patients (I571). The physical premises of the facility and those areas used by clients (stairways, hallways) must meet the following requirements:
  - All applicable Federal, State and local building, fire and safety codes must be met (I572).
  - Fire extinguishers must be easily accessible and fire regulations must be posted (I573).

  - A fire alarm system with local (in-house) capability must be functional and where power is generated via electricity, an alternate power source with automatic triggering must be present (I574). If there are no State or local laws governing the fire alarm system, surveyors should ensure that the fire alarm system has been inspected by the State Fire Marshall's office.
  - Lights supported by emergency power source must be placed at exits (I575).
  - There must be a sufficient number of staff available to evacuate all clients on the premises in case of emergency (I576). The number of staff considered "sufficient" will vary depending on the types of clients being treated. For example, if the client population is largely dependent on what/who for mobility, there must be more staff available to evacuate clients.
  - Lighting must be sufficient to carry out services safely; room temperatures must be comfortable; and ventilation must be provided, via windows, mechanical means or a combination of the two (I577).
- Standard: sanitary environment (I579). The facility must maintain a sanitary environment and establish a program to identify, investigate, prevent and control the cause of client infections.

Surveyors must ensure that the facility has established written policies and procedures to control and prevent infection and to investigate and identify possible causes of infection (I580). Surveyors must review the written policies and procedures to verify that they are adequate in light of the volume and types of clients treated at the CORF and that they are in accordance with current accepted standards of clinical practice for infection control.

The facility must monitor the infection control program to ensure that all staff are following the established policies and procedures (I581). After the surveyor has reviewed the infection control policies, he/she should observe staff to determine if they are correctly implementing the CORF's procedures. In addition, he/she should interview staff to ascertain how familiar they are with infection control policies and procedures. This is a particularly important area if the CORF is treating clients with open wounds.

Surveyors should also ask how equipment such as whirlpools and paraffin baths is cleaned; how biohazardous material is handled and disposed of; whether staff are washing their hands appropriately.

The facility must have sufficient linen onsite. In addition, linen must be handled, stored and processed in a manner that prevents the spread of infection (I582). Surveyors should check to see if there is enough linen to meet the needs of the clients served and that the linen is in acceptable condition (linen should be clean, should not be torn). Clean linen should be stored separately from soiled linen. All soiled linen should be stored and processed in an area away from any client areas. If the CORF washes linens on the premises, review its policies and procedures regarding how this is to be done.

The facility must have provisions in effect that ensure that the CORF is free of rodents and insects (I583). Ask the facility administrator about the CORF's pest control program and review any related policies and procedures. If the surveyor notices any evidence of pests,

he/she should investigate further to determine the effectiveness of the CORF's pest control program.

- Standard: maintenance of equipment, physical location and grounds (I584). The facility must establish a written preventative maintenance program to ensure that:
  - All equipment is properly maintained and calibrated consistent with the manufacturer's recommendations (I585). All equipment should be inspected at least annually or more frequently, depending on the recommendation of the manufacturer. Surveyors should review the CORF's written policies for maintenance of equipment. The written policy should include a list of equipment to be inspected, the frequency of inspection for each piece of equipment and a brief statement about the inspection process. Surveyors should check equipment to ensure that it has been inspected per recommendation. Often when equipment is inspected, there will be a sticker placed on the equipment with the date of the most recent inspection. If that information is not available, the surveyors should review service statements to ensure that equipment maintenance is being conducted.
  - The interior of the facility, the exterior of the facility, the exterior of walkways and parking areas are clean and orderly and there are no accident hazards (e.g., broken windows, blocked passageways, potholes in parking lots or sidewalks and dangerous floor surfaces) (I586).
- Standard: access for the physically impaired (I587). For clients with physical impairments, the CORF must ensure the following:
  - Doorways, stairwells and corridors used by clients must be of width adequate for allowing access by clients in wheelchairs or on stretchers. In addition, stairwells must be equipped with firmly attached handrails (I588).
  - At least one toilet facility must be accessible to and constructed to allow access by both ambulatory and nonambulatory clients (I589).
  - At least one entrance must be accessible to clients in wheelchairs (I590). There must be a ramp to the entrance (if necessary).
  - If the building has multiple stories, elevators must be accessible to and usable by clients (I591).
  - Parking spaces must be large enough and close enough to the building to allow safe access by the physically impaired (I592).

Surveyors should inspect the premises of the CORF to be sure that clients who are physically impaired have access to the building itself and to restroom facilities.

E. CoP: Disaster Procedures (I593). The facility must have written policies and procedures that specifically define the handling of clients, personnel, clinical records and the public in case of disaster. All personnel associated with the CORF must have knowledge of these procedures, must have received training in the procedures and must be aware of their specific duties in case of disaster.

Surveyors should review the written disaster plan and should check to be sure that evacuation routes are posted. Verify that the plan includes locations and instructions for use of alarm systems and fire extinguishers. Verify that all CORF personnel have been instructed in

disaster preparedness. The dates of training and all personnel attending should be documented.

- Standard: disaster plan (I594). The CORF's written disaster plan must be developed and maintained and must include the following:
  - Procedures for prompt transfer of casualties and clinical records (I595).
  - Procedures for notifying community emergency personnel (e.g., fire departments, ambulance) (I596).
  - Instructions regarding the location and use of alarm systems and fire extinguishers (I597).
  - Evacuation routes and procedures for leaving the facility (I598).
- Standard: drills and staff training (I599). The CORF must provide *ongoing training and drills* for all personnel associated with the facility (I600). Surveyors should review documentation to ensure that all personnel have been trained in disaster procedures and have participated in disaster drills.

The CORF must ensure that all new personnel are oriented to the facility's disaster plan within two weeks of their first workday (I601). Surveyors should review personnel records of employees to ensure that they were trained in disaster preparedness within two weeks of their first day of work.

F. CoP: Utilization Review Plan (I602). The facility must have a written utilization review plan that is implemented *at least quarterly*. The purpose of utilization review is to assess the appropriateness of services and promote the most efficient use of services. It is the responsibility of the CORF to ensure that at least one physician participates in the utilization review process.
   - Standard: utilization review committee (I603). The utilization review committee must consist of at least one physician and one professional representing each of the services provided by the CORF.

Surveyors should review utilization review committee meeting minutes to determine if the necessary professionals have participated.

- Standard: utilization review plan (I604). The utilization review plan must contain written procedures for evaluating the following:
  - Admissions, continued care and discharges, using at a minimum the criteria established in the client care policies (I605).
  - The applicability of the plan of treatment to established goals (I606).
  - The adequacy of clinical records with regard to assessing the quality of services provided and determining whether the CORF's policies and clinical practices are promoting effective utilization of services (I607).

Surveyors should review utilization review committee meeting minutes to determine that meetings are being held at least quarterly and that the required members are participating in the meetings (physician and at least one representative from each service offered at the CORF). In addition, the results of the utilization reviews conducted should be evident from

the meeting minutes and should also be available to all CORF staff. If recommendations were made as a result of utilization review activity, determine how the recommendations were communicated to the administrator, the governing body and the group of professional personnel responsible for development and implementation of patient care policies. In addition, if recommendations were made, determine how those recommendations were implemented.

Task Six: Compliance Determination

- Follow the *State Operations Manual (SOM)* and the State agency policy in determining provider compliance with Federal regulations.
- Review the evidence gathered during the survey.
- Review the regulations and identify evidence of deficient practice.
- Determine the level of deficient practice.

Task Seven: Exit Interview

Upon completion of the tour of the CORF, review of the documentation and completion of any interviews, the surveyor should compile all information.

A meeting should be held to discuss the findings with the facility administrator. If the administrator chooses, CORF staff may be invited to the exit interview.

During the exit interview, the surveyor should discuss his/her findings and concerns, but in general terms. It is not necessary to provide specific regulatory references. However, if the surveyor feels that the CORF is out of compliance with the Conditions of Participation, he/she should let the administrator know and provide the administrator with the findings related specifically to the Condition-level deficiencies. The CORF staff should be given the opportunity to provide the surveyor with any additional information that they feel would help to clarify any issues the surveyor may have discussed.

Inform the administrator that all State agency findings will be forwarded to CMS, along with the State agency's recommendation regarding certification of the CORF.

Describe to the administrator the timeframes and the procedures for submitting a plan of correction for the deficiencies cited.

Task Eight: Documentation of Findings

Follow the CMS Principles of Documentation when developing the Statement of Deficiencies.

Follow the State agency procedure for processing the Statement of Deficiencies and relaying the State agency recommendation for certification to CMS.

6.2 Q&A

Frequently Asked Questions and Answers on CORFs

Q: Can psychotherapy services provided in a CORF and related to a patient's plan of care be provided by a social worker?

A: Psychotherapy services related to a patient's plan of care can be provided by a psychologist or a social worker (if the state practice act allows the social worker to provide psychotherapy services).

Q: Suppose survey determines that the CORF is faxing the Plan of Treatment (PoT) to the physician for approval. The signed PoT is being faxed back to the CORF, but then the original is never signed by the physician. Is this acceptable?

A: Yes, it is acceptable.

Q: Can a CORF provide PT, OT and/or SLP services to people living in rest homes or assisted-living facilities?

A: The CORF can provide services at both assisted-living centers and rest homes as long as the patients are under the care of a physician who refers the patients for rehabilitation services and who signs the Plan(s) of Treatment before treatment is initiated.

Q: Can CORF services begin before the Plan of Treatment is signed by the physician? Can CORF services continue if the 60 day recertification is not signed in a timely manner?

A: No, the CORF services *cannot* begin until the initial Plan of Treatment is signed, nor can CORF services continue if the 60-day recertification is not signed in a timely manner.

Q: Can a CORF provide services offsite at a patient's place of employment (e.g., a "work hardening program")?

A: Only PT, OT and SLP services can be provided offsite. Therefore, any other components of a "work hardening program" (vocational rehabilitation, psychology services, social services, physician services) need to be provided on the premises of the CORF.

Q: Can a provider operate a CORF and an OPT at the same location?

A: Yes, but not during the same hours of operation (for example, the CORF could operate on Monday, Wednesday and Friday, and the OPT could operate on Tuesday and Thursday).

Q: Can respiratory services, infusion therapy or hyperbaric treatment be performed as specialized services in a CORF?

A: Hyperbaric oxygen (HBO) services are considered physician therapeutic services and are not CORF services. (Refer to Appendix K, page 9). Therefore they cannot be offered

under the CORF outpatient therapy benefit. Respiratory therapy is an optional CORF service and can be offered as part of the patient's rehabilitation program. However, the respiratory therapist cannot be administering HBO as part of their CORF service.

Q: Can individual diagnostic treatment facility (IDTF) services be performed in the facility that houses the CORF?

A: An IDTF can lease space from a CORF to provide IDTF services (sleep therapy or sleep study services) long as the IDTF services are not provided in the CORF at the time the CORF is operational (not on the same days nor at the same times). Neither sleep therapy nor sleep study services are covered as part of the CORF outpatient therapy benefit and therefore cannot be provided in the CORF under the CORF outpatient therapy benefit.

Q: Must a CORF have a 3-year capital expenditure plan?

A: While a CORF must have an institutional budget plan, the CORF does not have to have a 3-year budget plan unless expenditures in excess of $100,000 are anticipated for that period of time.

Q: How does a surveyor verify accuracy of disclosure of ownership information of a CORF (§485.56(a)).

A: The fiscal intermediary is responsible for verifying information regarding ownership and control (owners/director/managers) contained on the completed CMS-855A and for recommending approval. The State Agency should keep a copy of the 855A and the recommendation for their files.

Q: Can a chiropractor, dentist or podiatrist refer patients to a CORF? What about a nurse practitioner or a physician's assistant?

A: Section 1861(r) defines the term physician. A podiatrist can refer because it is within the scope of services he/she is legally authorized to perform, a dentist is only authorized to refer when it is within the scope of his/her license and a chiropractor is only considered a physician as it relates to manual manipulation of the spine to correct subluxation (see 1861(r)); therefore, they would not be able to refer patients to a CORF. Section 1861(s)(2)(K) defines nonphysician practitioners. Nurse practitioners (NPs)or clinical nurse specialists can perform services which would be physician services if furnished by a physician (as defined in §1861(r)) and which they are legally authorized to perform by the State in which the services are performed. Therefore, NPs can refer patients to CORFs for services. Physician's assistants (PAs) cannot because the statute at 1861(s)(2)(K) states that a PA must be under the supervision of a physician to perform services that would be physician services if furnished by a physician.

Q: If a physician refers a patient to a CORF, is it acceptable for a nurse practitioner or physician's assistant to sign the Medicare 30-day recertifications?

A: The PA can not for reasons stated above. NPs can sign a recertification if they are employees of the physician practice and have their own provider identification number.

Q: If a physician makes a CORF referral and writes an order that says "physical therapy, occupational therapy and social services evaluations for low back pain, humerus fracture and severe pain secondary to MVA (motor vehicle accident)," does this mean that once the ordered evaluations are completed, the therapists and social worker cannot treat this patient until they get a signed order from the physician? This could cause a delay in treatment.

A: Once the physician makes a referral to a CORF there is no requirement that the order for the evaluation be signed by the physician prior to beginning therapy.

Q: Must changing areas and shower rooms of a pool used by CORF patients also be closed to the public during use by CORF patients? Must more than one person be on the pool premises when a patient is receiving aquatic therapy?

A: There is no Medicare requirement that the changing area and shower rooms be used only by CORF patients when the CORF has leased the pool area for aquatic therapy. There is no Federal requirement for more than one person to be on the premises when a patient is receiving aquatic therapy (please note this differs from requirements for OPTs). The fiscal intermediary may have local contractor requirements that must be met. Also, the State may have water safety requirements.

Rehabilitation Reference Manual

Tab 7:
Form for CORF Survey

7.1 Form CMS-360

7.1 Form CMS-360

Form Approved
OMB No. 0938-0267

COMPREHENSIVE OUTPATIENT REHABILITATION FACILITY SURVEY REPORT

§485.70 Personnel qualifications.

This section sets forth the qualifications that must be met, as a condition of participation, under §485.58, and as a condition of coverage of services under §410.100 of this chapter.

(a) A facility physician must be a doctor of medicine or osteopathy who—

(1) Is licensed under State law to practice medicine or surgery; and

(2) Has had, subsequent to completing a 1-year hospital internship, at least 1 year of training in the medical management of patients requiring rehabilitation services; or

(3) Has had at least 1 year of full-time or part-time experience in a rehabilitation setting providing physicians' services similar to those required in this subpart.

(b) A licensed practical nurse must be licensed as a practical or vocational nurse by the State in which practicing, if applicable.

(c) An occupational therapist and an occupational therapist assistant must meet the qualifications set forth in §484.4 of this chapter.

(d) An orthotist must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program in orthotics that is jointly recognized by the American Council on Education and the American Board for Certification in Orthotics and Prosthetics; and

(3) Be eligible to take that Board's certification examination in orthotics.

(e) A physical therapist and a physical therapist assistant must meet the qualifications set forth in §485.705.

(f) A prosthetist must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program in prosthetics that is jointly recognized by the American Council on Education and the American Board for Certification in Orthotics and Prosthetics; and

(3) Be eligible to take the Board's certification examination in prosthetics.

(g) A psychologist must be certified or licensed by the State in which he or she is practicing, if that State requires certification or licensing, and must hold a master's degree in psychology from an educational institution approved by the State in which the institution is located.

(h) A registered nurse must be a graduate of an approved school of nursing and be licensed as a registered nurse by the State in which practicing, if applicable.

(i) A rehabilitation counselor must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Hold at least a bachelor's degree; and

(3) Be eligible to take the certification examination administered by the Commission on Rehabilitation Counselor Certification.

(j) A respiratory therapist must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program accredited by the Committee on Allied Health Education and Accreditation (CAHEA) in collaboration with the Joint Review Committee for Respiratory Therapy Education; and

(3) Either—

(i) Be eligible to take the registry examination for respiratory therapists administered by the National Board for Respiratory Therapy, Inc.; or

(ii) Have equivalent training and experience as determined by the National Board for Respiratory Therapy, Inc.

(k) A respiratory therapy technician must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program accredited by the Committees on Allied Health Education and Accreditation (CAHEA) in collaboration with the Joint Review Committee of Respiratory Therapy Education; and

(3) Either—

(i) Be eligible to take the certification examination for respiratory therapy technicians administered by the National Board for Respiratory Therapy, Inc.; or

(ii) Have equivalent training and experience as determined by the National Board for Respiratory Therapy, Inc.

(l) A social worker must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Hold at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education; and

(3) Have 1 year of social work experience in a health care setting.

(m) A speech-language pathologist must meet the qualifications set forth in §485.705(b)(2) of this chapter.

Form Approved
OMB No. 0938-0267

COMPREHENSIVE OUTPATIENT REHABILITATION FACILITY SURVEY REPORT

PROVIDER NUMBER		FACILITY NAME AND ADDRESS *(City, State, Zip Code)*
VENDOR NUMBER		
SURVEY DATE	Type of Survey 1. ☐ Initial Survey 2. ☐ Resurvey	

Name of Facility

CODE		YES	NO	N/A	EXPLANATORY STATEMENT
I-501	**§485.54 Condition of Participation: Compliance with State and local laws.** The facility and all personnel who provide services must be in compliance with applicable State and local laws and regulations.				
I-502	**(a) Standard: Licensure of facility.** If State or local law provides for licensing, the facility must be currently licensed or approved as meeting the standards established for licensure.				
I-503	**(b) Standard: Licensure of Personnel.** Personnel that provide service must be licensed, certified, or registered in accordance with applicable State and local laws.				
I-504	State licensure, certification or registration is not required for: (Check those applicable) 1 ☐ Occupational Therapist 4 ☐ Psychologist 2 ☐ Speech Pathologist 5 ☐ Rehabilitation Counselor 3 ☐ Social Worker 6 ☐ All of the Above				
I-505	**§485.56 Condition of Participation: Governing body and administration.** The facility must have a governing body that assumes full legal responsibility for establishing and implementing policies regarding the management and operation of the facility.				
I-506	**(a) Standard: Disclosure of Ownership.** The facility must comply with the provisions of part 420, subpart C of this chapter that require health care providers and fiscal agents to disclose certain information about ownership and control.				

Name of Facility

CODE		YES	NO	N/A	EXPLANATORY STATEMENT
I-507	**(b) Standard: Administrator.** The governing body must appoint an administrator who—				
I-508	(1) Is responsible for the overall management of the facility under the authority delegated by the governing body;				
I-509	(2) Implements and enforces the facility's policies and procedures;				
I-510	(3) Designates, in writing, an individual who, in the absence of the administrator, acts on behalf of the administrator; and				
I-511	(4) Retains professional and administrative responsibility for all personnel providing facility services.				
I-512	**(c) Standard: Group of professional personnel.** The facility must have a group of professional personnel associated with the facility that—				
I-513	(1) Develops and periodically reviews policies to govern the services provided by the facility; and				
I-514	(2) Consists of at least one physician and one professional representing each of the services provided by the facility.				
I-515	**(d) Standard: Institutional budget plan.** The facility must have an institutional budget plan that meets the following conditions:				
I-516	(1) It is prepared, under the direction of the governing body, by a committee consisting of representatives of the governing body and the administrative staff.				
I-517	(2) It provides for: (i) An annual operating budget prepared according to generally accepted accounting principles. (ii) A 3-year capital expenditure plan if expenditures in excess of $100,000 are anticipated, for that period, for the acquisition of land; the improvement of land, buildings and equipment; and the replacement, modernization, and expansion of buildings and equipment; and				

Name of Facility

CODE		YES	NO	N/A	EXPLANATORY STATEMENT
	(iii) Annual review and updating by the governing body.				
I-518	**(e) Standard: Patient care policies.** The facility must have written care policies that govern the services it furnishes. The patient care policies must include the following:				
I-519	(1) A description of the services the facility furnishes through employees and those furnished under arrangements.				
I-520	(2) Rules for and personnel responsibilities in handling medical emergencies.				
I-521	(3) Rules for the storage, handling, and administration of drugs and biologicals.				
I-522	(4) Criteria for patient admission, continuing care, and discharge.				
I-523	(5) Procedures for preparing and maintaining clinical records on all patients.				
I-524	(6) A procedure for explaining to the patient and the patient's family the extent and purpose of the services to be provided.				
I-525	(7) A procedure to assist the referring physician in locating another level of care for patients whose treatment has terminated and who are discharged.				
I-526	(8) A requirement that patients accepted by the facility must be under the care of a physician.				
I-527	(9) A requirement that there be a plan of treatment established by a physician for each patient.				
I-528	(10) A procedure to ensure that the group of professional personnel reviews and takes appropriate action on recommendations from the utilization review committee regarding patient care policies.				
I-529	**(f) Standard: Delegation of authority.** The responsibility for overall administration, management and operation must be retained by the facility itself and not delegated to others.				

CODE		YES	NO	N/A	EXPLANATORY STATEMENT
I-530	(1) The facility may enter into a contract for purposes of assistance in financial management and may delegate to others the following and similar services: (i) Bookkeeping. (ii) Assistance in the development of procedures for billing and accounting systems. (iii) Assistance in the development of an operating budget. (iv) Purchase of supplies in bulk form. (v) The preparation of financial statements.				
I-531	(2) When the services listed in paragraph (f)(1) of this section are delegated, a contract must be in effect and: (i) May not be a term of more than 5 years; (ii) Must be subject to termination within 60 days of written notice by either party; (iii) Must contain a clause requiring renegotiation of any provision that CMS finds to be in contravention to any new, revised, or amended Federal regulation or law; (iv) Must state that only the facility may bill the Medicare program; and (v) May not include clauses that state or imply that the contractor has power and authority to act on behalf of the facility, or clauses that give the contractor rights, duties, discretions, or responsibilities that enable it to dictate the administration, management, or operations of the facility.				
I-532	**§485.58 Condition of Participation: Comprehensive rehabilitation program** The facility must provide a coordinated rehabilitation program that includes, at a minimum, physicians' services, physical therapy services and social or psychological services. The services must be furnished by personnel that meet the qualifications set forth in §485.70 and must be consistent with the plan of treatment and the results of comprehensive patient assessments.				

Name of Facility

CODE		YES	NO	N/A	EXPLANATORY STATEMENT
I-533	**(a) Standard: Physician services.** (1) A facility physician must be present in the facility for a sufficient time to— (i) Provide, in accordance with accepted principles of medical practice, medical direction, medical care services and consultation; (ii) Establish the plan of treatment in cases where a plan has not been established by the referring physician; (iii) Assist in establishing and implementing the facility's patient care policies; and (iv) Participate in plan of treatment reviews, patient case review conferences, comprehensive patient assessment and reassessments and utilization reviews.				
I-534	(2) The facility must provide for emergency physician services during the facility operating hours.				
I-535	**(b) Standard: Plan of treatment.** For each patient, a physician must establish a plan of treatment before the facility initiates treatment. The plan of treatment must meet the following requirements:				
I-536	(1) It must delineate anticipated goals and specify the type, amount, frequency and duration of services to be provided.				
I-537	(2) It must be promptly evaluated after changes in the patient's condition and revised when necessary.				
I-538	(3) It must, if appropriate, be developed in consultation with the facility physician and the appropriate facility professional personnel.				
I-539	(4) It must be reviewed at least every 60 days by a facility physician who, when appropriate, consults with the professional personnel providing services. The results of this review must be communicated to the patient's referring physician for concurrence before treatment is continued or discontinued.				

CODE		YES	NO	N/A	EXPLANATORY STATEMENT
I-540	(5) It must be revised if the comprehensive reassessment of the patient's status or the results of the patient case review conference indicate the need for revision.				
I-541	**(c) Standard: Coordination of services.** The facility must designate, in writing, a qualified professional to ensure that professional personnel coordinate their related activities and exchange information about each patient under their care. Mechanisms to assist in the coordination of services must include—				
I-542	(1) Providing to all personnel associated with the facility, a schedule indicating the frequency and type of services provided at the facility;				
I-543	(2) A procedure for communicating to all patient care personnel pertinent information concerning significant changes in the patient's status;				
I-544	(3) Periodic clinical record entries, noting at least the patient's status in relationship to goal attainment; and				
I-545	(4) Scheduling patient case review conferences for purposes of determining appropriateness of treatment, when indicated by the results of the initial comprehensive patient assessment, reassessment(s), the recommendation of the facility physician (or other physician who established the plan of treatment), or upon recommendation of one of the professionals providing services.				
I-546	**(d) Standard: Provision of services.** (1) All patient's must be referred to the facility by a physician who provides the following information to the facility before treatment is initiated: (i) The patient's significant medical history. (ii) Current medical findings. (iii) Diagnosis(es) and contraindications to any treatment modality. (iv) Rehabilitation goals, if determined.				
I-547	(2) Services may be provided by facility employees or by others under arrangements made by the facility.				

CODE		YES	NO	N/A	EXPLANATORY STATEMENT
I-548	(3) The facility must have on its premises the necessary equipment to implement the plan of treatment and sufficient space to allow adequate care.				
I-549	(4) The services must be furnished by personnel that meet the qualifications of §485.70 and the number of qualified personnel must be adequate for the volume and diversity of services offered. Personnel that do not meet the qualifications specified in §485.70 may be used by the facility in assisting qualified staff. When a qualified individual is assisted by these personnel, the qualified individual must be on the premises, and must instruct these personnel in appropriate patient care service techniques and retain responsibility for their activities.				
I-550	(5) A qualified professional must initiate and coordinate the appropriate portions of the plan of treatment, monitor the patient's progress, and recommend changes in the plan, if necessary.				
I-551	(6) A qualified professional representing each service made available at the facility must be either on the premises of the facility or must be available through direct telecommunication for consultation and assistance during the facility's operating hours. At least one qualified professional must be on the premises during the facility's operating hours.				
I-552	(7) All services must be provided consistent with accepted professional standards and practice.				
I-553	**(e) Standard: Scope and site of services.** (1) Basic Requirements: The facility must provide all the CORF services required in the plan of treatment and, except as provided in paragraph (e) (2) of this section, must provide the services on its premises. (2) Exceptions: Physical therapy, occupational therapy and speech pathology services furnished away from the premises of the CORF may be covered as CORF services if Medicare payment is not otherwise made for these services. In addition, a single home visit is covered if there is need to evaluate the potential impact of the home environment on the rehabilitation goals.				

Name of Facility

CODE		YES	NO	N/A	EXPLANATORY STATEMENT
I-554	**(f) Standard: Patient assessment.** Each qualified professional involved in the patient's care, as specified in the plan of treatment, must—				
I-555	(1) Carry out an initial patient assessment; and				
I-556	(2) In order to identify whether or not the current plan of treatment is appropriate, perform a patient reassessment after significant changes in the patient's status.				
I-557	**(g) Standard: Laboratory services** (1) If the facility provides its own laboratory services, the services must meet the applicable requirements for laboratories specified in part 493 of this chapter.				
I-558	(2) If the facility chooses to refer specimens for laboratory testing, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the requirements of part 493 of this chapter.				
I-559	**§485.60 Condition of Participation: Clinical records.** The facility must maintain clinical records on all patients in accordance with accepted professional standards and practice. The clinical records must be completely, promptly, and accurately documented, readily accessible, and systematically organized to facilitate retrieval and compilation of information.				
I-560	**(a) Standard: Content.** Each clinical record must contain sufficient information to identify the patient clearly and to justify the diagnosis and treatment. Entries in the clinical record must be made as frequently as is necessary to insure effective treatment, and must be signed by personnel providing services. All entries made by assistant level personnel must be countersigned by the corresponding professional. Documentation on each patient must be consolidated into one clinical record that must contain—				

Name of Facility

CODE		YES	NO	N/A	EXPLANATORY STATEMENT
I-561	(1) The initial assessment and subsequent reassessments of the patient's needs;				
I-562	(2) Current plan of treatment;				
I-563	(3) Identification data and consent or authorization forms;				
I-564	(4) Pertinent medical history, past and present;				
I-565	(5) A report of pertinent physical examinations if any;				
I-566	(6) Progress notes or other documentation that reflect patient reaction to treatment, tests, or injury, or the need to change the established plan of treatment; and				
I-567	(7) Upon discharge, a discharge summary including patient status relative to goal achievement, prognosis, and future treatment considerations.				
I-568	**(b) Standard: Protection of clinical record information.** The facility must safeguard clinical record information against loss, destruction, or unauthorized use. The facility must have procedures that govern the use and removal of records and the conditions for release of information. The facility must obtain the patient's written consent before releasing information not required to be released by law.				
I-569	**(c) Standard: Retention and preservation.** The facility must retain clinical record information for 5 years after patient discharge and must make provision for the maintenance of such records in the event that it is no longer able to treat patients.				
I-570	**§485.62 Condition of Participation: Physical environment.** The facility must provide a physical environment that protects the health and safety of patients, personnel, and the public.				
I-571	**(a) Standard: Safety and comfort of patients.** The physical premises of the facility and those areas of its surrounding physical structure that are used by the patients (including at least all stairwells, corridors and passageways) must meet the following requirements:				

Name of Facility

CODE		YES	NO	N/A	EXPLANATORY STATEMENT
I-572	(1) Applicable Federal, State, and local building, fire and safety codes must be met.				
I-573	(2) Fire extinguishers must be easily accessible and fire regulations must be prominently posted.				
I-574	(3) A fire alarm system with local (in-house) capability must be functional, and where power is generated by electricity, an alternate power source with automatic triggering must be present.				
I-575	(4) Lights, supported by an emergency power source, must be placed at exits.				
I-576	(5) A sufficient number of staff to evacuate patients during a disaster must be on the premises of the facility whenever patients are being treated.				
I-577	(6) Lighting must be sufficient to carry out services safely; room temperature must be maintained at comfortable levels; and ventilation through windows, mechanical means, or a combination of both must be provided.				
I-578	(7) Safe and sufficient space must be available for the scope of services offered.				
I-579	**(b) Standard: Sanitary environment.** The facility must maintain a sanitary environment and establish a program to identify, investigate, prevent, and control the cause of patient infections.				
I-580	(1) The facility must establish written policies and procedures designed to control and prevent infection in the facility and to investigate and identify possible causes of infection.				
I-581	(2) The facility must monitor the infection control program to ensure that the staff implement the policies and procedures and that the policies and procedures are consistent with current practices in the field.				

CODE		YES	NO	N/A	EXPLANATORY STATEMENT
I-582	(3) The facility must make available at all times a quantity of laundered linen adequate for proper care and comfort of patients. Linens must be handled, stored, and processed in a manner that prevents the spread of infection.				
I-583	(4) Provisions must be in effect to ensure that the facility's premises are maintained free of rodent and insect infestation.				
I-584	**(c) Standard: Maintenance of equipment, physical location, and grounds.** The facility must establish a written preventive maintenance program to ensure that—				
I-585	(1) All equipment is properly maintained and equipment needing periodic calibration is calibrated consistent with the manufacturer's recommendations; and				
I-586	(2) The interior of the facility, the exterior of the physical structure housing the facility, and the exterior walkways and parking areas are clean and orderly and maintained free of any defects that are a hazard to patients, personnel, and the public.				
I-587	**(d) Standard: Access for the physically impaired.** The facility must ensure the following:				
I-588	(1) Doorways, stairwells, corridors, and passageways used by patients are— (i) Of adequate width to allow for easy movement of all patients (including those on stretchers or in wheelchairs); and (ii) In the case of stairwells, equipped with firmly attached handrails on at least one side.				
I-589	(2) At least one toilet facility is accessible and constructed to allow utilization by ambulatory and nonambulatory individuals.				
I-590	(3) At least one entrance is usable by individuals in wheelchairs.				

Name of Facility

CODE		YES	NO	N/A	EXPLANATORY STATEMENT
I-591	(4) In multi-story buildings, elevators are accessible to and usable by the physically impaired on the level that they use to enter the building and all levels normally used by the patients of the facility.				
I-592	(5) Parking spaces are large enough and close enough to the facility to allow safe access by the physically impaired.				
I-593	**§485.64 Condition of Participation: Disaster procedures.** The facility must have written policies and procedures that specifically define the handling of patients, personnel, records, and the public during disasters. All personnel associated with the facility must be knowledgeable with respect to these procedures, be trained in their application, and be assigned specific responsibilities.				
I-594	**(a) Standard: Disaster plan.** The facility's written disaster plan must be developed and maintained with assistance of qualified fire, safety, and other appropriate experts. The plan must include—				
I-595	(1) Procedures for prompt transfer of casualties and records;				
I-596	(2) Procedures for notifying community emergency personnel (for example, fire department, ambulance, etc.);				
I-597	(3) Instructions regarding the location and use of alarm systems and signals and fire fighting equipment; and				
I-598	(4) Specification of evacuation routes and procedures for leaving the facility.				
I-599	**(b) Standard: Drills and staff training.**				
I-600	(1) The facility must provide ongoing training and drills for all personnel associated with the facility in all aspects of disaster preparedness.				
I-601	(2) All new personnel must be oriented and assigned specific responsibilities regarding the facility's disaster plan within 2 weeks of their first workday.				

Name of Facility

CODE		YES	NO	N/A	EXPLANATORY STATEMENT
I-602	**§485.66 Condition of Participation: Utilization review plan.** The facility must have in effect a written utilization review plan that is implemented at least each quarter, to assess the necessity of services and promotes the most efficient use of services provided by the facility.				
I-603	**(a) Standard: Utilization review committee.** The utilization review committee, consisting of the group of professional personnel specified in §485.56(c), a committee of this group, or a group of similar composition, comprised by professional personnel not associated with the facility, must carry out the utilization review plan.				
I-604	**(b) Standard: Utilization review plan** The utilization review plan must contain written procedures for evaluating—				
I-605	(1) Admissions, continued care, and discharges using, at a minimum, the criteria established in the patient care policies;				
I-606	(2) The applicability of the plan of treatment to established goals; and				
I-607	(3) The adequacy of clinical records with regard to— (i) Assessing the quality of services provided; (ii) Determining whether the facility's policies and clinical practices are compatible and promote appropriate and efficient utilization of services.				

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0267. The time required to complete this information collection is estimated to average 3 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to CMS, Attn: PRA Reports Clearance Officer, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Rehabilitation Reference Manual

Tab 8: References for CORF Survey

8.1 *Code of Federal Regulations*

8.2 Survey & Certification Memoranda

8.3 Social Security Act, Section 1861(cc)

8.4 *Medicare Benefit Policy Manual,* Chapter 12

8.5 CMS Program Memorandum Transmittal AB-02-183 (2002)

8.6 Other Print and Online References

8.1 *Code of Federal Regulations*

42 CFR 410.100–105
42 CFR 485.50–74

(v) A hospital (as defined in section 1861(e) of the Act).

(4) Originating sites must be located in either a rural health professional shortage area as defined under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A)) or in a county that is not included in a Metropolitan Statistical Area as defined in section 1886(d)(2)(D) of the Act. Entities participating in a Federal telemedicine demonstration project that have been approved by, or receive funding from, the Secretary as of December 31, 2000 qualify as an eligible originating site regardless of geographic location.

(5) The medical examination of the patient is under the control of the physician or practitioner at the distant site.

(c) *Telepresenter not required.* A telepresenter is not required as a condition of payment unless a telepresenter is medically necessary as determined by the physician or practitioner at the distant site.

(d) *Exception to the interactive telecommunications system requirement.* For Federal telemedicine demonstration programs conducted in Alaska or Hawaii only, Medicare payment is permitted for telehealth when asynchronous store and forward technologies, in single or multimedia formats, are used as a substitute for an interactive telecommunications system.

(e) *Limitation.* A clinical psychologist and a clinical social worker may bill and receive payment for individual psychotherapy via a telecommunications system, but may not seek payment for medical evaluation and management services.

(f) *Process for adding or deleting services.* Changes to the list of Medicare telehealth services are made through the annual physician fee schedule rulemaking process.

[66 FR 55330, Nov. 1, 2001, as amended at 67 FR 80041, Dec. 31, 2002]

Subpart C—Home Health Services Under SMI

§410.80 Applicable rules.

Home health services furnished under Medicare Part B are subject to the rules set forth in subpart E of part 409 of this chapter.

Subpart D—Comprehensive Outpatient Rehabilitation Facility (CORF) Services

§410.100 Included services.

Subject to the conditions and limitations set forth in §§410.102 and 410.105, CORF services means the following services furnished to an outpatient of the CORF by personnel that meet the qualifications set forth in §485.70 of this chapter.

(a) *Physicians' services.* The following services of the facility physician constitute CORF services: consultation with and medical supervision of nonphysician staff, establishment and review of the plan of treatment, and other medical and facility administration activities. Those services are reimbursed on a reasonable cost basis under part 413 of this chapter. Diagnostic and therapeutic services furnished to an individual patient are not CORF physician's services. If covered, payment for these services would be made by the carrier on a reasonable charge basis subject to the provisions of subpart E of part 405 of this chapter.

(b) *Physical therapy services.* (1) These services include—

(i) Testing and measurement of the function or dysfunction of the neuromuscular, musculoskeletal, cardiovascular and respiratory systems; and.

(ii) Assessment and treatment related to dysfunction caused by illness or injury, and aimed at preventing or reducing disability or pain and restoring lost function.

(2) The establishment of a maintenance therapy program for an individual whose restoration potential has been reached is a physical therapy service; however, maintenance therapy itself is not covered as part of these services.

(c) *Occupational therapy services.* These services include—

(1) Teaching of compensatory techniques to permit an individual with a physical impairment or limitation to engage in daily activities.

(2) Evaluation of an individual's level of independent functioning.

(3) Selection and teaching of task-oriented therapeutic activities to restore sensory-integrative function; and

(4) Assessment of an individual's vocational potential, except when the assessment is related solely to vocational rehabilitation.

(d) *Speech-language pathology services.* These are services for the diagnosis and treatment of speech and language disorders that create difficulties in communication.

(e) *Respiratory therapy services.* (1) These are services for the assessment, diagnostic evaluation, treatment, management, and monitoring of patients with deficiencies or abnormalities of cardiopulmonary function.

(2) These services include—

(i) Application of techniques for support of oxygenation and ventilation of the patient and for pulmonary rehabilitation.

(ii) Therapeutic use and monitoring of gases, mists, and aerosols and related equipment;

(iii) Bronchial hygiene therapy;

(iv) Pulmonary rehabilitation techniques such as exercise conditioning, breathing retraining and patient education in the management of respiratory problems.

(v) Diagnostic tests to be evaluated by a physician, such as pulmonary function tests, spirometry and blood gas analysis; and

(vi) Periodic assessment of chronically ill patients and their need for respiratory therapy.

(f) *Prosthetic device services.* These services include—

(1) Prosthetic devices (excluding dental devices and renal dialysis machines), that replace all or part of an internal body organ or external body member (including contiguous tissue) or replace all or part of the function of a permanently inoperative or malfunctioning external body member or internal body organ; and

(2) Services necessary to design the device, select materials and components, measure, fit, and align the device, and instruct the patient in its use.

(g) *Orthotic device services.* These services include—

(1) Orthopedic devices that support or align movable parts of the body, prevent or correct deformities, or improve functioning; and

(2) Services necessary to design the device, select the materials and components, measure, fit, and align the device, and instruct the patient in its use.

(h) *Social services.* These services include—

(1) Assessment of the social and emotional factors related to the individual's illness, need for care, response to treatment, and adjustment to care furnished by the facility;

(2) Casework services to assist in resolving social or emotional problems that may have an adverse effect on the beneficiary's ability to respond to treatment; and

(3) Assessment of the relationship of the individual's medical and nursing requirements to his or her home situation, financial resources, and the community resources available upon discharge from facility care.

(i) *Psychological services.* These services include—

(1) Assessment, diagnosis and treatment of an individual's mental and emotional functioning as it relates to the individual's rehabilitation;

(2) Psychological evaluations of the individual's response to and rate of progress under the treatment plan; and

(3) Assessment of those aspects of an individual's family and home situation that affect the individual's rehabilitation treatment.

(j) *Nursing care services.* These services include nursing services specified in the plan of treatment and any other nursing services necessary for the attainment of the rehabilitation goals.

(k) *Drugs and biologicals.* These are drugs and biologicals that are—

(1) Prescribed by a physician and administered by or under the supervision of a physician or a registered professional nurse; and

(2) Not excluded from Medicare Part B payment for reasons specified in § 410.29.

(l) *Supplies, appliances, and equipment.* These include—

(1) Non-reusable supplies such as oxygen and bandages;

(2) Medical equipment and appliances; and

(3) Durable medical equipment of the type specified in §410.38, (except renal dialysis systems) for use outside the CORF, whether purchased or rented.

(m) *Home environment evaluation.* This is a single home visit to evaluate the potential impact of the home situation on the rehabilitation goals.

[51 FR 41339, Nov. 14, 1986; 52 FR 4499, Feb. 12, 1987]

§410.102 Excluded services.

None of the services specified in §410.100 is covered as a CORF service if the service—

(a) Would not be covered as an inpatient hospital service if furnished to a hospital inpatient;

(b) Is not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. An example would be services furnished as part of a maintenance program involving repetitive activities that do not require the skilled services of nurses or therapists.

§410.105 Requirements for coverage of CORF services.

Services specified in §410.100 and not excluded under §410.102 are covered as CORF services if they are furnished by a participating CORF (that is, a CORF that meets the conditions of subpart B of part 485 of this chapter, and has in effect a provider agreement under part 489 of this chapter) and if the following requirements are met:

(a) *Referral and medical history.* The services must be furnished to an individual who is referred by a physician who certifies that the individual needs skilled rehabilitation services, and makes the following information available to the CORF before or at the time treatment is begun:

(1) The individual's significant medical history.

(2) Current medical findings.

(3) Diagnosis(es) and contraindications to any treatment modality.

(4) Rehabilitation goals, if determined.

(b) *When and where services are furnished.* (1) All services must be furnished while the individual is under the care of a physician.

(2) Except as provided in paragraph (b)(3) of this section, the services must be furnished on the premises of the CORF.

(3) *Exceptions.* (i) Physical therapy, occupational therapy, and speech pathology services may be furnished away from the premises of the CORF.

(ii) The single home visit specified in §410.100(m) is also covered.

(c) *Plan of treatment.* (1) The services must be furnished under a written plan of treatment that—

(i) Is established and signed by a physician before treatment is begun; and

(ii) Prescribes the type, amount, frequency, and duration of the services to be furnished, and indicates the diagnosis and anticipated rehabilitation goals.

(2) The plan must be reviewed at least every 60 days by a facility physician who, when appropriate, consults with the professional personnel providing the services.

(3) The reviewing physician must certify or recertify that the plan is being followed, the patient is making progress in attaining the rehabilitation goals, and the treatment is having no harmful effects on the patient.

[51 FR 41339, Nov. 14, 1986, as amended at 56 FR 8841, Mar. 1, 1991]

Subpart E—Community Mental Health Centers (CMHCs) Providing Partial Hospitalization Services

§410.110 Requirements for coverage of partial hospitalization services by CMHCs.

Medicare part B covers partial hospitalization services furnished by or under arrangements made by a CMHC if they are provided by a CMHC as defined in §410.2 that has in effect a provider agreement under part 489 of this chapter and if the services are—

(a) Prescribed by a physician and furnished under the general supervision of a physician;

§ 484.260 Limitation on review.

An HHA is not entitled to judicial or administrative review under sections 1869 or 1878 of the Act, or otherwise, with regard to the establishment of the payment unit, including the national 60-day prospective episode payment rate, adjustments and outlier payments. An HHA is not entitled to the review regarding the establishment of the transition period, definition and application of the unit of payments, the computation of initial standard prospective payment amounts, the establishment of the adjustment for outliers, and the establishment of case-mix and area wage adjustment factors.

§ 484.265 Additional payment.

QIO photocopy and mailing costs. An additional payment is made to a home health agency in accordance with § 476.78 of this chapter for the costs of photocopying and mailing medical records requested by a QIO.

[68 FR 67960, Dec. 5, 2003]

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

Subpart A [Reserved]

Subpart B—Conditions of Participation: Comprehensive Outpatient Rehabilitation Facilities

Sec.
485.50 Basis and scope.
485.51 Definition.
485.54 Condition of participation: Compliance with State and local laws.
485.56 Condition of participation: Governing body and administration.
485.58 Condition of participation: Comprehensive rehabilitation program.
485.60 Condition of participation: Clinical records.
485.62 Condition of participation: Physical environment.
485.64 Condition of participation: Disaster procedures.
485.66 Condition of participation: Utilization review plan.
485.70 Personnel qualifications.
485.74 Appeal rights.

Subparts C–E [Reserved]

Subpart F—Conditions of Participation: Critical Access Hospitals (CAHs)

485.601 Basis and scope.
485.602 Definitions.
485.603 Rural health network.
485.604 Personnel qualifications.
485.606 Designation and certification of CAHs.
485.608 Condition of participation: Compliance with Federal, State, and local laws and regulations.
485.610 Condition of participation: Status and location.
485.612 Condition of participation: Compliance with hospital requirements at the time of application.
485.616 Condition of participation: Agreements.
485.618 Condition of participation: Emergency services.
485.620 Condition of participation: Number of beds and length of stay.
485.623 Condition of participation: Physical plant and environment.
485.627 Condition of participation: Organizational structure.
485.631 Condition of participation: Staffing and staff responsibilities.
485.635 Condition of participation: Provision of services.
485.638 Condition of participation: Clinical records.
485.639 Condition of participation: Surgical services.
485.641 Condition of participation: Periodic evaluation and quality assurance review.
485.643 Condition of participation: Organ, tissue, and eye procurement.
485.645 Special requirements for CAH providers of long-term care services ("swing-beds").
485.647 Condition of participation: psychiatric and rehabilitation distinct part units.

Subpart G [Reserved]

Subpart H—Conditions of Participation for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services

485.701 Basis and scope.
485.703 Definitions.
485.705 Personnel qualifications.
485.707 Condition of participation: Compliance with Federal, State, and local laws.
485.709 Condition of participation: Administrative management.
485.711 Condition of participation: Plan of care and physician involvement.
485.713 Condition of participation: Physical therapy services.
485.715 Condition of participation: Speech pathology services.

485.717 Condition of participation: Rehabilitation program.
485.719 Condition of participation: Arrangements for physical therapy and speech pathology services to be performed by other than salaried organization personnel.
485.721 Condition of participation: Clinical records.
485.723 Condition of participation: Physical environment.
485.725 Condition of participation: Infection control.
485.727 Condition of participation: Disaster preparedness.
485.729 Condition of participation: Program evaluation.

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

SOURCE: 48 FR 56293, Dec. 15, 1982, unless otherwise noted. Redesignated at 50 FR 33034, Aug. 16, 1985.

Subpart A [Reserved]

Subpart B—Conditions of Participation: Comprehensive Outpatient Rehabilitation Facilities

§ 485.50 Basis and scope.

This subpart sets forth the conditions that facilities must meet to be certified as comprehensive outpatient rehabilitation facilities (CORFs) under section 1861(cc)(2) of the Social Security Act and be accepted for participation in Medicare in accordance with part 489 of this chapter.

§ 485.51 Definition.

As used in this subpart, unless the context indicates otherwise, "*comprehensive outpatient rehabilitation facility*", "*CORF*", or "*facility*" means a nonresidential facility that—

(a) Is established and operated exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons, at a single fixed location, by or under the supervision of a physician; and

(b) Meets all the requirements of this subpart.

§ 485.54 Condition of participation: Compliance with State and local laws.

The facility and all personnel who provide services must be in compliance with applicable State and local laws and regulations.

(a) *Standard: Licensure of facility.* If State or local law provides for licensing, the facility must be currently licensed or approved as meeting the standards established for licensure.

(b) *Standard: Licensure of personnel.* Personnel that provide service must be licensed, certified, or registered in accordance with applicable State and local laws.

§ 485.56 Condition of participation: Governing body and administration.

The facility must have a governing body that assumes full legal responsibility for establishing and implementing policies regarding the management and operation of the facility.

(a) *Standard: Disclosure of ownership.* The facility must comply with the provisions of part 420, subpart C of this chapter that require health care providers and fiscal agents to disclose certain information about ownership and control.

(b) *Standard: Administrator.* The governing body must appoint an administrator who—

(1) Is responsible for the overall management of the facility under the authority delegated by the governing body;

(2) Implements and enforces the facility's policies and procedures;

(3) Designates, in writing, an individual who, in the absence of the administrator, acts on behalf of the administrator; and

(4) Retains professional and administrative responsibility for all personnel providing facility services.

(c) *Standard: Group of professional personnel.* The facility must have a group of professional personnel associated with the facility that—

(1) Develops and periodically reviews policies to govern the services provided by the facility; and

(2) Consists of at least one physician and one professional representing each of the services provided by the facility.

(d) *Standard: Institutional budget plan.* The facility must have an institutional budget plan that meets the following conditions:

(1) It is prepared, under the direction of the governing body, by a committee consisting of representatives of the governing body and the administrative staff.

(2) It provides for—

(i) An annual operating budget prepared according to generally accepted accounting principles;

(ii) A 3-year capital expenditure plan if expenditures in excess of $100,000 are anticipated, for that period, for the acquisition of land; the improvement of land, buildings, and equipment; and the replacement, modernization, and expansion of buildings and equipment; and

(iii) Annual review and updating by the governing body.

(e) *Standard: Patient care policies.* The facility must have written patient care policies that govern the services it furnishes. The patient care policies must include the following:

(1) A description of the services the facility furnishes through employees and those furnished under arrangements.

(2) Rules for and personnel responsibilities in handling medical emergencies.

(3) Rules for the storage, handling, and administration of drugs and biologicals.

(4) Criteria for patient admission, continuing care, and discharge.

(5) Procedures for preparing and maintaining clinical records on all patients.

(6) A procedure for explaining to the patient and the patient's family the extent and purpose of the services to be provided.

(7) A procedure to assist the referring physician in locating another level of care for—patients whose treatment has terminated and who are discharged.

(8) A requirement that patients accepted by the facility must be under the care of a physician.

(9) A requirement that there be a plan of treatment established by a physician for each patient.

(10) A procedure to ensure that the group of professional personnel reviews and takes appropriate action on recommendations from the utilization review committee regarding patient care policies.

(f) *Standard: Delegation of authority.* The responsibility for overall administration, management, and operation must be retained by the facility itself and not delegated to others.

(1) The facility may enter into a contract for purposes of assistance in financial management and may delegate to others the following and similar services:

(i) Bookkeeping.

(ii) Assistance in the development of procedures for billing and accounting systems.

(iii) Assistance in the development of an operating budget.

(iv) Purchase of supplies in bulk form.

(v) The preparation of financial statements.

(2) When the services listed in paragraph (f)(1) of this section are delegated, a contract must be in effect and:

(i) May not be for a term of more than 5 years;

(ii) Must be subject to termination within 60 days of written notice by either party;

(iii) Must contain a clause requiring renegotiation of any provision that CMS finds to be in contravention to any new, revised or amended Federal regulation or law;

(iv) Must state that only the facility may bill the Medicare program; and

(v) May not include clauses that state or imply that the contractor has power and authority to act on behalf of the facility, or clauses that give the contractor rights, duties, discretions, or responsibilities that enable it to dictate the administration, mangement, or operations of the facility.

§ 485.58 Condition of participation: Comprehensive rehabilitation program.

The facility must provide a coordinated rehabilitation program that includes, at a minimum, physicians' services, physical therapy services, and social or psychological services. The services must be furnished by personnel that meet the qualifications set forth in § 485.70 and must be consistent

with the plan of treatment and the results of comprehensive patient assessments.

(a) *Standard: Physician services.* (1) A facility physician must be present in the facility for a sufficient time to—

(i) Provide, in accordance with accepted principles of medical practice, medical direction, medical care services, and consultation;

(ii) Establish the plan of treatment in cases where a plan has not been established by the referring physician;

(iii) Assist in establishing and implementing the facility's patient care policies; and

(iv) Participate in plan of treatment reviews, patient case review conferences, comprehensive patient assessment and reassessments, and utilization review.

(2) The facility must provide for emergency physician services during the facility operating hours.

(b) *Standard: Plan of treatment.* For each patient, a physician must establish a plan of treatment before the facility initiates treatment. The plan of treatment must meet the following requirements:

(1) It must delineate anticipated goals and specify the type, amount, frequency and duration of services to be provided.

(2) It must be promptly evaluated after changes in the patient's condition and revised when necessary.

(3) It must, if appropriate, be developed in consultation with the facility physician and the appropriate facility professional personnel.

(4) It must be reviewed at least every 60 days by a facility physician who, when appropriate, consults with the professional personnel providing services. The results of this review must be communicated to the patient's referring physician for concurrence before treatment is continued or discontinued.

(5) It must be revised if the comprehensive reassessment of the patient's status or the results of the patient case review conference indicate the need for revision.

(c) *Standard: Coordination of services.* The facility must designate, in writing, a qualified professional to ensure that professional personnel coordinate their related activities and exchange information about each patient under their care. Mechanisms to assist in the coordination of services must include—

(1) Providing to all personnel associated with the facility, a schedule indicating the frequency and type of services provided at the facility;

(2) A procedure for communicating to all patient care personnel pertinent information concerning significant changes in the patient's status;

(3) Periodic clinical record entries, noting at least the patient's status in relationship to goal attainment; and

(4) Scheduling patient case review conferences for purposes of determining appropriateness of treatment, when indicated by the results of the initial comprehensive patient assessment, reassessment(s), the recommendation of the facility physician (or other physician who established the plan of treatment), or upon the recommendation of one of the professionals providing services.

(d) *Standard: Provision of services.* (1) All patients must be referred to the facility by a physician who provides the following information to the facility before treatment is initiated:

(i) The patient's significant medical history.

(ii) Current medical findings.

(iii) Diagnosis(es) and contraindications to any treatment modality.

(iv) Rehabilitation goals, if determined.

(2) Services may be provided by facility employees or by others under arrangements made by the facility.

(3) The facility must have on its premises the necessary equipment to implement the plan of treatment and sufficient space to allow adequate care.

(4) The services must be furnished by personnel that meet the qualifications of § 485.70 and the number of qualified personnel must be adequate for the volume and diversity of services offered. Personnel that do not meet the qualifications specified in § 485.70 may be used by the facility in assisting qualified staff. When a qualified individual is assisted by these personnel, the qualified individual must be on the

premises, and must instruct these personnel in appropriate patient care service techniques and retain responsibility for their activities.

(5) A qualified professional must initiate and coordinate the appropriate portions of the plan of treatment, monitor the patient's progress, and recommend changes, in the plan, if necessary.

(6) A qualified professional representing each service made available at the facility must be either on the premises of the facility or must be available through direct telecommunication for consultation and assistance during the facility's operating hours. At least one qualified professional must be on the premises during the facility's operating hours.

(7) All services must be provided consistent with accepted professional standards and practice.

(e) *Standard: Scope and site of services*—(1) *Basic requirements.* The facility must provide all the CORF services required in the plan of treatment and, except as provided in paragraph (e)(2) of this section, must provide the services on its premises.

(2) *Exceptions.* Physical therapy, occupational therapy, and speech pathology services furnished away from the premises of the CORF may be covered as CORF services if Medicare payment is not otherwise made for these services. In addition, a single home visit is covered if there is need to evaluate the potential impact of the home environment on the rehabilitation goals.

(f) *Standard: Patient assessment.* Each qualified professional involved in the patient's care, as specified in the plan of treatment, must—

(1) Carry out an initial patient assessment; and

(2) In order to identify whether or not the current plan of treatment is appropriate, perform a patient reassessment after significant changes in the patient's status.

(g) *Standard: Laboratory services.* (1) If the facility provides its own laboratory services, the services must meet the applicable requirements for laboratories specified in part 493 of this chapter.

(2) If the facility chooses to refer specimens for laboratory testing, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the requirements of part 493 of this chapter.

[48 FR 56293, Dec. 15, 1982, as amended at 56 FR 8852, Mar. 1, 1991; 57 FR 7137, Feb. 28, 1992]

§ 485.60 Condition of participation: Clinical records.

The facility must maintain clinical records on all patients in accordance with accepted professional standards and practice. The clinical records must be completely, promptly, and accurately documented, readily accessible, and systematically organized to facilitate retrieval and compilation of information.

(a) *Standard: Content.* Each clinical record must contain sufficient information to identify the patient clearly and to justify the diagnosis and treatment. Entries in the clinical record must be made as frequently as is necessary to insure effective treatment and must be signed by personnel providing services. All entries made by assistant level personnel must be countersigned by the corresponding professional. Documentation on each patient must be consolidated into one clinical record that must contain—

(1) The initial assessment and subsequent reassessments of the patient's needs;

(2) Current plan of treatment;

(3) Identification data and consent or authorization forms;

(4) Pertinent medical history, past and present;

(5) A report of pertinent physical examinations if any;

(6) Progress notes or other documentation that reflect patient reaction to treatment, tests, or injury, or the need to change the established plan of treatment; and

(7) Upon discharge, a discharge summary including patient status relative to goal achievement, prognosis, and future treatment considerations.

(b) *Standard: Protection of clinical record information.* The facility must safeguard clinical record information against loss, destruction, or unauthorized use. The facility must have procedures that govern the use and removal

of records and the conditions for release of information. The facility must obtain the patient's written consent before releasing information not required to be released by law.

(c) *Standard: Retention and preservation.* The facility must retain clinical record information for 5 years after patient discharge and must make provision for the maintenance of such records in the event that it is no longer able to treat patients.

§ 485.62 Condition of participation: Physical environment.

The facility must provide a physical environment that protects the health and safety or patients, personnel, and the public.

(a) *Standard: Safety and comfort of patients.* The physical premises of the facility and those areas of its surrounding physical structure that are used by the patients (including at least all stairwells, corridors and passageways) must meet the following requirements:

(1) Applicable Federal, State, and local building, fire, and safety codes must be met.

(2) Fire extinguishers must be easily accessible and fire regulations must be prominently posted.

(3) A fire alarm system with local (in-house) capability must be functional, and where power is generated by electricity, an alternate power source with automatic triggering must be present.

(4) Lights, supported by an emergency power source, must be placed at exits.

(5) A sufficient number of staff to evacuate patients during a disaster must be on the premises of the facility whenever patients are being treated.

(6) Lighting must be sufficient to carry out services safely; room temperature must be maintained at comfortable levels; and ventilation through windows, mechanical means, or a combination of both must be provided.

(7) Safe and sufficient space must be available for the scope of services offered.

(b) *Standard: Sanitary environment.* The facility must maintain a sanitary environment and establish a program to identify, investigate, prevent, and control the cause of patient infections.

(1) The facility must establish written policies and procedures designed to control and prevent infection in the facility and to investigate and identify possible causes of infection.

(2) The facility must monitor the infection control program to ensure that the staff implement the policies and procedures and that the policies and procedures are consistent with current practices in the field.

(3) The facility must make available at all times a quantity of laundered linen adequate for proper care and comfort of patients. Linens must be handled, stored, and processed in a mannner that prevents the spread of infection.

(4) Provisions must be in effect to ensure that the facility's premises are maintained free of rodent and insect infestation.

(c) *Standard: Maintenance of equipment, physical location, and grounds.* The facility must establish a written preventive maintenance program to ensure that—

(1) All equipment is properly maintained and equipment needing periodic calibration is calibrated consistent with the manufacturer's recommendations; and

(2) The interior of the facility, the exterior of the physical structure housing the facility, and the exterior walkways and parking areas are clean and orderly and maintained free of any defects that are a hazard to patients, personnel, and the public.

(d) *Standard: Access for the physically impaired.* The facility must ensure the following:

(1) Doorways, stairwells, corridors, and passageways used by patients are—

(i) Of adequate width to allow for easy movement of all patients (including those on stretchers or in wheelchairs); and

(ii) In the case of stairwells, equipped with firmly attached handrails on at least one side.

(2) At least one toilet facility is accessible and constructed to allow utilization by ambulatory and non-ambulatory individuals.

(3) At least one entrance is usable by individuals in wheelchairs.

(4) In multi-story buildings, elevators are accessible to and usable by the

physically impaired on the level that they use to enter the building and all levels normally used by the patients of the facility.

(5) Parking spaces are large enough and close enough to the facility to allow safe access by the physically impaired.

§ 485.64 Condition of participation: Disaster procedures.

The facility must have written policies and procedures that specifically define the handling of patients, personnel, records, and the public during disasters. All personnel associated with the facility must be knowledgeable with respect to these procedures, be trained in their application, and be assigned specific responsibilities.

(a) *Standard: Disaster plan.* The facility's written disaster plan must be developed and maintained with assistance of qualified fire, safety, and other appropriate experts. The plan must include—

(1) Procedures for prompt transfer of casualties and records;

(2) Procedures for notifying community emergency personnel (for example, fire department, ambulance, etc.);

(3) Instructions regarding the location and use of alarm systems and signals and fire fighting equipment; and

(4) Specification of evacuation routes and procedures for leaving the facility.

(b) *Standard: Drills and staff training.* (1) The facility must provide ongoing training and drills for all personnel associated with the facility in all aspects of disaster preparedness.

(2) All new personnel must be oriented and assigned specific responsibilities regarding the facility's disaster plan within two weeks of their first workday.

§ 485.66 Condition of participation: Utilization review plan.

The facility must have in effect a written utilization review plan that is implemented at least each quarter, to assess the necessity of services and promotes the most efficient use of services provided by the facility.

(a) *Standard: Utilization review committee.* The utilization review committee, consisting of the group of professional personnel specified in § 485.56(c), a committee of this group, or a group of similar composition, comprised by professional personnel not associated with the facility, must carry out the utilization review plan.

(b) *Standard: Utilization review plan.* The utilization review plan must contain written procedures for evaluating—

(1) Admissions, continued care, and discharges using, at a minimum, the criteria established in the patient care policies;

(2) The applicability of the plan of treatment to established goals; and

(3) The adequacy of clinical records with regard to—

(i) Assessing the quality of services provided; and

(ii) Determining whether the facility's policies and clinical practices are compatible and promote appropriate and efficient utilization of services.

§ 485.70 Personnel qualifications.

This section sets forth the qualifications that must be met, as a condition of participation, under § 485.58, and as a condition of coverage of services under § 410.100 of this chapter.

(a) A facility physician must be a doctor of medicine or osteopathy who—

(1) Is licensed under State law to practice medicine or surgery; and

(2) Has had, subsequent to completing a 1-year hospital internship, at least 1 year of training in the medical management of patients requiring rehabilitation services; or

(3) Has had at least 1 year of full-time or part-time experience in a rehabilitation setting providing physicians' services similar to those required in this subpart.

(b) A licensed practical nurse must be licensed as a practical or vocational nurse by the State in which practicing, if applicable.

(c) An occupational therapist and an occupational therapist assistant must meet the qualifications set forth in § 405.1202(f) and (g) of this chapter.

(d) An orthotist must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program in orthotics that is jointly recognized by the American

Council on Education and the American Board for Certification in Orthotics and Prosthetics; and

(3) Be eligible to take that Board's certification examination in orthotics.

(e) A *physical therapist* and a *physical therapist assistant* must meet the qualifications set forth in paragraphs (b) and (c) of § 485.705.

(f) A *prosthetist* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program in prosthetics that is jointly recognized by the American Council on Education and the American Board for Certification in Orthotics and Prosthetics; and

(3) Be eligible to take that Board's certification examination in prosthetics.

(g) A *psychologist* must be certified or licensed by the State in which he or she is practicing, if that State requires certification or licensing, and must hold a masters degree in psychology from and educational institution approved by the State in which the institution is located.

(h) A *registered nurse* must be a graduate of an approved school of nursing and be licensed as a registered nurse by the State in which practicing, if applicable.

(i) A *rehabilitation counselor* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Hold at least a bachelor's degree; and

(3) Be eligible to take the certification examination administered by the Commission on Rehabilitation Counselor Certification.

(j) A *respiratory therapist* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program accredited by the Committee on Allied Health Education and Accreditation (CAHEA) in collaboration with the Joint Review Committee for Respiratory Therapy Education; and

(3) Either—

(i) Be eligible to take the registry examination for respiratory therapists administered by the National Board for Respiratory Therapy, Inc.; or

(ii) Have equivalent training and experience as determined by the National Board for Respiratory Therapy, Inc.

(k) A *respiratory therapy technician* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program accredited by the Committees on Allied Health Education and Accreditation (CAHEA) in collaboration with the Joint Review Committee for Respiratory Therapy Education; and

(3) Either—

(i) Be eligible to take the certification examination for respiratory therapy technicians administered by the National Board for Respiratory Therapy, Inc,; or

(ii) Have equivalent training and experience as determined by the National Board for Respiratory Therapy, Inc.

(l) A *social worker* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Hold at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education; and

(3) Have 1 year of social work experience in a health care setting.

(m) A *speech-language pathologist* must meet the qualifications set forth in § 485.705(f) of this chapter.

[48 FR 56293, Dec. 15, 1982. Redesignated and amended at 50 FR 33034, Aug. 16, 1985; 51 FR 41352, Nov. 14, 1986; 60 FR 2327, Jan. 9, 1995]

§ 485.74 Appeal rights.

The appeal provisions set forth in part 498 of this chapter, for providers, are applicable to any entity that is participating or seeks to participate in the Medicare program as a CORF.

[48 FR 56293, Dec. 15, 1982, as amended at 52 FR 22454, June 12, 1987]

Subparts C–E [Reserved]

Subpart F—Conditions of Participation: Critical Access Hospitals (CAHs)

SOURCE: 58 FR 30671, May 26, 1993, unless otherwise noted.

8.2 Survey & Certification Memoranda

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-05-45

DATE: **September 22, 2005**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Updates to the State Operations Manual (SOM) for Outpatient Rehabilitation Therapy Services (OPTs) and Comprehensive Outpatient Rehabilitation Facilities (CORFs)

Letter Summary

Several sections of the SOM pertaining to providers of OPTs and CORFs have been updated. This letter briefly explains those changes.

In an effort to address the current practices of providers of OPT rehabilitation services, the following sections of the SOM have been updated and should be reviewed by state surveyors as well as regional office staff as they prepare to survey CORFs and providers of OPTs and Speech-Language Pathology (SLP) services.

SOM Sections Affected

- **Appendix E** (Providers of Outpatient Physical Therapy and Speech-Language Pathology Services) and SOM Section 2290 (Providers of Outpatient Physical Therapy and Speech-Language Pathology Services) were updated to address challenging issues such as documentation for the provision of social services in OPTs, what constitutes OPT extension locations, and what to look for if surveying community facilities such as a pool for the provision of aquatic therapy. These issues have generated much discussion over the last several years and we've attempted to clarify instructions. We've also added deficiency tags and regulation language to Appendix E.

- **Appendix K** (Comprehensive Outpatient Rehabilitation Facilities) and SOM Section 2360 (Comprehensive Outpatient Rehabilitation Facilities) were updated to include deficiency tags and regulation language. In addition, some of the issues that have been addressed are:

  - facility physician and physician services;
  - rehabilitation services (mandatory and optional services); and
  - discussion regarding hyperbaric oxygen (HBO) therapy.

Hyperbaric Oxygen Therapy

HBO therapy has been the object of abuse by some CORFs, as they have been specializing in the provision of HBO therapy, almost to the exclusion of mandatory services they must provide. HBO is not a CORF outpatient therapy benefit and therefore cannot be counted as either a mandatory or optional service. Surveyors should bear this in mind when they review medical records to determine what services are being provided at the CORF and if the CORF patients are actually receiving a coordinated, comprehensive, skilled rehabilitation program.

The revised sections of the SOM are expected to be placed on the CMS Web site by October 30, 2005. These same sections will be included in the Rehabilitation Reference Manual that will be soon be available in both hard copy and on CD for use by surveyors while conducting surveys.

For questions on this memo, please contact Georgia Johnson at (410) 786-6859 or e-mail at gjohnson4@cms.hhs.gov

Effective Date: Expected October 2005. An alert will be sent upon release of these changes. Please ensure that all appropriate staff is fully informed within 30 days of the date of this memorandum

Training: The information contained in this announcement should be shared with all survey and certification staff, their managers, the state/RO training coordinators.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)

8.3 Social Security Act, Section 1861(cc): Comprehensive Outpatient Rehabilitation Facility Services

Social Security Act, Section 1861(cc): Comprehensive Outpatient Rehabilitation Facility Services

(cc)(1) The term "comprehensive outpatient rehabilitation facility services" means the following items and services furnished by a physician or other qualified professional personnel (as defined in regulations by the Secretary) to an individual who is an outpatient of a comprehensive outpatient rehabilitation facility under a plan (for furnishing such items and services to such individual) established and periodically reviewed by a physician—

(A) physicians' services;
(B) physical therapy, occupational therapy, speech-language pathology services, and respiratory therapy;
(C) prosthetic and orthotic devices, including testing, fitting, or training in the use of prosthetic and orthotic devices;
(D) social and psychological services;
(E) nursing care provided by or under the supervision of a registered professional nurse;
(F) drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered;
(G) supplies and durable medical equipment; and
(H) such other items and services as are medically necessary for the rehabilitation of the patient and are ordinarily furnished by comprehensive outpatient rehabilitation facilities,

excluding, however, any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital. In the case of physical therapy, occupational therapy, and speech pathology services, there shall be no requirement that the item or service be furnished at any single fixed location if the item or service is furnished pursuant to such plan and payments are not otherwise made for the item or service under this title.

(2) The term "comprehensive outpatient rehabilitation facility" means a facility which—
(A) is primarily engaged in providing (by or under the supervision of physicians) diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons;
(B) provides at least the following comprehensive outpatient rehabilitation services: (i) physicians' services (rendered by physicians, as defined in section 1861(r)(1), who are available at the facility on a full-or part-time basis); (ii) physical therapy; and (iii) social or psychological services;
(C) maintains clinical records on all patients;
(D) has policies established by a group of professional personnel (associated with the facility), including one or more physicians defined in subsection (r)(1) to govern the comprehensive outpatient rehabilitation services it furnishes, and provides for the carrying out of such policies by a full-or part-time physician referred to in subparagraph (B)(i);
(E) has a requirement that every patient must be under the care of a physician;
(F) in the case of a facility in any State in which State or applicable local law provides for the licensing of facilities of this nature (i) is licensed pursuant to such law, or (ii) is

approved by the agency of such State or locality, responsible for licensing facilities of this nature, as meeting the standards established for such licensing;
(G) has in effect a utilization review plan in accordance with regulations prescribed by the Secretary;
(H) has in effect an overall plan and budget that meets the requirements of subsection (z);
(I) provides the Secretary on a continuing basis with a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000; and
(J) meets such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such facility, including conditions concerning qualifications of personnel in these facilities.

8.4 *Medicare Benefit Policy Manual,* Chapter 12

Medicare Benefit Policy Manual

Chapter 12 - Comprehensive Outpatient Rehabilitation Facility (CORF) Coverage

---

Table of Contents

(Rev. 21, 09-24-04)

Crosswalk to Old Manual

10 - Comprehensive Outpatient Rehabilitation Facility (CORF) Services Provided by Medicare

20 - Required and Optional CORF Services

- 20.1 - Required Services
- 20.2 - Optional CORF Services

30 - Rules for Provision of Services

40 - Specific CORF Services

- 40.1 - Physicians' Services
- 40.2 - Physical Therapy Services
- 40.3 - Occupational Therapy Services
- 40.4 – Speech Language Pathology Services
- 40.5 - Respiratory Therapy Services
- 40.6 - Prosthetic and Orthotic Devices and Supplies
- 40.7 - Social Services
- 40.8 - Psychological Services
- 40.9 - Nursing Services
- 40.10 - Drugs and Biologicals
- 40.11 - Home Environment Evaluation

50 - Outpatient Mental Health Treatment Limitation

- 50.1 - Outpatient Mental Health Limit Not Applicable for Hospital Inpatients
- 50.2 - Disorders Subject to Outpatient Mental Heath Limitation
- 50.3 - Diagnostic Services
- 50.4 - Application of Outpatient Mental Heath Limitation

50.5 - Computation of Limitation

10 - Comprehensive Outpatient Rehabilitation Facility (CORF) Services Provided by Medicare

(Rev. 21, Issued: 09-24-04, Effective: 06-30-04, Implementation: 10-25-04)

A3-3180, A3-3181, and CORF-251

The purpose of Comprehensive Outpatient Rehabilitation Facility (CORF) is to permit the beneficiary to receive *multidisciplinary* rehabilitation services at a *single* location in a coordinated fashion.

The statute specifies that no service may be covered as a CORF service if it would not be covered as an inpatient hospital service if provided to a hospital patient. This does not mean that the beneficiary must require a hospital level of care or meet other requirements unique to hospital care. This provision merely requires that the service, if otherwise covered, would be covered if provided in a hospital.

CORF services are not covered if not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the function of a malformed body member. Thus, there must be potential for restoration or improvement of lost or impaired functions. For example, *treatments* involving repetitive *exercises* (i.e., maintenance programs, general conditioning or ambulation) that do not require the skilled services of therapists *or other professional rehabilitation practitioners* are not covered. Nonmedical personnel such as family members *or exercise instructors* could perform these services in the patient's residence. It is not reasonable and necessary for such services to be performed in a *CORF* setting by CORF personnel.

The facility physician must be present in the facility for a sufficient time to provide, in accordance with accepted principles of medical practice, medical direction, medical care services and consultation. (§485.58) All services must be provided within acceptable professional standards and practice and meet the qualifications set forth in §485.70.

20 - Required and Optional CORF Services

(Rev. 1, 10-01-03)

A3-3180, CORF-250

20.1 - Required Services

(Rev. 21, Issued: 09-24-04, Effective: 06-30-04, Implementation: 10-25-04)

A CORF is defined as a facility that is primarily engaged in providing diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of the injured and disabled or to patients recovering from illness. The CORF must provide a comprehensive, coordinated, skilled rehabilitation program for its patients that includes, at a minimum, CORF physicians' services, physical therapy services, and social or psychological services. A physician must certify, as a condition of payment, that CORF services are required because the individual needs skilled rehabilitation services. Skilled rehabilitation services are defined as services requiring the skills of physical therapists, speech-language pathologists, or occupational therapists. In the CORF setting respiratory therapy services can be provided by physical therapists, occupational therapists, respiratory therapists or registered nurses, as recognized by applicable State law.

A CORF is recognized as a provider of services that is paid under the physician fee schedule for all services except for drugs and biologicals. To participate as a CORF, a facility or provider must furnish, as its major services, at least the following to patients requiring skilled rehabilitation services:

- *CORF* physicians' services *(rendered by a physician) - professional services performed by physicians, such as consultation, home, office, and institutional evaluation and management services rendered by a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he/she performs services (42 CFR 410.100(a)). The physician must have had, subsequent to completing a 1-year hospital internship, at least one year of training in the medical management of patients requiring rehabilitative services; (§485.70) or has had at least 1 year of full-time or part-time experience in a rehabilitation setting providing physician's services similar to those required in a rehabilitation facility. A physician who is specialized only in pulmonary rehabilitation are not likely to have the experience needed to medically manage patients that need skilled rehabilitation services;*

- Physical therapy *- services include testing, measurement, assessment and treatment of the function, or dysfunction, of the neuromuscular, musculoskeletal, cardiovascular and respiratory system, and establishment of a maintenance*

therapy program for an individual whose restoration potential has been reached (42 CFR 410.100(b)); and

- Social or psychological services *– social services include assessment of the social and emotional factors related to the individual's illness, need for care, response to treatment, adjustment to care furnished, casework services to assist in resolving social or emotional problems that may have an adverse effect on the beneficiary's ability to respond to treatment and assessment of the relationship of the individual's medical and nursing requirements to his or her home situation, financial resources, and the community resources available upon discharge from the CORF (42 CFR 410.100(h)). Psychological services include assessment, diagnosis and treatment of an individual's mental and emotional functioning as it relates to the individual's rehabilitation, psychological evaluations of the individual's progress under the treatment plan, and assessment of those aspects of an individual's family and home situation that affects the individual's rehabilitation treatment (42 CFR 410.100(i));*

In addition to this basic package of *medically necessary comprehensive coordinated skilled rehabilitation* services, the CORF may furnish as many of the other *covered* items and services listed in §20.2 as it *elects, as long as they are consistent with the plan of treatment, necessary to achieve the rehabilitation goals and performed in conjunction with core CORF services*.

To receive Medicare payment for covered services, the CORF must have adequate space and equipment necessary for any of the services provided. *Additionally, in order to accept a patient, the CORF must be able to provide all of the services required by the patient, as established in the plan of treatment. If the CORF does not have personnel to provide the service, it must arrange for the services to be provided at the CORF, as needed, by outside practitioners. In general, all services must be furnished on the premises of the CORF. The only exceptions are the home evaluation, physical therapy, occupational therapy, and speech-language pathology services. There is no restriction on where these services may be furnished with the exception of home evaluations. The home evaluation may be covered if furnished pursuant to the plan of treatment, and it does not duplicate services for which payment has been made under Medicare.* The CORF *must* bill their assigned fiscal intermediary, which makes payment for services provided under this arrangement.

The CORF services are subject to the Medicare Part B deductible and coinsurance provisions*, i.e., the CORF may bill the beneficiary only for the unmet portion of the deductible and 20 percent of the fee schedule amount for covered services, unless the services are subject to the outpatient mental health treatment limitation for psychological therapy.*

20.2 - Optional CORF Services

(Rev. 21, Issued: 09-24-04, Effective: 06-30-04, Implementation: 10-25-04)

A3-3181, CORF-251

The CORF may provide any or all of the following services:

- Occupational therapy– *services include assessment of an individual's level of independent functioning, selection and teaching of task-oriented therapeutic activities to restore sensory-integrative functions, teaching of compensatory techniques to permit an individual with a physical or cognitive impairment or limitation to engage in daily activities (42 CFR 410.100(c));*
- Speech-*Language pathology* - *services for the diagnosis and treatment of speech and language disorders that create difficulties in communication or dysphagia (swallowing difficulties). (42 CFR 410.100(d));*
- Respiratory therapy - *services for the functional assessment, diagnosis, and treatment of patients with deficiencies or abnormalities of cardiopulmonary function (42 CFR 410.100(e));*
- Prosthetic and orthotic devices - includes testing, fitting, or training in the use of such devices *(42 CFR 410.100(f) and (g));*
- Nursing *– includes nursing services (e.g., teaching self catheterization) specified in the plan of treatment and any other nursing services necessary for the attainment of the rehabilitation goals which are* provided by or under the supervision of a professional registered nurse *(42 CFR 410.100(j));*
- Drugs and biologicals - which *are not usually* self-administered *by the patient (42 CFR 410.100(k)).*
- Supplies, appliances and equipment, including the purchase or rental of Durable Medical Equipment (DME) from the CORF *(42 CFR 410.100(l)). Effective April 1, 2001, CORFs should not bill for the supplies they furnish. The payment of supplies is included in the payments under the physician fee schedule;* and
- A single home visit - *includes evaluating* the potential impact of the home environment on the rehabilitation goals (*42 CFR* 410.100(m)).

30 - Rules for Provision of Services

(Rev. 21, Issued: 09-24-04, Effective: 06-30-04, Implementation: 10-25-04)

A3-3182

A - Place of Treatment

In general, all services must be furnished on the premises of the CORF. The only exceptions are the home evaluation, physical therapy, occupational therapy, and speech-*language* pathology services. There is no restriction on where these services may be furnished *with the exception of home evaluations*. *The home evaluation* may be covered if furnished pursuant to the plan of treatment, and *it does* not duplicate services for which payment has been made under Medicare.

B - Personnel Qualification Requirements

Services must be furnished or supervised by personnel determined to be qualified in accordance with CMS regulations 42 CFR 484.4 and 485.70.

Determinations regarding whether services are furnished by or under the supervision of qualified personnel are primarily the responsibility of the State agency responsible for *survey and certification of* the facility. In the absence of evidence to the contrary, Medicare assumes that the services of a participating CORF are furnished or supervised by qualified personnel. Refer any questions in this regard to the regional office. If there is evidence that services are not being furnished or *appropriately* supervised by qualified personnel, the intermediary will withhold payment until the matter is resolved.

C - Services Furnished Under Arrangements

Any CORF service defined in §§20 or 40 may be furnished under arrangement *and must* meet the requirements of Pub 100-01 chapter 5, section 10.3.

D - Referral for Treatment

To become a patient of a CORF, the beneficiary must be under the care of a physician who certifies that the beneficiary needs skilled rehabilitation services.

The referring physician must advise the CORF of the beneficiary's medical history, current diagnosis and medical findings, desired rehabilitation goals, and any contraindications to specific activity or intensity of *skilled* rehabilitation services.

E - Plan of Treatment

The CORF services must be furnished under a written plan of treatment established *and signed* by a physician *who has recently evaluated the patient*. *It is expected that the*

physician will establish the plan in consultation with the physical therapists, occupational therapists or speech-language pathologists who will provide the actual therapy. The physician wholly establishes the respiratory therapy plan of treatment. The physician may be either a physician associated with the CORF or the referring physician if the physician provides a detailed plan of treatment that meets the following requirements.

The plan of treatment must contain the diagnosis, the type, amount, frequency, and duration of *skilled rehabilitation* services to be performed, and the anticipated *skilled* rehabilitation goals. The plan of treatment should be sufficiently detailed to permit an independent evaluation of the patient's specific need for the indicated *skilled rehabilitation* services and of the likelihood that the patient will derive meaningful benefit from them.

The CORF physician *or the referring* physician must review the plan of treatment at least once every 60 days. *The 60-day period begins with the first day of skilled rehabilitation therapy.* Following the review, the physician *must* certify that the plan of treatment is being followed and that the patient is making progress in attaining the established *skilled* rehabilitation goals. When the patient has reached a point where no further progress is being made toward one or more of the *skilled rehabilitation* goals, Medicare coverage ends with respect to that aspect of the plan of treatment.

40 - Specific CORF Services

(Rev. 1, 10-01-03)

A3-3183, CORF-253

40.1 - Physicians' Services

(Rev. 21, Issued: 09-24-04, Effective: 06-30-04, Implementation: 10-25-04)

A3-3183.1, B3-2220, CORF-253.1

Certain administrative services provided by the physician associated with the CORF are considered CORF *physician* services. *These services include administrative services provided by the physician associated with the CORF, consultation with and medical supervision of nonphysician staff, team conferences, case reviews, and other facility medical and administration activities relating to the comprehensive coordinated skilled rehabilitation service. Examinations for the purpose of establishing and reviewing the plan of care that do not result in a billable service would also represent CORF physician services.*

Physicians' diagnostic and therapeutic services *(e.g., evaluation and management services, debridement),* furnished to an individual patient are not CORF physicians' services. *They are physician services and are billable to the Part B carrier. The physician, not the CORF, bills for and is paid by Medicare for these services. The claim form must be clearly annotated to show the CORF as the place of treatment.*

40.2 - Physical Therapy Services

(Rev.21, Issued: 09-24-04, Effective: 06-30-04, Implementation: 10-25-04)

A3-3183.2, CORF-253.2

A qualified physical therapist has the knowledge, training, and experience required to evaluate and reevaluate a patient's level of function, determine whether a physical therapy program could reasonably be expected to improve, restore, or compensate for lost function, and recommend to the physician a plan of treatment. However, while the skills of a qualified physical therapist are required to evaluate and reevaluate the patient's level of function and to consult in the development of the plan of treatment, a qualified physical therapist assistant functioning under the general supervision of the qualified physical therapist may also carry out the implementation of the plan, in accordance with applicable State laws. Physical therapist assistants are not allowed to conduct the discharge visit as this visit is viewed as the final reassessment.

Physical therapy is not required to effect improvement or restoration of function when a patient suffers a temporary loss or reduction of function (e.g., temporary weakness resulting from prolonged bed rest after major abdominal surgery) that can reasonably be expected to improve spontaneously as the patient gradually resumes normal activities. Accordingly, physical therapy furnished in such situations is not considered reasonable and necessary for the treatment of the individual's illness or injury and the services are excluded from coverage.

40.3 - Occupational Therapy Services

(Rev. 21, Issued: 09-24-04, Effective: 06-30-04, Implementation: 10-25-04)

A3-3183.3, CORF-253.3

Occupational therapy is a medically prescribed treatment to improve or restore functions that have been impaired by illness or injury or, when function has been permanently lost or reduced by illness or injury, to improve the individual's ability to perform those tasks required for independent functioning. Occupational therapy services are covered CORF services if they are part of a comprehensive coordinated skilled rehabilitation program and performed in conjunction with core CORF services.

A qualified occupational therapist has the knowledge, training, and experience required to evaluate and reevaluate a patient's level of function, determine whether an occupational therapy program could reasonably be expected to improve, restore, or compensate for lost function, and recommend to the physician a plan of treatment. However, while the skills of a qualified occupational therapist are required to evaluate and reevaluate the patient's level of function and consult in the development of the plan of treatment, a qualified occupational therapy assistant functioning under the general

supervision of the qualified occupational therapist may also carry out the implementation of the plan, in accordance with applicable State laws. Occupational therapist assistants are not allowed to conduct the discharge visit as this visit is viewed as the final reassessment.

***NOTE**: General supervision requires initial direction and periodic inspection of the actual activity. However, the supervising therapist need not always be physically present or on the premises when the assistant is providing the services.*

40.4 – Speech-*Language* Pathology Services

(Rev. 21, Issued: 09-24-04, Effective: 06-30-04, Implementation: 10-25-04)

A3-3183.4, CORF-253.4

Services related to congenital speech difficulties, such as stuttering or lisping, would not be covered.

A qualified speech-language pathologist has the knowledge, training, and experience required to evaluate and reevaluate a patient's level of function, determine whether a speech-language program could reasonably be expected to improve, restore, or compensate for lost function, and, when appropriate, recommend to the physician a plan of treatment. A qualified speech-language pathologist will evaluate the patient's level of function and provide advice used in the development of the plan of treatment. Speech-language pathology therapy services are covered CORF services if they are part of a comprehensive coordinated skilled rehabilitation program and performed in conjunction with core CORF services.

Although in other outpatient settings, a speech-*language* pathologist is permitted to establish a plan of treatment, this is not the case with CORF services. However, as with other specialties, it is expected that the physician will *seek and use* advice from the speech-*language* pathologist.

40.5 - Respiratory Therapy Services

(Rev. 21, Issued: 09-24-04, Effective: 06-30-04, Implementation: 10-25-04)

A3-3183.5, CORF-253.5

Respiratory therapy services are covered CORF services if they are part of a comprehensive coordinated skilled rehabilitation program, included in the plan of treatment established and signed by the referring physician and performed in conjunction with core CORF services.

The facility physician must be present in the facility for a sufficient time to provide, in accordance with accepted principles of medical practice, medical direction, medical care

services and consultation (§485.58). All services must be provided within acceptable professional standards and practice and meet the qualifications set forth in §485.70.

A. Definition

Respiratory therapy (respiratory care) services are those services prescribed by a physician for the assessment, diagnostic evaluation, treatment, management, and monitoring of patients with respiratory deficiencies and abnormalities of function as part of a comprehensive coordinated skilled rehabilitation program.

To qualify for Medicare payment, respiratory therapy must be a covered service and must be reasonable and necessary for the diagnosis or treatment of an illness or injury and performed by respiratory therapists, physical therapists, occupational therapists, or registered nurses, as recognized by applicable State law. Covered services may include:

- *The application of techniques to support oxygenation and ventilation in the acutely ill patient. These techniques include but are not limited to:*

    1. *The establishment and maintenance of artificial airways;*

    2. *The development of ventilator therapy and other means of airway pressure manipulation;*

    3. *The development of techniques to improve the patient's function through delivery of oxygen; and*

    4. *Development of techniques to aid removal of secretions from the pulmonary tree;*

- *The therapeutic use and monitoring of medical gases (i.e., oxygen), active mists and aerosols (to humidify or for other therapeutic effects), and such equipment as nebulizers;*

- *Bronchial hygiene therapy, including deep breathing and coughing exercises, postural drainage, chest percussion and vibration, and nasotracheal suctioning;*

- *Diagnostic tests for evaluation by a physician, e.g., pulmonary function tests, spirometry, and blood gas analyses;*

- *Pulmonary rehabilitation techniques to improve respiratory function:*

    1. *Breathing retraining, including therapeutic procedures specifically targeted at improving the strength and endurance of respiratory muscles.*

2. *Therapeutic activities:*

    - *Exercise conditioning, including the performance of graded activity programs to increase strength and endurance of upper body and lower extremities;*

    - *Energy conservation strategies to perform tasks with less respiratory effort.*

- *Periodic assessment and monitoring of the acute and chronically ill patient for indications, and the effectiveness of, respiratory therapy services.*

B. Guidelines for Applying Coverage Criteria

There are many conditions for which respiratory therapy may be indicated. However, respiratory therapy performed as part of a standard protocol without regard to the individual patient's actual condition, capacity for improving, and need for such services, is not reasonable and necessary. All respiratory therapy services must meet the test of being "reasonable and necessary" pursuant to §1862(a)(1)(A) of the Act and must be performed in conjunction with core CORF services. Determinations of medical necessity are made based on local contractor decisions on a claim-by-claim basis.

C. Patient Education Programs

Instructing a patient in the use of equipment, breathing exercises, etc. may be considered reasonable and necessary to the treatment of the patient's condition and can usually be given to a patient during the course of treatment by any of the health personnel involved therein, e.g., physician, nurse, respiratory therapist.

40.6 - Prosthetic and Orthotic Devices *and Supplies*

(Rev. 21, Issued: 09-24-04, Effective: 06-30-04, Implementation: 10-25-04)

A3-3183.6, CORF-253.6

Prosthetic devices, other than dental devices and renal dialysis machines, are covered CORF services if they are part of a comprehensive coordinated skilled rehabilitation program, included in the plan of treatment established and signed by the referring physician, and performed in conjunction with core CORF services. Prosthetic devices (other than dental) are defined as devices that replace all or part of an internal body organ (including contiguous tissue), or which replace all or part of the function of a permanently inoperative or malfunctioning internal body organ. If the medical record, including the judgment of the attending physician, indicates the condition is of long and indefinite duration, the test of permanence is considered met.

Examples of prosthetic devices include maxillofacial devices and devices which replace all or part of the ear or nose. A urinary collection and retention system is a prosthetic device replacing bladder function in case of permanent urinary incontinence. The Foley catheter is also considered a prosthetic device when ordered for a patient with permanent urinary incontinence. However, disposable bed pads, diapers, rubber sheets, etc. are supplies that are not covered under this provision. Colostomy (and other ostomy) bags and necessary equipment required for attachment are covered as prosthetic devices. This coverage also includes irrigation and flushing equipment and other items and supplies directly related to ostomy care, whether or not the attachment of a bag is required.

Payment is made for supplies that are necessary for the effective use of a prosthetic device (e.g., the batteries needed to operate an artificial larynx). Adjustment of prosthetic devices required by wear or by a change in the patient's condition is covered when ordered by a physician.

Necessary supplies, adjustments, repairs, and replacements are covered even when the device was in use before the user enrolled in Part B of the program, as long as the device continues to be medically required. ***(Note:*** *Initial teaching in use of a prosthetic device is included in the price Medicare pays for these items and cannot be billed for separately.)*

Coverage of a prosthetic device includes all services necessary for formulating its design, material, and component selection; measurement, fittings, static and dynamic alignments; and instructing the patient in its use. Such coverage is included as an integral part of the fabrication of the device.

Orthotic devices are leg, arm, back, and neck braces. They are rigid and semi-rigid devices supporting weak or deformed body members or restricting or eliminating motion in a diseased or injured body part. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. Back braces include, but are not limited to, special corsets, e.g., sacroiliac, sacrolumbar, dorsolumbar corsets and belts.

Prosthetics are artificial legs, arms, and eyes. Stump stockings and harnesses (including replacements) are also covered when these appliances are essential to the effective use of the artificial limb.

Orthotics and prosthetics are covered when furnished in conjunction with a physician's service or on a physician's order. These devices are covered CORF services if they are part of a comprehensive coordinated skilled rehabilitation program. As with prosthetic devices, the payment for an orthosis or prosthesis includes its design, materials, measurements, fabrications, testing, fitting, or training in the use of the device.

Adjustments to an artificial limb or other appliance required by a change in the patient's condition are covered when ordered by a physician. Adjustments, repairs and replacements are covered even when the item had been in use before the user enrolled in Part B of the program so long as the device continues to be medically required.

40.7 - Social Services

(Rev. 21, Issued: 09-24-04, Effective: 06-30-04, Implementation: 10-25-04)

A3-3183.7, CORF-253.7

Social services *are covered CORF services if they are part of a comprehensive coordinated skilled rehabilitation program, included in the plan of treatment established and signed by the referring physician, and performed in conjunction with core CORF services. Social services must* contribute to the improvement of the individual's condition. Such services include:

- Assessment of the social and emotional factors related to the patient's illness, need for care, response to treatment, and adjustment to care in the CORF;
- Assessment of the relationship of the patient's medical and nursing requirements to his or her home situation, financial resources, and the community resources available upon discharge from the CORF; and
- Counseling and referral for casework assistance in resolving problems in these areas.

40.8 - Psychological Services

(Rev. 21, Issued: 09-24-04, Effective: 06-30-04, Implementation: 10-25-04)

A3-3183.8, CORF-253.8

Psychological services provided are covered CORF services if they are part of a comprehensive coordinated skilled rehabilitation program, included in the plan of treatment established and signed by the referring physician, and performed in conjunction with core CORF services. Covered services include:

- Assessment, diagnosis, and treatment of the beneficiary's mental and emotional functioning as it relates to his or her rehabilitation;
- Psychological evaluations of the individual's response to and rate of progress under the treatment plan; and
- Assessment of those aspects of an individual's family and home situation that affect the individual's rehabilitation treatment.

Although *anyone* who has a serious illness or injury may suffer from some degree of anxiety, the coverage of psychological services does not automatically extend to every CORF patient. For example, diagnostic testing for a mental problem is covered for a cardiac patient who exhibits excessive anxiety or fear following the acute phase of a

cardiac problem. However, the routine testing or treatment of all cardiac rehabilitation patients for mental, psychoneurotic, or personality disorders is not covered.

Family counseling services are covered only when the primary purpose of that counseling is the treatment of the patient's condition, that is, when there is a need to observe the patient's interaction with family members or to assess the capability of family members to aid in the rehabilitation of the patient. Family counseling services that are primarily directed toward the treatment of a family member's problem with respect to the patient's condition *are not reasonable and necessary and* are not covered.

40.9 - Nursing Services

(Rev. 21, Issued: 09-24-04, Effective: 06-30-04, Implementation: 10-25-04)

A3-3183.9, CORF-253.9

Nursing services provided by or under the supervision of a registered professional nurse are covered CORF services *if they are part of a comprehensive coordinated skilled rehabilitation program, included in the plan of treatment established and signed by the referring physician, and performed in conjunction with core CORF services.*

40.10 - Drugs and Biologicals

(Rev. 21, Issued: 09-24-04, Effective: 06-30-04, Implementation: 10-25-04)

A3-3183.10, CORF-253.10, AB-02-072

Drugs and biologicals are covered *if they are part of a comprehensive coordinated skilled rehabilitation program, included in the plan of treatment established and signed by the physician, and performed in conjunction with core CORF services. Drugs and biologicals are covered* when they:

- Are administered by or under the supervision of a physician or registered nurse,
- Are not otherwise excluded from Medicare coverage, such as most injections for immunization, and,
- Are not usually self-administered by the patient.

Base determinations of whether a drug or biological is of a type that cannot be self-administered on the usual method of administration furnished to the patient. If a patient receives an injection of a drug that is not usually self-injected and the drug is also available in oral form, the drug is not subject to the self-administrable drug exclusion because it is not self-administrable in the form furnished to the patient. The FI has the discretion to determine if it was medically necessary in that particular case to administer the injectable form of the drug instead of the oral form. If the FI determines that the oral form was appropriate, then the injectable drug would not be covered. Thus, when a patient is given tablets or other oral medication, the *medications* are excluded from

coverage since the form of the drug given to the patient is usually self-administered. Similarly, if a patient is given an injection that is usually self-injected, such as insulin, this drug is excluded from coverage even in an emergency situation. However, if a patient receives an injection of a drug that is not usually self-injected and that is also available in oral form, that drug is not subject to the self-administrable drug exclusion, since it is not self-administrable in the form in which it was furnished to the patient.

Most vaccinations or inoculations are excluded as immunizations unless they are directly related to the treatment of an injury or direct exposure such as anti-rabies treatment, tetanus antitoxin or booster vaccine, botulin antitoxin, antivenin, or immune globulin. The following three vaccinations are covered if a physician who is a doctor of medicine or osteopathy orders it:

- *Medicare pays for pneumococcal pneumonia vaccine and its administration furnished by a CORF.*
- *Medicare covers hepatitis B vaccine and its administration furnished to a beneficiary who is at high or intermediate risk of contracting hepatitis B.*
- *Medicare pays for influenza virus vaccine and its administration.*

High Risk for hepatitis B groups currently identified include:

- *End stage renal disease (ESRD) patients;*
- *Patients with hemophilia who receive Factor VIII or IX concentrates.*
- *Clients of institutions for individuals with mental retardation;*
- *Persons who live in the same household as a hepatitis B Virus (HBV) carrier;*
- *Homosexual men;*
- *Illicit injectable drug abusers.*

Intermediate risk groups currently identified include:

- *Staff in institutions with individuals with mental retardation;*
- *Workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work.*

Exception: Persons in the above-listed groups would not be considered at high or intermediate risk of contracting hepatitis B if they have laboratory evidence positive for antibodies to hepatitis B. (ESRD patients are routinely tested for hepatitis B antibodies as part of their continuing monitoring and therapy.)

For payment allowance limits for drugs and biologicals refer to Pub. 100-04, Medicare Claims Processing Manual, chapter 17, §20.

40.11 - *Home Environment Evaluation*

(Rev. 21, Issued: 09-24-04, Effective: 06-30-04, Implementation: 10-25-04)

A3-3183.12, CORF-253.12

One *single home environment evaluation visit is a covered CORF service if it is a part of a comprehensive coordinated skilled rehabilitation program, included in the plan of treatment established and signed by the referring physician, and performed in conjunction with core CORF services. The single home visit allows the therapist to evaluate the patient in the home environment and to assess the potential impact on the patient's rehabilitation goals.* The purpose of the evaluation is to permit the plan of treatment to be tailored to take into account the patient's home environment. The Medicare program does not pay for physical alterations to the home that facilitates the patient's rehabilitation.

The home evaluation is not covered as a routine service for all CORF patients. It is covered only if, in establishing or carrying out the plan of treatment, there is a clear indication that the home environment might adversely affect the patient's rehabilitation. Coverage is limited to the services of one professional *either physical or occupational therapist, (whose services are covered by the CORF benefit)* who is selected by the CORF.

50 - Outpatient Mental Health Treatment Limitation

(Rev. 21, Issued: 09-24-04, Effective: 06-30-04, Implementation: 10-25-04)

A3-3185, CORF-255

Regardless of the actual expenses a beneficiary incurs for treatment of mental, psychoneurotic, and personality disorders while the beneficiary is not an inpatient of a hospital, the amount of those expenses for CORF services that may be recognized for Part B deductible and payment purposes is limited to 62.5 percent of the allowable amount for those services. This limitation is called the outpatient mental health treatment limitation.

Expenses for diagnostic services (e.g., psychiatric testing and evaluation to diagnose the patient's illness) are not subject to this limitation. This limitation applies only to therapeutic services and to services performed to evaluate the progress of a course of treatment for a diagnosed *mental health* condition.

See *Pub. 100-04*, Medicare *Claims Processing* Manual, Chapter *12, "Physicians/Nonphysician Practitioners," §210, for a further description of the outpatient mental health treatment limitation and application of the limitation.*

50.1 - Outpatient Mental Health Limit Not Applicable for Hospital Inpatients

(Rev. 1, 10-01-03)

A3-3185.A, CORF-255.A

The limitation is applicable to expenses incurred in connection with the treatment of an individual who is not an inpatient of a hospital. Thus, the limitation applies to mental health services furnished to a CORF patient in a physician's office, in the patient's home, in a skilled nursing facility, as an outpatient, and so forth. The term "hospital" in this context means an institution which is primarily engaged in providing to inpatients the following services, by or under the supervision of a physician(s):

- Diagnostic and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons;
- Rehabilitation services for injured, disabled, or sick persons; or
- Psychiatric services for the diagnosis and treatment of mentally ill patients.

50.2 - Disorders Subject to Outpatient Mental Heath Limitation

(Rev. 1, 10-01-03)

A3-3185.B, CORF-255.B

The term "mental, psychoneurotic, and personality disorders" is defined as the specific psychiatric conditions described in the American Psychiatric Association's "Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition - Revised (DSM-IV-R)."

50.3 - Diagnostic Services

(Rev. 1, 10-01-03)

A3-3185.C, CORF-255.C

The limitation is not applied to tests and evaluations performed to establish or confirm the patient's diagnosis. Diagnostic services include psychiatric or psychological tests and interpretations, diagnostic consultations, and initial evaluations. However, testing services performed to evaluate a patient's progress during treatment are considered part of treatment and are subject to the limitation.

50.4 - Application of Outpatient Mental Heath Limitation

(Rev. 1, 10-01-03)

A3-3185.1, CORF-255.1.A

If the CORF treatment services rendered are for both a psychiatric condition and one or more nonpsychiatric conditions, the charges for the psychiatric aspects of treatment are billed under a separate revenue code from the charges for the nonpsychiatric services. See the Medicare Claims Processing publication for specific instructions.

See 100-1, the Medicare General Information, Eligibility, and Entitlement Manual, Chapter 3, for general policy about the mental health limitation.

50.5 - Computation of Limitation

(Rev. 1, 10-01-03)

A3-3185.1.B, CORF-255.1.C

The intermediary will determine the allowed amount for CORF services subject to the limitation. The allowed amount is the lower of the charge or the Medicare Physician Fee Schedule (MPFS) fee amount. The intermediary multiplies the allowed amount by 0.625 to obtain the limitation amount. This limitation amount is subject to the Part B deductible and 20 percent coinsurance.

The beneficiary is responsible for both the 37.5 percent reduction and the deductible and coinsurance applied to the reduced charges. Once the deductible has been satisfied, a beneficiary is responsible for 50 percent of the customary charges, which is the sum of 37.5 percent plus 12.5 percent (20 percent of 0.625).

8.5 CMS Program Memorandum Transmittal AB-02-183 (2002)

Program Memorandum Intermediaries/Carriers

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal AB-02-183 **Date: DECEMBER 27, 2002**

CHANGE REQUEST 2388

SUBJECT: Coverage of Hyperbaric Oxygen (HBO) Therapy for the Treatment of Diabetic Wounds of the Lower Extremities

This Program Memorandum (PM) summarizes the revision to §35-10 of the Coverage Issues Manual (CIM) regarding Hyperbaric Oxygen (HBO) Therapy. Please refer to this section of the CIM for complete information regarding this policy.

Conditions of Coverage

Hyperbaric oxygen therapy is a modality in which the entire body is exposed to oxygen under increased atmospheric pressure. Effective April 1, 2003, a National Coverage Decision expanded the use of Hyperbaric Oxygen (HBO) therapy to include coverage for the treatment of diabetic wounds of the lower extremities in patients who meet the following criteria:

(1) Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes; (ICD-9-CM diagnosis 250.7, 250.8, 707, 707.1, 707.10, 707.12, 707.13, 707.14, and 707.19).
(2) Patient has a wound classified as Wagner grade III or higher; and
(3) Patient has failed an adequate course of standard wound therapy.

The use of HBO therapy will be covered as adjunctive therapy only after there are no measurable signs of healing for at least 30 days of treatment with standard wound therapy and must be used in addition to standard wound care. Standard wound care in patients with diabetic wounds includes: assessment of a patient's vascular status and correction of any vascular problems in the affected limb if possible, optimization of nutritional status, optimization of glucose control, debridement by any means to remove devitalized tissue, maintenance of clean, moist bed of granulation tissue with appropriate moist dressings, appropriate off-loading, and necessary treatment to resolve any infection that might be present. Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days. Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO treatment is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

This PM also clarifies that CMS has concluded that special supervision and credentialing requirements should not be imposed on physicians who perform HBO therapy. You may not impose a higher level of supervision than direct supervision as is required for all "incident to" therapies. CMS encourages physicians who perform HBO therapy to obtain adequate training in the use of HBO therapy and in advanced cardiac life support.

NOTE: Topical application of oxygen does not meet the definition of HBO therapy as stated above. Also, its clinical efficacy had not been established. Therefore, no Medicare reimbursement may be made for the topical application of oxygen.

Billing Requirements for Intermediaries

Follow the general bill review instructions in §3604 of the Medicare Intermediary Manual, Part 3. Claims for HBO therapy should be submitted on Form HCFA-1450 or its electronic equivalent.

Applicable Bill Types

The applicable bill types are 11X, 13X and 85X.

HCPCS Coding

- 99183 – Physician attendance and supervision of hyperbaric oxygen therapy, per session.
- C1300 – Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval.

NOTE: Code C1300 is not available for use other than in a hospital outpatient department. In skilled nursing facilities (SNFs), HBO therapy is part of the SNF PPS payment for beneficiaries in covered Part A stays.

For hospital inpatients and critical access hospitals (CAHs) not electing Method I, HBO therapy is reported under revenue code 940 without any HCPCS code. For inpatient services, show ICD-9-CM procedure code 93.59 in FL 80 and 81.

For CAHs electing Method I, HBO therapy is reported under revenue code 940 along with HCPCS code 99183.

Payment Requirements for Intermediaries

Payment is as follows:

Intermediary payment is allowed for HBO therapy for diabetic wounds of the lower extremities when performed as a physician service in a hospital outpatient setting and for inpatients. Payment is allowed for claims with valid diagnostic ICD-9 codes as shown above with dates of service on or after April 1, 2003. Those claims with invalid codes should be denied as not medically necessary.

For hospitals, payment will be based upon the Ambulatory Payment Classification (APC) or the inpatient Diagnosis Related Group (DRG). Deductible and coinsurance apply.

Carrier Billing Requirements

The following HCPCS Code applies:

- 99183 - Physician attendance and supervision of hyperbaric oxygen therapy, per session

Claims Requirements

Follow the general instruction for preparing claims in §2010, Purpose of Health Insurance Claim Form CMS-1500, Medicare Carriers Manual (MCM) Part 4, Chapter 2. Claims for this service should be submitted on health insurance claim Form CMS-1500 or electronic equivalent. Claims should be processed in accordance with §4020, Review of Health Insurance Claim Form CMS-1500, of Part 3, Chapter IV of the Medicare Carriers Manual.

Payment Requirements

Payment and pricing information will be on the April update of the Medicare Physician Fee Schedule Database (MPFSDB). Pay for this service on the basis of the MPFSDB. Deductible and coinsurance apply. Claims from physicians or other practitioners where assignment was not taken are subject to the Medicare limiting charge (refer to MCM Part 3, chapter VII, §7555 for more information).

Medicare Summary Notices (MSNs)

Use the following MSN Messages where appropriate:

In situations, where the claim is being denied on the basis that the condition does not meet our coverage requirements, use one of the following MSN Messages:

"Medicare does not pay for this item or service for this condition." (MSN Message16.48)

The Spanish version of the MSN message should read:

"Medicare no paga por este articulo o servicio para esta afeccion."

OR "This service is not covered prior to April 1, 2003." (MSN Message 16.51)

The Spanish version of the MSN message should read:

" Esta servicio no se cubre antes del 1 de abril de 2003."

In situations where, upon medical review of the claim based upon the above utilization policy, you determine that the service is not medically necessary, use the following MSN message, 15.4.

"The information provided does not support the need for this service or item."

The Spanish version of the MSN message should read:

" La informacion proporcionada no confirma la necesidad para este servicio o articulo."

Remittance Advice Notices – Use appropriate existing remittance advice and reason codes at the line level to express the specific reason if you deny payment for HBO therapy for the treatment of diabetic wounds of lower extremities. If denying services as furnished before April 1, 2003, use existing ANSI X 12-835 claim adjustment reason code 26 "Expenses incurred prior to coverage" at the line level.

Provider Education – You must notify providers of this information through your next scheduled bulletin and on your website within two weeks.

The *effective date* for this PM is April 1, 2003.

The *implementation date* for this PM is April 1, 2003.

These instructions should be implemented within your current operating budget.

This PM may be discarded after April 1, 2004.

If you have any questions, contact the appropriate regional office.

8.6 Other Print and Online References

CMS forms:
http://www.cms.hhs.gov/forms/

Code of Federal Regulations search page:
http://www.gpoaccess.gov/cfr/index.html

Federal Register search page:
http://www.gpoaccess.gov/fr/index.html

Medicare Benefit Policy Manual, Chapter 12, Comprehensive Outpatient Rehabilitation Facility Coverage:
http://new.cms.hhs.gov/manuals/Downloads/bp102c12.pdf

Social Security Act index page:
http://www.ssa.gov/OP_Home/ssact/comp-ssa.htm

State Operations Manual Appendix index:
http://new.cms.hhs.gov/manuals/downloads/som107c09_appendixtoc.pdf

Survey & Certification letters:
http://www.cms.hhs.gov/SurveyCertificationGenInfo/01_Overview.asp#TopOfPage

Rehabilitation Reference Manual

Tab 9:
CORF Survey Deficiency Documentation

9.1 Examples

9.2 Survey Tool: CORFs

9.1 Examples

Sample Deficiencies for CORF

I-533—Physician Services

Based on review of documentation provided and interview with the administrative staff on June 25, 2002, the CORF failed to provide evidence that physician services were provided to patients at the CORF. Although the facility had a contract with a physician for the position of Medical Director, there was no evidence that a physician had provided any services since reviewing policies on August 29, 2000. The facility did not maintain a record and/or schedule to indicate the hours that the physician was at the CORF.

Additionally, there was no evidence that the designated medical director met the qualifications as set forth in 485.70. The facility lacked evidence of a curriculum vitae (CV) which indicated the physician's training and experience. Although the physician had recorded on the Medical Director Agreement that he was board-certified in adult and geriatric psychiatry, there was no indication of the physician's training and experience in physical rehabilitation services. Interview with the Administrator and one of the co-owners of the CORF on June 25, 2002 confirmed that there was no evidence that the designated medical director met the qualifications as set forth in 485.70.

I-536—Plan of Treatment

Based on documentation reviewed and interview with the facility administrator on 10/29/02, the facility failed to follow the physician's initial plan of treatment for one (1) of five (5) active patients (Patient #5). Findings include the following:

The initial physician order, dated 10/16/02, was for pulmonary rehabilitation. The orders indicated that the physician's treatment plan for pulmonary rehabilitation included an evaluation by physical therapy and respiratory therapy. In addition, the physician order called for "stress management," including an assessment for a possible change in psychiatric medications for Patient #5. Review of Patient #5's medical record on 10/29/02 revealed that the pulmonary rehabilitation evaluation had been conducted by a registered nurse (RN) and not a respiratory therapist. Furthermore, there was no evidence that an assessment had been done regarding the psychiatric medications, nor was there any evidence of a referral to social services or discussion of Patient #5 at a case conference. In an interview with the administrator on 10/29/02, she confirmed that there had been no referral made to social services. She also confirmed that Patient #5 had not been discussed at a case conference and that respiratory therapy had never evaluated Patient #5.

9.2 Survey Tool: CORFs

Comprehensive Outpatient Rehabilitation Facilities I Tags and I-Tag Identifiers

I-501 ***CoP: Compliance with Fed., State, and Local Laws (485.54)***
I-502 Licensure of facility
I-503 Licensure or registration of personnel

I-505 ***CoP: Governing Body and Administration (GB) (485.56)***
I-506 GB: Disclosure of ownership
I-507 GB: Administrator
I-508 GB: Administrator: responsible
I-509 GB: Administrator: implement and enforce
I-510 GB: Administrator: designate
I-511 GB: Administrator: retain responsibility
I-512 GB: Group of professionals
I-513 GB: Group: develop policies
I-514 GB: Group: composition
I-515 GB: Institutional Budget Plan (IBP)
I-516 GB: IBP: prepared by committee
I-517 GB: IBP:
- Operating budget
- Capital expenditure plan
- Annual review

I-518 GB: Patient Care Policies (PCP)
I-519 GB: PCP: description of services
I-520 GB: PCP: rules & responsibilities
I-521 GB: PCP: drugs & biologicals
I-522 GB: PCP: criteria
I-523 GB: PCP: procedure-clinical records
I-524 GB: PCP: procedure-explanation
I-525 GB: PCP: procedure-physician resources
I-526 GB: PCP: requirement-physician care
I-527 GB: PCP: requirement—plan of treatment
I-528 GB: PCP: procedure—guidance for professional personnel re: UR recommendations
I-529 GB: Delegation of authority (DA)
I-530 GB: DA: Contract & delegation for:
- Bookkeeping
- Billing and accounting
- Operating budget
- Purchase of supplies
- Financial statements

I-531 GB: DA: Contract
- No more than 5 years
- Termination
- Clause
- Facility billing
- Contractor—no rights/authority

I-532 ***CoP: Comprehensive Rehabilitation Program (CRP) (485.58)***
I-533 CRP: Physician services (PS)
- Provides medical services,
- Plan of treatment
- Patient care policies
- Participation

I-534 CRP: PS: Emergency physician services
I-535 CRP: PS: Plan of treatment (POT)
I-536 CRP: POT: Specifies goals & type, amount, frequency of services
I-537 CRP: POT: Promptly evaluated
I-538 CRP: POT: Consultation
I-539 CRP: POT: Reviewed every 60 days. Signed certification for continued care.
I-540 CRP: POT: Revision
I-541 CRP: POT: Coordination of services (CS)
I-542 CRP: POT: CS: Schedule
I-543 CRP: POT: CS: Procedure for communication
I-544 CRP: POT: CS: Periodic clinical entries
I-545 CRP: POT: CS: Patient case review conferences
I-546 CRP: POT: Provision of Services (PS)
I-547 CRP: POT: PS: Services provided directly or under arrangement
I-548 CRP: POT: PS: Necessary equipment
I-549 CRP: POT: PS: Qualified personnel
I-550 CRP: POT: PS: Responsibilities
I-551 CRP: POT: PS: Availability
I-552 CRP: POT: PS: Accepted standards of practice
I553 CRP: POT: Scope and site of services
- Basic requirements
- Exceptions

I-554 CRP: POT: Patient Assessment (PA)
I-555 CRP: POT: PA: Initial assessment
I-556 CRP: POT: PA: Patient reassessment
I-557 CRP: POT: PA: Laboratory services
I-558 CRP: POT: PA: Laboratory services

I-559 ***CoP: Clinical Records (CR) (485.60)***
I-560 CR: Content
I-561 CR: Content: Initial & Reassessments
I-562 CR: Content: POT
I-563 CR: Content: ID/consent forms
I-564 CR: Content: Pertinent medical history
I-565 CR: Content: Pertinent physical exam
I-566 CR: Content: Progress notes
I-567 CR: Content: Discharge summary
I-568 CR: Protection of clinical record information
I-569 CR: Retention & Preservation

I-570 ***CoP: Physical Environment (PE) (485.62)***
I-571 PE: Safety & comfort of patients (SCP)
I-572 PE: SCP: Building, fire & safety codes
I-573 PE: SCP: Fire extinguishers
I-574 PE: SCP: Fire alarm system
I-575 PE: SCP: Lights/emergency power
I-576 PE: SCP: Sufficient staff
I-577 PE: SCP: Lights, temperature, ventilation
I-578 PE: SCP: Safe & sufficient space
I-579 PE: Sanitary Environment (SE)
I-580 PE: SE: P&P for infection control (IC) & prevention
I-581 PE: SE: Monitor IC program
I-582 PE: SE: Linens
I-583 PE: SE: Rodents/insects
I-584 PE: Maintenance of Equipment, Physical location & Grounds (MEPG)
I-585 PE: MEPG: Equipment maintenance & calibration
I-586 PE: MEPG: Interior/exterior maintenance of facility
I-587 PE: Access for the physically impaired
I-588 PE: Access: Doorways, stairwells, corridors
I-589 PE: Access: Toilet facility
I-590 PE: Access: Entrance for w/c
I-591 PE: Access: Elevators
I-592 PE: Access: Parking spaces

I-593 ***CoP: Disaster Procedures (DP) (485.64)***
I-594 DP: Disaster plan (DPL) :
I-595 Procedures for transfers of casualties & records
I-596 DP: DPL: Notification of community emergency personnel
I-597 DP: DPL: Instructions for location & use of alarm systems
I-598 DP: DPL: Evacuation routes & procedures for leaving facility
I-599 DP: Drills & Staff Training (DST)
I-600 DP: DST: Ongoing training & drills
I-601 DP: DST: New personnel oriented to and assigned responsibilities under disaster plan

I-602 ***CoP: Utilization Review Plan (URP) (485.66)***
I-603 URP: Utilization Review Committee
I-604 URP: Utilization Review Plan
I-605 URP: URP: Criteria established for admissions, con't care, discharge
I-606 Utilization review: Applicability of POT to established goals
I-607 Utilization review: Adequacy of clinical records for:
- Assessing quality of services
- Compatibility of policies and practices to promote appropriate/efficient utilization of services

Rehabilitation Reference Manual

Tab 10: Introduction to Outpatient Therapy Facility Survey

10.1 Introductory Comments

10.2 Skills Checklist: OPTs

10.1 Introductory Comments

10.1 Introductory Comments

Outpatient therapy providers (OPTs) may be clinics, rehabilitation agencies, or public health agencies. Generally, providers of outpatient physical therapy or speech-language pathology services are rehabilitation agencies. When surveying, it is extremely rare to see a clinic or public health agency providing these services. Unlike the CORF, the OPT must provide physical therapy or speech-language pathology services and social or vocational adjustment services. Occupational therapy cannot be substituted for physical therapy, but it can be provided in addition to physical therapy services.

Section Three of the Reference Manual includes the updated *State Operations Manual* Appendix E. Appendix E now includes OPT tags in the interpretive guidelines. The guidelines contain an attempt at clearly defined expectations for OPT services. The updated Form CMS-381 is also included.

An OPT can provide physical therapy or speech-language pathology services offsite. These areas are called extension locations. The extension locations should meet all appropriate Conditions of Participation. In the past, CMS required that all extension locations be surveyed and certified, but current budgets do not permit this. CMS does require that OPT providers notify the Regional Offices of all extension locations. State agencies should determine whether any of the extension locations should be surveyed (especially if the extension locations are some distance from the primary site) to ensure that the extension locations are being adequately supervised by the primary site and that each extension location is providing a safe and private environment for the patients.

Specific criteria distinguish OPTs from other providers of outpatient rehabilitation services such as CORFs. The Conditions of Participation for OPTs are located in 42 CFR 485.701ff, Subpart H. The survey report form is Form CMS-1893.

There are occasions when an OPT will provide aquatic therapy in a community pool. Refer to the Survey & Certification policy letter (included in this section) regarding this topic.

OPTs may hire providers of rehabilitation services either directly or under arrangement. If the services are provided under arrangement, the OPT must have copies of the contracts between the OPT and the service provider. The OPT must ensure that services provided by a contractor are in compliance with the CoPs. Furthermore, the OPT retains professional and administrative control for the contractor's performance.

There should be clear evidence that the OPT has a social worker on staff. To determine this, the surveyor can review minutes of patient treatment planning meetings, medical records, agency timecards, and other administrative documents.

10.2 Skills Checklist: OPTs

10.2 Skills Checklist: OPTs

The following list summarizes the skills and knowledge necessary for successful survey. The surveyor should be able to:

- ☐ Identify and explain the difference between a CORF and an OPT.
- ☐ Describe the OPT survey process.
- ☐ Determine whether a facility meets the statutory and regulatory definition of an OPT.
- ☐ Describe appropriate means of assessing patients for and referring patients to social or vocational adjustment services.
- ☐ Explain the difference in scope of practice and supervision for registered therapists (physical therapists, occupational therapists) versus assistant-level therapists (physical therapy assistants, certified occupational therapy assistants) and rehabilitation aides.
- ☐ Describe OPT extension sites and related survey issues.
- ☐ Describe how services such as hyperbaric oxygen, infusion therapy, respiratory services, etc., can or cannot be appropriately provided in an OPT setting.
- ☐ Determine whether the facility physician is present in an OPT facility sufficiently to meet its needs.
- ☐ Prepare for and complete an onsite survey of an OPT.
- ☐ Detail the processes to be followed after the completion of an OPT survey.
- ☐ Describe the responsible party when services are provided “under arrangement.”
- ☐ When services are provided under arrangement, determine whether the contracts between the OPT and the contractor indicate the OPT retains full responsibility and oversight for the services provided by the contractor.

Rehabilitation Reference Manual

Tab 11: *State Operations Manual* Excerpts Pertaining to OPTs

11.1 Appendix E

11.2 Sections 2290–2306

11.1 Appendix E

This document is a replica of the official record copy maintained by the Issuances and Records Management Group.

State Operations Manual

Appendix E - Guidance to Surveyors: Outpatient Physical Therapy or Outpatient Speech Pathology (OPT/OSP) Services

Table of Contents

(Rev. 16, 01-10-06))

INDEX

§485.707 Condition of Participation: Compliance With Federal, State and Local Laws

§485.707(a) Standard: Licensure of Organization

§485.707(b) Standard: Licensure or Registration of Personnel

§485.709 Condition of *Participation*: Administrative Management

§485.709(a) Standard: Governing Body

§485.709(b) Standard: Administrator

§485.709(c) Standard: Personnel Policies

§485.709(d) Standard: Patient Care Policies

§485.711 Condition of *Participation*: Plan of Care and Physician Involvement

§485.711(a) Standard: Medical History and Prior Treatment

§485.711(b) Standard: Plan of Care

§485.711(c) Standard: Emergency Care

§485.713 Condition of *Participation*: Physical Therapy Services

§485.713(a) and (b) Standards: Adequate Program; Facilities, and Equipment

§485.713(c) Standard: Personnel Qualified to Provide Physical Therapy Services

§485.713(d) Standard: Supportive Personnel

§485.715 Condition of *Participation*: Speech Pathology Services

§485.715(a) and (b) Standards: Adequate Program; Facilities and Equipment

§485.715(c) Standard: Personnel Qualified to Provide Speech Pathology Services

§485.717 Condition of *Participation*: Rehabilitation Program

§485.717(a) Standard: Qualifications of Staff

§485.717(b) Standard: Arrangements for Social or Vocational Adjustment Services

§485.719 Condition of *Participation*: Arrangements for Physical Therapy and Speech Pathology Services to be Performed by Other Than Salaried Rehabilitation Agency Personnel

§485.719(b) Standard: Contract Provisions

§485.721 Condition of *Participation*: Clinical Records

§485.721(a) Standard: Protection of Clinical Record Information

§485.721(b) and (c) Standard: Content; Completion of Records and Centralization of Reports

§485.721(a) Standard: Protection of Clinical Record Information

§485.721(b) and (c) Standard: Content; Completion of Records and Centralization of Reports

§485.721(d) Standard: Retention and Preservation

§485.721(e) Standard: Indexes

§485.721(f) Standard: Location and Facilities

§485.723 Condition of *Participation*: Physical Environment

§485.723(a) Standard: Safety of Patients

§485.723(b): Standard: Maintenance of Equipment, Building, and Grounds

§485.723(c) Standard: Other Environmental Considerations

§485.725 Condition of *Participation*: Infection Control

§485.725(a) Standard: Infection Control Committee

§485.725(b) Standard: Aseptic Techniques

§485.725(c) Standard: Housekeeping

§485.725(d) Standard: Linen

§485.725(e) Standard: Pest Control

§485.727 Condition of *Participation*: Disaster Preparedness

§485.727(a) Standard: Disaster Plan

§485.727(b) Standard: Staff Training and Drills

§485.729 Condition of *Participation*: Program Evaluation

§485.729(a) Standard: Clinical Record Review

§485.729(b) Standard: Annual Statistical Evaluation

General Note: Extension Locations

I-7

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.70*7* Condition of *Participation*: Compliance With Federal, State and Local Laws

The organization and its staff are in compliance with all applicable Federal, State and local laws and regulations.

A - General

In order to assure that the clinic, rehabilitation agency, or public health agency and staff are in possession of current licenses as required by Federal, State and local laws, licenses should be available for review. Compliance with this Condition may have a direct bearing on other Conditions; e.g., physical therapy services (§485.713), speech pathology services (§485.715), rehabilitation program (§485.717), and physical environment (§485.723).

Review the licenses to assure the licenses are current and are applicable to the State in which the provider is providing services.

***B* - Major Sources of Information:**

- Federal, State and local laws governing health care; building, fire and safety codes;
- Applicable State and local licenses and organization personnel records containing up-to-date information; and
- Written policies pertaining to communicable and reportable diseases, conforming to applicable Federal, State and local laws.

I-8

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.*707(a)* Standard: Licensure of Organization

In any State in which State or applicable local law provides for the licensing of organizations, a clinic, rehabilitation agency or public health agency is licensed in accordance with applicable laws.

Where State law provides for the licensing of clinics, rehabilitation agencies or public health agencies, *the organization must* meet *all building, fire and safety codes, where required for licensure, before the organization is eligible for certification*.

Verify at the time of the survey that a current license is valid and in effect. A license must be in effect before the organization can be certified to participate in the program. Where a license for an organization currently participating has been temporarily suspended or revoked, contact the appropriate State department or authority to ascertain the status of the organization's licensure. If a license is not to be issued, *the facility should be found in noncompliance with this standard and* termination proceedings initiated.

Some States may issue provisional licenses. Contact the appropriate State department or authority and obtain information concerning the length of time the provisional status is to be in effect. If the limitations stipulated in a provisional license adversely affect the ability to render services in compliance with regulations, *the facility should be found in noncompliance with this standard.*

Document the reason(s) for such status and, most importantly, any limitation(s) imposed on the services rendered as a result.

I-9

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.707(b) Standard: Licensure or Registration of Personnel

Staff of the organization are licensed or registered in accordance with applicable laws.

Qualified personnel providing services at an OPT must be licensed, registered, or certified when licensure, registration or certification is applicable. This includes personnel providing services directly or under arrangement.

Review facility records, a central State listing, or other evidence of current licensure or registration of personnel, such as wallet size identification cards sometimes made available. Where personnel are required to be licensed but are not, notify the appropriate State licensing body. *If extension locations are located in other States, ensure that personnel who are providing services are licensed in the State in which the services are provided.*

I-11

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.709 Condition of *Participation*: Administrative Management

The clinic or rehabilitation agency has an effective governing body that is legally responsible for the conduct of the clinic or rehabilitation agency. The governing body designates an administrator, and establishes administrative policies.

A – General

The clinic or rehabilitation agency has a governing body responsible for developing, reviewing, and updating its administrative and clinical policies and procedures. The provision of adequate and effective services requires that the clinic or rehabilitation agency be responsive to internal and external needs and demands which may necessitate changes in program operation. *The governing body is responsible for designating an administrator.*

Review documentation of governing body activities to assess the effectiveness of the governing body's management and operation of the rehabilitation agency or clinic.

***B* – Major Sources of Information**

- Articles of incorporation, bylaws, policy statements, etc.;
- Minutes of governing body; staff and patient care policy committee meetings;
- Organizational chart showing administrative framework;
- Personnel records—employee qualifications and licenses;
- Patient care policies; and
- Clinical records.

I12

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.709(a) Standard: Governing Body

There is a governing body (or designated person(s) so functioning) which assumes full legal responsibility for the overall conduct of the clinic or rehabilitation agency and for compliance with applicable laws and regulations. The name of the owner(s) of the clinic or rehabilitation agency is fully disclosed to the State Agency. In the case of corporations, the names of the corporate officers are made known.

The governing body is the board of directors or trustees of a corporation, the owner(s) in the case of a proprietary clinic or rehabilitation agency, or others who have legal responsibility for the operation of the clinic or rehabilitation agency. The facility shall have an established and functioning governing body. It is not inappropriate for employees of an incorporated clinic or rehabilitation agency to also serve as members of the governing body. The governing body shall be responsible for compliance with all applicable laws and regulations pertaining to OPT/SLP facilities. The governing body is responsible for the quality and appropriateness of care. *Written* provisions should appear in the bylaws or equivalent, specifying:

- The basis upon which members of the governing body are selected (where applicable), their terms of office, and their duties and responsibilities;
- To whom responsibilities for direction of the program and evaluation of practices may be delegated, and the methods established by the governing body for holding appropriate individuals responsible; and
- The frequency of governing body meetings and that minutes are kept.

Verify that the names and addresses of all individuals having legal responsibility for the clinic or rehabilitation agency are available on the provider's CMS-855A. Verify that the Governing Body has by-laws, meetings and minutes of its meetings. Verify that the organization has policies and procedures that address who monitors the quality of care provided and methods to evaluate the quality (QI) of the services.

I-15

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.709(b) Standard: Administrator

The governing body:

- *Appoints a qualified full time administrator;*
- *Delegates to the administrator the internal operation of the clinic or rehabilitation agency in accordance with written policies;*
- *Defines clearly the administrator's responsibilities for procurement and direction of personnel; and*
- *Designates a competent individual to act in the temporary absence of the administrator.*

NOTE: *One qualified full-time administrator assumes overall administrative responsibility for the entirety of the rehabilitation agency's operation, including extension locations and any off-premises activities.*

The administrator who does not possess the required experience or specialized training in the administration of an outpatient physical therapy provider (rehabilitation agency, clinic, public health agency) may use training or experience acquired in the management or supervision of health institutions and agencies similar in scope to an outpatient physical therapy provider. College-level courses in health services administration and management approved by the appropriate State authority meet the necessary requirements for specialized training.

Verify the qualifications of the administrator.

The administrator should be familiar with all aspects of the operation of the clinic or rehabilitation agency such as scope of services provided, budgetary and fiscal matters, personnel, and other areas necessary to effectively direct operational activities. The administrator is also responsible for coordinating staff education, sometimes referred to as in-service education, or continuing education. In this regard, the administrator should see that each employee has the opportunity to increase the skills and knowledge necessary to promote effective and efficient patient care.

Review listing of in-service program content, type of instruction (e.g., lecture or demonstration), dates of instruction, and attendees.

When the administrator is unable to carry out delegated duties, a similarly qualified alternate is to be readily available (on the premises or by telephone) at all times during operating hours to assume the administrator's responsibilities.

Verify that an *alternate to the administrator* has been selected *and is noted in organization policies.*

I-19

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.709(c) Standard: Personnel Policies

Personnel practices are supported by appropriate written personnel policies that are kept current. Personnel records include the qualifications of all professional and assistant level personnel, as well as evidence of State licensure if applicable.

At a minimum, facilities should have procedures for selecting qualified personnel; a system for documenting the current licensure and/or certification status for those personnel whose positions or functions require such licensure or certification; and a system for assessing competency of all personnel providing healthcare services, upon hire and on an ongoing basis, on a schedule determined by the facility policy. Practices pertaining to the personnel of the organization should be written in personnel policies, be available to all personnel, and be updated and/or revised as appropriate. Such items as qualifications of staff employed, frequency of supervision, continuing education, hiring/firing practices, evaluations, etc. should be located in the personnel policies.

Review *personnel* policies. *During interviews with the facility administrator and staff, elicit evidence that personnel practices are based on written personnel policies.*

I-22

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.709(d) Standard: Patient Care Policies

Patient care practices and procedures are supported by written policies established by a group of professional personnel including one or more physicians associated with the clinic or rehabilitation agency, one or more qualified physical therapists (if physical therapy services are provided), and one or more qualified speech pathologists (if speech pathology services are provided). The policies govern the outpatient physical therapy and/or speech pathology services and related services that are provided. These policies are evaluated at least annually by the group of professional personnel, and revised as necessary based upon this evaluation.

The facility should have *written* patient care policies, *based on accepted standards of practice* for all services provided, *that govern the outpatient physical therapy and/or speech pathology services and related services that are provided. Patient care policies are established by the professional staff of the clinic or rehabilitation agency and, where appropriate, outside professionals who function as a patient care policy committee. The professional staff preparing the patient care policies should include at least one physician and at least one qualified physical therapist (if physical therapy services are provided) and at least one qualified speech pathologist (if speech pathology services are provided). Patient care policies should be reviewed for appropriateness at least annually by the group of professional personnel that prepared them.*

Review the written patient care policies and determine whether the facility operates in conformity with them.

Review minutes of meetings to determine whether the policies of the clinic or rehabilitation agency are current and responsive to the needs of patients, and whether,

when unresponsive, appropriate policy revisions are undertaken. Verify that patient care policies are being reviewed annually and revised as needed.

I-47

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.711 Condition of *Participation*: Plan of Care and Physician Involvement

For each patient in need of outpatient physical therapy or speech pathology services there is a written plan of care established and periodically reviewed by a physician, or by a physical therapist or speech pathologist respectively. The organization has a physician available to furnish necessary medical care in case of emergency.

A - General

All patients must be treated pursuant to a written plan of care that indicates anticipated goals and specifies the type, amount, frequency, and duration of services to be furnished. Non-Medicare patients are neither required to be under the care of a physician nor to have a plan of care established by a physician. *A physician will be available on call to furnish necessary medical care in case of an emergency.*

Review medical records to ensure Medicare patients have a written plan of care.

B - Major Sources of Information

- Patients' plans of care;
- Emergency Procedures;
- Patient care policies; and
- Clinical records.

–

I-49

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.711(a) Standard: Medical History and Prior Treatment

The following are obtained by the organization before or at the time of initiation of treatment:

(1) The patient's significant past history;

(2) Current medical findings, if any;

(3) Diagnosis(es), if established;

(4) Physician's orders, if any;

(5) Rehabilitation goals, if determined;

(6) Contraindications, if any;

(7) The extent to which the patient is aware of the diagnosis(es) and prognosis; and

(8) If appropriate, the summary of treatment furnished and results achieved during previous periods of rehabilitation services or institutionalization.

The regulations do not require the patients be referred to be the facility by a physician or that the services to be furnished pursuant to a physician's orders. However, since Medicare patients are still required under the statute to be under the care of a physician and to have the plan of care periodically reviewed by a physician to receive payment for Medicare covered services, *the organization should, if possible, obtain the following information at, or prior to, the time that therapy is initiated: Significant past medical history,* current medical findings, diagnosis(es), physician's orders (if any), rehabilitation goals and contraindications, (normally be made available to the facility by the attending physician) *and any previous therapy or hospitalization related to the current medical condition.* Non-Medicare patients are not required to be under the care of a physician, *or to* have a plan of care established or periodically reviewed by a physician, *though* you should *nevertheless* expect to find medical records maintained for the *non*-Medicare patients. When complete and appropriate past history *and/or* current medical findings are not made available to the organization, the organization should obtain the information from *other sources such as* the patient, family or from follow-up with the referring physician, if any.

Review medical record for evidence of prior medical history and/or treatment.

I-50

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.711(b) Standard: Plan of Care

(1) For each patient there is a written plan of care established by the physician; or (i) by the physical therapist; or (ii) by the speech-language pathologist who furnishes the services.

(2) The plan of care for physical therapy or speech pathology services indicates anticipated goals and specifies for those services the—(i) type; (ii) amount; (iii) frequency; and (iv) duration.

(3) The plan of care and results of treatment are reviewed by the physician or by the individual who established the plan at least as often as the patient's condition requires, and the indicated action taken. (For Medicare patients, the plan must be reviewed by a physician, nurse practitioner, clinical nurse specialist, or physician assistant at least every 30 days, in accordance with §410.61(e) of this chapter.)

(4) Changes in the plan of care are noted in the clinical record. If the patient has an attending physician, the therapist or speech-language pathologist who furnishes the services promptly notifies him or her of any change in the patient's condition or in the plan of care.

When you review a patient's record to determine if a plan of care has been established and is periodically reviewed, it is not necessary to establish whether the patient is a Medicare or non-Medicare patient. The condition statement and standard permit, for each patient, the plan of care to be established by a physician, or by the appropriate professional (i.e., a physical therapist or speech pathologist) and *to be* reviewed by a physician or the individual who established it. However, as a condition for Medicare payment, a physician must certify the necessity of the services. *As part of the certification, a* physician, nurse practitioner, clinical nurse specialist, or physician assistant must review the plan of care every 30 days. *For* each Medicare patient, *a physician must* re-certify the continued need for those services. This review will probably be the review the facility uses for Medicare patients to meet the Condition of Participation. Since Medicare patients must be under the care of a physician for purposes of receiving payment for Medicare covered services, the attending physician must be notified of any changes in current treatment or the patient's condition. A change requires a revision to the plan of care. The medical record should contain documentation regarding the notification (a dated written order signed by the physician or a dated verbal order signed by the professional receiving the order).

Review the medical record to determine that the patient has a plan of care that is being reviewed and updated every 30 days (for Medicare patients). The plan of care should not look identical from month to month as treatment and goals should be updated as the patient makes progress and meets existing goals. The plan of care must have the signature of the reviewing physician, non-physician practitioner, or therapist. If, for any reason, therapy services are discontinued prior to the end date indicated on the plan of care, the physician must be notified.

NOTE: The term physician includes a podiatrist *or optometrist* whose performance of functions are consistent with the OPT's *policies* and whose services are related to functions he/she is legally authorized to perform.

I-54

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.711(c) Standard: Emergency Care

The organization provides for one or more doctors of medicine or osteopathy to be available on call to furnish necessary medical care in the case of emergency. The established procedures to be followed by personnel in an emergency cover immediate care of the patient, persons to be notified, and reports to be prepared.

Organizational policies should contain the names and telephone numbers of physician(s) the organization has arranged to be on-call to provide medical care in case of an emergency during operating hours. *(This can include physicians at a near-by hospital emergency room.)* There may be instances in which the on-call physician provides emergency medical triage which results in a 911 call. *The OPT procedure to call 911 in cases of emergency doesn't supersede the requirement to have on-call physicians for emergencies.*

NOTE: *If an OPT/OSP is providing services at a community facility (such as a pool), the OPT staff must have a way to contact emergency medical care (i.e., if therapy services are being provided at a community pool, is another individual on duty and available to call for help?)*

Review the medical emergency procedures, and make certain in discussions with the appropriate persons that these procedures, when necessary, can be made immediately operational. Interview employees to determine whether their individual responsibilities, in case of an emergency, are known. <u>There must be two persons on duty whenever a patient is being treated (no matter where the services are being provided (§485.723(a)(6)) and no matter whether the facility is large or small.)</u>

NOTE: *If a patient receives emergency medical treatment at the organization, the* physician's emergency medical treatment plan and communication should be documented in the patient's medical record.

I-55

§485.713 Condition of *Participation*: Physical Therapy Services

If the organization offers physical therapy services, it provides an adequate program of physical therapy, has an adequate number of qualified personnel, and the equipment necessary to carry out its program and to fulfill its objectives.

A - General

The range of medically necessary physical therapy services should be adequate to treat the types of disabilities accepted for service. There should be an adequate number of qualified professionals to accommodate the number of patients treated by the organization. Also, there should be adequate equipment to treat the type of disabilities accepted by the organization.

NOTE: *OCCUPATIONAL THERAPY SERVICES CANNOT BE SUBSTITUTED FOR PHYSICAL THERAPY SERVICES. In other words, the OPT cannot provide solely occupational therapy services. Occupational therapy services may be provided in addition to physical therapy or speech-language pathology services.*

Review personnel rosters for adequacy of qualified professionals. Review facility for types and number of equipment available for patients.

NOTE: *If the rehabilitation agency is not providing either physical therapy or speech pathology services, the most appropriate Tag to cite would be I7 since the organization would not be in compliance with all applicable Federal, State, local laws and regulations.*

B - Major Sources of Information

- Physician orders, plans of care, and physical therapy evaluations and progress notes;
- Patient care policies—such policies should include a description of their scope of services, admission and discharge criteria. The facility must appropriately refer individuals who have needs that exceed their scope of service;
- Personnel records--job descriptions, employee qualifications, and current licensure information; and
- Clinical records.

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.713(a) Standard: Adequate Program

(1) The organization is considered to have an adequate outpatient physical therapy program if it can:

(i) Provide services using therapeutic exercise and the modalities of heat, cold, water, and electricity;

(ii) Conduct patient evaluations; and

(iii) Administer test and measurements of strength, balance, endurance, range of motion, and activities of daily living.

(2) A qualified physical therapist is present or readily available to offer supervision when a physical therapist assistant furnishes services:

(i) If a qualified physical therapist is not on the premises during all hours of operation, patients are scheduled so as to ensure that the therapist is present when special skills are needed, for example, evaluation and re-evaluation.

(ii) When a physical therapist assistant furnishes services off the organization's premises, those services are supervised by a qualified physical therapist who makes an onsite supervisory visit at least once every 30 days.

An adequate outpatient physical therapy program includes:

(a) Provision of services using therapeutic exercises and the modalities of heat, cold, water and electricity to provide the range of therapy services necessary to treat individuals with the types of disabilities it accepts for service;

(b) Conduct patient evaluations; and

(c) Administer tests and measurements of strength, balance, endurance, range of motion and activities of daily living. It is possible that not all patients will receive every modality listed above. The plan of care should address the modalities that are medically necessary for the treatment of the patient's condition.

Review patient care policies and procedures to assess the adequacy of the organizational program.

Physical therapy services are to be rendered only by qualified physical therapists or qualified physical therapist assistants under the supervision of qualified physical therapists. A qualified therapist must be onsite for evaluations and re-evaluations of patients. A physical therapist is readily available to offer supervision to a physical therapy assistant according to the organization's policies and procedures but when a physical therapy assistant furnishes services offsite, those services are supervised by a qualified physical therapist who makes an onsite supervisory visit at least every 30 days ***to observe the actual performance of the assistant.*** *Only physical therapists may supervise physical therapy assistants. Only occupational therapists may supervise occupational therapy assistants.*

Such supervision may include:

- Specific instructions regarding the treatment regimen;
- An explanation of responses to treatment indicative of adverse patient reactions;
- Discussions between the physical therapist and the physical therapist assistant; and
- *State practice acts and rules may include additional supervision requirements.*

NOTE: *This does not mean the physical therapist must be onsite full-time but must be able to respond and to be physically available onsite within a reasonable period of time to provide consultation in case of an unusual occurrence.* Response time is based on the condition of the patient, the patient's previous response to treatment, organization staffing, and competency of available personnel. For example, where the patient's previous response to treatment had been adverse, thereby possibly requiring that, in the future, the physical therapist keep himself readily available to provide needed supervisory assistance, the physical therapist should arrange times and schedules to allow for minimal delay in providing such assistance.

Review organizational policies regarding supervision and supervisory visits. Interview staff regarding supervision of assistants.

I-57

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.713(b) Standard: Facilities, and Equipment

The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of disabilities it accepts for service.

All equipment should be maintained according to manufacturer's guidelines.

NOTE: Where patient privacy is required, this may be accomplished through utilization of individual treatment booths, folding screens, draw curtains, etc.

Review patient care policies and procedures and tour clinic to assess the adequacy of equipment and facility to treat the disabilities it has accepted for service. Review organizational procedures and speak with staff to ensure equipment is being maintained according to manufacturer guidelines.

I-58

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.713(c) Standard: Personnel Qualified to Provide Physical Therapy Services

Physical Therapy services are provided by, or under the supervision of a qualified physical therapist. The number of qualified physical therapists and qualified physical therapist assistants is adequate for the volume and diversity of physical therapy services offered. A qualified physical therapist is on the premises or readily available during the operating hours of the organization.

The number of qualified physical therapists and qualified physical therapist assistants (if applicable) should be able to adequately and effectively provide services to patients. Adequate service cannot be determined *based upon* the mere proportion of the staff to patient ratio, *but rather*, it is to be based on knowledge of the types of patients treated and the type, amount, frequency, and duration of treatment required. *The qualified physical therapist is either on the premises or readily available during all hours of operation.*

To more accurately determine the sufficiency of personnel, review clinical records, together with the patient care policies, personnel records, and patient treatment schedules. Interview patients regarding availability of staff during scheduled treatment times.

I63

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.713(d) Standard: Supportive Personnel

If personnel are available to assist qualified physical therapists by performing services incident to physical therapy that do not require professional knowledge and skill, these

personnel are instructed in appropriate patient care services by qualified physical therapists who retain responsibility for the treatment prescribed by the attending physician.

Physical therapy aides, or individuals with less than assistant level qualifications, must be directly supervised by a qualified physical therapist. The physical therapist must be in the immediate vicinity and available to provide assistance and direction throughout the time services are provided.

Even if an aide is assisting a qualified physical therapy assistant in some activity, ultimate responsibility for the aide's activities rests with the qualified physical therapist. *In the provision of physical therapy services, any staff other than the qualified physical therapist or physical therapy assistant is considered supportive personnel.*

Review organization policies and procedures to determine the job responsibilities of the supportive personnel.

I-150

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.715 Condition of *Participation*: Speech Pathology Services

If speech pathology services are offered, the organization provides an adequate program of speech pathology and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objective.

A - *General*

The speech pathology services provided should be such that patients accepted for treatment are able to receive services as medically indicated. The personnel and equipment necessary to effectively treat those patients may, in part, be dictated by the type of patients ordinarily accepted for treatment.

Review personnel rosters and patient census to determine that the organization provides sufficient personnel to adequately serve the patients it accepts for services.

B - Major Sources of Information

- Physician orders, plans of care, and speech pathology evaluations and progress notes;
- Patient care policies;
- Personnel records--job descriptions, employee qualifications, and current

licensure information; and

- Clinical records.

I-151

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.715(a) Standard: Adequate Program

The organization is considered to have an adequate outpatient speech pathology program if it can provide the diagnostic and treatment services to effectively treat speech disorders.

Review the organization's patient care policies and clinical records to ascertain the adequacy of the speech pathology program.

I-152

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.715(b) Standard: Facilities and Equipment

The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of speech disorders it accepts for service.

Space suitable for treatment must be available. Observe the clinic area to determine the adequacy of space and equipment.

I-153

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.715(c) Standard: Personnel Qualified to Provide Speech Pathology Services

Speech pathology services are given or supervised by a qualified speech pathologist and the number of qualified speech pathologists is adequate for the volume and diversity of speech pathology services offered. At least one qualified speech pathologist is present at all times when speech pathology services are furnished.

The number of qualified speech pathologists should be adequate to effectively provide services to patients. As in the case of the physical therapist, this number is related to types of patients treated, the specifics of the plan of care, and the time required to carry out the plan.

Unlike physical therapy services where, at certain times, the application of certain modalities does not require the presence of the physical therapist, effective speech pathology treatment necessitates the continuing presence of the speech pathologist. Therefore, no formula utilizing numbers of physical therapists as a base for comparison can be used when determining whether or not the number of qualified speech pathology personnel is adequate.

At least one qualified speech pathologist must be present at all times when speech pathology services are provided as there are no recognized speech pathology assistants. Review personnel records to determine whether the speech pathologist is qualified to perform speech pathology services (most states require licensure or certification).

I-67

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.717 Condition for Coverage: Rehabilitation Program

This condition and its standards apply only to a rehabilitation agency's own patients, not to patients of hospitals, skilled nursing facilities (SNFs), or Medicaid nursing facilities (NFs) to whom the agency furnishes services. (The hospital, SNF, or NF is responsible for ensuring that qualified staff furnish services for which they arrange or contract for their patients.) The rehabilitation agency provides, in addition to physical therapy and/or speech-language pathology services, social or vocational adjustment services to all of its patients who need them. The agency provides for special qualified staff to evaluate the social and vocational factors, to counsel and advise on the social or vocational problems that arise from the patient's illness or injury, and to make appropriate referrals for needed services.

A - General

A rehabilitation agency must provide either physical therapy or speech pathology services plus a rehabilitation program which includes, at a minimum, social and/or vocational adjustment services. Such services may be furnished directly or under arrangement.

The rehabilitation agency is required to provide social or vocational adjustment services to all patients in need of such services. A qualified therapist can gather and document evidence regarding the need for social or vocational services via a screening tool or other written method deemed appropriate by the rehabilitation agency. This written

documentation must be reviewed by the social worker, vocational adjustment specialist, or psychologist who will then determine the patient's needs for further evaluation. This process must be documented in the patient's clinical record. If further evaluation or services are needed, the agency's special qualified staff must provide them or make appropriate referrals. ***Under no circumstances may a patient determine his or her vocational needs.***

However, there are circumstances when the provision of these services to certain patients by the rehabilitation agency would be unnecessary or would duplicate similar services provided by other organizations. The rehabilitation agency is neither required to evaluate patients, nor to provide social or vocational adjustment services to patients, under any of the following situations:

- The patient is receiving social or vocational adjustment services as an inpatient or outpatient of another provider or supplier of services, and a written agreement or contract between the rehabilitation agency and the provider or supplier specifies that the provider or supplier is responsible for social or vocational adjustment services for all patients receiving OPT/OSP from the rehabilitation agency.

- The other provider or supplier agrees in the written contract with the rehabilitation agency to clearly mark or identify the files of patients receiving OPT/OSP who have previously been evaluated for social or vocational adjustment services. A separate evaluation of those patients for social or vocational adjustment services by the rehabilitation agency is not required.

- The OPT/OSP provider provides diagnostic or therapeutic services to individuals for whom another agency or organization has overall responsibility.

Social or vocational adjustment services may be provided either on the premises or off the premises of the organization (e.g., in the office of the psychologist).

Review the organization's policies and procedures and discuss with staff the methods to determine whether a patient requires social/vocational services. Review staff meeting minutes or patient care meeting minutes. *Is the social worker or vocational specialist part of this meeting?*

***B* - Major Sources of Information:**

- Contract for services under arrangement;

- Personnel records - job descriptions, employee qualifications and health examinations as specified;

- Clinical records; and

- Patient care policies.

I-68

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.717(a) Standard: Qualifications of Staff

The agency's social or vocational adjustment services are furnished as appropriate, by qualified psychologist, qualified social workers, or qualified vocational specialists. Social or vocational adjustment services may be performed by a qualified psychologist or qualified social worker. Vocational adjustment services may be furnished by a qualified vocational specialist.

Review personnel folders to determine if the individuals providing social or vocational services meet the licensure, certification, registration, or other applicable qualifications of the state in which the services are being provided.

I-72

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.717(b) Standard: Arrangements for Social or Vocational Adjustment Services

(1) If a rehabilitation agency does not provide social or vocational adjustment services through salaried employees, it may provide those services through a written contract with others who meet the requirements and responsibilities set forth in this subpart for salaried personnel.

(2) The contract must specify the term of the contract and the manner of termination or renewal, and provide that the agency retains responsibility for the control and supervision of the services.

If an agency does not provide social or vocational adjustment services through its own employees, such services may be provided by means of written agreements with individuals or organizations. Their contracts must specify the agency's responsibility, control and supervision over the services and must *detail the manner of termination or renewal of the contract*. The appropriate professional staff (psychologists, social workers, vocational specialists) are responsible for developing, in conjunction with the physician, the regimen of social or vocational adjustment services to be provided to individuals requiring such services, and must assume the professional and administrative responsibility for services provided under arrangements.

Review the contracts to assure that the agency's responsibility is detailed.

I-79

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.719 Condition of *Participation*: Arrangements for Physical Therapy and Speech Pathology Services to be Performed by Other Than Salaried Organization Personnel

If an organization provides outpatient physical therapy or speech pathology services under an arrangement with others, the services are to be furnished in accordance with the terms of a written contract, which provides that the organization retains professional and administrative responsibility for, and control and supervision of, the services.

A - General

The rehabilitation agency has professional and administrative responsibility for the physical therapy and speech pathology services provided under an arrangement.

Review contracts to assure that the agency retains professional and administrative responsibility for any services provided under arrangement.

B - **Major Sources of Information**

- Contract for services under arrangement;
- Personnel records - job descriptions, employee qualifications and health examinations as specified;
- Clinical records; and
- Patient care policies.

I-80

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.719(b) Standard: Contract Provisions

The contract:

(1) Specifies the term of the contract and the manner of termination or renewal;

(2) Requires that personnel who furnish the services meet the requirements that are set forth in this subpart for salaried personnel; and

(3) Provides that the contracting outside resource may not bill the patient or Medicare for the services. This limitation is based on §1861 (w)(1) of the Act, which provides that:

(i) Only the provider may bill the beneficiary for covered services furnished under arrangements; and

(ii) Receipt of Medicare payment by the provider, on behalf of an entitled individual, discharges the liability of the individual or any other person to pay for those services.

Organizations can provide outpatient therapy services under arrangement with others. These services are to be furnished in accordance with a written contract. The terms of the contract provide that the organization maintains professional and administrative responsibility for, and control and supervision of, the services. The terms also include termination/renewal procedures as well as qualifications to be met by those furnishing services under arrangements. Only the agency, not the contracted outside resource, may bill for services performed by the contracted resource.

Review the contracts to assure that the organization has specified the qualifications the outside service provider must meet. The contract should state that the outside service provider may not bill for services rendered.

I-96

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.721 Condition of *Participation*: Clinical Records

The organization maintains clinical records on all patients in accordance with accepted professional standards and practices. The clinical records are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information.

A - General

The clinical record serves as a basis for documentation of medical care rendered to the patient. Clinical records should contain at least the following documentation: *Progress notes, monthly summaries, records of communication with the patient's physician and other therapists and discharge summaries.*

In addition to serving as a basis for documentation of care rendered to patients, clinical records provide evidence of the organization's implementation of policies and procedures as they relate to patient care.

Review the clinical record to determine whether the content of the clinical record presents a total or, at a minimum, an adequate picture of the care being given and that documentation by those under contract meets the documentation standards of the organization.

Review a sample of all clinical records, including those patients whose treatment is provided under arrangement, to make certain that evaluations, progress notes, and other pertinent clinical material are present and that the clinical records containing applicable information for all patients are maintained on the premises of any location at which services are rendered. However, if the surveyor is surveying only the primary location, clinical records should be available to the surveyor for review, during the course of the survey, regardless of where the records are kept.

***B* - Major Sources of Information**

- Active and closed clinical records; and
- Policies regarding retention and confidentiality of clinical records.

I-154

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.721(a) Standard: Protection of Clinical Record Information

Clinical records are to be stored where they are protected from fire and unauthorized use. *The organization must make every effort to safeguard the medical records against unauthorized access/use particularly if the organization shares space with another entity.* Organization policies are to note to whom records or copies thereof may be provided, the use to which the material may be put, and the circumstances describing the return of such material. For the release of all material not authorized by law, the patient's written consent is required.

Review the organization's policies for securing and safeguarding clinical records against loss, destruction, or unauthorized use.

§485.721(b) Standard: Content

The clinical record contains sufficient information to identify the patient clearly, to justify the diagnosis(es) and treatment, and to document the results accurately. All clinical records contain the following general categories of data:

(1) Documented evidence of the assessment of the needs of the patient, of an appropriate plan of care, and of the care and services furnished;

(2) Identification data and consent forms;

(3) Medical history;

(4) Report of physical examinations, if any;

(5) Observations and progress notes;

(6) Reports of treatments and clinical findings; and

(7) Discharge summary including final diagnosis(es) and prognosis.

Virtually all clinical records should contain an assessment of the needs of the patient (initial evaluation and reevaluations where appropriate), plan of care (including the types, amount, duration and frequency of services provided), identification data (name and address of patient), observations and progress notes, reports of treatments and clinical findings, and discharge summary. Other documentation should include coordination efforts between professionals providing services.

However, consent forms, medical history and report of the physician's physical examination may or may not appear in clinical records. This information would need to appear only where *demonstrably* relevant to patient treatment. Where medical history does appear in clinical records, it may not have been that transmitted by the physician but, rather, may have been obtained from the patient when the past and present history was related. *Progress notes should be updated in the patient's clinical record at least weekly.*

Where emergency care is provided, the clinical record should include the following: Type of care rendered, date, personnel involved, and the incident that precipitated the need for such care.

Examine a substantial number of both active and closed clinical records, selected on a random basis and not restricted to those of Medicare patients.

I-155

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.721(c) Standard: Completion of Records and Centralization of Reports

Current clinical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's clinical record. Each physician signs the entries that he or she makes in the clinical record.

If omission of any pertinent information is noted in the clinical records, additional clinical record reviews should be undertaken to determine the prevalence of such omissions.

A discharge summary should include the date and reason for discharge; a brief summary of the current status of the patient at the time of discharge; and, where applicable, provision for referral of the patient to another source for continuing care.

Regardless of whether the organization provides services through its own employees or through an arrangement with others, all materials that are pertinent to the patient's treatment are to be part of the clinical record, which is to be maintained on the premises of any location at which services are rendered. All information appearing in the clinical record is to be dated appropriately, signed, and incorporated weekly into the clinical record.

The survey should indicate on the Survey Report Form the number of clinical records reviewed and the number and types of deficiencies found in each. Where record reviews prompt questions concerning patient care, the surveyor should request additional information and assistance from the appropriate organization personnel.

I-108

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.721(d) Standard: Retention and Preservation

Clinical records are retained for at least:

(1) The period determined by the respective State statute, or the statute of limitations in the State, or

(2) In the absence of a State statute:

(i) Five years after the date of discharge, or

(ii) In the case of a minor, 3 years after the patient becomes of age under State law or 5 years after the date of discharge, whichever is longer.

Review the organization policy pertaining to retention and preservation of clinical records and verify that such policy is consistent with applicable State law or regulation where such exists. Verify that there is a provision in organization policies for the retention and transfer of clinical records if the organization ceases to function.

I-156

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.721(e) Standard: Indexes

Clinical records are indexed at least according to name of patient to facilitate acquisition of statistical information and retrieval of records for research or administrative action.

Clinical records are indexed according to the last name of each patient, but in some cases indexing may be according to file identification numbers assigned to patients on admission to the organization. This system may be utilized for indexing either active and/or discharged patient clinical records as determined by organizational need.

Review the organizational policies/procedures regarding the system for indexing clinical records.

I-157

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.721(f) Standard: Location and Facilities

The clinical records are to be easily retrievable and available to all professional staff members of the organization and other authorized individuals. Clinical records may be maintained at a site other than the primary location (the site issued the provider agreement/number) if the beneficiary receives outpatient therapy services at that other site. All records must be **available** to the surveyor **during the course of the survey regardless of where the records are kept**.

NOTE: Records may be delivered to the surveyor electronically or by other means as long as the delivery is within a reasonable amount of time during the course of the onsite survey.

I-117

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.723 Condition of *Participation*: Physical Environment

The building housing the organization is constructed, equipped, and maintained to protect the health and safety of patients, personnel, and the public and provides a functional, sanitary, and comfortable environment.

A - General

The structure housing the organization is such that it is held "open to the public." Patient treatment areas and other locations associated with organization function (e.g., storage and restrooms) are to be physically separated from non-organization areas. Restrooms, however, need not be located directly in the treatment area, but may be located, for example, down a hallway so long as they are easily accessible by non-ambulatory and semi-ambulatory individuals.

The physical environment should be considerate of patient privacy (away from public viewing). Patient privacy may be assured through utilization of individual treatment booths, folding screens, draw curtains, etc.

In order to ensure the safety of patients, personnel, and the public, examine the physical plant of the organization and ascertain whether or not it is maintained consistent with State and local building, fire, and safety codes.

B - Major Sources of Information

- Applicable Federal, State and local laws;
- Inspection reports of State and local building and fire authorities; and

- Organization policies regarding maintenance of equipment, building and grounds.

I-118

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.723(a) Standard: Safety of Patients

The organization satisfies the following requirements:

(1) It complies with all applicable State and local building, fire, and safety codes;

(2) Permanently attached automatic fire-extinguishing systems of adequate capacity are installed in all areas of the premises considered to have special fire hazards. Fire extinguishers are conveniently located on each floor of the premises. Fire regulations are prominently posted;

(3) Doorways, passageways and stairwells negotiated by patients are:

(i) Of adequate width to allow for easy movement of all patients (including those on stretchers or in wheelchairs),

(ii) Free from obstruction at all times, and

(iii) In the case of stairwells, equipped with firmly attached handrails on at least one side.

(4) Lights are placed at exits and in corridors used by patients and are supported by an emergency power source;

(5) A fire alarm system with local alarm capability and, where applicable, an emergency power source is functional;

(6) At least two persons are on duty on the premises of the organization whenever a patient is being treated;

(7) No occupancies or activities undesirable or injurious to the health and safety of patients are located in the building.

Areas *of the organization* considered to be especially hazardous (e.g., rooms or spaces used for combustible supplies and equipment) are to be equipped with a State fire authority approved, **permanently attached**, automatic fire extinguishing system, or shall be separated from the balance of the building by 1-hour *rated* fire resistant barriers. All areas occupied or accessible to the organization for use during emergency or non-

emergency activity, including corridors and stairwells, are to be protected by easily accessible fire extinguishers (e.g., the case of an organization located in a multilevel structure, *irrespective of* whether the entire structure, or only a portion thereof, is utilized). The doorways and passageways shall be *free of obstruction* to allow for ease in patient movement into and within the organization and shall be wide enough to *accommodate the type and condition of patients (i.e., in wheelchairs, etc.) accepted for treatment.* Stairwells should include handrails on at least one side and should be free from obstruction at all times.

An emergency power source (e.g., battery or auxiliary generator) is available to assure adequate lighting during emergency operation within the treatment areas and those passageways, stairwells, and exits (as noted above) accessible to the organization. In cases of power outage, the emergency power source should respond either automatically or require only minimal activation effort.

The fire alarm system should be adequate to alert organizational personnel in time to *permit* safe evacuation of the building. The premises of the organization are to be safeguarded by a fire alarm system or automatic detection system that is in operational condition. Provision is also to be made for an internally audible manual alarm capability, either separately contained, or functioning in combination, with the fire alarm or automatic detection system. In the absence of State or local requirements, the above systems are to be approved by the State Fire Marshal's Office. A system without the capacity for manual activation in response to a fire would not serve to alert other personnel, patients, and the public of danger and the need for action. Where the alarm system is activated by a disruption in the organization's electrical system, or is in other ways dependent on it, an emergency power source (e.g., battery or auxiliary generator) should be available to serve as backup.

The building housing the organization should be free of hazardous occupancies or activities such as the manufacturing of combustible materials.

Verify that applicable State and local building, fire, and safety codes are met and review available reports of State and local personnel responsible for enforcement of the above.

I-158

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.723(b) Standard: Maintenance of Equipment, Building, and Grounds

The organization establishes a written preventive-maintenance program to ensure that:

(1) The equipment is operative and is properly calibrated; and

(2) The interior and exterior of the building are clean and orderly and maintained free of any defects that are a potential hazard to patients, personnel, and the public.

All equipment should be inspected by the organization at least yearly or in accordance with manufacturers' guidelines and a *maintenance scheduled maintained*. Such inspection is determined in part by present equipment condition and its frequency of use, and is to be outlined in written procedures that include the following:

- Equipment to be inspected;
- A brief statement concerning the general inspection process; and
- Frequency of inspection for each piece of equipment.

For all electrically powered patient care equipment, appropriate manufacturer's operating and maintenance information should be on file. The surveyor should review this information and ascertain what specific recommendations, if any, are made for equipment calibration checks, periodic maintenance procedures, etc. Then, through copies of service repair statements or other documentation, determine whether such recommendations were followed.

Review organization maintenance checklists. Note any hazards to the health and safety of patients, personnel, and the public (e.g., broken window and door panes, obstruction of passageways, and dangerous floor surfaces) on the Survey Report Form (CMS-1893).

I-130

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.723(c) Standard: Other Environmental Considerations

The organization provides a functional, sanitary, and comfortable environment for patients, personnel, and the public.

(1) Provision is made for adequate and comfortable lighting levels in all areas; limitation of sounds at comfort levels; a comfortable room temperature; and adequate ventilation through windows, mechanical means, or a combination of both;

(2) Toilet rooms, toilet stalls, and lavatories are accessible and constructed so as to allow use by non-ambulatory and semi-ambulatory individuals; and

(3) Whatever the size of the building, there is an adequate amount of space for the services provided and disabilities treated, including reception area, staff space, examining room, treatment areas, and storage.

In order to make the organization's environment comfortable, sanitary and functional for patients, personnel and the public, the following provisions should be considered: lighting, sounds, temperature, ventilation, toilet facilities and space for the organization to comfortably function. Where necessary, ramps should be available to provide for easy access to facilities and equipment. Examination and treatment areas should be large enough to enable effective application of the plan of care. Where underwater exercise is utilized, a safe and effective patient lift device is available.

Verify that temperature control mechanisms maintain the temperature at a comfortable and constant level. Verify that restroom/toilet facilities are handicapped accessible. Observe all areas within the organization. Is the space adequate for storage, treatment, etc?

I-159

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.725 Condition of *Participation*: Infection Control

The organization that provides outpatient physical therapy services establishes an infection control committee of representative professional staff with responsibility for overall infection control. All necessary housekeeping and maintenance services are provided to maintain a sanitary and comfortable environment and to help prevent the development and transmission of infection.

A - General

An infection control committee, applicable for organizations offering physical therapy services, has overall responsibility for ensuring that environmental infection hazards are controlled. *The committee should consist of staff representing the various professional services provided by the organization and should ensure that the organization has up-to-date infection control policies and procedures for investigating, controlling, and preventing infections in the organization and monitors staff performance to ensure that the policies and procedures are being executed.*

Review the organization's Infection Control policies and procedures. Does the organization have the necessary housekeeping staff and supplies to maintain a sanitary environment.

B - Major Sources of Information

- Written policies and procedures; and
- Minutes of the infection control committee.

I-160

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.725(a) Standard: Infection Control Committee

The infection control committee establishes policies and procedures for investigating, controlling, and preventing infections in the organization and monitors staff performance to ensure that the policies and procedures are executed

Meetings are to be held at least annually with minutes being kept, and at least two or more individuals should constitute the committee. The committee should be composed of persons whose educational background and experience (e.g., M.D., R.N., and other interested professionals) is adequate to perform this function. The administrator, in the case of a clinic or rehabilitation agency, should assume responsibility for selecting the professionals to serve on the committee.

Written procedures covering infection control and cleanliness of certain physical therapy equipment such as whirlpools, paraffin baths, and moist hot pack units, *as well as provisions for disposal of bio-hazardous materials* should be available for review. This is particularly important in cases where whirlpools are used for debridement of wounds. *Written procedures covering infection control should also be available for any of the other professional services (i.e., equipment used by occupational therapy or speech-language pathology).*

The surveyor should review the policies and procedures *and minutes of the annual meeting* for preventing, controlling, and investigating infections and should ascertain whether the recommendations of the committee are acted upon.

I-161

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.725(b) Standard: Aseptic and isolation techniques

All personnel follow written procedures for effective aseptic techniques. The procedures are reviewed annually and revised if necessary to improve them.

Personnel are to follow written procedures for effective aseptic techniques.

Review the aseptic procedures developed and ascertain, through a discussion with available professional personnel and review of major sources of information, that the procedures are communicated to the staff. *Observe staff during the survey and note if staff are not following the correct procedures outlined in policies. Review the organization's documentation of its aseptic procedures—is it reviewed annually and updated as needed (look for dates).*

I-162

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.725(c) Standard: Housekeeping

(1) The organization employs sufficient housekeeping personnel and provides all necessary equipment to maintain a safe, clean, and orderly interior. A fulltime employee is designated as the one responsible for the housekeeping services and for supervision and training of housekeeping personnel;

(2) An organization that has a contract with an outside resource for housekeeping services may be found to be in compliance with this standard provided the organization or outside resource or both meet the requirements of the standard.

The organization identifies the individual(s) assigned primary responsibility for housekeeping duties. When there is a contract with an outside resource to provide such services, the organization retains responsibility for the housekeeping duties. *The organization is responsible for employing sufficient housekeeping staff to maintain a clean, safe environment.*

Inspect the organization for cleanliness and orderliness especially with regards to equipment, floors, tables, etc. Review contracts (if the organization contracts with outside housekeeping services) to ensure that the organization has retained responsibility and oversight for the housekeeping services performed by the outside source.

I-163

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.725(d) Standard: Linen

The organization has available at all times a quantity of linen essential for proper care and comfort of patients. Linens are handled, stored, processed, and transported in such a manner as to prevent the spread of infection.

Organization has a new supply of fresh clean linen, essential for proper care and comfort of all patients treated, plus an additional supply to provide for any possible increased usage that is to be stored in clean areas and available for daily use.

Verify that soiled linen is removed from patient areas at least daily and stored in an area away from patients, personnel, and the public and is stored away *from clean linen. Review policies and procedures for handling linen and see that policies and procedures are being followed.*

I-164

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.725(e) Standard: Pest Control

The organization premises are maintained free from insects and rodents through operation of a pest control program.

The organization's premises should be free from insects and rodents.

Review the organization's written policy covering the pest control program.

I-165

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.727 Condition of *Participation*: Disaster Preparedness

The organization has a written plan, periodically rehearsed with procedures to be followed in the event of an internal or external disaster and for the care of casualties (patients and personnel) arising from a disaster.

A - General

A well developed disaster plan must be documented and posted in areas accessible for continuing personnel review.

During the survey, ask staff members to describe their individual roles in the disaster plan.

B **- Major Sources of Information**

- Disaster plan; and
- Documentation as to ongoing training sessions and dates of disaster drills.

I-166

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.727(a) Standard: Disaster Plan

The organization has a written plan in operation, with procedures to be followed in the event of fire, explosion, or other disaster. The plan is developed and maintained with the assistance of qualified fire, safety, and other appropriate experts, and includes:

(1) Transfer of casualties and records;

(2) Location and use of alarm systems and signals;

(3) Methods of containing the fire;

(4) Notification of appropriate persons; and

(5) Evacuation routes and procedures.

Ensure that the written plan is operational and contains procedures to be followed, evacuation routes and assignment of staff responsibilities in the event of a disaster.

Verify that the description of the location of the alarms systems is accurate. *Verify that staff members know the sequence of events for which they are responsible during a fire or other disaster. Do staff members know the evacuation routes for patients in wheelchairs or with crutches?*

I-167

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.727(b) Standard: Staff Training and Drills

All employees are trained, as part of their employment orientation, in all aspects of preparedness for any disaster. The disaster program includes orientation and ongoing

training and drills for all personnel in all procedures so that each employee promptly and correctly carries out his assigned role in case of a disaster.

The organization should have annual staff training and disaster drills for all salaried and contracted employees. All personnel are to be exposed to practice drill situations calling for the exercise of their responsibilities as stated in the disaster plan.

Verify that disaster drills are carried out at least annually and include all salaried and contracted employees, and that the date and the names of those persons taking part are documented. Annual drill disasters must be carried out annually at extension locations.

I-168

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.729 Condition of *Participation*: Program Evaluation

The organization has procedures that provide for a systematic evaluation of its total program to ensure appropriate utilization of services and to determine whether the organization's policies are followed in providing services to patients through employees or under arrangements with others.

A - General

At least once a year the organization should assess the performance of its total operation. Total operation refers not only to those services provided to patients, but also to the broader concepts of overall organization administration, including, but not limited to, policies and procedures, personnel, fiscal, patient care, etc. Procedures *must be in place* which provide for an evaluation of the total organization program. *Written reports of the results of the evaluation should be maintained and the facility should have a performance improvement plan that collects data about the organization's performance on an ongoing basis.* The evaluation should be conducted by the professional staff of the organization and outside professionals, where appropriate. These reports should contain the names of those participating in the evaluation, the results, and expected action, if indicated.

Review dated reports of the most recent program evaluations.

B - Major Sources of Information

- Written policies and procedures concerning the evaluation process;
- Patient care policies; and
- Minutes of meetings on program evaluation.

I-169

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.729(a) Standard: Clinical Record Review

A sample of active and closed clinical records is reviewed quarterly by the appropriate health professionals to ensure that established policies are followed in providing services.

A substantial sample of records reviewed should be randomly selected from the active and closed files. Each service offered by the organization should be represented in the sample. In instances where a patient is receiving both physical therapy and speech pathology services, the record may be included in the sample of each service rendered. The clinical record review committee is composed of health professionals representing those services provided *directly and, if applicable*, under arrangement, by the organization. It is not necessary that those committee members be employees of the organization. Administrative personnel would ordinarily be committee participants.

Review minutes of the organization's clinical record review committee. *Do the minutes indicate corrective action to be taken if the organization finds that established policies are not being followed?*

I-170

(Rev. 16, Issued: 01-10-06; Effective/Implementation Date: 11-21-05)

§485.729(b) Standard: Annual Statistical Evaluation

An evaluation is conducted annually of statistical data such as number of different patients treated, number of patient visits, condition on admission and discharge, number of new patients, number of patients by diagnosis(es) sources of referral, number and cost of units of service by treatment given, and total staff days or work hours by discipline.

The organization must conduct an annual evaluation of statistical data. Each organization may decide the types of data it wishes to collect (in addition to numbers of patient visits, types of patients, etc.). Some organizations may find that a quarterly report, as opposed to an annual report, would prove more beneficial in determining the effect of organizational policies. Correct and consistent application of policies will, to some extent, be reflected in the statistical evaluation, and, where policy has not been followed, the evaluation can serve as a guidepost for any necessary change.

The surveyor should review and compare the prior years and current statistical reports to determine that the data similar in character to the organization's program evaluation purposes, is being kept.

GENERAL NOTE:

If during the survey process, the extension location(s) is found to be out of compliance with a CoP, the provider as a whole is considered out of compliance.

11.2 Sections 2290–2306

This document is a replica of the official record copy maintained by the Issuances and Records Management Group.

Providers of Outpatient Physical Therapy or Outpatient Speech Pathology (OPT/OSP) Services

2290 - OPT/OSP - Citations

(Rev. 1, 05-21-04)

The statutory basis for providers of OPT/OSP services is found in §1861(p) of the Act. The CoPs are found in 42 CFR 485, Subpart H. Appendix E contains surveyor and interpretive guidelines.

2292 - Types of OPT/OSP Providers

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

There are three types of organizations that may qualify as OPT/OSP providers. *However, almost all OPT/OSP providers are rehabilitation agencies.*

2292A - Rehabilitation Agency

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

An agency that provides an integrated, multidisciplinary program designed to upgrade the physical functions of handicapped, disabled individuals by bringing together, as a team, specialized rehabilitation personnel. At a **minimum**, a rehabilitation agency must provide physical therapy or speech language pathology services **and** a rehabilitation program that, in addition to physical therapy or speech language pathology services, **includes social or vocational adjustment services**. *The organization must have two persons on duty on the premises of the organization whenever a patient is being treated whether at the primary site or the extension locations.*

NOTE: *Occupational Therapy cannot be substituted for the physical therapy requirement. It may be provided in addition to physical therapy or speech-language pathology services.*

The organization has available a physician on call to furnish necessary medical care in case of an emergency.

2292B - *Clinics and Public Health Agencies*

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

- *On rare occasions,* a facility established primarily for the provision of outpatient physicians' services *or an official agency established by a State or local government, the primary function of which is to maintain the health of the population served by providing*

environmental health services, preventive medical services, may in certain instances provide therapeutic services. Those entities will want to contact their Fiscal Intermediaries/Carriers regarding the provision of OPT/OSP services. Definitions for clinics and public health agencies may be found at 42 CFR §485.703.

2292C - Public Health Agency

(Rev. 1, 05-21-04)

An official agency established by a State or local government, the primary function of which is to maintain the health of the population served by providing environmental health services, preventive medical services, and in certain instances, therapeutic services.

2294 - Exceptions to CoPs

(Rev. 1, 05-21-04)

In order for clinics, rehabilitation agencies, and public health agencies to be eligible to participate as providers of OPT/OSP services, they must be in compliance with all applicable CoPs, except the following: 42 CFR 485.709, Administrative Management, is not applicable to public health agencies, and 42 CFR 485.717, Rehabilitation Program, is not applicable to clinics or public health agencies.

2296 - SA Verification of Services Provided

(Rev. 1, 05-21-04)

During the course of the SA survey, it verifies that the services that the provider proposes to offer are actually being provided. The SA evaluates the cumulative records of services actually provided. Work schedules of personnel providing services will show utilization data for various services.

2298 - Site of Service Provision

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

An OPT/OSP provider (normally classified as a rehabilitation agency) furnishes services at its primary (that has an approved Medicare Provider number) site.

2298A - *OPT/OSP Services Provided at More Than One Location*

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

An OPT/OSP provider may also provide services from *locations other than its primary site. These locations may be freestanding offices, suites in an office or medical building*

or, in some cases, space in an existing Medicare/non-Medicare participating provider (SNF or hospital) and are called extension locations.

The extension location concept for OPT/OSP is applicable only in those cases in which a separate area of a host provider or facility is set aside for the provision of OPT/OSP services during the hours of the OPT's operations. (An example—SNF patients may not be treated in the OPT area during the OPT's hours of operation). The extension location must meet all applicable CoPs (refer to §2302). The OPT should have established policies and procedures related to service provision at the extension location. Medical records for patients treated at the extension locations must be readily available for surveyors during surveys.

The extension location cannot provide services that the primary location is not providing (with the exception of aquatic therapy). Extension locations do not have to provide all the services that are provided at the primary site. For example, an extension location may provide occupational therapy services as long as the occupational therapy services are being provided at the primary location. Alternatively, physical therapy may be provided at the primary location but does not have to be provided at the extension location.

***NOTE**: The OPT/OSP primary site must provide the therapeutic services that are provided at the extension locations. The OPT/OSP may provide a therapeutic service directly at one location while providing it under arrangement at another. A therapeutic service refers to a type of professional discipline (i.e., physical therapy, occupational therapy, social services, etc). Therapeutic services do not refer to particular types of treatment modalities (such as ultrasound or other types of physical agents) applied to produce therapeutic changes to biologic tissue. The primary site and the extension locations do not have to provide the same types of modalities. However, the primary site and the extension locations must have the appropriate modalities to treat the types of diagnoses/dysfunctions of the patients each serves.*

- *As long as an OPT/OSP is not operating in the same space at the same time, there appears no reason why the OPT/OSP cannot operate on the premises of a supplier (i.e., physician, chiropractor). However, the supplier cannot bill separately for the services provided by the OPT/OSP and the supplier must adhere to sections of the Social Security Act that prohibit suppliers from referring Medicare patients for certain designated health services (DHS) to an entity with which the supplier or a member of the supplier's immediate family has a financial relationship, unless an exception applies. The OPT has the responsibility to protect the medical records from unauthorized use.*

2298B - OPT/OSP Services at Locations Other than Extension Locations

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The OPT/OSP may provide therapy services in the patient's home or in a patient's room in a SNF. Because they are not considered extension locations, neither the home nor a patient's room need satisfy the requirements for an extension location.

Periodically, an OPT/OSP may wish to use a community facility to provide certain therapy services. For example, the OPT/OSP provider may want to use a community pool to provide aquatic therapy. The State agency (SA) shall verify that the community pool meets all applicable state laws (i.e., health and safety, infection control requirements, etc.) governing the use of the community facility. Also the SA shall review the OPT/OSP's policies and procedures regarding the type of therapy being provided, training for staff, supervision, etc. The pool must be closed to public use during the time the OPT/OSP is providing therapy to protect the privacy and safety of the patients being treated. The hours of operation and days of the week during which the facility will be used for therapy services, supervision, etc. must be clearly stated in the OPT/OSP's policies and procedures as well as the contractual agreement between the community pool and the OPT/OSP. Verify that the OPT/OSP has a carefully detailed policy regarding specific arrangements for emergency services in the event that a medical emergency were to occur at the community location (i.e., is a telephone in close proximity to the qualified professional providing the service, is there a second person on site? etc.)

The SA shall survey the site to determine if the location meets the State's health and safety standards. The SA should consult with their RO regarding their reasons and decision to accept or deny the community facility. The community facility would not be considered an extension location.

2300 - SA Annual Report to RO on Locations of Extensions Locations

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

OPT/OSP providers are required to report the proposed addition of all new extension locations. In addition, on an annual basis or on or before January 1 of the calendar year, the SA forwards a copy of the Identification of Extension Locations of OPT/OSP Providers (Form CMS-381) to all OPT/OSP providers. If possible, the SA should complete this activity within the same time period for all OPT/OSP providers. Each provider providing services from extension locations is to indicate, in the appropriate spaces, the name, address and the provider number of the primary site, as well as the name(s) and address(es) of extension location(s) and, under Part B, the specific services (OPT, OSP, or both) each extension location provides. Upon receipt of this form from the OPT/OSP provider, the SA reviews this information, identifies those locations requiring a survey and schedules the survey accordingly.

NOTE: The SA forwards an annual summary report of the information to the RO noting the number of extension locations for each certified OPT/OSP provider. *After reviewing the forwarded reports, the RO & SA may wish to mutually identify any required surveys.*

NOTE: *ROs are responsible for entering OPT/OSP extension locations identifiers (similar to HHA branches) into ASPEN. The identifiers can be included in the survey process.*

2302 - Survey of OPT/OSP Extension Locations

(Rev. 13, Issued: 10-21-05; Effective/Implementation Date: 11-21-05)

The extension location must meet all applicable CoPs. The SA may survey as many facility locations as it deems necessary to adequately determine the rehabilitation (OPT/OSP's) agency's overall compliance with the OPT/OSP CoPs.

The SA surveys each condition and standard in the OPT/OSP CoPs at each extension location with the following exceptions:

- 42 CFR 485.709(a) (Standard: Governing body) is based upon the evaluation of the total agency that has responsibility for the primary location as well as all extension locations. *However, if there are concerns with the day-to-day operations of the extension location, assess the effectiveness of the governing body.*

- Condition 485.717 (Rehabilitation program) is applicable only to a rehabilitation agency's own patients;

- Condition 485.715 (Speech pathology) is applicable only when speech pathology is rendered.

- *Condition 485.713 (Physical therapy services) is applicable only when physical therapy is rendered*

The SA completes a separate survey report, Form CMS-1893, for each surveyed OPT location. Failure to correct deficiencies noted as a result of a survey at any location (extension location or primary site) will jeopardize the certification of the OPT provider in its entirety. The SA completes only one Form CMS-2567, and indicates the names of all locations (primary and/or extension location) found to be deficient with respect to each survey item. Also, the SA completes only one Form CMS-1539, and notes the names of all facilities that serve as extension locations in "State Agency Remarks." Surveys of all locations must be coordinated; therefore, schedule and complete surveys of all locations within the same time period.

When the SA is certifying compliance, findings at all locations are to be considered as a whole. If the OPT provider has deficiencies in only some locations, but they are judged

significant enough to warrant termination, the SA initiates termination proceedings. Cessation of services at the location(s) at which the deficiency(ies) existed, in lieu of initiating corrective action, would enable the OPT provider to retain its certification.

NOTE: *For an OPT/OSP provider to establish an extension location across the State lines, the two States involved must have a signed reciprocal agreement with each other allowing approval of the extension location. Whether the extension location is in the same State as the primary site or in another State, it must conform to all regulatory requirements. An extension location that is situated in a different State should bill under the primary site's provider number.*

An extension location cannot be denied based solely on geographical distance. If there is considerable geographical distance between the primary site and the extension location(s), it is important to determine whether the primary site can adequately supervise the staff at the extension location(s) as well as manage and oversee all operations of the extension location. Supervisors should be available by telephone and be able to drive to the extension location in a reasonable amount of time, provide ongoing staff training, etc.

NOTE: *A physical therapist may not supervise an occupational therapy assistant nor may an occupational therapist supervise a physical therapy assistant. Non-professional personnel (generally physical and occupational therapy aides) cannot be supervised by anyone other than the qualified physical or occupational therapist while performing patient care activities.*

2306 - OPT/OSP Provider Relinquishes Primary Site to CORF

(Rev. 1, 05-21-04)

The OPT/OSP provider, following the conversion of its primary site to a CORF, may select one of its extension locations as a new primary site. The SA notifies the RO via Form CMS-1539 of the new primary location and existing, associated, certified extension locations for OPT/OSP services.

The SA surveys and certifies the new primary location under the OPT/OSP CoPs. If the extension unit now identified as the new primary location was never surveyed and approved, it must now be surveyed. However, existing extension locations do not have to be resurveyed with the survey of the new primary location.

Rehabilitation Reference Manual

Tab 12:
OPT Survey Process

12.1 OPT Survey Process

12.2 Q&A

12.1 OPT Survey Process

Survey Protocol for Outpatient Therapy Providers

Definition of Outpatient Physical Therapy (OPT)/Outpatient Speech Pathology (OSP) Providers

An OPT/OSP is a provider of outpatient physical therapy or speech therapy services which may be a clinic, a public health agency or a rehabilitation agency. (42 CFR § 485.703)

Scope and Site of Services

Most OPT/OSPs are rehabilitation agencies. According to the *State Operations Manual*, the rehabilitation agency "provides an integrated, multidisciplinary program designed to upgrade the physical functions of handicapped, disabled individuals by bringing together, as a team, specialized rehabilitation personnel. At a minimum, a rehabilitation agency must provide physical therapy or speech language pathology services and a rehabilitation program which, in addition to physical therapy or speech language pathology services, includes social or vocational adjustment services." (*SOM* 2292.A)

Rehabilitation agencies may provide services at an extension location. Any services provided at an extension location must also be provided at the primary site.

Conditions of Participation (CoPs) OPT/OSPs are found in 42 CFR Part 48 subpart H. Appendix E of the *State Operations Manual* contains interpretive guidelines.

The OPT/OSP will be referred to as an OPT throughout the remainder of this document.

References:

- 42 CFR 485.701–729, Conditions of Participation for Clinics, Rehabilitation Agencies and Public Health Agencies as Providers of Outpatient Physical Therapy (OPT) and Speech-Language Pathology Services.
- Social Security Act 1861(g). "The term 'outpatient occupational therapy services' has the meaning given the term 'outpatient physical therapy services' in subsection (p), except that 'occupational' shall be substituted for 'physical' each place it appears therein." Subsection (p) defines outpatient physical therapy services.
- *State Operations Manual (SOM)*, Appendix E, Interpretive Guidelines for Outpatient Physical Therapy or Speech Pathology Services.
- *State Operations Manual (SOM)* 2290–2306, Additional certification information regarding OPT.
- *State Operations Manual (SOM)* 2008.A. Initial certification information, including the description of a "fully operational" provider.

Survey Protocol

Task 1: Offsite Preparation
Task 2: Entrance Conference
Task 3: Initial Tour
Task 4: Clinical Review
Task 5: Review of Administration
Task 6: Compliance Determination
Task 7: Exit Conference
Task 8: Documentation of Findings

Task One: Offsite Preparation

A. The general objective of offsite preparation is to analyze various sources of information available in order to identify potential concerns prior to conducting the survey.

B. Gather and review provider information:
   - Documentation submitted by provider requesting certification.
     - Provider Enrollment Form (Form CMS-855).
     - *Request for Certification in the Medicare/ and/or Medicaid Program to Provide Outpatient Physical Therapy and/or Speech Pathology Services* (Form CMS-1856).
     - *Health Insurance Benefit Agreement* (Form CMS-1561).
     - Other information submitted by the provider.
   - Information about extension sites (if applicable).
   - Prior survey Statements of Deficiencies. Review for potential areas of concern to be investigated during the survey.
   - Provider file, OSCAR data, complaint history.
   - Written agreement between States if the OPT has offsite locations in more than one State. The written agreement should specify which State agency is responsible for surveying which location.

C. Prepare and review survey materials.
   - 42 CFR 485.701–729 and Appendix E of the *State Operations Manual (SOM)*.
   - Form CMS-1893 (*Outpatient Physical Therapy – Speech Pathology Survey Report*).
   - Survey protocol.
   - Applicable State practice acts and rules for the OPT's health care professionals.

Task Two: Entrance Conference

Meet briefly with the administrator of the OPT. A lengthy meeting may delay Task 3, the Initial Tour, and disrupt the gathering of evidence. The purpose of this meeting is to announce the survey to the provider, explain the survey process and request information from

the administrator. If the administrator is not on the premises, meet with the administrator-designee. [See 485.709(b)(4).]

Request documentation from the administrator, to be provided within one hour of request (a written list may be given to the administrator):

- The name of the owner of the OPT or the names of the OPT's corporate officers.
- Services provided by the OPT. Be sure the OPT is providing, at a minimum, physical, or speech therapy and social or vocational adjustment services.
- Name and location of extension sites, if applicable. Request information regarding services provided at each extension site.
- Roster of OPT patients. At the time of the survey, the OPT must be providing all required services to a sufficient number of patients in order to determine compliance with the regulations (*SOM* 2008.A). The adequacy of the number is based on surveyor judgment.
  - Current patients.
  - Patients discharged during the past year.
- Policy and procedure manuals.
  - Clinical: all services provided by the OPT primary site and by each extension site.
  - Administrative: infection control, disaster plan, preventive maintenance, program evaluation, maintenance of clinical records and others as needed.
- Personnel files.
  - At least one file representing each discipline (a therapist and an assistant, if both are employed by the OPT) *and* each other category of employee (office clerk, therapy aide) employed by the OPT.
  - If the OPT has any contracted employees, select *additional* personnel files to represent all types of contracted employees.
- Staff schedules for the past month, current month and the next month.
- Program evaluation records for the past year.
- Contracts that the OPT has in effect (e.g., contracts with therapists to provide services under arrangements, contracts for housekeeping/linen services, contracts for pickup of biohazardous waste, etc.).
- Facility map.

During the survey, interview the administrator. (In order to quickly initiate the tour of the facility, this may be done later in the survey, rather than at the Entrance Conference.)

- Ask what services are being provided offsite and then verify that those services are also being provided at the primary site. Does the OPT provide any services in the patients' residences? Verify that the required services are currently being provided. (See Task II.B.4.)
- Determine how the OPT decides and addresses patients' social/vocational needs. What is the combination of social or vocational adjustment services provided? Which employees are involved in this process?
- Ask the administrator to describe the OPT's system for maintaining clinical records.
- If any of the offsite facilities are in another State, request a copy of the written agreement between the two State agencies that specifies which State agencies are

responsible for surveying which sites. Verify the information reviewed during Task 1, if this information was available.
- Discuss the role of the physician in the OPT. Ask how emergency medical services are provided.
- Ask the administrator to identify the full-time employee or the contracted service responsible for housekeeping services [485.725(c)(1)].

Task Three: Initial Tour

Following the entrance conference with the administrator, conduct a tour of the facility.

A. Observe interactions between OPT staff and patients.
   - Are patients treated with dignity and respect?
   - Are provisions made to maintain patient privacy during treatment, such as privacy curtains or screens? (I130)
   - If patients are being treated, are at least two persons on duty and on the premises? (I118)
   - Is the work of supportive therapy personnel supervised? (485.703 and I56, I58, I63) *Note*: Supervision is also dictated by State practice acts.

B. Observe the equipment and the treatment areas.
   - Is there enough space and equipment for the services being provided? (I57, I152, I130 and I158)
   - Are treatment tables and equipment clean? (I158 and I162)
   - Is equipment in proper working order? Verify that equipment is being properly inspected and calibrated. (I158)

C. Check the linen.
   - Is the linen adequate for the provided services? (An OPT that does not provide water therapy may require fewer towels.) Is the linen in good condition? Is the linen handled and stored in a manner that prevents the spread of infection? (I163)

D. Observe staff infection control practices (I159).
   - Are staff washing their hands? Is protective equipment (such as gloves, masks and gowns) available, if applicable? (I161)
   - Is equipment (such as whirlpools, ultrasound machines and treatment tables) being disinfected? (I161)

E. Observe the general condition of the facility.
   - Is the confidentiality of patient records protected? (I154)
   - Are the lighting, room temperature, sound levels and ventilation adequate? (I130)
   - Is there evidence of pests or rodents? (I164)
   - Are potentially hazardous materials or chemicals accessible to patients? (I117, I158))

F. Observe the location of fire extinguishers, posting of the evacuation plan and exit lighting.
   - Does the facility have evidence of recent inspection by the local fire authority? (I118)
   - Are exit and corridor lights present and supported by an emergency power source? (I118)
   - Does the OPT have an automatic fire extinguishing system and fire extinguishers? Ask a staff member to show where these are kept and to demonstrate use. (I118)
   - Does the fire alarm system alert the local fire department? [485.723(a)(5)]
   - Interview a staff member regarding fire and disaster response. Do they know the OPT policies and their role? (I167)

G. Observe accessibility of the facility. Consider the scope of services provided and the needs of the OPT's patients.
   - Are doorways, passageways and stairwells used by patients of adequate width to allow for easy movement of all patients? Are these areas free of obstruction? Do stairwells have at least one firmly attached handrail? (I118)
   - Is there at least one toilet facility that is accessible to the patients of the OPT? (I130)
   - Is an adequate reception area available? (I130)
   - Do the activities of any other occupants of the building potentially threaten the health and safety of the OPT's patients? (I118) Observe the general functioning of other tenants of the building. Do these tenants interfere with patient access to the OPT?

Task Four: Clinical Review

A. Observe patient care.
   - Ask the therapist and the patient to describe the Plan of Care. Is the Plan of Care being followed?
   - Ask the therapist or assistant to describe the interventions provided. (This may be done after the session in order to protect the patient's privacy.) The therapist should be able to relate the intervention to the patient's Plan of Care.
   - Ask the therapist to describe the purpose and mechanism of the equipment and the goal related to the patient's Plan of Care. Is necessary equipment available and being used correctly? Does the therapist demonstrate expertise? Is the therapist following the OPT's policy for use and cleaning of the equipment?
   - Do the patients receive adequate supervision and assistance during provisions of services? Is care provided in a safe manner?
   - Are patients treated with dignity and respect and is individual privacy respected? Observe therapy sessions and ask the patients.
   - Are accepted standards of practice for infection control followed? Do staff members know and follow the OPT's policies regarding infection control?

B. Review patient care files. From the list provided by the administrator, randomly select at least 10 or 10% of the patients who have received or are receiving one or more of the required services during the past year. Select some of the files of patients whose care was observed. Select some closed records. Keep in mind that many State practice acts address documentation requirements.

- Review the content of the record for patient identification, history, consent, clinical findings, assessment, Plan of Care and interim notes. Each closed record must have a completed discharge summary, including at least the patient's status, prognosis and diagnosis(es) at the time of discharge. (I57, I155, I156)
- Ensure that prior to or at the initiation of treatment, the OPT had the patient's medical history, current medical findings, physician's orders, results of prior rehabilitation, patient's awareness of condition and, if applicable, the diagnosis(es), goals and contraindications. (I49)
- Evaluation:
  - Ask the therapist or administrator to identify the patient evaluation documentation.
  - The definition of "adequate program" for physical therapy (PT) and occupational therapy (OT) services includes patient evaluation and tests of strength, balance, endurance, range of motion and activities of daily living. If each of these areas is not included in the evaluation, ask the therapist to explain. (I56)
  - The definition of "adequate program" for speech-language pathology (SLP) services includes diagnostic services. Ask the therapist to explain the selection of the diagnostic tests that were used for the patient and the relation of those tests to the patient's diagnoses and Plan of Care. (I151)
- Plan of Care (I47):
  - Review the Plan of Care. Ensure that this plan was written by the physician or by a therapist of the discipline providing the care. Confirm that its writer reviews the Plan of Care as needed, documents any revisions and reports this to the physician. Ask the therapist to indicate an example of this in the record. (I50)
  - The PT, OT or SLP Plan of Care must include goals and the type, amount, frequency and duration of the services. "Amount" does not apply to all types of therapy interventions. If this information is not obvious in the record, interview the therapist(s). (I50)
- Review the progress notes to see that the provided care and the results of the treatment interventions are accurately documented. Verify the provided services are included in the Plan of Care. (I97 and I50)

C. Social or vocational adjustment services.

- The OPT is not required to provide social or vocational adjustment services (S/VS) for its patients who are in a hospital, skilled nursing facility or nursing facility. This exception applies only to the patients of the OPT who are also patients of these three providers.
- The OPT must provide S/VS for "its patients who need them." (I67) The OPT must determine which patients need S/VS. Review the system used by the OPT to make this determination. The OPT may use a screening tool for this purpose. If so, ask the OPT for evidence the qualified personnel (see IV. C., bullets 3 and 4) developed or approved this screening tool. Verify that these qualified personnel review each page and make the final decision regarding the patients' S/VS needs. The screening tool may not be a simple statement of declination by the patient.
- Verify that qualified personnel provide social services: psychologist or social worker. (I68)

- Verify that qualified personnel provide vocational adjustment services: psychologist, social worker or vocational specialist. (I68)
- During the review of clinical records, verify that any patient determined to need S/VS services was provided these services by the OPT. Do the therapy notes indicate a S/VS need of a patient such as difficulty adjusting to a disability, transportation problems, financial limitations or grocery shopping needs? If so, how did the OPT's psychologist, social worker or vocational specialist respond? (I68)

Task 5: Review of Administration

A. Governing body. (I12)
- The governing body may be one person.
- Review administrative records to ensure the governing body has assumed full legal responsibility for the OPT.

B. Administrator. (I15)
- Review staff schedules or time records to ensure the administrator works full-time for the OPT. The full-time status will be dictated by the hours of operation of the OPT, which may be less than 40 hours per week.
- Interview the administrator and review administrative policies to ensure the governing body has:
  - Appointed the administrator.
  - Delegated OPT operation to the administrator.
  - Defined the administrator's responsibilities regarding personnel.
  - Designated an acting administrator, if applicable.

C. Patient care policies and procedures. (I22)
- Review the OPT's written policies for all patient care services provided. Verify that the OPT has current policies for the interventions observed during the survey or referenced in clinical records.
- Verify that the OPT has an active committee to establish and revise the policies and procedures. This committee must include a physician associated with the OPT and at least one therapist representing each service provided by the OPT (PT, OT or SLP). Verify that this committee evaluates the patient care policies annually.

D. Personnel files. (485.705 and I19)
- Confirm the OPT's written policies for personnel practices. Are these current and are the policies followed?
- Review the personnel files that were requested during Task 2. Confirm that staff qualifications meet the regulations detailed at 42 CFR 485.705. Verify that these files include evidence of applicable and current State licensure. The OPT's personnel policies may dictate specific certifications for certain patient care services, such as neuro-developmental techniques, manual therapy or swallowing assessment. If so, verify the qualifications of staff providing these techniques.
- Review documentation of staff training and drills regarding disaster preparedness. This training must be included in initial orientation and ongoing training. (I167)

E. Contracts, if applicable.
- Review the contracts requested during Task 2 to ensure the OPT retains professional responsibility, administrative control and supervision of the contracted services that are provided. Contracted staff must meet the OPT requirements just as salaried personnel must. (I80 and I72)
- Verify that the contract includes the effective term and a statement of the way the contract will be continued or terminated. (I80 and I72)
- The contract must not allow the contracted party to bill Medicare for the provided services. Only the OPT, as provider of the services, may bill. (I80) *Note*: This requirement does not apply to S/VS.

F. Clinical record system.
- Review the OPT's system and written policies for preparing and maintaining clinical records. (Review patient consent during Task 4.B.1.) Verify that the OPT system protects the confidentiality of and prevents unauthorized use of clinical records. (I154)
- Ensure the clinical records are kept in an organized and efficient manner, as meets the needs of the patients served by the OPT. A file cabinet with a lock may be adequate; ensure only staff have access to the key. (I154 and I157)
- Ask the administrator to explain and show evidence of the OPT's system for retaining records. (I108)

G. Infection control.
- If the OPT provides PT or OT services, review the infection control system. (I159)
  - Verify that the infection control committee includes staff representing the PT and OT services provided. (I160)
  - Review the infection control policies and records for evidence that the committee investigates, controls and prevents infections, including evidence the OPT tracks and monitors trends on patient and staff infections. (I160)
  - Determine how the OPT monitors staff compliance with infection control policies. (I160 and I161)
- Ensure that the OPT's written policy regarding aseptic technique is reviewed annually and revised as needed. (I161)

H. Emergency care. (I54)
- Verify that the OPT has an agreement with a physician to be on call in case of emergency.
- Ensure that the plan and procedures for providing emergency care at the OPT include immediate care, notification and reporting.

I. Program evaluation.
- Review the OPT's program evaluation system, including documentation provided by the administrator. (I168)
  - Verify that this system includes quarterly review of active and closed clinical records. Documentation of these reviews must include an assessment of the staff's compliance with the OPT's policies and procedures. (I169)

  - Ensure that this review was done by professionals of the disciplines who provided care to the patients whose records were reviewed. (I169)
- Review the OPT's statistical evaluation system, including documentation provided by the administrator. (I170)
  - Verify that this statistical evaluation is completed annually.
  - Interview the administrator to ensure statistics pertinent to the OPT's scope of service are evaluated.

J. Disaster preparedness.
- Review the OPT's system for reacting to a disaster, including documentation provided by the administrator. (I165)
  - Verify that the OPT's written plan addresses internal and external disasters. This plan must be developed by or approved by appropriate fire or safety experts. (I166)
  - Ensure that the written plan includes directives regarding alarm systems, fire containment, notification, records, casualties and evacuation. (I166)

Task Six: Compliance Determination

- Follow the *State Operations Manual (SOM)* and the State agency policy in determining provider compliance with Federal regulations.
- Review the evidence gathered during the survey.
- Review the regulations and identify evidence of deficient practice.
- Determine the level of deficient practice.

Task Seven: Exit Conference

As the survey nears completion, seek the administrator's agreement on a time and location for the exit conference. Ask the administrator to determine staff attendance.

Inform the OPT staff of the opportunity to provide additional or clarifying information regarding the survey findings.

Describe any deficient practice identified during the survey and relate these findings to the Conditions of Participation for OPT. Inform the administrator that the deficient practice will be presented to CMS in the Statement of Deficiencies, along with a recommendation regarding certification. Follow the State agency policy regarding the timing of and responsibility for communicating the CMS decision to the provider.

Describe the process for correction, if applicable, of the deficient practice.

Task Eight: Documentation of Findings

Follow the CMS Principles of Documentation in preparation of the Statement of Deficiencies. Include specific evidence of deficient practice gathered during the survey.

Follow the State agency's policy for processing the Statement of Deficiencies and communicating the certification recommendation to CMS.

12.2 Q&A

Frequently Asked Questions and Answers on OPTs

Q: Are State surveyors required to survey all rehabilitation extension locations?

A: State Operations Manual section 2302 requires each rehabilitation agency extension site to be surveyed. However, when a rehab agency has multiple extension sites, State survey agencies lack the funding to survey all of them. Nevertheless, the expectation is that extension locations will meet the Medicare Conditions of Participation, the same as the primary site. All proposed extension locations must be approved by the State survey agency and Medicare regional office prior to becoming operational. The SA should survey as many extension locations as it deems necessary to adequately determine the rehabilitation agency's overall compliance with the OPT/OSP CoPs.

Q: What conditions and standards need to be surveyed when an OPT provides services at an extension location?

A: The extension location must meet all applicable CoPs. The SA surveys each condition and standard in the OPT/OSP CoPs at each extension location with the following exceptions:

- 42 CFR 485.709(a) (Standard: Governing body) is based upon the evaluation of the total agency that has responsibility for the primary location as well as all extension locations. However, if there are concerns with the day-to-day operations of the extension location, assess the effectiveness of the governing body.
- Condition 485.717 (Rehabilitation Program) is applicable only to a rehabilitation agency's own patients.
- Condition 485.715 (Speech Pathology) is applicable only when speech pathology is rendered.
- Condition 485.713 (Physical Therapy Services) is applicable only when physical therapy is rendered. Refer to Section 2302—Survey of OPT/OSP extension locations.

Q: Is there a limit on the number of extension locations an OPT may have?

A: There is no limit on the number of extension locations. However, the OPT must demonstrate its ability to manage and supervise the extension locations.

Q: Is there any guidance regarding the maximum distance an OPT extension location can be from the parent location?

A: At this time criteria have not been established regarding maximum distance or driving time an extension location can be from its parent site. If there is a question about an extension location, efforts should be directed toward determining whether the approved site is able to successfully supervise the proposed extension location.

Q: If an extension location is transferred between two existing OPT providers, does this constitute a change of ownership?

A: No. The provider agreements remain with their respective owners at the "primary" OPT site. SOM §3224 provides guidance regarding the survey of existing extension locations.

Q: Will the National Provider Identifier Number have any effect on the OPT/OSP extension identifiers?

A: The National Provider Identifier Number will not be affected by the OPT/OSP extension identifiers. The goal of CMS is to have surveyors identify the actual extension locations that may have condition or standard-level deficiencies and enter the information into ASPEN under the actual extension location as opposed to the primary site.

Q: Must all required services per 42 CFR 485.717 be available at all extension locations of a rehabilitation agency?

A: No. The extension location may provide any combination of OT/PT/SLP services as long as those same services are provided at the primary site. A social worker is not expected to be at the extension location as long as the social worker has reviewed written documentation on all OPT patients receiving therapy services at that location and can make a determination regarding the need for social services.

Q: If an extension site offers, for example, whirlpool services, must the primary site also be able to provide them?

A: No. Whirlpool is a therapy modality, a therapeutic intervention provided by a therapy service. The OPT is not required to offer the same modalities at the primary site as those offered at the extension site. However, the OPT is required to offer the same services (PT, SLP, OT) at the primary site as those offered at the extension sites.

Q: What forms is the OPT required to complete when it plans to operate extension locations?

A: The 855A should be revised for each extension location.

Q: Is the social worker expected to provide services to every OPT patient?

A: No. However, the OPT regulations do require that each OPT patient *who needs* social or vocational services receive those services. The OPT must have a system in place to determine which patients do or do not need social or vocational services. A social worker is expected to have input in that process and is also expected to review written documentation on every OPT patient to determine the social service needs of the patients. (Refer to Appendix E for further detail).

Q: If an OPT has an extension location in an assisted living complex, can the therapist from the OPT and an employee from the assisted living complex fulfill the requirement that two people be on-site while treatment is being provided?

A: The regulation states "two persons are on duty…whenever a patient is being treated." In order to be on duty at the OPT, both persons would have to be employees of the OPT. So no: the assisted living facility employee would not be counted as fulfilling this requirement.

Q: If a facility is small and has a limited number of staff, is the requirement "at least two persons are on duty on the premises of the organization whenever a patient is being treated" mandatory?

A: No matter how small the OPT is, there *must* be two people on duty whenever a patient is being treated.

Q: Must screens of patients be done in a timely manner? For example, can the social worker screen patients after discharge from the OPT?

A: After discharge, a person is no longer a patient of the OPT, so services could not be provided after discharge. The OPT must provide evidence that these screenings are completed during the time of provision of patient services.

Q: Can an individual who is certified in anatomy/physiology work without direct supervision (such as athletic trainers or kinesiologists)?

A: No. Only those personnel defined as qualified (in the *statute* and regulation) may provide therapy services without direct supervision. The statute does not define athletic trainers or kinesiologists.

Q: What do we do about rehab agency providers who have been certified providing outpatient OT services and social services?

A: Subpart H of 42 CFR 485 contains the Conditions of Participation for rehabilitation agencies that are providers of outpatient physical therapy and speech-language pathology (OPT) services. These conditions must be met for the provider to continue to be certified as a rehabilitation agency. If on a recertification survey of the rehabilitation agency only OT and social services are being provided, the agency must be notified that 42 CFR §485.703 must be met. This regulation specifically states that for a rehabilitation agency to continue providing outpatient physical therapy and speech-language pathology (OPT) services, it must provide PT or SLP services and social work or vocational adjustment services. If the rehabilitation agency is not providing these services, it does not meet the definition at §485.703 and should not be recertified. This requirement hasn't changed. All new providers currently seeking certification as an OPT (rehabilitation agency) must provide physical or speech language pathology services in addition to social work or vocational adjustment service.

Q: To what extent can administrators be "shared": must an administrator of an OPT be a full-time equivalent only at the parent site, or can the position be shared among several sites (primary and several extension locations)?

A: The OPT in its entirety is considered a single entity, even if it has several extension locations. Therefore, there is only one full-time administrator position. The OPT should have policies/procedures in place explaining the responsibilities of the administrator and the administrative oversight of all the locations. When the administrator is absent, there must be a competent individual to substitute for the administrator.

Q: Are separate certifications required if SNFs are providing PT/OT outpatient therapy services when services are provided to nonresidents of the SNF?

A: At the current time, CMS management is considering its options regarding the certification for the provision of outpatient therapy services by SNFs to nonresidents.

Q: Is there a cap on outpatient therapy reimbursement?

A: There is currently a moratorium on the therapy cap at this time. It is set to expire on 01/01/06 unless Congress extends the time period.

Q: Can a rehabilitation agency provide acupuncture or Pilates services?

A: No, there is no statutory or regulatory basis for Medicare payments to acupuncturists or Pilates instructors. Also, acupuncture and Pilates are *not* covered services under the PT benefit and therefore are not part of the rehabilitation program. Nowhere in statute or regulations are acupuncturists or Pilates instructors defined.

Rehabilitation Reference Manual

Tab 13:
Forms for OPT Survey

13.1 Form CMS-1893

13.2 Form CMS-381

13.1 Form CMS-1893

OUTPATIENT PHYSICAL THERAPY — SPEECH PATHOLOGY SURVEY REPORT

42 CFR 485.703 Definitions

(a) Clinic. A facility that is established primarily to furnish outpatient physician services and that meets the following tests of physician involvement:
(1) The medical services are furnished by a group of three or more physicians practicing medicine together.
(2) A physician is present during all hours of operation of the clinic to furnish medical services, as distinguished from purely administrative services.

(b) Organization. A clinic, rehabilitation agency, or public health agency.

(c) Public health agency. An official agency established by a State or local government, the primary function of which is to maintain the health of the population served by performing environmental health services, preventive medical services, and in certain cases, therapeutic services.

(d) Rehabilitation agency. An agency that provides an integrated multidisciplinary rehabilitation program designed to upgrade the physical functioning of handicapped disabled individuals by bringing specialized rehabilitation staff together to perform as a team; and provides at least the following services: physical therapy or speech-language pathology services; social or vocational adjustment services.

(e) Supervision. Authoritative procedural guidance that is for the accomplishment of a function or activity and that includes initial direction and periodic observation of the actual performance of the function or activity; and is furnished by a qualified person whose sphere of competence encompasses the particular function or activity; and who (unless otherwise provided in this subpart) is on the premises if the person performing the function or activity does not meet the assistant level practitioner qualifications specified in 485.705.

42 CFR 485.705 Personnel qualifications.

(a) General qualification requirements. Except as specified in paragraphs (b) and (c) of this section, all personnel who are involved in the furnishing of outpatient physical therapy, occupational therapy, and speech-language pathology services directly by or under arrangements with an organization must be legally authorized (licensed or, if applicable, certified or registered) to practice by the State in which they perform the functions or actions, and must act only within the scope of their State license or State certification or registration.

(b) Exception for federally defined qualifications. The following federally defined qualifications must be met:
(1) For a physician, the qualifications and conditions as defined in section 1861(r) of the Act and the requirements in part 484 of this chapter.
(2) For a speech-language pathologist, the qualifications specified in section 1861(ll)(1) of the Act and the requirements in part 484 of this chapter.

(c) Exceptions when no State Licensing laws or State certification or registration requirements exist. If no State licensing laws or State certification or registration requirements exist for the profession, the following requirements must be met—
(1) **Administrator.** A person who has a bachelor's degree and:
(i) Has experience or specialized training in the administration of health institutions or agencies; or
(ii) Is qualified and has experience in one of the professional health disciplines.
(2) **Occupational Therapist.** A person who:
(i) Is a graduate of an occupational therapy curriculum accredited jointly by the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or
(ii) Is eligible for the National Registration Examination of the American Occupational Therapy Association; or
(iii) Has 2 years of appropriate experience as an occupational therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapist after December 31, 1977.
(3) **Occupational Therapy Assistant.** A person who:
(i) Meets the requirements for certification as an occupational therapy assistant established by the American Occupational Therapy Association; or
(ii) Has 2 years of appropriate experience as an occupational therapy assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapy assistant after December 31, 1977.
(4) **Physical Therapist.** A person who is licensed as a physical therapist by the State in which he or she is practicing, and
(i) Has graduated from a physical therapy curriculum approved by:
(a) The American Physical Therapy Association, or
(b) The Committee on Allied Health Education and Accreditation of the American Medical Association, or
(c) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association; or
(ii) Prior to January 1, 1966,
(a) Was admitted to membership by the American Physical Therapy Association, or
(b) Was admitted to registration by the American Registry of

Physical Therapists; or

(c) Has graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education; or

(i) Has 2 years of appropriate experience as a physical therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking qualification as a physical therapist after December 31, 1977; or

(ii) Was licensed or registered prior to January 1, 1966, and prior to January 1, 1970 had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy; or

(iii) If trained outside the United States,

(a) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy.

(b) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.

(5) **Physical Therapy Assistant.** A person who is licensed as a physical therapy assistant, if applicable, by the State in which practicing, and

(i) Has graduated from a 2-year college-level program approved by the American Physical Therapy Association; or

(ii) Has 2 years of appropriate experience as a physical therapy assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a physical therapy assistant after December 31, 1977.

(6) **Psychologist.** A person who:

(i) Holds a doctoral degree in psychology from a training program approved by the American Psychological Association; or

(ii) Has attained certification or licensing by the State, or non-statutory certification by the State psychological association.

(7) **Social Worker.** A person who has a master's degree from a school of social work accredited by the Council on Social Work Education, and has 1 year of social work experience in a health care setting.

(8) **Speech-language pathologist.** A person who:

(i) Meets the education and experience requirements for a Certificate of Clinical Competence in (speech pathology or audiology) granted by the American Speech-Language-Hearing Association; or

(ii) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

(9) **Vocational specialist.** A person who has a baccalaureate degree and—

(i) Two years experience in vocational counseling in a rehabilitation setting such as a sheltered workshop, State employment service agency, etc.; or

(ii) At least 18 semester hours in vocational rehabilitation educational or vocational guidance, psychology, social work, special education or personnel administration, and 1 year of experience in vocational counseling in a rehabilitation setting; or

(iii) A master's degree in vocational counseling.

(9) **Nurse practitioner.** A person who must:

(i) Possess a master's degree in nursing;

(ii) Be a registered professional nurse who is authorized by the State in which the services are furnished, to practice as a nurse practitioner in accordance with State law; and

(iii) Be certified as a nurse practitioner by the American Nurses Credentialing Center.

(10) **Clinical nurse specialist.** A person who must:

(i) Be a registered nurse who is currently licensed to practice in the State where he or she practices and be authorized to perform the services of a clinical nurse specialist in accordance with State law;

(ii) Have a master's degree in a defined clinical area of nursing from an accredited educational institution; or

(iii) Be certified as a clinical nurse specialist by the American Nurses Credentialing Center.

(11) **Physician Assistant.** A person who:

(i) Has graduated from a physician assistant educational program that is accredited by the National Commission on Accreditation of Allied Health Education Programs; and

(ii) Has passed the national certification examination that is certified by the National Commission on Certification of Physician Assistants; and

(iii) Is licensed by the State as a physician assistant to practice as a physician assistant.

FORM APPROVED
OMB NO. 0938-0065

OUTPATIENT PHYSICAL THERAPY — SPEECH PATHOLOGY SURVEY REPORT

PROVIDER NUMBER I1	SURVEY DATE I2

NAME OF ORGANIZATION	STREET NUMBER	CITY	COUNTY	STATE	ZIP CODE

SURVEYED BY I3

TYPE OF SURVEY I4

- ☐ INITIAL SURVEY
- ☐ RESURVEY

SURVEYOR'S PROFESSIONAL TITLE

ORGANIZATION MEETS DEFINITION OF:

- ☐ CLINIC
- ☐ REHABILITATION AGENCY
- ☐ PUBLIC HEALTH AGENCY

I6

LIST ADDITIONAL PHYSICAL THERAPISTS

NAME	I.D. NUMBER	TITLE

CODE	STANDARDS	MET	NOT MET	N/A	EXPLANATORY STATEMENT
I7	**§485.707 Compliance with Federal, State and Local Laws** The organization and its staff are in compliance with all applicable Federal, State, and local laws and regulations.				EXPIRATION DATE OF LICENSURE, IF APPLICABLE _____
I8	**(a) Licensure of organization.** In any State in which State or applicable local law provides for the licensing of organizations, a clinic, rehabilitation agency, or public health agency is licensed in accordance with applicable laws.				
I9	**(b) Licensure or registration of personnel.** Staff of the organization are licensed or registered in accordance with applicable laws.				
I11	**§485.709 Administrative Management** The clinic or rehabilitation agency has an effective governing body that is legally responsible for the conduct of the clinic or rehabilitation agency. The governing body designates an administrator, and establishes administrative policies.				
I12	**(a) Governing body.** There is a governing body (or designated person(s) so functioning) which assumes full legal responsibility for the overall conduct of the clinic or rehabilitation agency and for compliance with applicable laws and regulations. The name of the owner(s) of the clinic or rehabilitation agency is fully disclosed to the State agency. In the case of corporations, the names of the corporate officers are made known.				

NAME

CODE	STANDARDS	MET	NOT MET	N/A	EXPLANATORY STATEMENT
I15	**(b) Administrator.** The governing body — (1) Appoints a qualified full time administrator; (2) Delegates to the administrator the internal operation of the clinic or rehabilitation agency in accordance with written policies; (3) Defines clearly the administrator's responsibilities for procurement and direction of personnel; and (4) Designates a competent individual to act in the temporary absence of the administrator.				
I19	**(c) Personnel policies.** Personnel practices are supported by appropriate written personnel policies that are kept current. Personnel records include the qualifications of all professional and assistant level personnel, as well as evidence of State licensure if applicable.				
I22	**(d) Patient care policies.** Patient care practices and procedures are supported by written policies established by a group of professional personnel including one or more physicians associated with the clinic or rehabilitation agency, one or more qualified physical therapists (if physical therapy services are provided), and one or more qualified speech pathologists (if speech pathology services are provided). The policies govern the outpatient physical therapy and/or speech pathology services and related services that are provided. These policies are evaluated at least annually by the group of professional personnel, and revised as necessary based upon this evaluation.				
I47	**§485.711 Plan of care and physician involvement** For each patient in need of outpatient physical therapy or speech pathology services there is a written plan of care established and periodically reviewed by a physician, or by a physical therapist or speech pathologist respectively. The organization has a physician available to furnish necessary medical care in case of emergency.				

NAME

CODE	STANDARDS	MET	NOT MET	N/A	EXPLANATORY STATEMENT
I49	**(a) Medical history and prior treatment.** The following are obtained by the organization before or at the time of initiation of treatment: (1) The patient's significant past history. (2) Current medical findings, if any. (3) Diagnosis(es), if established. (4) Physician's orders, if any. (5) Rehabilitation goals, if determined. (6) Contraindications, if any. (7) The extent to which the patient is aware of the diagnosis(es) and prognosis. (8) If appropriate, the summary of treatment furnished and results achieved during previous periods of rehabilitation services or institutionalization.				
I50	**(b) Plan of care.** (1) For each patient there is a written plan of care established by the physician; or (i) by the physical therapist; *or* (ii) by the speech-language pathologist who furnishes the services. (2) The plan of care for physical therapy or speech pathology services indicates anticipated goals and specifies for those services the — (i) Type; (iii) Frequency; and (ii) Amount; (iv) Duration. (3) The plan of care and results of treatment are reviewed by the physician or by the individual who established the plan at least as often as the patient's condition requires, and the indicated action taken. (For Medicare patients, the plan must be reviewed by a physician, nurse practitioner, clinical nurse specialist, or physician assistant at least every 30 days, in accordance with §410.61 (e) of this chapter.) (4) Changes in the plan of care are noted in the clinical record. If the patient has an attending physician, the				

NAME

CODE	STANDARDS	MET	NOT MET	N/A	EXPLANATORY STATEMENT
	therapist or speech-language pathologist who furnishes the services promptly notifies him or her of any change in the patient's condition or in the plan of care.				
I54	**(c) Emergency care.** The organization provides for one or more doctors of medicine or osteopathy to be available on call to furnish necessary medical care in the case of emergency. The established procedures to be followed by personnel in an emergency cover immediate care of the patient, persons to be notified, and reports to be prepared.				
I55	**§485.713 Physical Therapy Services** If the organization offers physical therapy services, it provides an adequate program of physical therapy and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.				
I56	**(a) Adequate program.** (1) The organization is considered to have an adequate outpatient physical therapy program if it can: (i) Provide services using therapeutic exercise and the modalities of heat, cold, water, and electricity; (ii) Conduct patient evaluations; and (iii) Administer tests and measurements of strength, balance, endurance, range of motion, and activities of daily living. (2) A qualified physical therapist is present or readily available to offer supervision when a physical therapist assistant furnishes services. (i) If a qualified physical therapist is not on the premises during all hours of operation, patients are scheduled so as to ensure that the therapist is present when special skills are needed, for example, evaluation and reevaluation. (ii) When a physical therapist assistant furnishes services off the organization's premises, those services are supervised by a qualified physical therapist who makes an onsite supervisory visit at least once every 30 days.				

NAME

CODE	STANDARDS	MET	NOT MET	N/A	EXPLANATORY STATEMENT
I57	**(b) Facilities and equipment.** The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of disabilities it accepts for service.				
I58	**(c) Personnel qualified to provide physical therapy services.** Physical therapy services are provided by, or under the supervision of, a qualified physical therapist. The number of qualified physical therapists and qualified physical therapist assistants is adequate for the volume and diversity of physical therapy services offered. A qualified physical therapist is on the premises or readily available during the operating hours of the organization.				
I63	**(d) Supportive personnel.** If personnel are available to assist qualified physical therapists by performing services incident to physical therapy that do not require professional knowledge and skill, these personnel are instructed in appropriate patient care services by qualified physical therapists who retain responsibility for the treatment prescribed by the attending physician.				
I150	**§485.715 Speech pathology services** If speech pathology services are offered, the organization provides an adequate program of speech pathology and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.				
I151	**(a) Adequate program.** The organization is considered to have an adequate outpatient speech pathology program if it can provide the diagnostic and treatment services to effectively treat speech disorders.				
I152	**(b) Facilities and equipment.** The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of speech disorders it accepts for service.				
I153	**(c) Personnel qualified to provide speech pathology services.** Speech pathology services are given or supervised by a qualified speech pathologist and the number of qualified speech pathologists is adequate for the volume and diversity of speech pathology services offered.				

NAME

CODE	STANDARDS	MET	NOT MET	N/A	EXPLANATORY STATEMENT
	At least one qualified speech pathologist is present at all times when speech pathology services are furnished.				
I67	**§485.717 Rehabilitation program** This condition and its standards apply only to a rehabilitation agency's own patients, not to patients of hospitals, skilled nursing facilities (SNFs), or Medicaid nursing facilities (NFs) to whom the agency furnishes services. (The hospital, SNF, or NF is responsible for ensuring that qualified staff furnish services for which they arrange or contract for their patients.) The rehabilitation agency provides, in addition to physical therapy and speech-language pathology services, social or vocational adjustment services to all of its patients who need them. The agency provides for special qualified staff to evaluate the social and vocational factors, to counsel and advise on the social or vocational problems that arise from the patient's illness or injury, and to make appropriate referrals for needed services.				
I68	**(a) Qualification of staff.** The agency's social or vocational adjustment services are furnished as appropriate, by qualified psychologists, qualified social workers, or qualified vocational specialists. Social or vocational adjustment services may be performed by a qualified psychologist or qualified social worker. Vocational adjustment services may be furnished by a qualified vocational specialist.				
I72	**(b) Arrangements for social or vocational adjustment services.** (1) If a rehabilitation agency does not provide social or vocational adjustment services through salaried employees, it may provide those services through a written contract with others who meet the requirements and responsibilities set forth in this subpart for salaried personnel. (2) The contract must specify the term of the contract and the manner of termination or renewal, and provide that the agency retains responsibility for the control and supervision of the services.				

NAME

CODE	STANDARDS	MET	NOT MET	N/A	EXPLANATORY STATEMENT
I79	**§485.719 Arrangements for physical therapy and speech pathology services to be performed by other than salaried organization personnel** If an organization provides outpatient physical therapy or speech pathology services under an arrangement with others, the services are to be furnished in accordance with the terms of a written contract, which provides that the organization retains professional and administrative responsibility for, and control and supervision of, the services.				
I80	**(a) Contract provisions.** The contract: (1) Specifies the term of the contract and the manner of termination or renewal; (2) Requires that personnel who furnish the services meet the requirements that are set forth in this subpart for salaried personnel; and (3) Provides that the contracting outside resource may not bill the patient or Medicare for the services. This limitation is based on section 1861(w)(1) of the Act, which provides that — (i) Only the provider may bill the beneficiary for covered services furnished under arrangements; and (ii) Receipt of Medicare payment by the provider, on behalf of an entitled individual, discharges the liability of the individual or any other person to pay for those services.				
I96	**§485.721 Clinical records** The organization maintains clinical records on all patients in accordance with accepted professional standards and practices. The clinical records are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information.				
I154	**(a) Protection of clinical record information.** The organization recognizes the confidentiality of clinical record information and provides safeguards against loss, destruction, or unauthorized use. Written procedures govern the use and removal of records and the conditions for release of information. The patient's written consent is required for release of information not authorized by law.				

NAME

CODE	STANDARDS	MET	NOT MET	N/A	EXPLANATORY STATEMENT
I97	**(b) Content.** The clinical record contains sufficient information to identify the patient clearly, to justify the diagnosis(es) and treatment, and to document the results accurately. All clinical records contain the following general categories of data: (1) Documented evidence of the assessment of the needs of the patient, of an appropriate plan of care, and of the care and services furnished. (2) Identification data and consent forms. (3) Medical history. (4) Report of physical examinations, if any. (5) Observations and progress notes. (6) Reports of treatments and clinical findings. (7) Discharge summary including final diagnosis(es) and prognosis.				
I155	**(c) Completion of records and centralization of reports.** Current clinical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's clinical record. Each physician signs the entries that he or she makes in the clinical record.				
I108	**(d) Retention and preservation.** Clinical records are retained for at least: (1) The period determined by the respective State statute, or the statute of limitations in the State, or (2) In the absence of a State statute: (i) Five years after the date of discharge, *or* (ii) In the case of a minor, 3 years after the patient becomes of age under State law or 5 years after the date of discharge, whichever is longer.				
I156	**(e) Indexes.** Clinical records are indexed at least according to name of patient to facilitate acquisition of statistical medical information and retrieval of records for research or administrative action.				

NAME

CODE	STANDARDS	MET	NOT MET	N/A	EXPLANATORY STATEMENT
I157	**(f) Location and facilities.** The organization maintains adequate facilities and equipment, conveniently located, to provide efficient processing of clinical records (reviewing, indexing, filing, and prompt retrieval).				
I117	**§485.723 Physical Environment** The building housing the organization is constructed, equipped, and maintained to protect the health and safety of patients, personnel, and the public and provides a functional, sanitary, and comfortable environment.				
I118	**(a) Safety of patients.** The organization satisfies the following requirements: (1) It complies with all applicable State and local building, fire, and safety codes. (2) Permanently attached automatic fire-extinguishing systems of adequate capacity are installed in all areas of the premises considered to have special fire hazards. Fire extinguishers are conveniently located on each floor of the premises. Fire regulations are prominently posted. (3) Doorways, passageways and stairwells negotiated by patients are: (i) Of adequate width to allow for easy movement of all patients (including those on stretchers or in wheelchairs), (ii) free from obstruction at all times, *and* (iii) in the case of stairwells, equipped with firmly attached handrails on at least one side. (4) Lights are placed at exits and in corridors used by patients and are supported by an emergency power source. (5) A fire alarm system with local alarm capability and, where applicable, an emergency power source is functional. (6) At least two persons are on duty on the premises of the organization whenever a patient is being treated. (7) No occupancies or activities undesirable or injurious to the health and safety of patients are located in the building.				

NAME

CODE	STANDARDS	MET	NOT MET	N/A	EXPLANATORY STATEMENT
I158	**(b) Maintenance of equipment, building, and grounds.** The organization establishes a written preventive-maintenance program to ensure that: (1) The equipment is operative and is properly calibrated, *and* (2) The interior and exterior of the building are clean and orderly and maintained free of any defects that are a potential hazard to patients, personnel, and the public.				
I130	**(c) Other environmental considerations.** The organization provides a functional, sanitary, and comfortable environment for patients, personnel, and the public. (1) Provision is made for adequate and comfortable lighting levels in all areas; limitation of sounds at comfort levels; a comfortable room temperature; and adequate ventilation through windows, mechanical means, or a combination of both. (2) Toilet rooms, toilet stalls, and lavatories are accessible and constructed so as to allow use by nonambulatory and semiambulatory individuals. (3) Whatever the size of the building, there is an adequate amount of space for the services provided and disabilities treated, including reception area, staff space, examining room, treatment areas, and storage.				
I159	**§485.725 Infection Control** The organization that provides outpatient physical therapy services establishes an infection-control committee of representative professional staff with responsibility for overall infection control. All necessary housekeeping and maintenance services are provided to maintain a sanitary and comfortable environment and to help prevent the development and transmission of infection.				
I160	**(a) Infection-control committee.** The infection-control committee establishes policies and procedures for investigating, controlling, and preventing infections in the organization and monitors staff performance to ensure that the policies and procedures are executed.				

NAME

CODE	STANDARDS	MET	NOT MET	N/A	EXPLANATORY STATEMENT
I161	**(b) Aseptic and isolation techniques.** All personnel follow written procedures for effective aseptic techniques. The procedures are reviewed annually and revised if necessary to improve them.				
I162	**(c) Housekeeping.** (1) The organization employs sufficient housekeeping personnel and provides all necessary equipment to maintain a safe, clean, and orderly interior. A full-time employee is designated as the one responsible for the housekeeping services and for supervision and training of housekeeping personnel. (2) An organization that has a contract with an outside resource for housekeeping services may be found to be in compliance with this standard provided the organization or outside resource or both meet the requirements of the standard.				
I163	**(d) Linen.** The organization has available at all times a quantity of linen essential for proper care and comfort of patients. Linens are handled, stored, processed, and transported in such a manner as to prevent the spread of infection.				
I164	**(e) Pest control.** The organization premises are maintained free from insects and rodents through operation of a pest-control program.				
I165	**§485.727 Disaster preparedness** The organization has a written plan, periodically rehearsed with procedures to be followed in the event of an internal or external disaster and for the care of casualties (patients and personnel) arising from a disaster.				
I166	**(a) Disaster plan.** The organization has a written plan in operation, with procedures to be followed in the event of fire, explosion, or other disaster. The plan is developed and maintained with the assistance of qualified fire, safety, and other appropriate experts, and includes: (1) Transfer of casualties and records; (2) The location and use of alarm systems and signals; (3) Methods of containing fire;				

NAME

CODE	STANDARDS	MET	NOT MET	N/A	EXPLANATORY STATEMENT
	(4) Notification of appropriate persons; and (5) Evacuation routes and procedures.				
I167	**(b) Staff training and drills.** All employees are trained, as part of their employment orientation, in all aspects of preparedness for any disaster. The disaster program includes orientation and ongoing training and drills for all personnel in all procedures so that each employee promptly and correctly carries out his assigned role in case of a disaster.				
I168	**§485.729 Program evaluation** The organization has procedures that provide for a systematic evaluation of its total program to ensure appropriate utilization of services and to determine whether the organization's policies are followed in providing services to patients through employees or under arrangements with others.				
I169	**(a) Clinical record review.** A sample of active and closed clinical records is reviewed quarterly by the appropriate health professionals to ensure that established policies are followed in providing services.				
I170	**(b) Annual statistical evaluation.** An evaluation is conducted annually of statistical data such as number of different patients treated, number of patient visits, condition on admission and discharge, number of new patients, number of patients by diagnosis(es), sources of referral, number and cost of units of service by treatment given, and total staff days or work hours by discipline.				

According to the Paperwork Reduction of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0065. The time required to complete this information collection is estimated to average 1.75 hours per response, including the time to review instructions, searching existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimates(s) or suggestions for improving this form, please write to: CMS, Attn: PRA Reports Clearance Officer, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

13.2 Form CMS-381

FORM APPROVED
OMB NO. 0938-0273

MODEL LETTER REQUESTING IDENTIFICATION OF EXTENSION UNITS

Dear (Administrator)

Our records indicate that the facility below is approved in the Medicare program as an outpatient physical therapy/speech pathology provider (OPT/OSP). Providers, in addition to rendering services on their already approved premises at times render services on the premises of other institutions (e.g., skilled nursing facilities). If the OPT/OSP bills the Medicare program for these services and renders these services in an area within the institution set aside for rehabilitation care, these premises are considered extension units of the OPT/OSP. In addition, a premise owned or rented by the OPT/OSP and from which services are rendered, is also considered an extension unit of the OPT/OSP.

Extension units are considered part of the OPT/OSP and are subject to the same approval policy as is applicable to the OPT/OSP. In addition to meeting applicable sections of the conditions of participation for all outpatient physical therapy/speech pathology providers, these extension units fall under the OPT/OSP provider agreement and are identified under the OPT/OSP provider number.

Below is a form for the purpose of identifying the extension units of your OPT/OSP. Please complete this form and return it to the State agency listed below within 30 days. If at any time following completion of this form you plan to delete or add a service or close or add an extension unit, please notify the State agency immediately. If you have any questions or problems, please call the State agency.

STATE AGENCY NAME	STATE AGENCY ADDRESS
FACILITY NAME	SIGNATURE OF AUTHORIZED STATE AGENCY INDIVIDUAL

IDENTIFICATION OF EXTENSION UNITS OF OPT/OSP PROVIDERS

Indicate the name, address and provider number of your approved outpatient physical therapy/speech pathology provider (OPT/OSP) and complete, as applicable, section A or B.

NAME	PROVIDER NO.
ADDRESS	TELEPHONE (Area Code)

A. Where services are rendered off the above premises and on the premises of other institutions (including those owned and/or rented by the OPT/OSP), list the name and address of these institutions. If more space is needed, attach an additional sheet of paper.

NAME	ADDRESS
NAME	ADDRESS
NAME	ADDRESS

B. List the number of OPT/OSP services rendered from the premises of any extension unit(s).

_____ OPT _____ OSP _____ Both

List the number of OPT/OSP services rendered from your primary site.

_____ OPT _____ OSP _____ Both

Whoever knowingly and willfully makes or causes to be made a false statement may be prosecuted under applicable Federal or State laws. In addition, knowingly and willfully failing to fully and accurately disclose the information requested may result in a denial of a request to participate, or where the entity already participates, a termination of its agreement or contract with the State agency or the Secretary, as appropriate.

SIGNATURE OF AUTHORIZED PERSON	TITLE	DATE

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid 0MB control number. The valid 0MB control number for this information collection is 0938-0273. The time required to complete this information collection is estimated to average 15 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection, If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, Mailstop N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Rehabilitation Reference Manual

Tab 14: References for OPT Survey

14.1 *Code of Federal Regulations*

14.2 *Federal Register*

14.3 Survey & Certification Memoranda

14.4 Social Security Act, Sections 1861(g) and (p)

14.5 *Medicare Benefit Policy Manual*, Chapter 15

14.6 Other Print and Online References

14.1 *Code of Federal Regulations*

42 CFR 410.59–62
42 CFR 485.701–729

(D) Absence of three negative or any Pap smears within the previous 7 years.

(ii) High risk factor for vaginal cancer: DES (diethylstilbestrol)-exposed daughters of women who took DES during pregnancy.

(3) *More frequent screening for women of childbearing age.* Subject to the limitation as specified in paragraph (b)(4) of this section, payment may be made for a screening pelvic examination performed more frequently than once every 24 months if the test is performed by a physician or other practitioner as specified in paragraph (a) of this section for a woman of childbearing age who has had an examination that indicated the presence of cervical or vaginal cancer or other abnormality during any of the preceding 3 years. The term "woman of childbearing age" means a woman who is premenopausal, and has been determined by a physician, or a qualified practitioner, as specified in paragraph (a) of this section, to be of childbearing age, based on her medical history or other findings.

(4) *Limitation applicable to women at high risk and those of childbearing age.* Payment is not made for a screening pelvic examination for women considered to be at high risk (under any of the criteria described in paragraph (b)(2) of this section), or who qualify for coverage under the childbearing provision (under the criteria described in paragraph (b)(3) of this section) more frequently than once every 11 months after the month that the last screening pelvic examination covered by Medicare was performed.

[62 FR 59101, Oct. 31, 1997; 63 FR 4596, Jan. 30, 1998, as amended at 66 FR 55329, Nov. 1, 2001]

§410.57 Pneumococcal vaccine and flu vaccine.

(a) Medicare Part B pays for pneumococcal vaccine and its administration when reasonable and necessary for the prevention of disease, if the vaccine is ordered by a doctor of medicine or osteopathy.

(b) Medicare Part B pays for the influenza virus vaccine and its administration.

[63 FR 35066, June 26, 1998]

§410.58 Additional services to HMO and CMP enrollees.

Services not usually covered under Medicare Part B may be covered as medical and other health services if they are furnished to an enrollee of an HMO or a CMP and the following conditions are met:

(a) The services are—

(1) Furnished by a physician assistant or nurse practitioner as defined in §491.2 of this chapter, or are incident to services furnished by such a practitioner; or

(2) Furnished by a clinical psychologist as defined in §417.416 of this chapter to an enrollee of an HMO or CMP that participates in Medicare under a risk-sharing contract, or are incident to those services.

(b) The services are services that would be covered under Medicare Part B if they were furnished by a physician or as incident to a physician's professional services.

§410.59 Outpatient occupational therapy services: Conditions.

(a) *Basic rule.* Medicare Part B pays for outpatient occupational therapy services if they meet the following conditions:

(1) They are furnished to a beneficiary while he or she is under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine.

(2) They are furnished under a written plan of treatment that meets the requirements of §410.61.

(3) They are furnished—

(i) By a provider as defined in §489.2 of this chapter, or by others under arrangements with, and under the supervision of, a provider; or

(ii) By or under the personal supervision of an occupational therapist in private practice as described in paragraph (c) of this section.

(b) *Outpatient occupational therapy services furnished to certain inpatients of a hospital or a CAH or SNF.* Medicare Part B pays for outpatient occupational therapy services furnished to an inpatient of a hospital, CAH, or SNF who requires them but who has exhausted or is otherwise ineligible for benefit days under Medicare Part A.

(c) *Special provisions for services furnished by occupational therapists in private practice.*

(1) *Basic qualifications.* In order to qualify under Medicare as a supplier of outpatient occupational therapy services, each individual occupational therapist in private practice must meet the following requirements:

(i) Be legally authorized (if applicable, licensed, certified, or registered) to engage in the private practice of occupational therapy by the State in which he or she practices, and practice only within the scope of his or her license, certification, or registration.

(ii) Engage in the private practice of occupational therapy on a regular basis as an individual, in one of the following practice types:

(A) An unincorporated solo practice.

(B) A partnership or unincorporated group practice.

(C) An unincorporated solo practice, partnership, or group practice, or a professional corporation or other incorporated occupational therapy practice.

(D) An employee of a physician group.

(E) An employee of a group that is not a professional corporation.

(iii) Bill Medicare only for services furnished in his or her private practice office space, or in the patient's home. A therapist's private practice office space refers to the location(s) where the practice is operated, in the State(s) where the therapist (and practice, if applicable) is legally authorized to furnish services, during the hours that the therapist engages in practice at that location. When services are furnished in private practice office space, that space must be owned, leased, or rented by the practice and used for the exclusive purpose of operating the practice. A patient's home does not include any institution that is a hospital, an CAH, or a SNF.

(iv) Treat individuals who are patients of the practice and for whom the practice collects fees for the services furnished.

(2) *Supervision of occupational therapy services.* Occupational therapy services are performed by, or under the personal supervision of, the occupational therapist in private practice. All services not performed personally by the therapist must be performed by employees of the practice, personally supervised by the therapist, and included in the fee for the therapist's services.

(d) *Excluded services.* No service is included as an outpatient occupational therapy service if it would not be included as an inpatient hospital service if furnished to a hospital or CAH inpatient.

(e) *Annual limitation on incurred expenses.* (1) Amount of limitation. (i) In 1999, 2000, and 2001, no more than $1,500 of allowable charges incurred in a calendar year for outpatient occupational therapy services are recognized incurred expenses.

(ii) In 2002 and thereafter, the limitation is determined by increasing the limitation in effect in the previous calendar year by the increase in the Medicare Economic Index for the current year.

(2) For purposes of applying the limitation, outpatient occupational therapy includes:

(i) Except as provided in paragraph (e)(3) of this section, outpatient occupational therapy services furnished under this section;

(ii) Outpatient occupational therapy services furnished by a comprehensive outpatient rehabilitation facility;

(iii) Outpatient occupational therapy services furnished by a physician or incident to a physician's service;

(iv) Outpatient occupational therapy services furnished by a nurse practitioner, clinical nurse specialist, or physician assistant or incident to their services.

(3) For purposes of applying the limitation, outpatient occupational therapy services excludes services furnished by a hospital directly or under arrangements.

[63 FR 58906, Nov. 2, 1998, as amended at 67 FR 80040, Dec. 31, 2002]

§ 410.60 Outpatient physical therapy services: Conditions.

(a) *Basic rule.* Medicare Part B pays for outpatient physical therapy services if they meet the following conditions:

(1) They are furnished to a beneficiary while he or she is under the care

of a physician who is a doctor of medicine, osteopathy, or podiatric medicine.

(2) They are furnished under a written plan of treatment that meets the requirements of §410.61.

(3) They are furnished—

(i) By a provider as defined in §489.2 of this chapter, or by others under arrangements with, and under the supervision of, a provider; or

(ii) By or under the personal supervision of a physical therapist in private practice as described in paragraph (c) of this section.

(b) *Outpatient physical therapy services furnished to certain inpatients of a hospital or a CAH or SNF.* Medicare Part B pays for outpatient physical therapy services furnished to an inpatient of a hospital, CAH, or SNF who requires them but who has exhausted or is otherwise +ineligible for benefit days under Medicare Part A.

(c) *Special provisions for services furnished by physical therapists in private practice.* (1) *Basic qualifications.* In order to qualify under Medicare as a supplier of outpatient physical therapy services, each individual physical therapist in private practice must meet the following requirements:

(i) Be legally authorized (if applicable, licensed, certified, or registered) to engage in the private practice of physical therapy by the State in which he or she practices, and practice only within the scope of his or her license, certification, or registration.

(ii) Engage in the private practice of physical therapy on a regular basis as an individual, in one of the following practice types:

(A) An unincorporated solo practice.

(B) An unincorporated partnership or unincorporated group practice.

(C) An unincorporated solo practice, partnership, or group practice, or a professional corporation or other incorporated physical therapy practice.

(D) An employee of a physician group.

(E) An employee of a group that is not a professional corporation.

(iii) Bill Medicare only for services furnished in his or her private practice office space, or in the patient's home. A therapist's private practice office space refers to the location(s) where the practice is operated, in the State(s) where the therapist (and practice, if applicable) is legally authorized to furnish services, during the hours that the therapist engages in practice at that location. When services are furnished in private practice office space, that space must be owned, leased, or rented by the practice and used for the exclusive purpose of operating the practice. A patient's home does not include any institution that is a hospital, a CAH, or a SNF.

(iv) Treat individuals who are patients of the practice and for whom the practice collects fees for the services furnished.

(2) *Supervision of physical therapy services.* Physical therapy services are performed by, or under the personal supervision of, the physical therapist in private practice. All services not performed personally by the therapist must be performed by employees of the practice, personally supervised by the therapist, and included in the fee for the therapist's services.

(d) *Excluded services.* No service is included as an outpatient physical therapy service if it would not be included as an inpatient hospital service if furnished to a hospital or CAH inpatient.

(e) *Annual limitation on incurred expenses.* (1) Amount of limitation. (i) In 1999, 2000, and 2001, no more than $1,500 of allowable charges incurred in a calendar year for outpatient physical therapy services are recognized incurred expenses.

(ii) In 2002 and thereafter, the limitation shall be determined by increasing the limitation in effect in the previous calendar year by the increase in the Medicare Economic Index for the current year.

(2) For purposes of applying the limitation, outpatient physical therapy includes:

(i) Except as provided in paragraph (e)(3) of this section, outpatient physical therapy services furnished under this section;

(ii) Except as provided in paragraph (e)(3) of this section outpatient speech-language pathology services furnished under §410.62;

(iii) Outpatient physical therapy and speech-language pathology services

furnished by a comprehensive outpatient rehabilitation facility;

(iv) Outpatient physical therapy and speech-language pathology services furnished by a physician or incident to a physician's service;

(v) Outpatient physical therapy and speech-language pathology services furnished by a nurse practitioner, clinical nurse specialist, or physician assistant or incident to their services.

(3) For purposes of applying the limitation, outpatient physical therapy excludes services furnished by a hospital or CAH directly or under arrangements.

[63 FR 58906, Nov. 2, 1998, as amended at 67 FR 80041, Dec. 31, 2002]

§ 410.61 Plan of treatment requirements for outpatient rehabilitation services.

(a) *Basic requirement.* Outpatient rehabilitation services (including services furnished by a qualified physical or occupational therapist in private practice), must be furnished under a written plan of treatment that meets the requirements of paragraphs (b) through (e) of this section.

(b) *Establishment of the plan.* The plan is established before treatment is begun by one of the following:

(1) A physician.

(2) A physical therapist who furnishes the physical therapy services.

(3) A speech-language pathologist who furnishes the speech-language pathology services.

(4) An occupational therapist who furnishes the occupational therapy services.

(5) A nurse practitioner, a clinical nurse specialist, or a physician assistant.

(c) *Content of the plan.* The plan prescribes the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology services to be furnished to the individual, and indicates the diagnosis and anticipated goals.

(d) *Changes in the plan.* Any changes in the plan—

(1) Are made in writing and signed by one of the following:

(i) The physician.

(ii) The physical therapist who furnishes the physical therapy services.

(iii) The occupational therapist that furnishes the occupational therapy services.

(iv) The speech-language pathologist who furnishes the speech-language pathology services.

(v) A registered professional nurse or a staff physician, in accordance with oral orders from the physician, physical therapist, occupational therapist, or speech-language pathologist who furnishes the services.

(vi) A nurse practitioner, a clinical nurse specialist, or a physician assistant.

(2) The changes are incorporated in the plan immediately.

(e) *Review of the plan.* (1) The physician reviews the plan as often as the individual's condition requires, but at least every 30 days.

(2) Each review is dated and signed by the physician who performs it.

[53 FR 6638, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988, as amended at 54 FR 38680, Sept. 20, 1989; 54 FR 46614, Nov. 6, 1989. Redesignated at 56 FR 8854, Mar. 1, 1991; 56 FR 23022, May 20, 1991; 63 FR 58907, Nov. 2, 1998; 67 FR 80040, Dec. 31, 2002]

§ 410.62 Outpatient speech-language pathology services: Conditions and exclusions.

(a) *Basic rule.* Medicare Part B pays for outpatient speech pathology services if they meet the following conditions:

(1) They are furnished to a beneficiary while he or she is under the care of a physician who is a doctor of medicine or osteopathy.

(2) They are furnished under a written plan of treatment that—

(i) Is established by a physician or, effective January 1, 1982, by either a physician or the speech pathologist who will provide the services to the particular individual;

(ii) Is periodically reviewed by a physician; and

(iii) Meets the requirements of § 410.63.

(3) They are furnished by a provider as defined in § 489.2 of this chapter or by others under arrangements with, or under the supervision of, a provider.

(b) *Outpatient speech pathology services to certain inpatients of a hospital, CAH, or SNF.* Medicare Part B pays for outpatient speech pathology services

furnished to an inpatient of a hospital, CAH, or SNF who requires them but has exhausted or is otherwise ineligible for benefit days under Medicare Part A.

(c) *Excluded services.* No service is included as an outpatient speech pathology service if it would not be included as an inpatient hospital service if furnished to a hospital or CAH inpatient.

(d) *Limitation.* After 1998, outpatient speech-language pathology services are subject to the limitation in §410.60(e).

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988; 56 FR 8852, Mar. 1, 1991; 56 FR 23022, May 20. 1991; 58 FR 30668, May 26, 1993; 63 FR 58907, Nov. 2, 1998]

§410.63 Hepatitis B vaccine and blood clotting factors: Conditions.

Notwithstanding the exclusion from coverage of vaccines (see §405.310 of this chapter) and self-administered drugs (see §410.29), the following services are included as medical and other health services covered under §410.10, subject to the specified conditions:

(a) *Hepatitis B vaccine: Conditions.* Effective September 1, 1984, hepatitis B vaccinations that are reasonable and necessary for the prevention of illness for those individuals who are at high or intermediate risk of contracting hepatitis B as listed below:

(1) *High risk groups.* (i) End-Stage Renal Disease (ESRD) patients;

(ii) Hemophiliacs who receive Factor VIII or IX concentrates;

(iii) Clients of institutions for the mentally retarded;

(iv) Persons who live in the same household as a hepatitis B carrier;

(v) Homosexual men;

(vi) Illicit injectable drug abusers; and

(vii) Pacific Islanders (that is, those Medicare beneficiaries who reside on Pacific islands under U.S. jurisdiction, other than residents of Hawaii).

(2) *Intermediate risk groups.* (i) Staff in institutions for the mentally retarded and classroom employees who work with mentally retarded persons;

(ii) Workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work (including workers who work outside of a hospital and have frequent contact with blood or other infectious secretions); and

(iii) Heterosexually active persons with multiple sexual partners (that is, those Medicare beneficiaries who have had at least two documented episodes of sexually transmitted diseases within the preceding 5 years).

(3) *Exception.* Individuals described in paragraphs (a) (1) and (2) of this section are not considered at high or intermediate risk of contracting hepatitis B if they have undergone a prevaccination screening and have been found to be currently positive for antibodies to hepatitis B.

(b) *Blood clotting factors.* Effective July 18, 1984, blood clotting factors to control bleeding for hemophilia patients competent to use these factors without medical or other supervision, and items related to the administration of those factors. The amount of clotting factors covered under this provision is determined by the carrier based on the historical utilization pattern or profile developed by the carrier for each patient, and based on consideration of the need for a reasonable reserve supply to be kept in the home in the event of emergency or unforeseen circumstance.

[55 FR 22790, June 4, 1990; 55 FR 31186, Aug. 1, 1990]

§410.66 Emergency outpatient services furnished by a nonparticipating hospital and services furnished in Mexico or Canada.

Conditions for payment of emergency outpatient services furnished by a nonparticipating U.S. hospital and for services furnished in Mexico or Canada are set forth in subparts G and H of part 424 of this chapter.

[53 FR 6634, Mar. 1, 1988; 53 FR 12945, Apr. 20, 1988]

§410.68 Antigens: Scope and conditions.

Medicare Part B pays for—

(a) Antigens that are furnished as services incident to a physician's professional services; or

(b) A supply of antigen sufficient for not more than 12 months that is—

(1) Prepared for a patient by a doctor of medicine or osteopathy who has examined the patient and developed a plan of treatment including dosage levels; and

section may request that its application to be a CAH and swing-bed provider be reevaluated under paragraph (a) of this section. If this request is approved, the approval is effective not earlier than October 1, 1997. As of the date of approval, the CAH no longer has any status under paragraph (b)(1) of this section and may not request reinstatement under paragraph (b)(1) of this section.

(c) *Payment.* Payment for inpatient RPCH services to a CAH that has qualified as a CAH under the provisions in paragraph (a) of this section is made in accordance with §413.70 of this chapter. Payment for post-hospital SNF-level of care services is made in accordance with the payment provisions in §413.114 of this chapter.

(d) *SNF services.* The CAH is substantially in compliance with the following SNF requirements contained in subpart B of part 483 of this chapter:

(1) Residents rights (§483.10(b)(3) through (b)(6), (d) (e), (h), (i), (j)(1)(vii) and (viii), (l), and (m) of this chapter).

(2) Admission, transfer, and discharge rights (§483.12(a) of this chapter).

(3) Resident behavior and facility practices (§483.13 of this chapter).

(4) Patient activities (§483.15(f) of this chapter), except that the services may be directed either by a qualified professional meeting the requirements of §485.15(f)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy.

(5) Social services (§483.15(g) of this chapter).

(6) Comprehensive assessment, comprehensive care plan, and discharge planning (§483.20(b), (k), and (l) of this chapter, except that the CAH is not required to use the resident assessment instrument (RAI) specified by the State that is required under §483.20(b), or to comply with the requirements for frequency, scope, and number of assessments prescribed in §413.343(b) of this chapter).

(7) Specialized rehabilitative services (§483.45 of this chapter).

(8) Dental services (§483.55 of this chapter).

(9) Nutrition (§483.25(i) of this chapter).

[63 FR 26359, May 12, 1998 as amended at 64 FR 41544, July 30, 1999; 67 FR 50120, Aug. 1, 2002; 69 FR 49272, Aug. 11, 2004]

§485.647 Condition of participation: psychiatric and rehabilitation distinct part units.

(a) *Conditions.* (1) If a CAH provides inpatient psychiatric services in a distinct part unit, the services furnished by the distinct part unit must comply with the hospital requirements specified in Subparts A, B, C, and D of Part 482 of this subchapter, the common requirements of §412.25(a)(2) through (f) of Part 412 of this chapter for hospital units excluded from the prospective payment systems, and the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

(2) If a CAH provides inpatient rehabilitation services in a distinct part unit, the services furnished by the distinct part unit must comply with the hospital requirements specified in Subparts A, B, C, and D of Part 482 of this subchapter, the common requirements of §412.25(a)(2) through (f) of Part 412 of this chapter for hospital units excluded from the prospective payments systems, and the additional requirements of §§412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

(b) *Eligibility requirements.* (1) To be eligible to receive Medicare payments for psychiatric or rehabilitation services as a distinct part unit, the facility provides no more than 10 beds in the distinct part unit.

(2) The beds in the distinct part are excluded from the 25 inpatient-bed count limit specified in §485.620(a).

(3) The average annual 96-hour length of stay requirement specified under §485.620(b) does not apply to the 10 beds in the distinct part units specified in paragraph (b)(1) of this section, and admissions and days of inpatient care in the distinct part units are not taken into account in determining the CAH's compliance with the limits on the

number of beds and length of stay in § 485.620.

[69 FR 49272, Aug. 11, 2004]

Subpart G [Reserved]

Subpart H—Conditions of Participation for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services

§ 485.701 Basis and scope.

This subpart implements section 1861(p)(4) of the Act, which—

(a) Defines outpatient physical therapy and speech pathology services;

(b) Imposes requirements with respect to adequate program, facilities, policies, staffing, and clinical records; and

(c) Authorizes the Secretary to establish by regulation other health and safety requirements.

[60 FR 2327, Jan. 9, 1995]

§ 485.703 Definitions.

Clinic. A facility that is established primarily to furnish outpatient physician services and that meets the following tests of physician involvement:

(1) The medical services are furnished by a group of three or more physicians practicing medicine together.

(2) A physician is present during all hours of operation of the clinic to furnish medical services, as distinguished from purely administrative services.

Organization. A clinic, rehabilitation agency, or public health agency.

Public health agency. An official agency established by a State or local government, the primary function of which is to maintain the health of the population served by performing environmental health services, preventive medical services, and in certain cases, therapeutic services.

Rehabilitation agency. An agency that—

(1) Provides an integrated interdisciplinary rehabilitation program designed to upgrade the physical functioning of handicapped disabled individuals by bringing specialized rehabilitation staff together to perform as a team; and

(2) Provides at least the following services:

(i) Physical therapy or speech-language pathology services.

(ii) Social or vocational adjustment services.

Supervision. Authoritative procedural guidance that is for the accomplishment of a function or activity and that—

(1) Includes initial direction and periodic observation of the actual performance of the function or activity; and

(2) Is furnished by a qualified person—

(i) Whose sphere of competence encompasses the particular function or activity; and

(ii) Who (unless otherwise provided in this subpart) is on the premises if the person performing the function or activity does not meet the assistant-level practitioner qualifications specified in § 485.705.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988; 54 FR 38679, Sept. 20, 1989. Redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

§ 485.705 Personnel qualifications.

(a) *General qualification requirements.* Except as specified in paragraphs (b) and (c) of this section, all personnel who are involved in the furnishing of outpatient physical therapy, occupational therapy, and speech-language pathology services directly by or under arrangements with an organization must be legally authorized (licensed or, if applicable, certified or registered) to practice by the State in which they perform the functions or actions, and must act only within the scope of their State license or State certification or registration.

(b) *Exception for Federally defined qualifications.* The following Federally defined qualifications must be met:

(1) For a physician, the qualifications and conditions as defined in section 1861(r) of the Act and the requirements in part 484 of this chapter.

(2) *For a speech-language pathologist,* the qualifications specified in section

1861(11)(1) of the Act and the requirements in part 484 of this chapter.

(c) *Exceptions when no State Licensing laws or State certification or registration requirements exist.* If no State licensing laws or State certification or registration requirements exist for the profession, the following requirements must be met—

(1) An *administrator* is a person who has a bachelor's degree and:

(i) Has experience or specialized training in the administration of health institutions or agencies; or

(ii) Is qualified and has experience in one of the professional health disciplines.

(2) An *occupational therapist* must meet the requirements in part 484 of this chapter.

(3) *An occupational therapy assistant* must meet the requirements in part 484 of this chapter.

(4) A *physical therapist* must meet the requirements in part 484 of this chapter.

(5) A *physical therapist assistant* must meet the requirements in part 484 of this chapter.

(6) A *social worker* must meet the requirements in part 484 of this chapter.

(7) A *vocational specialist* is a person who has a baccalaureate degree and—

(i) Two years experience in vocational counseling in a rehabilitation setting such as a sheltered workshop, State employment service agency, etc.; or

(ii) At least 18 semester hours in vocational rehabilitation, educational or vocational guidance, psychology, social work, special education or personnel administration, and 1 year of experience in vocational counseling in a rehabilitation setting; or

(iii) A master's degree in vocational counseling.

(8) A nurse practitioner is a person who must:

(i) Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law; *and*

(ii) Be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners; *or*

(iii) Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law and have been granted a Medicare billing number as a nurse practitioner by December 31, 2000; *or*

(iv) Be a nurse practitioner who on or after January 1, 2001, applies for a Medicare billing number for the first time and meets the standards for nurse practitioners in paragraphs (c)(8)(i) and (c)(8)(ii) of this section; *or*

(v) Be a nurse practitioner who on or after January 1, 2003, applies for a Medicare billing number for the first time and possesses a master's degree in nursing and meets the standards for nurse practitioners in paragraphs (b)(1)(i) and (b)(1)(ii) of this section.

(9) *A clinical nurse specialist* is a person who must:

(i) Be a registered nurse who is currently licensed to practice in the State where he or she practices and be authorized to perform the services of a clinical nurse specialist in accordance with State law;

(ii) Have a master's degree in a defined clinical area of nursing from an accredited educational institution; and,

(iii) Be certified as a clinical nurse specialist by the American Nurses Credentialing Center.

(10) *A physician assistant* is a person who:

(i) Has graduated from a physician assistant educational program that is accredited by the Commission on Accreditation of Allied Health Education Programs; or

(ii) Has passed the national certification examination that is administered by the National Commission on Certification of Physician Assistants; and

(iii) Is licensed by the State to practice as a physician assistant.

[63 FR 58912, Nov. 2, 1998; 64 FR 25457, May 12, 1999; 64 FR 59442, Nov. 2, 1999]

§ 485.707 Condition of participation: Compliance with Federal, State, and local laws.

The organization and its staff are in compliance with all applicable Federal, State, and local laws and regulations.

(a) *Standard: Licensure of organization.* In any State in which State or applicable local law provides for the licensing of organizations, a clinic, rehabilitation agency, or public health agency is licensed in accordance with applicable laws.

(b) *Standard: Licensure or registration of personnel.* Staff of the organization are licensed or registered in accordance with applicable laws.

[41 FR 20865, May 21, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995]

§ 485.709 Condition of participation: Administrative management.

The clinic or rehabilitation agency has an effective governing body that is legally responsible for the conduct of the clinic or rehabilitation agency. The governing body designates an administrator, and establishes administrative policies.

(a) *Standard: Governing body.* There is a governing body (or designated person(s) so functioning) which assumes full legal responsibility for the overall conduct of the clinic or rehabilitation agency and for compliance with applicable laws and regulations. The name of the owner(s) of the clinic or rehabilitation agency is fully disclosed to the State agency. In the case of corporations, the names of the corporate officers are made known.

(b) *Standard: Administrator.* The governing body—

(1) Appoints a qualified full-time administrator;

(2) Delegates to the administrator the internal operation of the clinic or rehabilitation agency in accordance with written policies;

(3) Defines clearly the administrator's responsibilities for procurement and direction of personnel; and

(4) Designates a competent individual to act during temporary absence of the administrator.

(c) *Standard: Personnel policies.* Personnel practices are supported by appropriate written personnel policies that are kept current. Personnel records include the qualifications of all professional and assistant level personnel, as well as evidence of State licensure if applicable.

(d) *Standard: Patient care policies.* Patient care practices and procedures are supported by written policies established by a group of professional personnel including one or more physicians associated with the clinic or rehabilitation agency, one or more qualified physical therapists (if physical therapy services are provided), and one or more qualified speech pathologists (if speech pathology services are provided). The policies govern the outpatient physical therapy and/or speech pathology services and related services that are provided. These policies are evaluated at least annually by the group of professional personnel, and revised as necessary based upon this evaluation.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988. Redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

§ 485.711 Condition of participation: Plan of care and physician involvement.

For each patient in need of outpatient physical therapy or speech pathology services there is a written plan of care established and periodically reviewed by a physician, or by a physical therapist or speech pathologist respectively. The organization has a physician available to furnish necessary medical care in case of emergency.

(a) *Standard: Medical history and prior treatment.* The following are obtained by the organization before or at the time of initiation of treatment:

(1) The patient's significant past history.

(2) Current medical findings, if any.

(3) Diagnosis(es), if established.

(4) Physician's orders, if any.

(5) Rehabilitation goals, if determined.

(6) Contraindications, if any.

(7) The extent to which the patient is aware of the diagnosis(es) and prognosis.

(8) If appropriate, the summary of treatment furnished and results achieved during previous periods of rehabilitation services or institutionalization.

(b) *Standard: Plan of care.* (1) For each patient there is a written plan of care

established by the physician or by the physical therapist or speech-language pathologist who furnishes the services.

(2) The plan of care for physical therapy or speech pathology services indicates anticipated goals and specifies for those services the—

(i) Type;

(ii) Amount;

(iii) Frequency; and

(iv) Duration.

(3) The plan of care and results of treatment are reviewed by the physician or by the individual who established the plan at least as often as the patient's condition requires, and the indicated action is taken. (For Medicare patients, the plan must be reviewed by a physician, nurse practitioner, clinical nurse specialist, or physician assistant at least every 30 days, in accordance with §410.61(e) of this chapter.)

(4) Changes in the plan of care are noted in the clinical record. If the patient has an attending physician, the therapist or speech-language pathologist who furnishes the services promptly notifies him or her of any change in the patient's condition or in the plan of care.

(c) *Standard: Emergency care.* The organization provides for one or more doctors of medicine or osteopathy to be available on call to furnish necessary medical care in case of emergency. The established procedures to be followed by personnel in an emergency cover immediate care of the patient, persons to be notified, and reports to be prepared.

[54 FR 38679, Sept. 20, 1989. Redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 63 FR 58913, Nov. 2, 1998]

§485.713 Condition of participation: Physical therapy services.

If the organization offers physical therapy services, it provides an adequate program of physical therapy and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.

(a) *Standard: Adequate program.* (1) The organization is considered to have an adequate outpatient physical therapy program if it can:

(i) Provide services using therapeutic exercise and the modalities of heat, cold, water, and electricity;

(ii) Conduct patient evaluations; and

(iii) Administer tests and measurements of strength, balance, endurance, range of motion, and activities of daily living.

(2) A qualified physical therapist is present or readily available to offer supervision when a physical therapist assistant furnishes services.

(i) If a qualified physical therapist is not on the premises during all hours of operation, patients are scheduled so as to ensure that the therapist is present when special skills are needed, for example, for evaluation and reevaluation.

(ii) When a physical therapist assistant furnishes services off the organization's premises, those services are supervised by a qualified physical therapist who makes an onsite supervisory visit at least once every 30 days.

(b) *Standard: Facilities and equipment.* The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of disabilities it accepts for service.

(c) *Standard: Personnel qualified to provide physical therapy services.* Physical therapy services are provided by, or under the supervision of, a qualified physical therapist. The number of qualified physical therapists and qualified physical therapist assistants is adequate for the volume and diversity of physical therapy services offered. A qualified physical therapist is on the premises or readily available during the operating hours of the organization.

(d) *Standard: Supportive personnel.* If personnel are available to assist qualified physical therapists by performing services incident to physical therapy that do not require professional knowledge and skill, these personnel are instructed in appropriate patient care services by qualified physical therapists who retain responsibility for the treatment prescribed by the attending physician.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

§ 485.715 Condition of participation: Speech pathology services.

If speech pathology services are offered, the organization provides an adequate program of speech pathology and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.

(a) *Standard: Adequate program.* The organization is considered to have an adequate outpatient speech pathology program if it can provide the diagnostic and treatment services to effectively treat speech disorders.

(b) *Standard: Facilities and equipment.* The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of speech disorders it accepts for service.

(c) *Standard: Personnel qualified to provide speech pathology services.* Speech pathology services are given or supervised by a qualified speech pathologist and the number of qualified speech pathologists is adequate for the volume and diversity of speech pathology services offered. At least one qualified speech pathologist is present at all times when speech pathology services are furnished.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326–2328, Jan. 9, 1995]

§ 485.717 Condition of participation: Rehabilitation program.

This condition and its standards apply only to a rehabilitation agency's own patients, not to patients of hospitals, skilled nursing facilities (SNFs), or Medicaid nursing facilities (NFs) to whom the agency furnishes services. (The hospital, SNF, or NF is responsible for ensuring that qualified staff furnish services for which they arrange or contract for their patients.) The rehabilitation agency provides, in addition to physical therapy and speech-language pathology services, social or vocational adjustment services to all of its patients who need them. The agency provides for special qualified staff to evaluate the social and vocational factors, to counsel and advise on the social or vocational problems that arise from the patient's illness or injury, and to make appropriate referrals for needed services.

(a) *Standard: Qualification of staff.* The agency's social or vocational adjustment services are furnished as appropriate, by qualified psychologists, qualified social workers, or qualified vocational specialists. Social or vocational adjustment services may be performed by a qualified psychologist or qualified social worker. Vocational adjustment services may be furnished by a qualified vocational specialist.

(b) *Standard: Arrangements for social or vocational adjustment services.* (1) If a rehabilitation agency does not provide social or vocational adjustment services through salaried employees, it may provide those services through a written contract with others who meet the requirements and responsibilities set forth in this subpart for salaried personnel.

(2) The contract must specify the term of the contract and the manner of termination or renewal and provide that the agency retains responsibility for the control and supervision of the services.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 56 FR 46562, Sept. 13, 1991. Redesignated and amended at 60 FR 2326, 2328, Jan. 9, 1995; 60 FR 11632, Mar. 2, 1995; 60 FR 50447, Sept. 29, 1995]

§ 485.719 Condition of participation: Arrangements for physical therapy and speech pathology services to be performed by other than salaried organization personnel.

(a) *Conditions.* If an organization provides outpatient physical therapy or speech pathology services under an arrangement with others, the services are to be furnished in accordance with the terms of a written contract, which provides that the organization retains of professional and administrative responsibility for, and control and supervision of, the services.

(b) *Standard: Contract provisions.* The contract—

(1) Specifies the term of the contract and the manner of termination or renewal;

(2) Requires that personnel who furnish the services meet the requirements that are set forth in this subpart for salaried personnel; and

(3) Provides that the contracting outside resource may not bill the patient or Medicare for the services. This limitation is based on section 1861(w)(1) of the Act, which provides that—

(i) Only the provider may bill the beneficiary for covered services furnished under arrangements; and

(ii) Receipt of Medicare payment by the provider, on behalf of an entitled individual, discharges the liability of the individual or any other person to pay for those services.

[56 FR 46562, Sept. 13, 1991. Redesignated and amended at 60 FR 2326, 2328, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

§ 485.721 Condition of participation: Clinical records.

The organization maintains clinical records on all patients in accordance with accepted professional standards, and practices. The clinical records are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information.

(a) *Standard: Protection of clinical record information.* The organization recognizes the confidentiality of clinical record information and provides safeguards against loss, destruction, or unauthorized use. Written procedures govern the use and removal of records and the conditions for release of information. The patient's written consent is required for release of information not authorized by law.

(b) *Standard: Content.* The clinical record contains sufficient information to identify the patient clearly, to justify the diagnosis(es) and treatment, and to document the results accurately. All clinical records contain the following general categories of data:

(1) Documented evidence of the assessment of the needs of the patient, of an appropriate plan of care, and of the care and services furnished.

(2) Identification data and consent forms.

(3) Medical history.

(4) Report of physical examinations, if any.

(5) Observations and progress notes.

(6) Reports of treatments and clinical findings.

(7) Discharge summary including final diagnosis(es) and prognosis.

(c) *Standard: Completion of records and centralization of reports.* Current clinical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's clinical record. Each physician signs the entries that he or she makes in the clinical record.

(d) *Standard: Retention and preservation.* Clinical records are retained for at least:

(1) The period determined by the respective State statute, or the statute of limitations in the State; or

(2) In the absence of a State statute—

(i) Five years after the date of discharge; or

(ii) In the case of a minor, 3 years after the patient becomes of age under State law or 5 years after the date of discharge, whichever is longer.

(e) *Standard: Indexes.* Clinical records are indexed at least according to name of patient to facilitate acquisition of statistical medical information and retrieval of records for research or administrative action.

(f) *Standard: Location and facilities.* The organization maintains adequate facilities and equipment, conveniently located, to provide efficient processing of clinical records (reviewing, indexing, filing, and prompt retrieval).

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326–2328, Jan. 9, 1995]

§ 485.723 Condition of participation: Physical environment.

The building housing the organization is constructed, equipped, and maintained to protect the health and safety of patients, personnel, and the public and provides a functional, sanitary, and comfortable environment.

(a) *Standard: Safety of patients.* The organization satisfies the following requirements:

(1) It complies with all applicable State and local building, fire, and safety codes.

(2) Permanently attached automatic fire-extinguishing systems of adequate capacity are installed in all areas of the premises considered to have special fire hazards. Fire extinguishers are conveniently located on each floor of

the premises. Fire regulations are prominently posted.

(3) Doorways, passageways and stairwells negotiated by patients are:

(i) Of adequate width to allow for easy movement of all patients (including those on stretchers or in wheelchairs), (ii) free from obstruction at all times, and (iii) in the case of stairwells, equipped with firmly attached handrails on at least one side.

(4) Lights are placed at exits and in corridors used by patients and are supported by an emergency power source.

(5) A fire alarm system with local alarm capability and, where applicable, an emergency power source, is functional.

(6) At least two persons are on duty on the premises of the organization whenever a patient is being treated.

(7) No occupancies or activities undesirable or injurious to the health and safety of patients are located in the building.

(b) *Standard: Maintenance of equipment, building, and grounds.* The organization establishes a written preventive-maintenance program to ensure that—

(1) The equipment is operative, and is properly calibrated; and

(2) The interior and exterior of the building are clean and orderly and maintained free of any defects that are a potential hazard to patients, personnel, and the public.

(c) *Standard: Other environmental considerations.* The organization provides a functional, sanitary, and comfortable environment for patients, personnel, and the public.

(1) Provision is made for adequate and comfortable lighting levels in all areas; limitation of sounds at comfort levels; a comfortable room temperature; and adequate ventilation through windows, mechanical means, or a combination of both.

(2) Toilet rooms, toilet stalls, and lavatories are accessible and constructed so as to allow use by nonambulatory and semiambulatory individuals.

(3) Whatever the size of the building, there is an adequate amount of space for the services provided and disabilities treated, including reception area, staff space, examining room, treatment areas, and storage.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326–2328, Jan. 9, 1995]

§ 485.725 Condition of participation: Infection control.

The organization that provides outpatient physical therapy services establishes an infection-control committee of representative professional staff with responsibility for overall infection control. All necessary housekeeping and maintenance services are provided to maintain a sanitary and comfortable environment and to help prevent the development and transmission of infection.

(a) *Standard: Infection-control committee.* The infection-control committee establishes policies and procedures for investigating, controlling, and preventing infections in the organization and monitors staff performance to ensure that the policies and procedures are executed.

(b) All personnel follow written procedures for effective aseptic techniques. The procedures are reviewed annually and revised if necessary to improve them.

(c) *Standard: Housekeeping.* (1) The organization employs sufficient housekeeping personnel and provides all necessary equipment to maintain a safe, clean, and orderly interior. A full-time employee is designated as the one responsible for the housekeeping services and for supervision and training of housekeeping personnel.

(2) An organization that has a contract with an outside resource for housekeeping services may be found to be in compliance with this standard provided the organization or outside resource or both meet the requirements of the standard.

(d) *Standard: Linen.* The organization has available at all times a quantity of linen essential for proper care and comfort of patients. Linens are handled, stored, processed, and transported in such a manner as to prevent the spread of infection.

(e) *Standard: Pest control.* The organization's premises are maintained free

from insects and rodents through operation of a pest-control program.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, 2328, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

§ 485.727 Condition of participation: Disaster preparedness.

The organization has a written plan, periodically rehearsed, with procedures to be followed in the event of an internal or external disaster and for the care of casualties (patients and personnel) arising from a disaster.

(a) *Standard: Disaster plan.* The organization has a written plan in operation, with procedures to be followed in the event of fire, explosion, or other disaster. The plan is developed and maintained with the assistance of qualified fire, safety, and other appropriate experts, and includes:

(1) Transfer of casualties and records;

(2) The location and use of alarm systems and signals;

(3) Methods of containing fire;

(4) Notification of appropriate persons; and

(5) Evacuation routes and procedures.

(b) *Standard: Staff training and drills.* All employees are trained, as part of their employment orientation, in all aspects of preparedness for any disaster. The disaster program includes orientation and ongoing training and drills for all personnel in all procedures so that each employee promptly and correctly carries out his assigned role in case of a disaster.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988. Redesignated and amended at 60 FR 2326–2327, 2329, Jan. 9, 1995]

§ 485.729 Condition of participation: Program evaluation.

The organization has procedures that provide for a systematic evaluation of its total program to ensure appropriate utilization of services and to determine whether the organization's policies are followed in providing services to patients through employees or under arrangements with others.

(a) *Standard: Clinical-record review.* A sample of active and closed clinical records is reviewed quarterly by the appropriate health professionals to ensure that established policies are followed in providing services.

(b) *Standard: Annual statistical evaluation.* An evaluation is conducted annually of statistical data such as number of different patients treated, number of patient visits, condition on admission and discharge, number of new patients, number of patients by diagnosis(es), sources of referral, number and cost of units of service by treatment given, and total staff days or work hours by discipline.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326–2327, 2329, Jan. 9, 1995]

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

Subpart A—General Provisions

Sec.
486.1 Basis and scope.

Subpart B [Reserved]

Subpart C—Conditions for Coverage: Portable X-Ray Services

486.100 Condition for coverage: Compliance with Federal, State, and local laws and regulations.
486.102 Condition for coverage: Supervision by a qualified physician.
486.104 Condition for coverage: Qualifications, orientation, and health of technical personnel.
486.106 Condition for coverage: Referral for service and preservation of records.
486.108 Condition for coverage: Safety standards.
486.110 Condition for coverage: Inspection of equipment.

Subpart D—Conditions for Coverage: Outpatient Physical Therapy Services Furnished by Physical Therapists in Independent Practice

486.150 Condition for coverage: General requirements.
486.151 Condition for coverage: Supervision.
486.153 Condition for coverage: Compliance with Federal, State, and local laws.
486.155 Condition for coverage: Plan of care.
486.157 Condition for coverage: Physical therapy services.
486.159 Condition for coverage: Coordination of services with other organizations, agencies, or individuals.

486.161 Condition for coverage: Clinical records.
486.163 Condition for coverage—physical environment.

Subparts E–F [Reserved]

Subpart G—Conditions for Coverage: Organ Procurement Organizations

486.301 Basis and scope.
486.302 Definitions.
486.304 General requirements.
486.306 Qualifications for designation as an OPO.
486.307 OPO service area size designation and documentation requirements.
486.308 Condition: Participation in organ procurement and transplantation network.
486.309 Recertification from January 1, 2002 through December 31, 2005.
486.310 Condition: Adherence to performance standards.
486.314 Effect of failure to meet requirements.
486.316 Designation of one OPO for each service area.
486.318 Changes in ownership or service area.
486.325 Termination of agreement with CMS.
APPENDIX A TO SUBPART G OF PART 486—GUIDELINES FOR PREVENTING TRANSMISSION OF HUMAN IMMUNODEFICIENCY VIRUS THROUGH TRANSPLANTATION OF HUMAN TISSUE AND ORGANS

AUTHORITY: Sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provisions

§ 486.1 Basis and scope.

(a) *Statutory basis.* This part is based on the following sections of the Act:

1138(b)—for coverage of organ procurement services.

1861(p)—for coverage of outpatient physical therapy services furnished by physical therapists in independent practice.

1861(s) (3), (15), and (17)—for coverage of portable X-ray services.

(b) *Scope.* (1) This part sets forth the conditions for coverage of certain specialized services that are furnished by suppliers and that are not specified in other portions of this chapter.

(2) The conditions for coverage of other specialized services furnished by suppliers are set forth in the following regulations which, unless otherwise indicated, are part of this chapter:

(i) Ambulatory surgical center (ASC) services—Part 416.

(ii) Ambulance services—Part 410, subpart B.

(iii) ESRD services—Part 405, subpart U.

(iv) Laboratory services—Part 493.

(v) Mammography services—Part 410, subpart B (§ 410.34) and 21 CFR Part 900, subpart B, of the Food and Drug Administration regulations.

(vi) Rural health clinic and Federally qualified health center services—Part 491, subpart A.

[60 FR 50447, Sept. 29, 1995]

Subpart B [Reserved]

Subpart C—Conditions for Coverage: Portable X-Ray Services

AUTHORITY: Secs. 1102, 1861(s) (3), (11) and (12), 1864, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x(s) (3), (11), and (12), 1395aa and 1395hh).

SOURCE: 34 FR 388, Jan. 10, 1969, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, Jan. 9, 1995.

§ 486.100 Condition for coverage: Compliance with Federal, State, and local laws and regulations.

The supplier of portable X-ray services is in conformity with all applicable Federal, State, and local laws and regulations.

(a) *Standard—licensure or registration of supplier.* In any State in which State or applicable local law provides for the licensure or registration of suppliers of X-ray services, the supplier is (1) licensed or registered pursuant to such law, or (2) approved by the agency of the State or locality responsible for licensure or registration as meeting the standards established for such licensure or registration.

(b) *Standard—licensure or registration of personnel.* All personnel engaged in operating portable X-ray equipment are currently licensed or registered in accordance with all applicable State and local laws.

(c) *Standard—licensure or registration of equipment.* All portable X-ray equipment used in providing portable X-ray

14.2 *Federal Register*

policy to establish two annual per-beneficiary limits of $1,500. There will be (1) an annual per-beneficiary limit for all outpatient physical therapy services excluding hospital outpatient therapy services furnished to an outpatient or an inpatient who is not in a covered Part A stay and, (2) an annual per beneficiary limit for all outpatient occupational therapy services excluding hospital outpatient therapy services furnished to an outpatient or an inpatient who is not in a covered Part A stay. As stated previously, outpatient physical therapy services include speech-language pathology services. A provider of outpatient rehabilitation services with a provider agreement under section 1866 of the Act, as well as physicians, PTIPs and OTIPs, will be allowed to collect payment from a beneficiary for therapy services after the $1,500 limit is reached. This is consistent with current policy allowing PTIPs and OTIPs to collect payment from a beneficiary for therapy services in excess of the current $900 limit.

Required Congressional Report on Financial Limitation

We note that a report to the Congress is due from the Secretary no later than January 1, 2001. This report must include recommendations on the establishment of a revised coverage policy of outpatient physical therapy services, including speech-language pathology services and outpatient occupational therapy services. The revised policy must be based on a classification of individuals by diagnosis category and prior use of services in both inpatient and outpatient settings. The report should include recommendations on how such durational limits by diagnostic category could be implemented in a budget-neutral manner.

Comment: It was recommended by a commenter for the report to the Congress that, in addition to basing a revised policy on classification by diagnosis category and prior use of services, an individual's functional status should be a component of any system that purports to address a patient's need for rehabilitation.

Response: As we develop the report to the Congress, we will consider the feasibility of the recommendation.

4. Qualified Therapists

Section 1861(p) includes services furnished an individual by a physical therapist who meets licensing and other standards prescribed by the Secretary if the services meet the conditions relating to health and safety the Secretary finds necessary. The services must be furnished in the therapist's office or the individual's home. By regulation, we have defined therapists meeting the conditions for coverage of services under this provision as physical therapists in independent practice. The conditions for coverage are set forth in part 486, subpart D (Conditions for coverage: Outpatient Physical Therapy Services Furnished by Physical Therapists in Independent Practice) and require that the services be provided by a therapist in independent practice under § 410.60. Under § 410.60, a therapist in independent practice is one who:

- Engages in the practice of therapy on a regular basis.
- Furnishes services on his or her own responsibility without the administrative and professional control of an employer.
- Maintains at his or her own expense office space and equipment.
- Furnishes services only in the office or patient's home.
- Treats individuals who are his or her own patients and collects fees or other compensation for the services.

Under § 486.151 (Conditions for coverage: Supervision), all therapy services must be furnished under the direct supervision of a qualified therapist in independent practice. In other words, the therapist in independent practice must be on the premises whenever services are provided to Medicare beneficiaries, including services provided by a licensed physical therapist. This long-standing requirement has been controversial with therapists in independent practice. For example, a therapist in independent practice cannot have more than one office open for services at the same time since he or she could not be on both premises at once.

We are revising our policy to replace the existing "Conditions for Coverage: Outpatient Physical Therapy Services Furnished by Physical Therapists in Independent Practice" (part 486, subpart D), which requires survey and certification, with a simplified criteria for physical therapists in private practice that would use a carrier enrollment process. The impetus for this change comes from congressional statements associated with the fiscal year 1997 appropriations process. Statements in both the House and Senate committee reports accompanying HCFA's fiscal year 1997 appropriations addressed the issue of requiring that the certified physical or occupational therapist in independent practice directly supervise all services performed by his or her employees, even if those employees are fully-licensed therapists. The House committee report urged that we modify the regulations so that the certified therapist need not be on premises to supervise other licensed therapists. The Senate urged us to review this concern and recommend regulatory or instructional changes.

We are redefining those therapists who are qualified under section 1861(p) of the Act. That is, we would discontinue the focus of the regulation on their "independent" status (which is not statutory) and recognize therapists in private practice who are employed by others and, therefore, do not meet our current "independent" criteria. This would be consistent with health and safety concerns and would conform to normal private sector practice standards. The following new requirements replace the current ones for qualified therapists:

- The term "independent" is dropped and the benefit would be for an individual physical therapist or occupational therapist in private practice.

Private practice includes an "individual" whose practice is in an unincorporated solo practice, unincorporated partnership, or unincorporated group practice. Private practice also includes an "individual" who is practicing therapy as an employee of one of the above or of a professional corporation or other incorporated therapy practice. However, private practice does not include individuals when they are working as employees of a provider. A provider as defined in § 400.202 includes a hospital, CAH, SNF, HHA, hospice, CORF, CMHC, or an organization qualified under part 485, subpart H (Conditions of Participation for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services), as a clinic, rehabilitation agency, or public health agency.

- In implementing the statutory requirement that services be furnished to an individual in the therapist's office, or in the individual's home, "in his office" is defined as the location(s) where the practice is operated, in the State(s) where the therapist (and practice, if applicable) is legally authorized to furnish services, during the hours that the therapist engages in practice at that location.

A therapist in private practice must maintain a private office, if services always are furnished in patients' homes. However, if services are furnished in private practice office space, that space would have to be owned, leased, or

rented by the practice and used for the exclusive purpose of operating the practice. For example, because of the statutory restriction on the site of services, a therapist in private practice cannot furnish covered services in an SNF. Therefore, if a therapist wished to locate his or her private office on site at a nursing facility, special care would need to be taken. The private office space could not be part of the Medicare-participating SNF's space, and the therapist's services could be furnished only within that private office space. Neither the therapist nor any assistants or aides who help furnish services could be employed by the SNF during the same hours that they are working in the private practice. Another example where special attention would be needed is space that generally serves other purposes and is only used by a therapy practice during limited hours. For example, a therapist in private practice may furnish aquatic therapy in a community center pool on Wednesday mornings. The practice would have to rent or lease the pool for those hours, and the use of the pool during that time would have to be restricted to the therapist's patients, in order to recognize the pool as part of the therapist's own private office during those hours.

In describing other services that are specifically limited to the patient's home, the statute uses qualifying language. For example, the durable medical equipment definition in section 1861(n) of the Act refers to a patient's home as "including an institution used as his home other than an institution that meets the requirements of subsection (e)(1) of this section or section 1819(a)(1)." This definition of home is codified under our regulations at § 410.38(b). The same definition always has been used in the Medicare Carriers Manual for purposes of covering therapists' services in a patient's home. We are continuing the current practice and are adopting the definition formally in this regulation.

- Assistants and aides have to be personally supervised by the therapist and employed directly by the therapist, by the partnership or group to which the therapist belongs, or by the same private practice that employs the therapist. Personal supervision requires that the therapist be in the room during the performance of the service. Levels of supervision are defined in § 410.32 of our regulations.
- The therapist must be licensed or otherwise legally authorized to engage in private practice. We understand that all States license or certify physical therapists, so no alternative personnel qualifications need to be specified.
- Each therapist enrolls "as an individual" with the carrier.

There would be no survey and no certification by HCFA. The Medicare carrier would verify that the qualifications proposed in §§ 410.59(c)(1) or 410.60(c)(1) of our regulations are met. All applicants for new enrollment would become subject to these new rules and procedures upon the effective date of the final rule. For transition purposes, we intend that independent therapists who are certified and enrolled at that time would be "grandfathered" temporarily and would become subject to the new enrollment rules and procedures at the time of their next regular periodic reenrollment.

These changes would address the concern that current rules require each independent therapist to personally supervise services performed by any other licensed therapists that he or she employs. Under our proposal, each individual therapist in a practice could qualify to separately enroll, and enrolled therapists would not be required for purposes of Medicare to be supervised by their employer. These changes also address the concern that current rules prohibit an independent therapist from being employed by any entity. Under our proposal, a variety of employment situations would be permitted.

These new requirements are established in a revised § 410.60(c) for physical therapists. To date, the statutory requirements for coverage of outpatient occupational therapy services have not been codified. We are codifying these requirements by establishing a new § 410.59 for outpatient occupational therapy services. The regulations section for outpatient occupational therapy parallels the § 410.60 requirements for outpatient physical therapy, as revised in this final rule. We are also making conforming changes in § 410.61 to include occupational therapy.

Therapists in private practice do not participate in the Medicare program in the same way that "providers of services" do. Though they must be approved as meeting certain requirements, unlike "providers of services," they do not execute a formal provider agreement with the Secretary as described in 42 CFR part 489 (Provider Agreements and Supplier Approval). Like physicians, they do have the option of accepting a beneficiary's assignment of his or her claim for Medicare Part B benefits and of becoming a Medicare-participating supplier that agrees to accept assignment in all cases.

Comment: One commenter strongly supports the carrier enrollment process for physical therapists instead of the existing conditions of coverage. However, the commenter wanted operational issues addressed such as a specification that payments will be made under the practice or corporation's tax ID number for services furnished by physical therapists in private practice who are employees of other practices or corporations. This is the same payment system used by a physician group practice, and the treating therapist's Medicare number or license number would be included on the bill. In addition, the commenter urged that the same process be used for the carrier enrollment process as for the current physician enrollment. Another commenter supported the changes for OTPPs; however, assuming that payment is made to the individual, the commenter inquired as to whether group numbers would be assigned so that payment could be issued to the group under the tax identification number of the business entity.

Response: We will use the same enrollment and billing process as is currently used for individual physicians and physician group practices. This process is delineated at section 1030.7 of the Medicare Carriers Manual, HCFA Pub. 14–Part 4. We note that payment is not made on the basis of the corporate or group practice tax identification number. This number is just one of the data elements that can be related to the Medicare individual and/or group billing number.

Comment: A commenter recommended that direct supervision of assistants and aides be required instead of personal supervision. The commenter provided that direct supervision would be consistent with state laws, the supervision requirements for nonphysician personnel performing services in a physician's office, and with the supervision requirements for aides and assistants of PTIPs.

Another commenter agreed that personal supervision over therapy aides by a qualified occupational therapist or qualified occupational therapy assistant is appropriate. However, the commenter strongly disagreed with the proposal to require personal supervision over occupational therapy assistants and instead urged the adoption of a policy for practicing occupational therapists whereby occupational therapy assistants can perform covered services under the general supervision (that is, initial direction and periodic inspection) of a qualified occupational therapist. In

14.3 Survey & Certification Memoranda

Review of Plans of Care
Aquatic therapy
OPT extension locations
Updates to the SOM

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Care Financing Administration

MEMORANDUM

DATE: MAR 2 1999

FROM: Acting Director
Disabled and Elderly Health Programs Group
Center for Medicaid and State Operations

SUBJECT: Revision of Part 485.701ff--Conditions of Participation for Clinics, Rehabilitation Agencies and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech Language Pathology Services: Plan of Care and Physician Involvement

TO: Associate Regional Administrators
Division for Medicaid and State Operations
Regions I - X

The purpose of this memorandum is to inform you that effective January 1, 1999, as a result of a revision to 42 CFR 485.711(b), nurse practitioners, clinical nurse specialists, and physician assistants are able to review plans of care and results of treatment at least every 30 days for Medicare patients. Formerly, only physicians could review the plans of care and results of treatment for Medicare patients. Definitions of these personnel have been added to Part 485.705.

The Health Care Financing Administration's Form 1893 (Outpatient Physical Therapy and Speech/Language Survey Report Form) will be updated to include the changes. However, as this may take some time, it is important that you inform State survey agencies of the change to avoid unnecessary surveyor documented deficiencies. The changes noted above are located in the Federal Register/Vol. 63, No. 211 and are attached for your convenience.

If you have additional questions, you may contact Georgia Johnson of my staff at (410) 786-6859.

Theresa A. Derville

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Care Financing Administration

MEMORANDUM

DATE: **September 20, 2000**

FROM: Steven A. Pelovitz
Director
Survey and Certification Group

SUBJECT: Aquatic Therapy

TO: Walter Kummer
Associate Regional Administrator
Division of Medicaid and State Operations
Region V

The purpose of this memorandum is to clarify the provision of aquatic therapy by outpatient therapy providers at the request of Robert Anderson of your office. Aquatic therapy is considered a "therapeutic procedure" as listed in the Current Procedure Terminology (CPT) manual. It is not a modality. Medicare will reimburse the aquatic therapy procedure under CPT code 97113.

"Procedures" are defined as a manner of effecting change through the application of clinical skills and/or services that attempt to improve function. This can be achieved through exercise or training and must include active interaction between therapist and beneficiary. "Modalities" are defined as any physical agent applied to produce therapeutic changes to biologic tissue and include, but are not limited to, thermal, acoustic, light, mechanical, or electric energy.

An outpatient therapy (OPT) provider can contract with a local pool to offer aquatic therapy under the following conditions: a qualified therapist must be present and providing treatment to the beneficiary; the pool must be closed to the public during the therapy times and the pool must meet any health and safety criteria established by the local health department.

The OPT provider should have written policies governing the OPT services provided (including aquatic therapy). Aquatic therapy should have a doctor's order and be indicated on the plan of care. If aquatic therapy is provided under arrangement, the services are to be furnished in accordance with the terms of a written contract, including the identification of the qualified professional providing the service.

Please share this information with the States in your region.

Page 2 – Walter Kummer, ARA, DMSO, Region V

If you have additional questions, you may contact Georgia Johnson of my staff at (410) 786-6859.

/s/

Steven A. Pelovitz

cc: ARAs: RO I-IV
RO VI-X

Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-05-36

DATE: **June 22, 2005**

FROM: Director
Survey and Certification Group

TO: State Survey Agency Directors

SUBJECT: Assigning Provider Identification Numbers to Extension Locations of Outpatient Physical Therapy or Outpatient Speech Pathology Service Providers

Letter Summary

We are assigning provider identification numbers to Outpatient Physical Therapy or Outpatient Speech Pathology Services Providers.

Effective immediately, the Center for Medicare & Medicaid Services will begin assigning identification numbers to every existing extension location of an Outpatient Physical Therapy or Outpatient Speech Pathology Services (OPT/OSP) Provider. The identification system will be implemented nationally and will uniquely identify every extension location of every OPT/OSP provider certified to participate in the Medicare OPT/OSP program. It will also link the extension location to the primary site of the OPT/OSP provider.

Each extension location will be numbered with the same Federally-assigned provider number as the primary site with two modifications. There will be a "P" between the state code and four-digit provider designation plus three more digits for a 10-character extension location identifier.

The last three digits will allow us the capability of assigning up to 999 extension locations to one primary OPT/OSP site. Extension location identification numbers will be used only once. In the event that an OPT/OSP extension location closes, its unique extension location identification number is terminated and not re-used to identify another extension location of that OPT/OSP.

Page 2 –State Survey Agency Directors

EXAMPLE:

- XYZ OPT/OSP in Louisiana has two extension locations.
- XYZ's Medicare Provider number is 196001
- XYZ's extension locations would be assigned the extension location numbers 19P6001001 and 19P6001002.

The programming in the Automated Survey Processing Environment (ASPEN) and the Online Survey Certification and Reporting (OSCAR) system to accommodate a Federal extension location identification system has been done and will be released to production with the ASPEN 8.5 release the week of June 27, 2005. An actual extension location field has been created in both the ASPEN and OSCAR systems. The addition of an extension location identification field will allow data entry of the extension location number into ASPEN and the upload of the extension location data to the OSCAR system.

Assignment of Extension Location Identification Numbers

As part of the ASPEN 8.5 release we will automatically assign an identifier and bulk upload to the OSCAR system OPT extension locations currently identified in ASPEN under the affiliations node that are open and are not flagged as licensure only.

As surveys are conducted, states should verify that the information they have on extension locations is current and accurate. It is incumbent upon the ROs to ensure that their respective State Survey Agencies (SAs) have entered into ASPEN all currently known extension locations by June 24, 2005, if you wish to have Central Office enumerate the existing extension locations.

Effective July 1, 2005, it will be the ROs responsibility to assign the identifier to OPT extension locations. ROs must assure that all extension locations nationwide are identified, enumerated and entered into ASPEN. As extension location identification numbers are assigned, the RO must ensure that OPT/OSPs and their respective extension locations are informed of the assigned extension location identification number(s). A sample letter is attached to this memorandum for use by the RO or SA to notify OPT/OSPs of the extension location identification numbers(s). At this time, the fiscal intermediaries are not in need of extension location information.

Although the extension locations will have their own identification numbers, all services provided at the extension locations will be billed under the OPT's primary Medicare Provider number.

For questions on this memo, please contact Georgia Johnson at (410) 786-6859 or e-mail at gjohnson4@cms.hhs.gov

Page 3 – Associate Regional Administrators and State Survey Agency Directors

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum, and disseminate the information to affected providers. Attached is an example of a notification letter..

Training: The information contained in this announcement should be shared with all survey and certification staff, their managers, the state/RO training coordinators.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)

Attachment

Attachment A

Model Letter To OPTs Assigning Extension Location Numbers

Dear OPT Administrator:

The Centers for Medicare & Medicaid Services (CMS) is assigning identification numbers to every existing extension location of a primary site outpatient therapy provider (OPT). The identification system is being implemented nationally and will uniquely identify every extension location of every OPT certified to participate in the Medicare outpatient therapy provider program. It will link the primary site to the extension locations.

Each extension location will be numbered with the same Federally assigned provider number as the primary site with two modifications. There will be a **"P"** between the state code and four-digit provider designation plus three more digits for a 10-character extension location identifier. Extension location identification numbers will be used only once. In the event that an OPT extension location closes, its unique extension location identification number is terminated and not re-used to identify another extension location of that OPT.

On the next page, please review the information we have on file for your primary site and take note of your assigned extension location identification numbers.

If you have any questions or concerns, or wish to submit additional information, please contact

Sincerely,

THE NAME, ADDRESS AND MEDICARE PROVIDER NUMBER FOR YOUR PRIMARY SITE IS:

Name: _____

Address: _____

Provider Number: _____

The following are your extension locations and Federally-assigned extension location identification number(s) associated with the above primary site OPT:

Extension Location Name and Address	Extension Location Identification Number
1. _____	
_____	_____
2. _____	
_____	_____
3. _____	
_____	_____
4. _____	
_____	_____
5. _____	
_____	_____
6. _____	
_____	_____
7. _____	
_____	_____
8. _____	
_____	_____

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-05-45

DATE: **September 22, 2005**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Updates to the State Operations Manual (SOM) for Outpatient Rehabilitation Therapy Services (OPTs) and Comprehensive Outpatient Rehabilitation Facilities (CORFs)

Letter Summary

Several sections of the SOM pertaining to providers of OPTs and CORFs have been updated. This letter briefly explains those changes.

In an effort to address the current practices of providers of OPT rehabilitation services, the following sections of the SOM have been updated and should be reviewed by state surveyors as well as regional office staff as they prepare to survey CORFs and providers of OPTs and Speech-Language Pathology (SLP) services.

SOM Sections Affected

- **Appendix E** (Providers of Outpatient Physical Therapy and Speech-Language Pathology Services) and SOM Section 2290 (Providers of Outpatient Physical Therapy and Speech-Language Pathology Services) were updated to address challenging issues such as documentation for the provision of social services in OPTs, what constitutes OPT extension locations, and what to look for if surveying community facilities such as a pool for the provision of aquatic therapy. These issues have generated much discussion over the last several years and we've attempted to clarify instructions. We've also added deficiency tags and regulation language to Appendix E.

Page 2 – State Survey Agency Directors

- **Appendix K** (Comprehensive Outpatient Rehabilitation Facilities) and SOM Section 2360 (Comprehensive Outpatient Rehabilitation Facilities) were updated to include deficiency tags and regulation language. In addition, some of the issues that have been addressed are:

  - facility physician and physician services;
  - rehabilitation services (mandatory and optional services); and
  - discussion regarding hyperbaric oxygen (HBO) therapy.

Hyperbaric Oxygen Therapy

HBO therapy has been the object of abuse by some CORFs, as they have been specializing in the provision of HBO therapy, almost to the exclusion of mandatory services they must provide. HBO is not a CORF outpatient therapy benefit and therefore cannot be counted as either a mandatory or optional service. Surveyors should bear this in mind when they review medical records to determine what services are being provided at the CORF and if the CORF patients are actually receiving a coordinated, comprehensive, skilled rehabilitation program.

The revised sections of the SOM are expected to be placed on the CMS Web site by October 30, 2005. These same sections will be included in the Rehabilitation Reference Manual that will be soon be available in both hard copy and on CD for use by surveyors while conducting surveys.

For questions on this memo, please contact Georgia Johnson at (410) 786-6859 or e-mail at gjohnson4@cms.hhs.gov

Effective Date: Expected October 2005. An alert will be sent upon release of these changes. Please ensure that all appropriate staff is fully informed within 30 days of the date of this memorandum

Training: The information contained in this announcement should be shared with all survey and certification staff, their managers, the state/RO training coordinators.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)

14.4 Social Security Act, Sections 1861(g) and (p)

Social Security Act, Sections 1861(g) and (p)

Outpatient Occupational Therapy Services

(g) The term "outpatient occupational therapy services" has the meaning given the term "outpatient physical therapy services" in subsection (p), except that "occupational" shall be substituted for "physical" each place it appears therein.

Outpatient Physical Therapy Services

(p) The term "outpatient physical therapy services" means physical therapy services furnished by a provider of services, a clinic, rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient—

(1) who is under the care of a physician (as defined in paragraph (1), (3), or (4) of section 1861(r)), and

(2) with respect to whom a plan prescribing the type, amount, and duration of physical therapy services that are to be furnished such individual has been established by a physician (as so defined) or by a qualified physical therapist and is periodically reviewed by a physician (as so defined);

excluding, however—

(3) any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital; and

(4) any such service—

(A) if furnished by a clinic or rehabilitation agency, or by others under arrangements with such clinic or agency, unless such clinic or rehabilitation agency—

(i) provides an adequate program of physical therapy services for outpatients and has the facilities and personnel required for such program or required for the supervision of such a program, in accordance with such requirements as the Secretary may specify,

(ii) has policies, established by a group of professional personnel, including one or more physicians (associated with the clinic or rehabilitation agency) and one or more qualified physical therapists, to govern the services (referred to in clause (i)) it provides,

(iii) maintains clinical records on all patients,

(iv) if such clinic or agency is situated in a State in which State or applicable local law provides for the licensing of institutions of this nature, (I) is licensed pursuant to such law, or (II) is approved by the agency of such State or locality responsible for licensing institutions of this nature, as meeting the standards established for such licensing; and

(v) meets such other conditions relating to the health and safety of individuals who are furnished services by such clinic or agency on an outpatient basis, as the Secretary

> may find necessary, and provides the Secretary on a continuing basis with a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000, or
> (B) if furnished by a public health agency, unless such agency meets such other conditions relating to health and safety of individuals who are furnished services by such agency on an outpatient basis, as the Secretary may find necessary.

The term “outpatient physical therapy services” also includes physical therapy services furnished an individual by a physical therapist (in his office or in such individual's home) who meets licensing and other standards prescribed by the Secretary in regulations, otherwise than under an arrangement with and under the supervision of a provider of services, clinic, rehabilitation agency, or public health agency, if the furnishing of such services meets such conditions relating to health and safety as the Secretary may find necessary. In addition, such term includes physical therapy services which meet the requirements of the first sentence of this subsection except that they are furnished to an individual as an inpatient of a hospital or extended care facility. The term “outpatient physical therapy services” also includes speech-language pathology services furnished by a provider of services, a clinic, rehabilitation agency, or by a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient, subject to the conditions prescribed in this subsection. Nothing in this subsection shall be construed as requiring, with respect to outpatients who are not entitled to benefits under this title, a physical therapist to provide outpatient physical therapy services only to outpatients who are under the care of a physician or pursuant to a plan of care established by a physician. The Secretary may waive the requirement of a surety bond under paragraph (4)(A)(v) in the case of a clinic or agency that provides a comparable surety bond under State law.

14.5 *Medicare Benefit Policy Manual,* Chapter 15, Sections 220–230

Medicare Benefit Policy Manual, Chapter 15 – Outpatient Physical Therapy

220 - Coverage of Outpatient Rehabilitation Therapy Services (Physical Therapy, Occupational Therapy, and Speech-Language Pathology Services) Under Medical Insurance

(Rev. 34, Issued: 05-06-05, Effective: 06-06-05, Implementation: 06-06-05)

A comprehensive knowledge of the policies that apply to therapy services cannot be obtained through manuals alone. The most definitive policies are Local Coverage Determinations found at the Web site of the contractor to whom the provider or supplier submits claims. A list of these contractors is found at the CMS Web site: www.cms.hhs.gov/medlearn/therapy. Specific questions about all Medicare policies should be addressed to the contractors through the contact information supplied on their Web sites. General Medicare questions may be addressed to the Medicare Regional Offices.

A - Definitions

The following defines terms used in this section and §230:

ASSESSMENT is included in services or procedures and is not separately payable (as distinguished from Current Procedural Terminology (CPT) codes that specify assessment, e.g., 97755, Assistive Technology Assessment which may be payable). Assessment requires professional skill to gather data by observation and patient inquiry and may include limited objective testing and measurement to make clinical judgments regarding the patient's condition(s). Assessment determines, e.g., changes in the patient's status since the last visit and whether the planned procedure or service should be modified. Based on these assessment data, the professional may make judgment about progress toward goals and/or determine that a more complete evaluation or reevaluation (see definitions below) is indicated.

CERTIFICATION is the physician's/NonPhysician Practitioner's (NPP) approval of the plan of care.

EVALUATION is a separately payable comprehensive service that requires professional skills to make clinical judgments about conditions for which services are indicated based on objective measurements and subjective evaluations of patient performance and functional abilities. Evaluation is warranted e.g., for a new diagnosis or when a condition is treated in a new setting. These evaluative judgments are essential to development of the plan of care, including goals and the selection of interventions. The time spent in evaluation does not also count as treatment time.

REEVALUATION is separately payable and is periodically indicated during an episode of care when the professional assessment indicates a significant improvement or decline in the patient's condition or functional status. Some regulations and state practice acts require reevaluation at specific intervals. Reevaluation may also be appropriate at a planned discharge. A reevaluation is focused on evaluation of progress toward current goals and making a professional judgment about continued care, modifying goals and/or treatment or terminating services. Reevaluation requires the same professional skills as evaluation. Current Procedural Terminology does not define a reevaluation code for speech-language pathology; use the evaluation code.

INTERVAL of treatment consists of 1 month or 30 calendar days.

NONPHYSICIAN PRACTITIONERS (NPP) means physician assistants, clinical nurse specialists, and nurse practitioners who may, if state and local laws permit it, and when appropriate rules are followed, provide, certify or supervise therapy services.

PHYSICIAN with respect to outpatient rehabilitation therapy services means a doctor of medicine, osteopathy (including an osteopathic practitioner), podiatric medicine, or optometry (for low vision rehabilitation only). Chiropractors and doctors of dental surgery or dental medicine are not considered physicians for therapy services and may neither refer patients for rehabilitation therapy services nor establish therapy plans of care.

PROVIDERS of services are defined in §1861(u) of the Act, 42CFR400.202 and 42CFR485 Subpart H as participating hospitals, critical access hospitals (CAH), skilled nursing facilities (SNF), comprehensive outpatient rehabilitation facilities (CORF), home health agencies (HHA), hospices, participating clinics, rehabilitation agencies or outpatient rehabilitation facilities (ORF). Providers are also defined as public health agencies with agreements only to furnish outpatient therapy services, or community mental health centers with agreements only to furnish partial hospitalization services. To qualify as providers of services, these providers must meet certain conditions enumerated in the law and enter into an agreement with the Secretary in which they agree not to charge any beneficiary for covered services for which the program will pay and to refund any erroneous collections made. Note that the word PROVIDER in sections 220 and 230 is not used to mean a person who provides a service, but is used as in the statute to mean a facility.

QUALIFIED PROFESSIONAL means a physical therapist, occupational therapist, speech-language pathologist, physician, nurse practitioner, clinical nurse specialist, or physician's assistant, who is licensed or certified by the state to perform therapy services, and who also may appropriately perform therapy services under Medicare policies. Qualified professionals may also include physical therapist assistants (PTA) and occupational therapy assistants (OTA) when working under the supervision of a qualified therapist, within the scope of practice allowed by state law. Assistants may not supervise others.

QUALIFIED PERSONNEL means staff (auxiliary personnel) who may or may not be licensed as therapists or therapist assistants but who meet all of the requirements for therapists with the exception of licensure. Qualified personnel have been educated and trained as therapists and qualify to furnish therapy services only under direct supervision incident to a physician or NPP. See §230.5 of this manual.

SIGNATURE means a legible identifier of any type (e.g., hand written, electronic, or signature stamp). Policies in Pub. 100-08, Medicare Program Integrity Manual, chapter 3, §3.4.1.1 (B) concerning signatures apply.

SUPERVISION LEVELS for outpatient rehabilitation therapy services are the same as those for diagnostic tests defined in 42CFR410.32. Depending on the setting, the levels include personal supervision (in the room), direct supervision (in the office suite), and general supervision (physician/NPP is available but not necessarily on the premises).

SUPPLIERS of therapy services include individual practitioners such as physicians, NPPs, physical therapists and occupational therapists who have Medicare provider numbers. Regulatory references on physical therapists in private practice (PTPPs) and occupational

therapists in private practice (OTPPs) are at 42CFR410.60 (C)(1), 485.701-729, and 486.150-163. Speech-language pathologists are not suppliers because the Act does not provide coverage of any speech-language pathology services furnished by a speech-language pathologist as an independent practitioner. (See §230.3.)

THERAPIST refers only to qualified physical therapists, occupational therapists and speech-language pathologists, as defined in §230. Qualifications that define therapists are in §§230.1, 230.2, and 230.3.

THERAPY, or outpatient rehabilitation services, includes only outpatient physical therapy, occupational therapy and speech-language pathology services paid using the Medicare Physician Fee Schedule.

Therapy services referred to in this manual are those skilled rehabilitative services provided according to the standards and conditions in CMS manuals, (e.g., in this chapter and in the Medicare Claims Processing Manual, Pub. 100-04, chapter 5), within their scope of practice by qualified professionals or qualified personnel, as defined in this section, represented by procedures found in the American Medical Association's "Current Procedural Terminology (CPT)." A list of CPT and HCPCS codes is provided in Pub. 100-04, Chapter 5, §20, and in Local Coverage Determinations developed by contractors.

Unless modified by the words "maintenance" or "not", the term therapy refers to rehabilitative therapy services as described in §220.2(C).

B - References

Paper Manuals. The following manuals, now outdated, were resources for the Internet Only Manuals.

- *Part A Medicare Intermediary Manual, (Pub. 13)*
- *Part B Medicare Carrier Manual, (Pub. 14)*
- *Hospital Manual, (Pub. 10)*
- *Outpatient Physical Therapy/CORF Manual, (Pub. 9)*

Regulation and Statute. The information in this section is based in part on the following current references:

- *42CFR refers to Title 42, Code of Federal Regulation (CFR).*
- *The Act refers to the Social Security Act.*

Internet Only Manuals. Current Policies that concern providers and suppliers of therapy services are located in many places throughout CMS Manuals. Sites that may be of interest include:

- *Pub.100-01 GENERAL INFORMATION, ELIGIBILITY, AND ENTITLEMENT,*
  - *Chapter 1- General Overview*

    10.1 - Hospital Insurance (Part A) for Inpatient Hospital, Hospice and SNF Services - A Brief Description

    10.2 - Posthospital Home Health Services

10.3 - Supplementary Medical Insurance (Part B) - A Brief Description

20.2 - Discrimination Prohibited

- *Pub. 100-02, MEDICARE BENEFIT POLICY MANUAL*
  - *Ch 6 - Hospital Services Covered Under Part B*

    10 - Medical and Other Health Services Furnished to Inpatients of Participating Hospitals

    20 - Outpatient Hospital Services

    20.2 - Distinguishing Outpatient Hospital Services Provided Outside the Hospital

    20.4.1 - Coverage of Outpatient Therapeutic Services

    70 - Outpatient Hospital Psychiatric Services
  - *Ch 8 - Coverage of Extended Care (SNF) Services Under Hospital Insurance*

    30.4. - Direct Skilled Rehabilitation Services to Patients

    40 - Physician Certification and Recertification

    50.3 - Physical, Speech, and Occupational Therapy Furnished by the Skilled Nursing Facility or by Others Under Arrangements with the Facility and Under Its Supervision

    70.3 - Inpatient Physical Therapy, Occupational Therapy, and Speech Pathology Services
- *Pub. 100-03 MEDICARE NATIONAL COVERAGE DETERMINATIONS MANUAL*
  - *Part 1*

    20.10 - Cardiac Rehabilitation Programs

    30.1 - Biofeedback Therapy

    30.1.1 - Biofeedback Therapy for the Treatment of Urinary Incontinence

    50.1 – Speech Generating Devices

    50.2 - Electronic Speech Aids

    50.4 - Tracheostomy Speaking Valve
  - *Part 2*

    150.2 - Osteogenic Stimulator

    150.4 - Neuromuscular Electrical Stimulator (NMES) in the Treatment of Disuse Atrophy

    160.3 - Assessing Patient's Suitability for Electrical Nerve Stimulation

    160.7 - Electrical Nerve Stimulators

    160.11 - Osteogenic Stimulation

160.12 - Neuromuscular Electrical Stimulation (NMES)

160.13 - Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES)

160.17 - L-Dopa

- *Part 3*

  170.1 - Institutional and Home Care Patient Education Programs

  170.2 - Melodic Intonation Therapy

  170.3 - Speech Pathology Services for the Treatment of Dysphagia

  180 - Nutrition

- *Part 4*

  230.8 - Non-implantable Pelvic Flood Electrical Stimulator

  240.7 - Postural Drainage Procedures and Pulmonary Exercises

  270.1 -Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds

  270.4 - Treatment of Decubitus Ulcers

  280.3 - Specially Sized Wheelchairs

  280.4 - Seat Lift

  280.5 - Safety Roller

  280.9 - Power Operated Vehicles That May Be Used as Wheelchairs

  280.13 - Transcutaneous Electrical Nerve Stimulators (TENS)

  290.1 - Home Health Visits to A Blind Diabetic

- *Pub. 100-08 PROGRAM INTEGRITY MANUAL*
  - *Chapter 3 - Verifying Potential Errors and Taking Corrective Actions*

    3.4.1.1 - Documentation Specifications for Areas Selected for Prepayment or Postpayment MR

  - *Chapter 13 - Local Coverage Determinations*

    13.5.1 - Reasonable and Necessary Provisions in LCDs

Specific Therapy Policies. Sections 220 and 230 of this chapter describe the standards and conditions that apply generally to outpatient rehabilitation therapy services. Specific policies may differ by setting. Other policies concerning therapy services are found in other manuals. When a therapy service policy is specific to a setting, it takes precedence over these general outpatient policies. For special rules on:

- *CORFs - See chapter 12 of this manual and also Pub. 100-04, chapter 5;*
- *SNF - See chapter 8 of this manual and also Pub. 100-04, chapter 6, for SNF claims/billing;*

- *HHA - See chapter 7 of this manual, and Pub. 100-04, chapter 10;*
- *GROUP THERAPY AND STUDENTS - See Pub.100-04, chapter 5, §100.10;*
- *ARRANGEMENTS - Pub. 100-01, chapter 5, §10.3;*
- *COVERAGE is described in the Medicare Program Integrity Manual, Pub. 100-08, chapter 13, §13.5.1; and*

THERAPY CAPS - See Pub. 100-04, chapter 5, §10.2, for a complete description of this financial limitation.

C - General

Therapy services are a covered benefit in §§1861(g), 1861(p), and 1861(ll) of the Act. Therapy services may also be provided incident to the services of a physician/NPP under §§1861(s)(2) and 1862(a)(20) of the Act.

Covered therapy services are furnished by providers, by others under arrangements with and under the supervision of providers, or furnished by suppliers (e.g., physicians, NPP, enrolled therapists), who meet the requirements in Medicare manuals for therapy services.

Where a prospective payment system (PPS) applies, therapy services are paid when services conform to the requirements of that PPS. For example, see Pub. 100-04 for a description of applicable Inpatient Hospital Part B and Outpatient PPS rules. Reimbursement for therapy provided to Part A inpatients of hospitals or residents of SNFs in covered stays is included in the respective PPS rates.

Payment for therapy provided by an HHA under a plan of treatment is included in the home health PPS rate. Therapy may be billed by an HHA on bill type 34x if there are no home health services billed under a home health plan of care at the same time (e.g., the patient is not homebound), and there is a valid therapy plan of treatment.

In addition to the requirements described in this chapter, the services must be furnished in accordance with health and safety requirements set forth in regulations at 42CFR484, and 42CFR485.

220.1 - Conditions of Coverage and Payment for Outpatient Physical Therapy, Occupational Therapy, or Speech-Language Pathology Services

(Rev. 34, Issued: 05-06-05, Effective: 06-06-05, Implementation: 06-06-05)

Reference: 42CFR424.24

Refer to §230.4 for physical therapist/occupational therapist in private practice rules.

Coverage rules for specific services are in Pub. 100-03, the Medicare National Coverage Determinations Manual.

Other payment rules are found in Pub. 100-04, chapter 5.

Since the outpatient therapy benefit under Part B provides coverage only of therapy services, payment can be made only for those services that constitute therapy. In cases where there is doubt about whether a service is therapy, the contractor's local coverage determination (LCD) shall prevail.

In order for a service to be covered, it must have a benefit category in the statute, it must not be excluded and it must be reasonable and necessary. Therapy services are a benefit under §1861 of the Act. Consult Pub. 100-08, chapter 13, §13.5.1 for full descriptions of a reasonable and necessary service.

Outpatient therapy services furnished to a beneficiary by a provider or supplier are payable only when furnished in accordance with certain conditions. The following conditions of coverage apply. The requirements noted (*) are also conditions of payment in 42CFR424.24(c) and according to the Act §1835 (a)(2)(D) are the three conditions that must be certified:

- *(i) such services are or were required because the individual needed therapy services* (see §220.1.3); and*
- *(ii) a plan for furnishing such services has been established by a physician/NPP or by the therapist providing such services and is periodically reviewed by a physician/NPP* (see §220.1.2); and*
- *(iii) such services are or were furnished while the individual is or was under the care of a physician* (see §220.1.1); and*
- *Services must be furnished on an outpatient basis. (See §220.1.4)*
- *All of the conditions are met when a physician/NPP certifies an outpatient plan of care for therapy. Certification is required for coverage and payment of a therapy claim. Each of these conditions is discussed separately in the sections that follow.*

220.1.1 - Outpatient Therapy Must be Under the Care of a Physician/Nonphysician Practitioners (NPP) (Orders/Referrals and Need for Care)

(Rev. 34, Issued: 05-06-05, Effective: 06-06-05, Implementation: 06-06-05)

An order (sometimes called a referral) for therapy service, if it is documented in the medical record, provides evidence of both the need for care and that the patient is under the care of a physician. However, the certification requirements are met when the physician certifies the plan of care. If the signed order includes a plan of care (see essential requirements of plan in §220.1.2), no further certification of the plan is required. Payment is dependent on the certification of the plan of care rather than the order, but the use of an order is prudent to determine that a physician is involved in care and available to certify the plan.

(The CORF services benefit does not recognize an NPP for orders and certification.)

220.1.2 - Plans of Care for Outpatient Physical Therapy, Occupational Therapy, or Speech-Language Pathology Services

(Rev. 34, Issued: 05-06-05, Effective: 06-06-05, Implementation: 06-06-05)

Reference: 42CFR 410.61

***A - Establishing the plan** (See §220.1.3 for certifying the plan.)*

The services must relate directly and specifically to a written treatment plan as described in this chapter. The plan, (also known as a plan of care or plan of treatment) must be established before treatment is begun. The plan is established when it is developed (e.g., written or dictated).

The signature and professional identity (e.g., MD, OTR/L) of the person who established the plan, and the date it was established must be recorded with the plan. Establishing the plan, which is described below, is not the same as certifying the plan, which is described in §§220.1.1 and 220.1.3

Outpatient therapy services shall be furnished under a plan established by:

- *A physician/NPP (consultation with the treating physical therapist, occupational therapist, or speech-language pathologist is recommended. Only a physician may establish a plan of care in a CORF);*
- *The physical therapist who will provide the physical therapy services;*
- *The occupational therapist who will provide the occupational therapy services; or*
- *The speech-language pathologist who will provide the speech-language pathology services.*

The plan may be entered into the patient's therapy record either by the person who established the plan or by the provider's or supplier's staff when they make a written record of that person's oral orders before treatment is begun.

Treatment under a Plan. The evaluation and treatment may occur and are both billable either on the same day or at subsequent visits. It is appropriate that treatment begins when a plan is established.

Therapy may be initiated by qualified professionals or qualified personnel based on a dictated plan after it has been committed to writing and before it is signed. A dictated plan must be signed by close of business on the day following dictation by the person who established it.

Treatment may begin before the plan is committed to writing only if the treatment is performed or supervised by the same qualified professional who establishes the plan and that plan is established and signed by close of business on the next day by the same qualified professional. Payment for services provided before a plan is established may be denied.

***B - Contents of Plan** (See §220.1.3 for certifying the plan.)*

The plan of care shall contain, at minimum, the following information as required by regulation (42CFR424.24 and 410.61):

- *Diagnoses;*
- *Long term treatment goals; and*
- *Type, amount, duration and frequency of therapy services.*

C - Changes to the Therapy Plan

Changes are made in writing in the patient's record and signed by one of the following professionals responsible for the patient's care:

- *The physician/NPP;*
- *The qualified physical therapist (in the case of physical therapy);*
- *The qualified speech-language pathologist (in the case of speech-language pathology services);*
- *The qualified occupational therapist (in the case of occupational therapy services; or*
- *The registered professional nurse or physician/NPP on the staff of the facility pursuant to the oral orders of the physician/NPP or therapist.*

While the physician/NPP may change a plan of treatment established by the therapist providing such services, the therapist may not significantly alter a plan of treatment established or certified by a physician/NPP without their documented written or verbal approval [See §220.1.3(C)]. A change in long-term goals would be a significant change. An insignificant alteration in the plan would be a decrease in the frequency or duration due to the patient's illness, or a modification of short-term goals to adjust for improvements made toward the same long-term goals. If a patient has achieved a goal and/or has had no response to a treatment that is part of the plan, the therapist may delete a specific intervention from the plan of care prior to physician/ NPP approval. This shall be reported to the physician/NPP responsible for the patient's treatment prior to the next certification.

Procedures (e.g., neuromuscular reeducation) and modalities (e.g., ultrasound) are not goals, but are the means by which long and short term goals are obtained. Changes to procedures and modalities do not require physician signature when they represent adjustments to the plan that result from a normal progression in the patient's disease or condition. Only when the patient's condition changes significantly, making revision of long term goals necessary, is a physician's/NPP's signature required on the change, (long term goal changes may be accompanied by changes to procedures and modalities).

220.1.3 - Certification and Recertification of Need for Treatment and Therapy Plans of Care

(Rev. 34, Issued: 05-06-05, Effective: 06-06-05, Implementation: 06-06-05)

Reference: 42CFR424.24(c)

See specific certification rules for CORF in this manual, chapter 12, §30(E) and in Pub. 100-01, chapter 4, §20 for hospital services.

A - Method and Disposition of Certifications

Certification requires a dated signature on the plan of care or some other document that indicates approval of the plan of care. It is not appropriate for a physician/NPP to certify a plan of care if the patient was not under the care of some physician/NPP at the time of the treatment or if the patient did not need the treatment. Since delayed certification is allowed, the date the certification is signed is important only to determine if it is timely or delayed. The certification must relate to treatment during the interval on the claim. Unless there is reason to believe the plan was not signed appropriately, or it is not timely, no further evidence that the patient was under the care of a physician/NPP and that the patient needed the care is required.

The format of all certifications and recertifications and the method by which they are obtained is determined by the individual facility and/or practitioner. Acceptable documentation of certification may be, for example, a physician's progress note, a physician/NPP order, or a plan of care that is signed and dated during the interval of treatment by a physician/NPP, and indicates the physician/NPP is aware that therapy service is or was in progress and the physician/NPP makes no record of disagreement with the plan when there is evidence the plan was sent (e.g., to the office) or is available in the record (e.g., of the institution that employs the physician/NPP) for the physician/NPP to review.

The certification should be retained in the clinical record and available if requested by the contractor.

B - Initial Certification of Plan

The physician's/NPP's certification of the plan for the first 30 days of treatment (with or without an order) satisfies all of the certification requirements noted above in §220.1 for the first interval of 30 calendar days or 1 month of treatment.

Timing of Initial Certification. The provider or supplier (e.g., facility, physician/NPP, or therapist) should obtain certification as soon as possible after the plan of care is established, unless the requirements of delayed certification are met. "As soon as possible" means that the physician/NPP shall certify the plan as soon as it is obtained, or before the end of the first interval beginning at the initial therapy treatment. Since payment may be denied if a physician does not certify the plan, the therapist should forward the plan to the physician as soon as it is established. Evidence of diligence in providing the plan to the physician may be considered by the contractor during review in the event of a delayed certification.

Timely certification of the first interval of treatment is met when physician/NPP certification of the plan for the first interval of treatment is documented, by signature or verbal order, and dated before the end of the interval. If the order to certify is verbal, it must be followed within 14 days by a signature to be timely. A dated notation of the order to certify the plan should be made in the patient's medical record.

C - Review of Plan and Recertification

Reference: 42CFR424.24(c), 1861(r)

Payment and coverage conditions require that the plan must be reviewed, dated and signed by a physician/NPP every 30 days to complete the certification requirements in 42CFR 410.61(e), unless delayed certification requirements are met. When therapy services are continued for longer than 1 month, the physician/NPP who is responsible for the patient's care at that time should review and certify the plan for each interval of therapy. It is not required that the same physician/NPP order, certify and/or recertify the plans.

Recertifications that document the need for continued therapy in subsequent intervals should be signed before or during the subsequent intervals of treatment (when they are timely) or later, when they are delayed. Subsequent recertifications should be completed before or during the next interval, unless they are delayed.

Physician/NPP options for Certification. A physician/NPP may certify or recertify a plan for less than 30 days of treatment, if the physician/NPP determines it is appropriate. This

direction should be included in an order preceding the treatment (preferably), or in the plan of care.

Physicians/NPPs may require that the patient make a visit for an examination if, in the professional's judgment, the visit is needed prior to certifying the plan. Physicians/NPPs should indicate their requirement for visits, preferably on an order preceding the treatment, or on the plan of care. Physicians/NPPs should not sign a certification if they require a visit and a visit was not made. However, Medicare does not require a visit unless the National Coverage Determination (NCD) for a particular treatment requires it (e.g., see Pub. 100-03, §270.1 - Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds).

Restrictions on Certification. Certifications and recertifications by doctors of podiatric medicine must be consistent with the scope of the professional services provided by a doctor of podiatric medicine as authorized by applicable state law. Optometrists may order and certify only low vision services. Chiropractors may not certify or recertify plans of care for therapy services.

D - Delayed Certification

References: §1835(a) of the Act

42CFR424.11(d)(3)

Certifications are required for each 30 day interval of treatment and are timely when the certification occurs before or during the interval. Certification and recertification requirements shall be deemed satisfied where, at any later date, a physician/NPP makes a certification accompanied by a reason for the delay. Certifications are acceptable without justification for 30 days after they are due. Delayed certification should include one or more certifications or recertifications on a single signed and dated document.

Delayed certifications should include any evidence the provider or supplier considers necessary to justify the delay. For example, a certification may be delayed because the physician did not sign it, or the original was lost. In the case of a long delayed certification (over 6 months), the provider or supplier may choose to submit with the delayed certification some other documentation (e.g., an order, progress notes, telephone contact, requests for certification or signed statement of a physician/NPP) indicating need for care and that the patient was under the care of a physician at the time of the treatment. Such documentation may be requested by the contractor for delayed certifications if it is required for review.

It is not intended that needed therapy be stopped or denied when certification is delayed. The delayed certification of otherwise covered services should be accepted unless the contractor has reason to believe that there was no physician involved in the patient's care, or treatment did not meet the patient's need (and therefore, the certification was signed inappropriately).

Example. Payment should be denied if there is a certification signed 2 years after treatment by a physician/NPP who has/had no knowledge of the patient when the medical record also shows no order, note, physician/NPP attended meeting, correspondence with a physician/NPP, documentation of discussion of the plan with a physician/NPP, documentation of sending the plan to any physician/NPP, or other indication that there was a physician/NPP involved in the case.

Example Payment should not be denied, even when certified 2 years after treatment, when there is evidence that a physician approved needed treatment, such as an order, documentation of therapist/physician/NPP discussion of the plan, chart notes, meeting notes, requests for certification, or certifications for intervals before or after the service in question.

E - Denials Due to Certification

Denial for payment that is based on absence of certification is a technical denial, which means a statutory requirement has not been met. Certification is a statutory requirement in SSA 1835(a)(2)- ('periodic review" of the plan).

For example, if a patient is treated and the provider/supplier cannot produce (on contractor request) a plan of care (timely or delayed) for the billed treatment dates certified by a physician/NPP, then that service might be denied for lack of the required certification. If an appropriate certification is later produced, the denial shall be overturned.

In the case of a service furnished under a provider agreement as described in 42CFR489.21, the provider is precluded from charging the beneficiary for services denied as a result of missing certification.

However, if the service is provided by a supplier (in the office of the physician/NPP, or therapist) a technical denial due to absence of a certification results in beneficiary liability. For that reason, it is recommended that the patient be made aware of the need for certification and the consequences of its absence.

A technical denial decision may be reopened by the contractor or reversed on appeal as appropriate, if delayed certification is later produced.

220.1.4 - Requirement That Services Be Furnished on an Outpatient Basis

(Rev. 34, Issued: 05-06-05, Effective: 06-06-05, Implementation: 06-06-05)

Reference: 42CFR410.60

Therapy services are payable under the Physician Fee Schedule when furnished by 1.) a provider to its outpatients in the patient's home; 2.) a provider to patients who come to the facility's outpatient department; 3.) a provider to inpatients of other institutions, or 4.) a supplier to patients in the office or in the patient's home. (CORF rules differ on providing therapy at home.)

Coverage includes therapy services furnished by participating hospitals and SNFs to their inpatients who have exhausted Part A inpatient benefits or who are otherwise not eligible for Part A benefits. Providers of therapy services that have inpatient facilities, other than participating hospitals and SNFs, may not furnish covered therapy services to their own inpatients. However, since the inpatients of one institution may be considered the outpatients of another institution, all providers of therapy services may furnish such services to inpatients of another health facility.

A certified distinct part of an institution is considered to be a separate institution from a nonparticipating part of the institution. Consequently, the certified distinct part may render covered therapy services to the inpatients of the noncertified part of the institution or to outpatients. The certified part must bill the intermediary under Part B.

Therapy services are payable when furnished in the home at the same physician fee schedule payments as in other outpatient settings. Additional expenses incurred by providers due to travel to a person who is not homebound will not be covered.

Under the Medicare law, there is no authority to require a provider to furnish a type of service. Therefore, a hospital or SNF may furnish therapy to its inpatients without having to set up facilities and procedures for furnishing those services to its outpatients. However, if the provider chooses to furnish a particular service, it may not charge any individual or other person for items or services for which the individual is entitled to have payment made under the program because it is bound by its agreement with Medicare. Thus, whenever a hospital or SNF furnishes outpatient therapy to a Medicare beneficiary (either directly or under arrangements with others) it must bill the program under Part B and may charge the patient only for the applicable deductible and coinsurance.

220.2 - Reasonable and Necessary Outpatient Rehabilitation Therapy Services

(Rev. 34, Issued: 05-06-05, Effective: 06-06-05, Implementation: 06-06-05)

References: Pub. 100-08, chapter 13, §13.5.1

42CFR410.59,

42CFR410.60

A - General

To be covered, services must be skilled therapy services as described in this chapter and be rendered under the conditions specified. Services provided by professionals or personnel who do not meet the qualification standards, and services by qualified people that are not appropriate to the setting or conditions are unskilled services. Unskilled services are palliative procedures that are repetitive or reinforce previously learned skills, or maintain function after a maintenance program has been developed. These services are not covered because they do not involve complex and sophisticated therapy procedures, or the judgment and skill of a qualified therapist for safety and effectiveness.

Services which do not meet the requirements for covered therapy services in Medicare manuals are not payable using codes and descriptions for therapy services. For example, services related to activities for the general good and welfare of patients, e.g., general exercises to promote overall fitness and flexibility and activities to provide diversion or general motivation, do not constitute therapy services for Medicare purposes. Also, services not provided under a therapy plan of care, or are provided by staff who are not qualified or appropriately supervised, are not covered or payable therapy services.

Examples of coverage policies that apply to all outpatient therapy claims are in this chapter, in Pub. 100-04, chapter 5, and Pub. 100-08, chapter 13. Some policies in other manuals are repeated here for emphasis and clarification.

B - Reasonable and Necessary

To be considered reasonable and necessary the following conditions must each be met:

- *The services shall be considered under accepted standards of medical practice to be a specific and effective treatment for the patient's condition. Acceptable practices for therapy services are found in:*
  - *Medicare manuals (such as this manual and Publications 100-03 and 100-04),*
  - *Contractors Local Coverage Determinations (LCDs and NCDs are available on the Medicare Coverage Database: http://www.cms.hhs.gov/mcd, and*
  - *Guidelines and literature of the professions of physical therapy, occupational therapy and speech-language pathology.*
- *The services shall be of such a level of complexity and sophistication or the condition of the patient shall be such that the services required can be safely and effectively performed only by a qualified therapist, or in the case of physical therapy and occupational therapy by or under the supervision of a qualified therapist. Services that do not require the performance or supervision of a therapist are not skilled and are not considered reasonable or necessary therapy services, even if they are performed or supervised by a qualified professional.*
- *If the contractor determines the services furnished were of a type that could have been safely and effectively performed only by or under the supervision of such a qualified professional, it shall presume that such services were properly supervised when required. However, this presumption is rebuttable, and, if in the course of processing claims it finds that services are not being furnished under proper supervision, it shall deny the claim and bring this matter to the attention of the Division of Survey and Certification of the Regional Office.*
- *The skills of a therapist are needed to manage and periodically reevaluate the appropriateness of a maintenance program as described below.*
- *While a beneficiary's particular medical condition is a valid factor in deciding if skilled therapy services are needed, a beneficiary's diagnosis or prognosis should never be the sole factor in deciding that a service is or is not skilled. The key issue is whether the skills of a qualified therapist are needed to treat the illness or injury, or whether the services can be carried out by nonskilled personnel. See item C for descriptions of skilled (rehabilitative) services.*
- *There must be an expectation that the patient's condition will improve significantly in a reasonable (and generally predictable) period of time, or the services must be necessary for the establishment of a safe and effective maintenance program required in connection with a specific disease state. In the case of a progressive degenerative disease, service may be intermittently necessary to determine the need for assistive equipment and/or establish a program to maximize function (see item D for descriptions of maintenance services); and*

- *The amount, frequency, and duration of the services must be reasonable under accepted standards of practice. The contractor shall consult local professionals or the state or national therapy associations in the development of any utilization guidelines.*

***NOTE**: Claims for therapy services denied because they are not considered reasonable and necessary are excluded by §1862(a)(1) of the Act and are thus subject to consideration under the waiver of liability provision in §1879 of the Act.*

C - Rehabilitative Therapy

Covered therapy services shall be rehabilitative therapy services unless they meet the criteria for maintenance therapy requiring the skills of a therapist described below. Rehabilitative therapy services are skilled procedures that may include but are not limited to:

Evaluations; reevaluations

Establishment of treatment goals specific to the patient's disability or dysfunction and designed to specifically address each problem identified in the evaluation;

Design of a plan of care addressing the patient's disorder, including establishment of procedures to obtain goals, determining the frequency and intensity of treatment;

Continued assessment and analysis during implementation of the services at regular intervals;

Instruction leading to establishment of compensatory skills;

Selection of devices to replace or augment a function (e.g., for use as an alternative communication system and short-term training on use of the device or system); and

Patient and family training to augment rehabilitative treatment or establish a maintenance program. Education of staff and family should be ongoing through treatment and instructions may have to be modified intermittently if the patient's status changes.

Rehabilitative therapy occurs when the skills of a therapist (as defined by the scope of practice for therapists in the state), are necessary to safely and effectively furnish a recognized therapy service whose goal is improvement of an impairment or functional limitation. Rehabilitative therapy services are reasonable and necessary services furnished by or under the supervision of qualified professionals.

Skilled therapy may be needed, and improvement in a patient's condition may occur, even where a chronic or terminal condition exists. For example, a terminally ill patient may begin to exhibit self-care, mobility, and/or safety dependence requiring skilled therapy services. The fact that full or partial recovery is not possible does not necessarily mean that skilled therapy is not needed to improve the patient's condition. In the case of a progressive degenerative disease, for example, service may be intermittently necessary to determine the need for assistive equipment and establish a program to maximize function. The deciding factors are always whether the services are considered reasonable, effective treatments for

the patient's condition and require the skills of a therapist, or whether they can be safely and effectively carried out by nonskilled personnel without the supervision of qualified professionals.

If an individual's expected rehabilitation potential would be insignificant in relation to the extent and duration of physical therapy services required to achieve such potential, therapy would not be covered because it is not considered rehabilitative or reasonable and necessary.

Services that can be safely and effectively furnished by nonskilled personnel without the supervision of qualified professionals are not rehabilitative therapy services. If at any point in the treatment of an illness it is determined that the treatment is not rehabilitative, or does not legitimately require the services of a qualified professional for management of a maintenance program as described below, the services will no longer be considered reasonable and necessary. Services that are not reasonable or necessary should be excluded from coverage under §1862(a)(1) of the Act.

Therapy is not required to effect improvement or restoration of function where a patient suffers a transient and easily reversible loss or reduction of function (e.g., temporary weakness which may follow a brief period of bed rest following abdominal surgery) which could reasonably be expected to improve spontaneously as the patient gradually resumes normal activities. Therapy furnished in such situations is not considered reasonable and necessary for the treatment of the individual's illness or injury and the services are not covered. (See exceptions for maintenance in §220.2D of this manual).

D - Maintenance Programs

During the last visits for rehabilitative treatment, the qualified professional may develop a maintenance program. The goals of a maintenance program would be, for example, to maintain functional status or to prevent decline in function. The specialized knowledge and judgment of a qualified therapist would be required, and services are covered, to design or establish the plan, assure patient safety, train the patient, family members and/or unskilled personnel and make infrequent but periodic reevaluations of the plan.

The services of a qualified professional are not necessary to carry out a maintenance program, and are not covered under ordinary circumstances. The patient may perform such a program independently or with the assistance of unskilled personnel or family members.

Where a maintenance program is not established until after the rehabilitative physical therapy program has been completed (and the skills of a therapist are not necessary) development of a maintenance program would not be considered reasonable and necessary for the treatment of the patient's condition. It would be excluded from coverage under §1862(a)(1) of the Act unless the patient's safety was at risk (see below).

Example. A Parkinson patient who has been under a rehabilitative physical therapy program may require the services of a therapist during the last week or two of treatment to determine what type of exercises will contribute the most to maintain the patient's present functional level following cessation of treatment. In such situations, the design of a maintenance program appropriate to the capacity and tolerance of the patient by the qualified therapist, the instruction of the patient or family members in carrying out the

program, and such infrequent reevaluations as may be required would constitute covered therapy because of the need for the skills of a qualified professional.

Evaluation and Maintenance Plan without Rehabilitative Treatment. After the initial evaluation of the extent of the disorder, illness, or injury, if the treating qualified professional determines the potential for rehabilitation is insignificant, an appropriate maintenance program may be established prior to discharge. Since the skills of a therapist are required for the development of the maintenance program and training the patient or caregivers, this service is covered.

Example. The skills of a qualified speech-language pathologist may be covered to develop a maintenance program for a patient with multiple sclerosis, for services intended to prevent or minimize deterioration in communication ability caused by the medical condition, when the patient's current medical condition does not yet justify the need for the skilled services of a speech-language pathologist. Evaluation, development of the program and training the family or support personnel would require the skills of a therapist and would be covered. The skills of a therapist are not required and services are not covered to carry out the program.

Skilled Maintenance Therapy for Safety. If the services required to maintain function involve the use of complex and sophisticated therapy procedures, the judgment and skill of a therapist may be necessary for the safe and effective delivery of such services. When the patient's safety is at risk, those reasonable and necessary services shall be covered, even if the skills of a therapist are not ordinarily needed to carry out the activities performed as part of the maintenance program.

Example. Where there is an unhealed, unstable fracture, which requires regular exercise to maintain function until the fracture heals, the skills of a therapist would be needed to ensure that the fractured extremity is maintained in proper position and alignment during maintenance range of motion exercises.

220.3 - Conditions for Coverage of Outpatient Physical Therapy, Occupational Therapy, or Speech-Language pathology Services

(Rev. 5, 01-09-04)

B3-2206, A3-3148, HO-242

Refer to §230.4 for independent practitioner rules.

Outpatient physical therapy, occupational therapy, or speech-language pathology services furnished to a beneficiary by a participating provider are payable only when furnished in accordance with the following conditions:

- Physician's or non-physician practitioner's certification and recertification;
- Outpatient must be under the care of a physician or non-physician practitioner;
- Outpatient physical therapy, occupational therapy or speech-language pathology services furnished under a plan; and
- Services must be furnished on an outpatient basis.

Each of these conditions is discussed separately in the subsections that follow. In addition, outpatient physical therapy, occupational and speech-language pathology services must meet all of the conditions set forth in the Medicare Benefit Policy Manual, Chapter 1, "Inpatient Hospital Services," §100 and §220, and its subsections of this chapter.

220.3.1 - Physician's Certification and Recertification

(Rev. 5, 01-09-04)

B3-2206.1, A3-3148.1, HO-242.1, A3-3350, A3-3322

A - Content of Physician's Certification

The contractor must not pay for outpatient physical therapy, occupational therapy or speech-language pathology services unless a physician or non-physician practitioner certifies that:

- The services are or were required by the patient.
- A plan for furnishing such services is or was established and periodically reviewed by the physician, or non-physician practitioner. Either the physician, or non-physician practitioner or the qualified physical therapist providing such services establishes a plan of treatment for outpatient physical therapy services. Either the physician, or non-physician practitioner or the qualified occupational therapist providing such services establishes a plan of treatment for outpatient occupational therapy services. Either the physician, or non-physician practitioner or the speech-language pathologist providing such services establishes a plan of treatment for outpatient speech-language pathology services. However, a physician or non-physician practitioner must periodically review a plan established by a speech-language pathologist, occupational therapist or physical therapist. (See §220.3.3.) See §230 for specific requirements for a plan established for physical, occupational, and speech-language pathology therapy services.
- The outpatient physical therapy, occupational therapy or speech-language pathology services are or were furnished while the patient was under the care of a physician or non-physician practitioner. (See §220.3.2.)

Since the certification is closely associated with the plan of treatment, the same physician or non-physician practitioner who established or reviews the plan of treatment must certify the necessity for services. The plan must be written and developed by the physician or non-physician practitioner caring for the patient. The carrier will obtain certification at the time the plan of treatment is established or as soon thereafter as possible.

Physician means a doctor of medicine, osteopathy (including an osteopathic practitioner), podiatric medicine legally authorized to practice by the State in which they perform the services and optometrist (for low vision only). In addition, physician certifications and recertifications by doctors of podiatric medicine or optometry must be consistent with the scope of the professional services provided by a doctor of podiatric medicine or optometry as authorized by applicable State law.

B - Recertification

When outpatient physical therapy, occupational therapy or speech-language pathology services are continued under the same plan of treatment for a period of time, the physician or

non-physician practitioner must recertify at intervals of at least once every 30 days from the date last seen by the referring physician or non-physician practitioner that there is a continuing need for such services and estimate how long services are needed. Obtain the recertification at the time the plan of treatment is reviewed since the same interval (at least once every 30 days) is required for the review of the plan. The form of the recertification and the manner of obtaining timely recertification is up to the individual facility and/or practitioner.

C - Method and Disposition of Certifications

There is no requirement that the certification or recertification be entered on any specific form or handled in any specific way as long as the carrier can determine, where necessary, that the certification and recertification requirements are met. The certification by the physician or non-physician practitioner is retained by the individual facility and/or practitioner, which also certifies on the billing form that the requisite certifications and recertifications have been made by the physician or non-physician practitioner and are on file when it forwards the request for payment to the carrier.

D - Delayed Certification

The individual facility and/or practitioner must obtain certifications and recertifications as promptly as possible. Payment is not made unless the necessary certifications are secured. In addition to complying with the usual content requirements, delayed certifications and recertifications are to include an explanation for the delay and any other evidence the clinic considers necessary in the case. The format of delayed certifications and recertifications and the method by which they are obtained is left to the individual facility and/or practitioner.

220.3.2 - Outpatient Must be Under Care of Physician

(Rev. 5, 01-09-04)

B3-2206.2, A3-3148.2, HO-242.2

Outpatient physical therapy, occupational therapy, or speech-language pathology services must be furnished to an individual who is under the care of a physician or non-physician practitioner who certifies the patient's outpatient therapy services. If the therapy service continues past the 60th day, there must be evidence in the patient's clinical record, which is a part of the therapy documentation, that a physician or non-physician practitioner has seen him/her within 60 days after the therapy began and every 30 days past the 60th day. If the requirement is not met, the therapy services are not covered (reasonable and necessary). The 60-day period begins with the therapist or pathologist initial encounter with the patient, i.e., the day when the evaluation is performed. In the event that an evaluation is not indicated the first treatment session begins the 60-day period. The therapist's or pathologist's first encounter with the patient should occur in a timely manner from the date of the physician's therapy referral. For continuity of care the physician or non-physician practitioner who certifies the patient's need for outpatient therapy services is the same person who meets the visit requirements. In addition, timing of recertifications and the visit requirements should coincide. However, the physician or non-physician practitioner still makes the necessary certifications. (See §§220.3.1, 220.3.3, and 220.3.4.)

220.3.3 - Outpatient Physical Therapy, Occupational Therapy, or Speech-Language Pathology Services Furnished Under Plan

(Rev. 5, 01-09-04)

B3-2206.3, A3-3148.3, HO-242.3

Outpatient physical therapy, occupational therapy, or speech-language pathology services are furnished under a plan established by:

- A physician or non-physician practitioner after any necessary consultation with the physical therapist, occupational therapist, or speech-language pathologist, as appropriate;
- The physical therapist who will provide the physical therapy services;
- The occupational therapist who will provide the occupational therapy services; or
- The speech-language pathologist that will provide the speech-language pathology services.

The plan must be established (that is, reduced to writing either by the person who established the plan or by the provider or clinic itself when it makes a written record of that person's oral orders) before treatment is begun. The plan is promptly signed by the ordering physician, non-physician practitioner, therapist, or pathologist and incorporated into the facility's permanent record for the patient.

The plan relates the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology to its inpatients without having to set up facilities and procedures for furnishing those services to its outpatients. However, if the provider chooses to furnish a particular service, it is bound by its agreement not to charge any individual or other person for items or services for which the individual is entitled to have payment made under the program. Thus, whenever a hospital or SNF furnishes outpatient physical therapy, occupational therapy, or speech-language pathology services to a Medicare beneficiary (either directly or under arrangements with others) it must bill the program under Part B and may charge the patient only for the applicable deductible and coinsurance.

220.3.4 - Requirement That Services Be Furnished on an Outpatient Basis

(Rev. 1, 10-01-03)

B3-2206.4, A3-3148.4, HO-242.4

Outpatient physical therapy, occupational therapy, and speech-language pathology services are payable when furnished by a provider to its outpatients, i.e., to patients in their homes, to patients who come to the facility's outpatient department, or to inpatients of other institutions.

Coverage includes physical therapy, occupational therapy, and speech-language pathology services furnished by participating hospitals and SNFs to their inpatients who have exhausted Part A inpatient benefits or who are otherwise not eligible for Part A benefits. Providers of outpatient physical therapy, occupational therapy, and speech-language pathology services that have inpatient facilities, other than participating hospitals and SNFs, may not furnish covered outpatient physical therapy or speech-language pathology services to their own inpatients. However, since the inpatients of one institution may be considered the outpatients

of another institution, all providers of outpatient physical therapy and speech-language pathology services may furnish such services to inpatients of another health facility.

A certified distinct part of an institution is considered to be a separate institution from a nonparticipating remainder. Consequently, the certified distinct part may render covered outpatient physical therapy, occupational therapy, or speech-language pathology services to the inpatients of the noncertified remainder or to outpatients. The certified part must bill the intermediary under Part B.

While outpatient physical therapy, occupational therapy, and speech-language pathology are payable when furnished in the home, when added expense is caused by a visit to the home, a question must be raised as to whether the rendition of the service in the home is reasonable and necessary. Where the patient is not confined to home, such added expense cannot be considered as reasonable and necessary for the treatment of an illness or injury since the home visit is substantially more costly than the medically appropriate and realistically feasible alternative pattern of care; e.g., in the facility's outpatient department. Consequently, these additional expenses incurred by providers due to travel to a person who is not homebound will not be covered.

Under the Medicare law, there is no authority to require a provider to furnish a type of service. Therefore, a hospital or SNF may furnish physical therapy, occupational therapy, or speech-language pathology to its inpatients without having to set up facilities and procedures for furnishing those services to its outpatients. However, if the provider chooses to furnish a particular service, it is bound by its agreement not to charge any individual or other person for items or services for which the individual is entitled to have payment made under the program. Thus, whenever a hospital or SNF furnishes outpatient physical therapy, occupational therapy, or speech-language pathology to a Medicare beneficiary (either directly or under arrangements with others) it must bill the program under Part B and may charge the patient only for the applicable deductible and coinsurance.

230 - Practice of Physical Therapy, Occupational Therapy, and Speech-Language Pathology

(Rev. 34, Issued: 05-06-05, Effective: 06-06-05, Implementation: 06-06-05)

230.1 - Practice of Physical Therapy

(Rev. 34, Issued: 05-06-05, Effective: 06-06-05, Implementation: 06-06-05)

A - General

Physical therapy services are those services provided within the scope of practice of physical therapists and necessary for the diagnosis and treatment of impairments, functional limitations, disabilities or changes in physical function and health status. (See Pub. 100-03, the Medicare National Coverage Determinations Manual, for specific conditions or services.)

B - Qualified Physical Therapist Defined

Reference: 42CFR484.4

A qualified physical therapist for program coverage purposes is a person who is licensed as a physical therapist by the state in which he or she is practicing and meets one of the following requirements:

- *Has graduated from a physical therapy curriculum approved by (1) the American Physical Therapy Association, or by (2) the Committee on Allied Health Education and Accreditation of the American Medical Association, or (3) Council on Medical Education of the American Medical Association, and the American Physical Therapy Association; or*
- *Prior to January 1, 1966, (1) was admitted to membership by the American Physical Therapy Association, or (2) was admitted to registration by the American Registry of Physical Therapists, or (3) has graduated from a physical therapy curriculum in a 4-year college or university approved by a state department of education; or*
- *Has 2 years of appropriate experience as a physical therapist and has achieved a satisfactory grade on a proficiency examination conducted, approved or sponsored by the Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a state or seeking qualification as a physical therapist after December 31, 1977; or*
- *Was licensed or registered prior to January 1, 1966, and prior to January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy; or*
- *If trained outside the United States, (1) was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy, (2) meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.*

C - Services of Physical Therapy Support Personnel

Reference: 42CFR 484.4

A physical therapist assistant (PTA) is a person who is licensed as a physical therapist assistant, if applicable, by the State in which practicing, and

- *Has graduated from a 2-year college-level program approved by the American Physical Therapy Association; or*
- *Has 2 years of appropriate experience as a physical therapist assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a PTA after December 31, 1977.*

The services of PTAs used when providing covered therapy benefits are included as part of the covered service. These services are billed by the supervising physical therapist. PTAs may not provide evaluation services, make clinical judgments or decisions or take

responsibility for the service. They act at the direction and under the supervision of the treating physical therapist and in accordance with state laws.

A physical therapist must supervise PTAs. The level and frequency of supervision differs by setting (and by state or local law). General supervision is required for PTAs in all settings except private practice (which requires direct supervision) unless state practice requirements are more stringent, in which case state or local requirements must be followed. See specific settings for details. For example, in clinics, rehabilitation agencies, and public health agencies, 42CFR485.713 indicates that when a PTA provides services, either on or off the organization's premises, those services are supervised by a qualified physical therapist who makes an onsite supervisory visit at least once every 30 days or more frequently if required by state or local laws or regulation.

The services of a PTA shall not be billed as services incident to a physician/NPP's service, because they do not meet the qualifications of a therapist.

The cost of supplies (e.g., theraband, hand putty, electrodes) used in furnishing covered therapy care is included in the payment for the HCPCS codes billed by the physical therapist, and are, therefore, not separately billable. Separate coverage and billing provisions apply to items that meet the definition of brace in §130.

Services provided by aides, even if under the supervision of a therapist, are not therapy services in the outpatient setting and are not covered by Medicare. Although an aide may help the therapist by providing unskilled services, those services that are unskilled are not covered by Medicare and shall be denied as not reasonable and necessary if they are billed as therapy services.

D- Application of Medicare Guidelines to PT Services

This subsection will be used in the future to illustrate the application of the above guidelines to some of the physical therapy modalities and procedures utilized in the treatment of patients.

230.2 - Practice of Occupational Therapy

(Rev. 34, Issued: 05-06-05, Effective: 06-06-05, Implementation: 06-06-05)

A - General

Occupational therapy services are those services provided within the scope of practice of occupational therapists and necessary for the diagnosis and treatment of impairments, functional disabilities or changes in physical function and health status. (See Pub. 100-03, the Medicare National Coverage Determinations Manual, for specific conditions or services.)

Occupational therapy is medically prescribed treatment concerned with improving or restoring functions which have been impaired by illness or injury or, where function has been permanently lost or reduced by illness or injury, to improve the individual's ability to perform those tasks required for independent functioning. Such therapy may involve:

The evaluation, and reevaluation as required, of a patient's level of function by administering diagnostic and prognostic tests;

The selection and teaching of task-oriented therapeutic activities designed to restore physical function; e.g., use of woodworking activities on an inclined table to restore shoulder, elbow, and wrist range of motion lost as a result of burns;

The planning, implementing, and supervising of individualized therapeutic activity programs as part of an overall "active treatment" program for a patient with a diagnosed psychiatric illness; e.g., the use of sewing activities which require following a pattern to reduce confusion and restore reality orientation in a schizophrenic patient;

The planning and implementing of therapeutic tasks and activities to restore sensory-integrative function; e.g., providing motor and tactile activities to increase sensory input and improve response for a stroke patient with functional loss resulting in a distorted body image;

The teaching of compensatory technique to improve the level of independence in the activities of daily living, for example:

- *Teaching a patient who has lost the use of an arm how to pare potatoes and chop vegetables with one hand;*
- *Teaching an upper extremity amputee how to functionally utilize a prosthesis;*
- *Teaching a stroke patient new techniques to enable the patient to perform feeding, dressing, and other activities as independently as possible; or*
- *Teaching a patient with a hip fracture/hip replacement techniques of standing tolerance and balance to enable the patient to perform such functional activities as dressing and homemaking tasks.*

The designing, fabricating, and fitting of orthotics and self-help devices; e.g., making a hand splint for a patient with rheumatoid arthritis to maintain the hand in a functional position or constructing a device which would enable an individual to hold a utensil and feed independently; or

Vocational and prevocational assessment and training, subject to the limitations specified in item B below.

Only a qualified occupational therapist has the knowledge, training, and experience required to evaluate and, as necessary, reevaluate a patient's level of function, determine whether an occupational therapy program could reasonably be expected to improve, restore, or compensate for lost function and, where appropriate, recommend to the physician/NPP a plan of treatment.

B - Qualified Occupational Therapist Defined

Reference: 42CFR484.4

A qualified occupational therapist for program coverage purposes is an individual who meets one of the following requirements:

- *Is a graduate of an occupational therapy curriculum accredited jointly by the Committee on Allied Health Education of the American Medical Association and the American Occupational Therapy Association;*

- *Is eligible for the National Registration Examination of the American Occupational Therapy Association; or*
- *Has 2 years of appropriate experience as an occupational therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapist after December 31, 1977.*

C - Services of Occupational Therapy Support Personnel

Reference: 42CFR 484.4

An occupational therapy assistant (OTA) is a person who:

- *Meets the requirements for certification as an occupational therapy assistant established by the American Occupational Therapy Association; or*
- *Has 2 years of appropriate experience as an occupational therapy assistant and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapy assistant after December 31, 1977.*

The services of OTAs used when providing covered therapy benefits are included as part of the covered service. These services are billed by the supervising occupational therapist. OTAs may not provide evaluation services, make clinical judgments or decisions or take responsibility for the service. They act at the direction and under the supervision of the treating occupational therapist and in accordance with state laws.

An occupational therapist must supervise OTAs. The level and frequency of supervision differs by setting (and by state or local law). General supervision is required for OTAs in all settings except private practice (which requires direct supervision) unless state practice requirements are more stringent, in which case state or local requirements must be followed. See specific settings for details. For example, in clinics, rehabilitation agencies, and public health agencies, 42CFR485.713 indicates that when an OTA provides services, either on or off the organization's premises, those services are supervised by a qualified occupational therapist who makes an onsite supervisory visit at least once every 30 days or more frequently if required by state or local laws or regulation.

The services of an OTA shall not be billed as services incident to a physician/NPP's service, because they do not meet the qualifications of a therapist.

The cost of supplies (e.g., looms, ceramic tiles, or leather) used in furnishing covered therapy care is included in the payment for the HCPCS codes billed by the occupational therapist and are, therefore, not separately billable. Separate coverage and billing provisions apply to items that meet the definition of brace in §130 of this manual.

Services provided by aides, even if under the supervision of a therapist, are not therapy services in the outpatient setting and are not covered by Medicare. Although an aide may help the therapist by providing unskilled services, those services that are unskilled are not

covered by Medicare and shall be denied as not reasonable and necessary if they are billed as therapy services.

D - Application of Medicare Guidelines to Occupational Therapy Services

Occupational therapy may be required for a patient with a specific diagnosed psychiatric illness. If such services are required, they are covered assuming the coverage criteria are met. However, where an individual's motivational needs are not related to a specific diagnosed psychiatric illness, the meeting of such needs does not usually require an individualized therapeutic program. Such needs can be met through general activity programs or the efforts of other professional personnel involved in the care of the patient. Patient motivation is an appropriate and inherent function of all health disciplines, which is interwoven with other functions performed by such personnel for the patient. Accordingly, since the special skills of an occupational therapist are not required, an occupational therapy program for individuals who do not have a specific diagnosed psychiatric illness is not to be considered reasonable and necessary for the treatment of an illness or injury. Services furnished under such a program are not covered.

Occupational therapy may include vocational and prevocational assessment and training. When services provided by an occupational therapist are related solely to specific employment opportunities, work skills, or work settings, they are not reasonable or necessary for the diagnosis or treatment of an illness or injury and are not covered. However, carriers and intermediaries exercise care in applying this exclusion, because the assessment of level of function and the teaching of compensatory techniques to improve the level of function, especially in activities of daily living, are services which occupational therapists provide for both vocational and nonvocational purposes. For example, an assessment of sitting and standing tolerance might be nonvocational for a mother of young children or a retired individual living alone, but could also be a vocational test for a sales clerk. Training an amputee in the use of prosthesis for telephoning is necessary for everyday activities as well as for employment purposes. Major changes in life style may be mandatory for an individual with a substantial disability. The techniques of adjustment cannot be considered exclusively vocational or nonvocational.

230.3 - Practice of Speech-Language Pathology

(Rev. 34, Issued: 05-06-05, Effective: 06-06-05, Implementation: 06-06-05)

A - General

Speech-language pathology services are those services provided within the scope of practice of speech-language pathologists and necessary for the diagnosis and treatment of speech and language disorders, which result in communication disabilities and for the diagnosis and treatment of swallowing disorders (dysphagia), regardless of the presence of a communication disability. (See Pub. 100-03, chapter 1, §170.3)

B - Qualified Speech-Language Pathologist Defined

A qualified speech-language pathologist for program coverage purposes meets one of the following requirements:

- *The education and experience requirements for a Certificate of Clinical Competence in (speech-language pathology or audiology) granted by the American Speech-Language Hearing Association; or*
- *Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.*

Speech-language pathologists may not enroll and submit claims directly to Medicare. The services of speech-language pathologists may be billed by providers such as rehabilitation agencies, HHAs, CORFs, hospices, outpatient departments of hospitals, and suppliers such as physicians, NPPs, physical and occupational therapists in private practice.

C - Services of Speech-Language Pathology Support Personnel

Services of speech-language pathology assistants are not recognized for Medicare coverage. Services provided by speech-language pathology assistants, even if they are licensed to provide services in their states, will be considered unskilled services and denied as not reasonable and necessary if they are billed as therapy services.

Services provided by aides, even if under the supervision of a therapist, are not therapy services and are not covered by Medicare. Although an aide may help the therapist by providing unskilled services, those services are not covered by Medicare and shall be denied as not reasonable and necessary if they are billed as therapy services.

D- Application of Medicare Guidelines to Speech-Language Pathology Services

1 - Evaluation Services

Speech-language pathology evaluation services are covered if they are reasonable and necessary and not excluded as routine screening by §1862(a)(7) of the Act. The speech-language pathologist employs a variety of formal and informal speech, language, and dysphagia assessment tests to ascertain the type, causal factor(s), and severity of the speech and language or swallowing disorders. Reevaluation of patients for whom speech, language and swallowing were previously contraindicated is covered only if the patient exhibits a change in medical condition. However, monthly reevaluations; e.g., a Western Aphasia Battery, for a patient undergoing a rehabilitative speech-language pathology program, are considered a part of the treatment session and shall not be covered as a separate evaluation for billing purposes. Although hearing screening by the speech-language pathologist may be part of an evaluation, it is not billable as a separate service.

2 - Therapeutic Services

The following are examples of common medical disorders and resulting communication deficits, which may necessitate active rehabilitative therapy. <u>This list is not all-inclusive</u>:

Cerebrovascular disease such as cerebral vascular accidents presenting with dysphagia, aphasia/dysphasia, apraxia, and dysarthria;

Neurological disease such as Parkinsonism or Multiple Sclerosis with dysarthria, dysphagia, inadequate respiratory volume/control, or voice disorder; or

Laryngeal carcinoma requiring laryngectomy resulting in aphonia.

3 - Aural Rehabilitation

Aural rehabilitation may be covered and medically necessary when it has been determined by a speech-language pathologist in collaboration with an audiologist that the beneficiary's current amplification options (hearing aid, other amplification device or cochlear implant) will not sufficiently meet the patient's functional communication needs.

Assessment for the need for aural rehabilitation may be done by a speech language pathologist and includes evaluation of comprehension and production of language in oral, signed or written modalities, speech and voice production, listening skills, speech reading, communications strategies, and the impact of the hearing loss on the patient/client and family.

Aural rehabilitation consists of treatment that focuses on comprehension, and production of language in oral, signed or written modalities; speech and voice production, auditory training, speech reading, multimodal (e.g., visual, auditory-visual, and tactile) training, communication strategies, education and counseling. In determining the necessity for treatment, the beneficiary's performance in both clinical and natural environment should be considered.

4 - Dysphagia

Dysphagia, or difficulty in swallowing, can cause food to enter the airway, resulting in coughing, choking, pulmonary problems, aspiration or inadequate nutrition and hydration with resultant weight loss, failure to thrive, pneumonia and death. It is most often due to complex neurological and/or structural impairments including head and neck trauma, cerebrovascular accident, neuromuscular degenerative diseases, head and neck cancer, dementias, and encephalopathies. For these reasons, it is important that only qualified professionals with specific training and experience in this disorder provide evaluation and treatment.

The speech-language pathologist performs clinical and instrumental assessments and analyzes and integrates the diagnostic information to determine candidacy for intervention as well as appropriate compensations and rehabilitative therapy techniques. The equipment that is used in the examination may be fixed, mobile or portable. Professional guidelines recommend that the service be provided in a team setting with a physician/NPP who provides supervision of the radiological examination and interpretation of medical conditions revealed in it.

Swallowing assessment and rehabilitation are highly specialized services. The professional rendering care must have education, experience and demonstrated competencies. Competencies include but are not limited to: identifying abnormal upper aerodigestive tract structure and function; conducting an oral, pharyngeal, laryngeal and respiratory function examination as it relates to the functional assessment of swallowing; recommending methods of oral intake and risk precautions; and developing a treatment plan employing appropriate compensations and therapy techniques.

230.4 - Services Furnished by a Physical or Occupational Therapist in Private Practice

(Rev. 34, Issued: 05-06-05, Effective: 06-06-05, Implementation: 06-06-05)

A - General

In order to qualify to bill Medicare directly as a therapist, each individual must be enrolled as a private practitioner and employed in one of the following practice types: an unincorporated solo practice, unincorporated partnership, unincorporated group practice, physician/NPP group or groups that are not professional corporations, if allowed by state and local law. Physician/NPP group practices may employ physical therapists in private practice (PTPP) and/or occupational therapists in private practice (OTPP) if state and local law permits this employee relationship.

For purposes of this provision, a physician/NPP group practice is defined as one or more physicians/NPPs enrolled with Medicare who may bill as one entity. For further details on issues concerning enrollment, see the provider enrollment Web site at www.cms.hhs.gov/providers/enrollment.

Private practice also includes therapists who are practicing therapy as employees of another supplier, of a professional corporation or other incorporated therapy practice. Private practice does not include individuals when they are working as employees of an institutional provider.

Services should be furnished in the therapist's or group's office or in the patient's home. The office is defined as the location(s) where the practice is operated, in the state(s) where the therapist (and practice, if applicable) is legally authorized to furnish services, during the hours that the therapist engages in the practice at that location. If services are furnished in a private practice office space, that space shall be owned, leased, or rented by the practice and used for the exclusive purpose of operating the practice. For example, a therapist in private practice may furnish aquatic therapy in a community center pool. As required in other settings (such as rehabilitation agencies and CORFs), the practice would have to rent or lease the pool for those hours, and the use of the pool during that time would have to be restricted to the therapist's patients, in order to recognize the pool as part of the therapist's own practice office during those hours. Therapists in private practice must be approved as meeting certain requirements, but do not execute a formal provider agreement with the Secretary.

If therapists who have their own Medicare Personal Identification number (PIN) or National Provider Identifier (NPI) are employed by therapist groups, physician/NPP groups, or groups that are not professional organizations, the requirement that therapy space be owned, leased, or rented may be satisfied by the group that employs the therapist. Each physical or occupational therapist employed by a group should enroll as a PT or OT in private practice.

When therapists with a Medicare PIN/NPI provide services in the physician's/NPP's office in which they are employed, and bill using their PIN/NPI for each therapy service, then the direct supervision requirement for PTAs and OTAs apply.

When the PT or OT who has a Medicare PIN/ NPI is employed in a physician's/NPP's office the services are ordinarily billed as services of the PT or OT, with the PT or OT identified on the claim as the supplier of services. However, services of the PT or OT who has a Medicare PIN/NPI may also be billed by the physician/NPP as services incident to the physician's/NPP's service. (See §230.5 for rules related to PTA and OTA services incident

to a physician.) In that case, the physician/NPP is the supplier of service, the Unique Provider Identification Number (UPIN) or NPI of the physician/NPP (ordering or supervising, as indicated) is reported on the claim with the service and all the rules for incident to services (§230.5) must be followed.

B - Private Practice Defined

*Reference: **Federal Register** November, 1998, pages 58863-58869; 42CFR 410.38(b)*

The carrier considers a therapist to be in private practice if the therapist maintains office space at his or her own expense and furnishes services only in that space or the patient's home. Or, a therapist is employed by another supplier and furnishes services in facilities provided at the expense of that supplier.

The therapist need not be in full-time private practice but must be engaged in private practice on a regular basis; i.e., the therapist is recognized as a private practitioner and for that purpose has access to the necessary equipment to provide an adequate program of therapy.

The physical or occupational therapy services must be provided either by or under the direct supervision of the therapist in private practice. Each physical or occupational therapist in a practice should be enrolled as a Medicare provider. If a physical or occupational therapist is not enrolled, the services of that therapist must be directly supervised by an enrolled physical or occupational therapist. Direct supervision requires that the supervising private practice therapist be present in the office suite at the time the service is performed. These direct supervision requirements apply only in the private practice setting and only for physical therapists and occupational therapists and their assistants. In other outpatient settings, supervision rules differ. The services of support personnel must be included in the therapist's bill. The supporting personnel, including other therapists, must be W-2 or 1099 employees of the therapist in private practice or other qualified employer.

*Coverage of outpatient physical therapy and occupational therapy under Part B includes the services of a qualified therapist in private practice when furnished in the therapist's office or the beneficiary's home. For this purpose, "home" includes an institution that is used as a home, but not a hospital, CAH or SNF, (**Federal Register** Nov. 2, 1998, pg 58869). Place of Service (POS) includes:*

- *03/School, only if residential,*
- *04/Homeless Shelter,*
- *12/Home, other than a facility that is a private residence,*
- *14/Group Home,*
- *33/Custodial Care Facility.*

C - Assignment

*Reference: Nov. 2, 1998 **Federal Register**, pg. 58863*

See also Pub. 100-04 chapter 1, 30.2.

When physicians, NPPs, PTPPs or OTPPs obtain provider numbers, they have the option of accepting assignment (participating) or not accepting assignment (nonparticipating). In contrast, providers, such as outpatient hospitals, SNFs, rehabilitation agencies, and CORFs, do not have the option. For these providers, assignment is mandatory.

If physicians/NPPs, PTPPs or OTPPs accept assignment (are participating), they must accept the Medicare Physician Fee Schedule amount as payment. Medicare pays 80% and the patient is responsible for 20%. In contrast, if they do not accept assignment, Medicare will only pay 95% of the fee schedule amount. However, when these services are not furnished on an assignment-related basis, the limiting charge applies. (See §1848(g)(2)(c) of the Act.)

***NOTE**: Services furnished by a therapist in the therapist's office under arrangements with hospitals in rural communities and public health agencies (or services provided in the beneficiary's home under arrangements with a provider of outpatient physical or occupational therapy services) are not covered under this provision. See section 230.6.*

230.5 - Physical Therapy, Occupational Therapy and Speech-Language Pathology Services Provided Incident to the Services of Physicians and (Rev. 34, Issued: 05-06-05, Effective: 06-06-05, Implementation: 06-06-05)

References: §1861(s)(2)(A) of the Act

42 CFR 410.10(b)

42 CFR 410.26

Pub. 100-02, ch. 15, § 60.

The Benefit. Therapy services have their own benefit under §1861 of the Social Security Act and shall be covered when provided according to the standards and conditions of the benefit described in Medicare manuals. The statute 1862(a)(20) requires that payment be made for a therapy service billed by a physician/NPP only if the service meets the standards and conditions--other than licensing--that would apply to a therapist. (For example, see coverage requirements in Pub. 100-08, chapter 13, §13.5.1(C), Pub. 100-04, chapter 5, and also the requirements of this manual, §220 and §230.

Incident to a Therapist. There is no coverage for services provided incident to the services of a therapist. Although PTAs and OTAs work under the supervision of a therapist and their services may be billed by the therapist, their services are covered under the benefit for therapy services and not by the benefit for services incident to a physician/NPP. The services furnished by PTAs and OTAs are not incident to the therapist's service.

Qualifications of Auxiliary Personnel. Therapy services appropriately billed incident to a physician's/NPP's service shall be subject to the same requirements as therapy services that would be furnished by a physical therapist, occupational therapist or speech-language pathologist in any other outpatient setting with one exception. When therapy services are performed incident to a physician's/NPP's service, the qualified personnel who perform the service do not need to have a license to practice therapy, unless it is required by state law. The qualified personnel must meet all the other requirements except licensure. Qualifications for therapists are found in 42CFR484.4 and in section 230.1, 230.2, and 230.3 of this manual. In effect, these rules require that the person who furnishes the service to the

patient must, at least, be a graduate of a program of training for one of the therapy services as described above. Regardless of any state licensing that allows other health professionals to provide therapy services, Medicare is authorized to pay only for services provided by those trained specifically in physical therapy, occupational therapy or speech-language pathology. That means that the services of athletic trainers, massage therapists, recreation therapists, kinesiotherapists, low vision specialists or any other profession may not be billed as therapy services.

The services of PTAs and OTAs also may not be billed incident to a physician's/NPP's service. However, if a PT and PTA (or an OT and OTA) are both employed in a physician's office, the services of the PTA, when directly supervised by the PT or the services of the OTA, when directly supervised by the OT may be billed by the physician group as PT or OT services using the PIN/NPI of the enrolled PT (or OT). (See Section 230.4 for private practice rules on billing services performed in a physician's office.) If the PT or OT is not enrolled, Medicare shall not pay for the services of a PTA or OTA billed incident to the physician's service, because they do not meet the qualification standards in 42CFR484.4.

Therapy services provided and billed incident to the services of a physician/NPP also must meet all incident-to requirements in this manual in chapter 15, §60. Where the policies have different requirements, the more stringent requirement shall be met.

For example, when therapy services are billed as incident to a physician/NPP services, the requirement for direct supervision by the physician/NPP and other incident to requirements must be met, even though the service is provided by a licensed therapist who may perform the services unsupervised in other settings.

The mandatory assignment provision does not apply to therapy services furnished by a physician/NPP or "incident to" a physician's/NPP's service. However, when these services are not furnished on an assignment-related basis; the limiting charge applies.

For emphasis, following are some of the standards that apply to therapy services billed incident-to the services of a physician/NPP in the physician's/NPP's office or the beneficiary's residence.

A. *Therapy services provided to the beneficiary must be covered and payable outpatient rehabilitation services as described, for example, in this section as well as Pub. 100-08, chapter 13, §13.5.1.*

B. *Therapy services must be provided by, or under the direct supervision of a physician (a doctor of medicine or osteopathy) or NPP who is legally authorized to practice therapy services by the state in which he or she performs such function or action. Direct supervision requirements are the same as in 42CFR410.32(b)(3). The supervisor must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician/NPP must be present in the same room in the office where the service is performed.*

C. *The services must be of a level of complexity that require that they be performed by a therapist or under the direct supervision of the therapist, physician/NPP who is licensed to perform them. Services that do not require the performance or supervision of the therapist, physician/NPP, are not considered reasonable or*

necessary therapy services even if they are performed or supervised by a physician/NPP or other qualified professional.

D. *Services must be furnished under a plan of treatment as in §220.1.2 of this chapter. The services provided must relate directly to the physician/NPP service to which it is incident.*

230.6 - Therapy Services Furnished Under Arrangements With Providers and Clinics

(Rev. 34, Issued: 05-06-05, Effective: 06-06-05, Implementation: 06-06-05)

References: See also Pub. 100-01, chapter 5, §10.3.

A - General

For rules regarding services provided under arrangement, see Pub. 100-01, chapter 5, §10.3.

A provider may have others furnish outpatient therapy (physical therapy, occupational therapy, or speech-language pathology) services through arrangements under which receipt of payment by the provider for the services discharges the liability of the beneficiary or any other person to pay for the service.

However, it is not intended that the provider merely serve as a billing mechanism for the other party. For such services to be covered the provider must assume professional responsibility for the services.

The provider's professional supervision over the services requires application of many of the same controls that are applied to services furnished by salaried employees. The provider must:

- *Accept the patient for treatment in accordance with its admission policies;*
- *Maintain a complete and timely clinical record on the patient which includes diagnosis, medical history, orders, and progress notes relating to all services received;*
- *Maintain liaison with the attending physician/NPP with regard to the progress of the patient and to assure that the required plan of treatment is periodically reviewed by the physician/NPP;*
- *Secure from the physician/NPP the required certifications and recertifications; and*
- *Ensure that the medical necessity of such service is reviewed on a sample basis by the agency's staff or an outside review group.*

In addition, when a provider provides outpatient services under an arrangement with others, such services must be furnished in accordance with the terms of a written contract, which provides for retention by the provider of responsibility for and control and supervision of such services. The terms of the contract should include at least the following:

- *Provide that the therapy services are to be furnished in accordance with the plan of care established according to Medicare policies for therapy plans of care in Section 220.1.2 of this chapter;*

- *Specify the geographical areas in which the services are to be furnished;*
- *Provide that contracted personnel and services meet the same requirements as those which would be applicable if the personnel and services were furnished directly by the provider;*
- *Provide that the therapist will participate in conferences required to coordinate the care of an individual patient;*
- *Provide for the preparation of treatment records, with progress notes and observations, and for the prompt incorporation of such into the clinical records of the clinic;*
- *Specify the financial arrangements. The contracting organization or individual may not bill the patient or the health insurance program; and*
- *Specify the period of time the contract is to be in effect and the manner of termination or renewal.*

B - Special Rules for Hospitals

- *A hospital may bill Medicare for outpatient therapy (physical therapy, occupational therapy, or speech-language pathology) services that it furnishes to its outpatients either directly or under arrangements in the hospital's outpatient department. If a hospital furnishes medically necessary therapy services in its outpatient department to individuals who are registered as its outpatients, those services must be billed directly by the hospital using bill type 13X or 85X for critical access hospitals. Note that services provided to residents of a Medicare-certified SNF may not be billed by the hospital as services to its outpatients.*
- *When a hospital sends its therapists to the home of an individual who is registered as an outpatient of the hospital but who is unable, for medical reasons, to come to the hospital to receive medically necessary therapy services, the services must meet the requirements applicable to outpatient hospital therapy services, as set forth in the regulations and applicable Medicare manuals. The hospital may bill for those services directly using bill type 13X or 85X for critical access hospitals.*
- *If a hospital sends its therapists to provide therapy services to individuals who are registered as its outpatients and who are residing in the non-certified part of a SNF, or in another residential setting (e.g., a group home, assisted living facility or domiciliary care home), the hospital may bill for the services as hospital outpatient services if the services meet the requirements applicable to outpatient hospital therapy services, as set forth in the regulations and applicable Medicare manuals.*
- *A hospital may make an arrangement with another entity such as an Outpatient Rehab Facility (Rehabilitation Agency) or a private practice, to provide therapy services to individuals who are registered as outpatients of the hospital. These services must meet the requirements applicable to services furnished under arrangements and the requirements applicable to the outpatient hospital therapy services as set forth in the regulations and applicable Medicare manuals. The*

hospital uses bill type 13X or 85X for critical access hospitals to bill for the services that another entity furnishes under arrangement to its outpatients.

- *Where the provider is a public health agency or a hospital in a rural community, it may enter into arrangements to have outpatient physical therapy services furnished in the private office of a qualified physical therapist if the agency or hospital does not have the capacity to provide on its premises all of the modalities of treatment, tests, and measurements that are included in an adequate outpatient physical therapy program and the services and modalities which the public health agency or hospital cannot provide on its premises are not available on an outpatient basis in another accessible certified facility.*
- *In certain settings and under certain circumstances, hospitals may not bill Medicare for therapy services as services of the hospital:*
  - *If a hospital sends its therapists to provide therapy services to patients of another hospital, including a patient at an inpatient rehabilitation facility or a long term care facility, the services must be furnished under arrangements made with the hospital sending the therapists by the hospital having the patients and billed as hospital services by the facility whose patients are treated. These services would be subject to existing hospital bundling rules and would be paid under the payment method applicable to the hospital at which the individuals are patients.*
  - *A hospital may not send its therapists to provide therapy services to individuals who are receiving services from an HHA under a home health plan of care and bill for the therapy services as hospital outpatient services. For patients under a home health plan of care, payment for therapy services (unless provided by physicians/NPPs) is included or bundled into Medicare's episodic payment to the HHA, and those services must be billed by the HHA under the HHA consolidated billing rules. For patients receiving HHA services under an HHA plan of care, therapy services must be furnished directly or under arrangements made by the HHA, and only the HHA may bill for those services.*
  - *If a hospital sends its therapists to provide services under arrangements made by a SNF to residents of the Medicare-certified part of a SNF, SNF consolidated billing rules apply. For arrangements specific to SNF Part A, see Pub. 100-04, chapter 6, §10.4. This means that therapy services furnished to SNF residents in the Medicare-certified part of a SNF cannot be billed by any entity other than the SNF. Therefore, a hospital may not bill Medicare for PT/OT/SLP services furnished to residents of a Medicare-certified part of a SNF by its therapists as services of the hospital.*

    ***NOTE**: If the SNF resident is in a covered Part A stay, the therapy services would be included in the SNF's global PPS per diem payment for the covered Part A stay itself. If the resident is in a noncovered stay (Part A benefits exhausted, no prior qualifying hospital stay, etc.), but remains in the Medicare-certified part of a SNF, the SNF would submit the Part B therapy bill to its fiscal intermediary.*

SNF Setting	***Applicable Rules***	
Medicare Part A or B	***Consolidated Billing Rules Apply?***	***Hospital May Bill For Outpatient Services?***
Part A (Medicare Covered / PPS) Resident in Medicare-certified part of a SNF	*Yes*	*No*
Medicare Part B Resident in Medicare-certified part of a SNF	*Yes*	*No*
Medicare Part B *Not a Resident in Medicare-certified part of a SNF*	*No*	*Yes*

- *A hospital may not send therapy staff to provide therapy services in non-residential health care settings and bill for the services as if they were provided at the hospital, even if the hospital owns the other facility or entity. Examples of such non-residential settings include CORFs, rehabilitation agencies, ORFs and offices of physicians/NPPs or other practitioners, such as physical therapists. For example, services furnished to patients of a CORF must be billed as CORF services and not as outpatient hospital services. Even if a CORF contracts with a hospital to furnish services to CORF patients, the hospital may not bill Medicare for the services as hospital outpatient services. However, the CORF could have the hospital furnish services to its patients under arrangements, in which case the CORF would bill for the services.*

Psychiatric hospitals are treated the same as other hospitals for the purpose of therapy billing.

14.6 Other Print and Online References

CMS forms:
http://www.cms.hhs.gov/forms/

Code of Federal Regulations search page:
http://www.gpoaccess.gov/cfr/index.html

Federal Register search page:
http://www.gpoaccess.gov/fr/index.html

Medicare Benefit Policy Manual, Chapter 15, Covered Medical and Other Health Services:
http://new.cms.hhs.gov/manuals/Downloads/bp102c15.pdf

Social Security Act index page:
http://www.ssa.gov/OP_Home/ssact/comp-ssa.htm

State Operations Manual Appendix index:
http://new.cms.hhs.gov/manuals/downloads/som107c09_appendixtoc.pdf

Survey & Certification letters:
http://www.cms.hhs.gov/SurveyCertificationGenInfo/01_Overview.asp#TopOfPage

Rehabilitation Reference Manual

Tab 15: OPT Survey Deficiency Documentation

15.1 Example

15.2 Survey Tool: OPT

15.1 Example

Sample Deficiency for OPT

I058, Personnel Qualified to Provide PT

Based on observation, interview and record review, the provider failed to ensure a qualified physical therapist (PT) was readily available during the time PT services were provided by the physical therapist assistant (PTA).

Findings:

1. Review of the clinic record for Patient #1 revealed the evaluation was completed and a plan of treatment established by the PT on 4/12/05. The plan of treatment included gait training with a walker, for a 30-day period.
2. On 5/3/05 at 10:00 a.m., the PTA was observed as he provided PT services for Patient #1. The treatment session included training in the use of a walker. The PTA corrected Patient #1 as he frequently lifted and carried the walker. The PTA and Patient #1 both stated the patient was ready to try using a cane instead of a walker. The PTA stated he had called the PT on 4/26/05 but the PT had not come to the clinic to evaluate Patient #1 regarding the possible change of assistive device. Patient #1 stated he was tired of using the walker and of having to wait for the PT to come to the clinic.
3. During an interview on 5/3/05 at 10:15 a.m., the facility administrator verified the PTA's statement. The administrator stated he had called the PT at 10:10 a.m. today and the PT would be present tomorrow for Patient #1's PT session. The administrator stated the facility was not always available when needed for PT evaluations or reassessments.

15.2 Survey Tool: OPT

Outpatient Physical Therapy-Speech Pathology I Tags and I-Tag Identifiers

I-7 ***CoP: Compliance with Fed., State, and Local Laws (485.707)***

I-8 Licensure of organization

I-9 Licensure or registration of personnel

I-11 ***CoP: Administrative Management (485.709)***

I-12 Governing body (GB): Responsibilities

I-15 GB: Administrator

I-19 GB: Personnel policies

I-22 GB: Patient care policies

I-47 ***CoP: Plan of Care (PoC) and Physician Involvement (PI) (485.711)***

I-49 PoC: Medical history prior treatment
- Past current medical findings
- Physician orders may not be available (don't cite)

I-50 PoC: Plan of care
- Established by MD/PT/SLP
- Goals
- Specifies type/amount/frequency/duration
- Reviewed *and signed* every 30 days
- Documented changes in plans

I-54 PI: Emergency care
- At least one doctor to provide emergency care
- Emergency procedures documented

I-55 ***CoP: Physical Therapy Services (485.713)***
- Adequate personnel equipment

I-56 Adequate program
- Variety of modalities therapeutic procedures
- Evaluations
- Supervision

I-57 Facility equipment
- Equipment can service patient disabilities

I-58 Personnel qualified to provide physical therapy
- Qualified physical therapist (PT) or PT assistant
- Qualified PT present or available during all hours of operation

I-63 Supportive personnel
- Supervised directly by qualified PT

I-150 ***Speech Pathology Services (485.715)***

I-151 Adequate program
- Effectively treats disabilities it accepts

I-152 Facility equipment
- Equipment adequate to provide range of services

I-153 Personnel qualified to provide speech pathology
- Qualified speech language pathologist (SLP) present when services furnished

I-67 ***CoP: Rehabilitation Program (RP) (485.717)***
- Applies only to an OPT's own patients (not patients it treats for a SNF, hospital, etc.)
- PT/SLP services
- Social or vocational adjustment services for pts. who need them (How does the agency determine who needs services?)

I-68 RP: Qualification of staff

I-72 RP: Social worker/vocational assistant under arrangement
- Written contracts—terms/responsibilities

I-79 ***CoP: Arrangements for PT/SLP (485.719)***
- Written contract—organization retains responsibility/control/supervision

I-80 Contract provisions
- Contract—terms
- Personnel meet req. of salaried personnel
- Only provider can bill Medicare

I-96 ***CoP: Clinical Records (CR) (485.721)***
- Must be accessible to surveyors during survey

I-154 CR: Protection of CR information
- Policies—safeguards

I-97 CR: Content—Clear/adequate documentation

I-155 CR: Completion/centralization
- All clinical information stored in CR
- MD signatures

I-108 CR: Retention/preservation
- Determined by state *or*
- 5 yrs post d/c *or*
- 3 yrs after minor becomes of age or 5 yrs post d/c (whichever is longer)

I-156 CR: Indexed by name of patient

I-157 CR: Location/facilities—easy access

I-117 ***CoP: Physical Environment (PE) (485.723)***
- Protect health and safety

I-118 PE: Safety
- *Two* people must be on duty at all times patient care is provided (including ext. locations)

I-158 PE: Maintenance of equip/building/grounds
- Maintenance checklist
- No potential hazards

I-130 PE: Other environmental considerations
- Restrooms handicapped accessible
- Adequate space
- Environment conducive to treatment

I-159 ***CoP: Infection Control (IC) (485.725)***
- IC Committee
- Sanitary environment

I-606 Applicability of the Plan of Treatment to established goals

I-607 Adequacy of clinical records
- Assessing quality of services provided
- Policies and practices compatible
- Adequate and efficient use of services

I-160 IC: IC Committee—drafts and monitors staff

I-161 IC: Aseptic isolation techniques—procedures reviewed annually, followed by staff

I-162 IC: Housekeeping
- Housekeeping supervisor
- Are services contracted & do they meet standard?

I-163 IC: Linen—handled/stored to prevent infection

I-164 IC: Pest control—building free of insects/rodents

I-165 ***CoP: Disaster Preparedness (DP) (485.727)***
- Plan rehearsed with instructions for care of casualties

I-166 DP: Disaster plan

I-167 DP: Staff training/drills—staff know their roles

I-168 ***CoP: Program Evaluation (PE) (485.729)***

I-169 PE: Clinical record review quarterly

I-170 PE: Annual statistical evaluation

Rehabilitation Reference Manual

Tab 16: Introduction to Inpatient Rehabilitation Facility Survey

16.1 Introductory Comments

16.2 Medical Conditions That Count Towards the 75% Rule

16.3 Skills Checklist: IRFs

16.1 Introductory Comments

16.1: Introductory Comments

Inpatient rehabilitation facilities (IRFs) are defined as inpatient rehabilitation hospitals or acute care hospital rehabilitation units.

To be reimbursed under the IRF prospective payment system (PPS), the IRF must meet:

- The requirements for exclusion from the Inpatient PPS, as outlined in:
  - 42 CFR 412.22 through 412.30
  - 42 CFR 412, subpart P (412.600 through 412.632)
- The hospital Conditions of Participation specified in 42 CFR 482, subparts A, B, C and D.

An IRF must complete the IRF patient assessment instrument (IRF-PAI) for all Medicare Part A fee-for-service patients in order to be reimbursed under the IRF PPS rate. The IRF-PAI is included in this section of the Reference Manual. There must be written evidence in a patient's medical record indicating the patient was informed about their right to privacy regarding the collection of IRF-PAI information.

An IRF has no bed capacity restrictions. However, beds assigned to an IRF unit must be physically separate from (not commingled with) beds not included in the unit.

In 1984, CMS published a Final Rule which specified that in order to be classified as an IRF, 75% of a facility's total patient population during the facility's cost reporting period must match one or more of 10 medical conditions (listed in this section of the Reference Manual). The final rule became known as the 75% rule. The fiscal intermediary validates the 75% rule. On May 7, 2004, CMS published a Final Rule that revised 42 CFR 412.23(b)(2). The revision established that a specific percentage of patients must require intensive rehabilitation services for the treatment of one or more of 13 medical conditions in order for a facility to qualify as an IRF. This information was promulgated in the Medicare Claims Processing Transmittal 221 of June 25, 2004 for CMS Manual System Publication 100-04. The percentage of the total population required for a facility to qualify as an IRF will change over the next three years. For cost reporting periods on or after July 1, 2007, a facility must have served an inpatient population of whom at least 75% required intensive rehabilitative services for the treatment of one or more of the 13 medical conditions. The changes in the percentages over the next three years, as well as a list of the 13 medical conditions, have been included in this section of the Reference Manual for convenience.

An IRF (hospital) must have a full-time director of rehabilitation who is a doctor of medicine or osteopathy, is licensed under State law to practice medicine or surgery and who has had, after completing a one-year hospital internship, at least two years of training or experience in the medical management of inpatients requiring rehabilitation services. An IRF (unit) must have a half-time medical director who has similar training and experience. The IRF's policy will dictate the number of hours for a full-time and half-time employee. The full- and half-time hours should be the same for all employees throughout the facility. A physician assistant's hours may not be included in the part-time or full-time hours.

An IRF is subject to verification that it continues to meet the criteria necessary to allow for exclusion from the acute care hospital IPPS. The IRF must self-attest annually that it meets the requirements for continued exclusion. The State agency must validate the requirement for a director of rehabilitation. Form CMS-437A, *Rehabilitation Unit Criteria Work Sheet or Form CMS-437B Rehabilitation Hospital Criteria Work Sheet* must be completed on an annual basis by the IRF.

For more information regarding IRFs refer to the following websites:

- www.cms.hhs.gov/medlearn/irfpps1.pdf
- www.cms.hhs.gov/providers/irfpps

16.2 Medical Conditions That Count Towards the 75% Rule

16.2: Medical Conditions That Count Towards the 75% Rule

1. Stroke.
2. Spinal cord injury.
3. Congenital deformity.
4. Amputation.
5. Major multiple trauma.
6. Fracture of femur (hip fracture).
7. Brain injury.
8. Neurological disorders, including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy and Parkinson's disease.
9. Burns.
10. Active, polyarticular rheumatoid arthritis, psoriatic arthritis, and seronegative arthropathies resulting in significant function impairment of ambulation and other activities of daily living that have not improved after an appropriate, aggressive and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission, or that result from a systemic disease activation immediately before admission but have the potential to improve with more intensive rehabilitation.
11. Systemic vasculidities with joint inflammation, resulting in significant functional impairment of ambulation and other activities of daily living that have not improved after an appropriate, aggressive and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission, or that result from a systemic disease activation immediately before admission but have the potential to improve with more intensive rehabilitation.
12. Severe or advanced osteoarthritis (osteoarthrosis or degenerative joint disease) involving two or more major weight bearing joints (elbow, shoulders, hips, or knees, but not counting a joint with a prosthesis) with joint deformity and substantial loss of range of motion, atrophy of muscles surrounding the joint, significant functional impairment of ambulation and other activities of daily living that have not improved after the patient has participated in an appropriate, aggressive and sustained course of outpatient therapy services, or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission but have the potential to improve with more intensive rehabilitation. (A joint replaced by a prosthesis no longer is considered to have osteoarthritis or other arthritis, even though this condition was the reason for the joint replacement.)
13. Knee or hip-joint replacement, or both, during an acute hospitalization immediately preceding the inpatient rehabilitation stay which also meet one or more of the following specific criteria:
    a. The patient underwent bilateral knee or bilateral hip joint replacement surgery during the acute hospital admission immediately preceding the IRF admission.
    b. The patient is extremely obese with a Body Mass Index of at least 50 at the time of admission to the IRF.
    c. The patient is age 85 or older at the time of admission to the IRF.

16.3 Skills Checklist: IRFs

16.3: Skills Checklist: IRFs

The following list summarizes the skills and knowledge necessary for successful survey. The surveyor should be able to:

- ☐ Apply the sections of the *State Operations Manual* that refer to the PPS excluded rehabilitation hospitals or rehabilitation units during survey.
- ☐ Apply the sections of the 42 Code of Federal Regulations pertaining to IRFs during survey.
- ☐ Identify the Conditions of Participation relevant to rehabilitation services in Medicare hospitals.
- ☐ Use Forms CMS 437 A and CMS 437B when surveying a PPS-excluded rehabilitation hospital or a rehabilitation unit in an acute care hospital.
- ☐ Verify the hours per week worked by the director of rehabilitation in a rehabilitation unit.
- ☐ Identify the criteria expected of the director of rehabilitation in a rehabilitation unit or rehabilitation hospital.
- ☐ Identify the specific patient assessment instrument used to gather data on patients admitted to the rehabilitation hospital or rehabilitation unit.
- ☐ Explain the term “satellite location.”
- ☐ Know the number of PPS-excluded rehabilitation units that an acute care hospital or critical access hospital may have.

Rehabilitation Reference Manual

Tab 17: *State Operations Manual* Excerpts Pertaining to IRFs

17.1 Excerpts from Appendix A

17.2 Sections 3100–3112

17.1 Excerpts from Appendix A

Excerpt from State Operations Manual

Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals (Rev. 1, 05-21-04)

Survey Protocol

Introduction
- Task 1 - Off-Site Survey Preparation
- Task 2 - Entrance Activities
- Task 3 - Information Gathering/Investigation
- Task 4 - Preliminary Decision Making and Analysis of Findings
- Task 5 - Exit Conference
- Task 6 – Post-Survey Activities

Psychiatric Hospital Survey Module

Psychiatric Unit Survey Module

Rehabilitation Hospital Survey Module

Inpatient Rehabilitation Unit Survey Module

Hospital Swing-Bed Survey Module

Regulations and Interpretive Guidelines

§482.2 Provision of Emergency Services by Nonparticipating Hospitals

§482.11 Condition of Participation: Compliance With Federal, State and Local Laws

§482.12 Condition of Participation: Governing Body

§482.12(a) Standard: Medical Staff

§482.12(b) Standard: Chief Executive Officer

§482.12(c) Standard: Care of Patients

§482.12(d) Standard: Institutional Plan and Budget

§482.12(e) Standard: Contracted Services

§482.12(f) Standard: Emergency Services

§482.13 Condition of Participation: Patients' Rights

§482.13(a) Standard: Notice of Rights

§482.13(b) Standard: Exercise of Rights

§482.13(c) Standard: Privacy and Safety

§482.13(d) Standard: Confidentiality of Patient Records

§482.13(e) Standard: Restraint for Acute Medical and Surgical Care

§482.13(f) Standard: Seclusion and Restraint for Behavior Management
§482.21 Condition of Participation: Quality Assessment and Performance Improvement
§482.21(a) Standard: Program Scope
§482.21(b) Standard: Program Data
§482.21(c) Standard: Program Activities
§482.21(d) Standard: Performance Improvement Projects
§482.21(e) Standard: Executive Responsibilities
§482.22 Condition of Participation: Medical staff
§482.22(a) Standard: Composition of the Medical Staff
§482.22(b) Standard: Medical Staff Organization and Accountability
§482.22(c) Standard: Medical Staff Bylaws
§482.22(d) Standard: Autopsies
§482.23 Condition of Participation: Nursing Services
§482.23(a) Standard: Organization
§482.23(b) Standard: Staffing and Delivery of Care
§482.23(c) Standard: Preparation and Administration of Drugs
§482.24 Condition of Participation: Medical Record Services
§482.24(a) Standard: Organization and Staffing
§482.24(b) Standard: Form and Retention of Record
§482.24(c) Standard: Content of Record
§482.25 Condition of Participation: Pharmaceutical Services
§482.25(a) Standard: Pharmacy Management and Administration
§482.25(b) Standard: Delivery of Services
§482.26 Condition of Participation: Radiological Services
§482.26(a) Standard: Radiology Services
§482.26(b) Standard: Safety for Patients and Personnel
§482.26(c) Standard: Personnel
§482.26(d) Standard: Records
§482.27 Condition of Participation: Laboratory Services
§482.27(b) Standard: Adequacy of Laboratory Services
§482.27(c) Standard: Potentially Infectious Blood and Blood Products
§482.28 Condition of Participation: Food and Dietetic Services
§482.28(a) Standard: Organization
§482.28(b) Standard: Diets
§482.30 Condition of Participation: Utilization Review
§482.30(a) Standard: Applicability
§482.30(b) Standard: Composition of Utilization Review Committee
§482.30(c) Standard: Scope and Frequency of Review

§482.30(d) Standard: Determination Regarding Admissions or Continued Stays
§482.30(e) Standard: Extended Stay Review
§482.30(f) Standard: Review of Professional Services
§482.41 Condition of Participation: Physical Environment
§482.41(a) Standard: Buildings
§482.41(b) Standard: Life Safety From Fire
§482.41(c) Standard: Facilities
§482.42 Condition of Participation: Infection Control
§482.42(a) Standard: Organization and Policies
§482.42(b) Standard: Responsibilities of Chief Executive Officer, Medical Staff, and Director of Nursing Services
§482.43 Condition of Participation: Discharge Planning
§482.43(a) Standard: Identification of Patients in Need of Discharge Planning
§482.43(b) Standard: Discharge Planning Evaluation
§482.43(c) Standard: Discharge Plan
§482.43(d) Standard: Transfer or Referral
§483.43(e) Standard: Reassessment
§482.45 Condition of Participation: Organ, Tissue and Eye Procurement
§482.45(a) Standard: Organ Procurement Responsibilities
§482.45(b) Standard: Organ Transplantation Responsibilities
§482.51 Condition of Participation: Surgical Services
§482.51(a) Standard: Organization and Staffing
§482.51(b) Standard: Delivery of Service
§482.52 Condition of Participation: Anesthesia Services
§482.52(a) Standard: Organization and Staffing
§482.52(c) Standard: State Exemption
§482.52(b) Standard: Delivery of Services
§482.53 Condition of Participation: Nuclear Medicine Services
§482.53(a) Standard: Organization and Staffing
§482.53(b) Standard: Delivery of Service
§482.53(c) Standard: Facilities
§482.53(d) Standard: Records
§482.54 Condition of Participation: Outpatient Services
§482.54(a) Standard: Organization
§482.54(b) Standard: Personnel
§482.55 Condition of Participation: Emergency Services
§482.55(a) Standard: Organization and Direction
§482.55(b) Standard: Personnel

§482.56 Condition of Participation: Rehabilitation Services
§482.56(a) Standard: Organization and Staffing
§482.56(b) Standard: Delivery of Services
§482.57 Condition of Participation: Respiratory Services
§482.57(a) Standard: Organization and Staffing
§482.57(b) Standard: Delivery of Services

Survey Protocol
Introduction

Hospitals are required to be in compliance with the Federal requirements set forth in the Medicare Conditions of Participation (CoP) in order to receive Medicare/Medicaid payment. The goal of a hospital survey is to determine if the hospital is in compliance with the CoP set forth at 42 CFR Part 482. Also, where appropriate, the hospital must be in compliance with the PPS exclusionary criteria at 42 CFR 412 Subpart B and the swing-bed requirements at 42 CFR 482.66

Certification of hospital compliance with the CoP is accomplished through observations, interviews, and document/record reviews. The survey process focuses on a hospital's performance of patient-focused and organizational functions and processes. The hospital survey is the means used to assess compliance with Federal health, safety, and quality standards that will assure that the beneficiary receives safe, quality care and services.

Regulatory and Policy Reference

- The Medicare Conditions of Participation for hospitals are found at 42 CFR Part 482.
- Survey authority and compliance regulations can be found at 42 CFR Part 488 Subpart A.
- Should an individual or entity (hospital) refuse to allow immediate access upon reasonable request to either a State Agency or CMS surveyor, the Office of the Inspector General (OIG) may exclude the hospital from participation in all Federal healthcare programs in accordance with 42 CFR §1001.1301.
- The regulatory authority for the photocopying of records and information during the survey is found at 42 CFR §489.53(a)(13).
- The CMS State Operations Manual (SOM) provides CMS policy regarding survey and certification activities.

Surveyors assess the hospital's compliance with the CoP for all services, areas and locations in which the provider receives reimbursement for patient care services billed under its provider number.

Although the survey generally occurs during daytime working hours (Monday through Friday), surveyors may conduct the survey at other times. This may include weekends and times outside of normal daytime (Monday through Friday) working hours. When the survey begins at times outside of normal work times, the survey team modifies the survey, if needed, in recognition of patients' activities and the staff available.

All hospital surveys are unannounced. Do not provide hospitals with advance notice of the survey.

Tasks in the Survey Protocol

Listed below, and discussed in this document, are the tasks that comprise the survey protocol for hospital.

Task 1 Off-Site Survey Preparation
Task 2 Entrance Activities
Task 3 Information Gathering/ Investigation
Task 4 Preliminary Decision Making and Analysis of Findings
Task 5 Exit Conference
Task 6 Post-Survey Activities

Survey Modules for Specialized Hospital Services

The modules for PPS-exempt units (psychiatric and rehabilitation), psychiatric hospitals, rehabilitation hospitals and swing-bed hospitals are attached to this document. The survey team is expected to use all the modules that apply to the hospital being surveyed. For example, if the hospital has swing-beds, a PPS excluded rehabilitation unit, and a PPS excluded psychiatric unit, the team will use those three modules in addition to this protocol to conduct the survey. If the hospital is a rehabilitation hospital, the team will use the rehabilitation hospital module in addition to this protocol to conduct the survey. If the hospital is a psychiatric hospital and if the survey team will be assessing the hospital's compliance with both the hospital CoPs and psychiatric hospital special conditions, the team will use the psychiatric hospital module in addition to this protocol to conduct the survey.

Survey Team

Size and Composition

The SA (or the RO for Federal teams) decides the composition and size of the team. In general, a suggested survey team for a full survey of a mid-size hospital would include 2-4 surveyors who will be at the facility for three or more days. Each hospital survey team should include at least one RN with hospital survey experience, as well as other surveyors who have

the expertise needed to determine whether the facility is in compliance. Survey team size and composition are normally based on the following factors:

- Size of the facility to be surveyed, based on average daily census;
- Complexity of services offered, including outpatient services;
- Type of survey to be conducted;
- Whether the facility has special care units or off-site clinics or locations;
- Whether the facility has a historical pattern of serious deficiencies or complaints; and
- Whether new surveyors are to accompany a team as part of their training.

Training for Hospital Surveyors

Hospital surveyors should have the necessary training and experience to conduct a hospital survey. Attendance at a Basic Hospital Surveyor Training Course is suggested. New surveyors may accompany the team as part of their training prior to completing the Basic Hospital Surveyor Training Course.

Team Coordinator

The survey is conducted under the leadership of a team coordinator. The SA (or the RO for Federal teams) should designate the team coordinator. The team coordinator is responsible for assuring that all survey preparation and survey activities are completed within the specified time frames and in a manner consistent with this protocol, SOM, and SA procedures. Responsibilities of the team coordinator include:

- Scheduling the date and time of survey activities;
- Acting as the spokesperson for the team;
- Assigning staff to areas of the hospital or tasks for the survey;
- Facilitating time management;
- Encouraging on-going communication among team members;
- Evaluating team progress and coordinating daily team meetings;
- Coordinating any ongoing conferences with hospital leadership (as determined appropriate by the circumstances and SA/RO policy) and providing on-going feedback, as appropriate, to hospital leadership on the status of the survey;

- Coordinating Task 2, Entrance Conference;
- Facilitating Task 4, Preliminary Decision Making;
- Coordinating Task 5, Exit Conference; and
- Coordinating the preparation of the Form CMS-2567.

Task 1 - Off-Site Survey Preparation

General Objective

The objective of this task is to analyze information about the provider in order to identify areas of potential concern to be investigated during the survey and to determine if those areas, or any special features of the provider (e.g., provider-based clinics, remote locations, satellites, specialty units, PPS-exempt units, services offered, etc.) require the addition of any specialty surveyors to the team. Information obtained about the provider will also allow the SA (or the RO for Federal teams) to determine survey team size and composition, and to develop a preliminary survey plan. The type of provider information needed includes:

- Information from the provider file (to be updated on the survey using the Hospital/CAH Medicare Database Worksheet), such as the facility's ownership, the type(s) of services offered, any prospective payment system (PPS) exclusion(s), whether the facility is a provider of swing-bed services, and the number, type and location of any off-site locations;
- Previous Federal and state survey results for patterns, number, and nature of deficiencies, as well as the number, frequency, and types of complaint investigations and the findings;
- Information from CMS databases available to the SA and CMS. Note the exit date of the most recent survey;
- Waivers and variances, if they exist. Determine if there are any applicable survey directive(s) from the SA or the CMS Regional Office (RO); and
- Any additional information available about the facility (e.g., the hospital's Web site, any media reports about the hospital, etc).

Off-Site Survey Preparation Team Meeting

The team should prepare for the survey offsite so they are ready to begin the survey immediately upon entering the facility. The team coordinator should arrange an off-site preparation meeting with as many team members as possible, including specialty surveyors. This meeting may be a conference call if necessary.

During the meeting, discuss at least the following:

- Information gathered by the team coordinator;
- Significant information from the CMS databases that are reviewed;
- Update and clarify information from the provider file so a surveyor can update the Medicare database using the "Hospital/CAH Medicare Database Worksheet," Exhibit 288;
- Layout of the facility (if available);
- Preliminary team member assignments;
- Date, location and time team members will meet to enter the facility;
- The time for the daily team meetings; and
- Potential date and time of the exit conference.

Gather copies of resources that may be needed. These may include:

- Medicare Hospital CoP and Interpretive Guidelines (Appendix A);
- Survey protocol and modules;
- Immediate Jeopardy (Appendix Q);
- Responsibilities of Medicare Participating Hospitals in Emergency Cases (Appendix V);
- Hospital Swing-Bed Regulations and Interpretive Guidelines (Appendix T);
- Hospital/CAH Medicare Database Worksheet, Exhibit 286;
- Letter of Authorization, Exhibit 287, to obtain facilities most recent accreditation survey;
- Form CMS-1537, "Hospital Surveyor's Worksheet"; and
- Worksheets for swing-bed, PPS exclusions, and restraint/seclusion death reporting.

Task 2 - Entrance Activities

General Objectives

The objectives of this task are to explain the survey process to the hospital and obtain the information needed to conduct the survey.

General Procedures

Arrival

The entire survey team should enter the hospital together. Upon arrival, surveyors should present their identification. The team coordinator should announce to the Administrator, or whoever is in charge, that a survey is being conducted. If the Administrator (or person in charge) is not onsite or available (e.g., if the survey begins outside normal daytime Monday-Friday working hours), ask that they be notified that a survey is being conducted. Do not delay the survey because the Administrator or other hospital staff is/are not on site or available.

Entrance Conference

The entrance conference sets the tone for the entire survey. Be prepared and courteous, and make requests, not demands. The entrance conference should be informative, concise, and brief; it should not utilize a significant amount of time. Conduct the entrance conference with hospital administrative staff that is available at the time of entrance. During the entrance conference, the Team Coordinator should address the following:

- Explain the purpose and scope of the survey;
- Briefly explain the survey process;
- Introduce survey team members, including any additional surveyors who may join the team at a later time, the general area that each will be responsible for, and the various documents that they may request;
- Clarify that all hospital areas and locations, departments, and patient care settings under the hospital provider number may be surveyed, including any contracted patient care activities or patient services located on hospital campuses or hospital provider based locations;
- Explain that all interviews will be conducted privately with patients, staff, and visitors, unless requested otherwise by the interviewee;
- Discuss and determine how the facility will ensure that surveyors are able to obtain the photocopies of material, records, and other information as they are needed;
- Obtain the names, locations, and telephone numbers of key staff to whom questions should be addressed;

- Discuss the approximate time, location, and possible attendees of any meetings to be held during the survey. The team coordinator should coordinate any meetings with facility leadership; and

- Propose a preliminary date and time for the exit conference.

During the entrance conference, the Team Coordinator will arrange with the hospital administrator, or available hospital administrative supervisory staff if he/she is unavailable to obtain the following:

- A location (e.g., conference room) where the team may meet privately during the survey;

- A telephone for team communications, preferably in the team meeting location;

- A list of current inpatients**,** providing each patient's name, room number, diagnosis(es), admission date, age, attending physician, and other significant information as it applies to that patient. The team coordinator will explain to the hospital that in order to complete the survey within the allotted time it is important the survey team is given this information as soon as possible, and request that it be no later than 3 hours after the request is made. SAs may develop a worksheet to give to the facility for obtaining this information;

- A list of department heads with their locations and telephone numbers;

- A copy of the facility's organizational chart;

- The names and addresses of all off-site locations operating under the same provider number;

- The hospital's infection control plan;

- A list of employees;

- The medical staff bylaws and rules and regulations;

- A list of contracted services; and

- A copy of the facility's floor plan, indicating the location of patient care and treatment areas;

Arrange an interview with a member of the administrative staff to complete the Hospital/CAH Medicare Database Worksheet that will be used to update the provider's file

in the Medicare database. The worksheet may not be given to hospital personnel for completion.

Hospital Tours

Guided tours of the hospital are not encouraged and should be avoided. While a tour of a small facility may take place in less than one-man hour, a tour of a large facility could consume several man hours of allocated survey time and resources that are needed to conduct the survey.

Initial On-Site Team Meeting

After the conclusion of the Entrance Conference, the team will meet in order to evaluate information gathered, and modify surveyor assignments, as necessary. Do not delay the continuation of the survey process waiting for information from the provider, but adjust survey activities as necessary. During the on-site team meeting, team members should:

- Review the scope of hospital services;
- Identify hospital locations to be surveyed, including any off-site locations;
- Add survey protocol modules and adjust surveyor assignments, as necessary, based on new information;
- Discuss issues such as change of ownership, sentinel events, construction activities, and disasters, if they have been reported;
- Make an initial patient sample selection (The patient list may not be available immediately after the entrance conference, therefore the team may delay completing the initial patient sample selection a few hours as meets the needs of the survey team); and
- Set the next meeting time and date.

Sample Size and Selection

To select the patient sample, review the patient list provided by the hospital and select patients who represent a cross-section of the patient population and the services provided. Patient logs (ER, OB, OR, restraint, etc) may be used in conjunction with the patient list to assure the sample is reflective of the scope of services provided by the hospital.

Whenever possible and appropriate, select patients who are in the facility during the time of survey (i.e., open records). Open records allow surveyors to conduct a patient-focused survey and enable surveyors to validate the information obtained through record reviews with observations and patient and staff interviews. There may be situations where closed records are needed to supplement the open records reviewed (e.g., too few open records, complaint

investigation, etc), surveyors should use their professional judgment in these situations and select sample that will enable them to make compliance determinations. If it is necessary to remove a patient from the sample during the survey, (e.g., the patient refuses to participate in an interview), replace the patient with another who fits a similar profile. This should be done as soon as possible in the survey.

Select the number of patient records for review based on the facility's average daily census. The sample should be at least 10 percent of the average daily census, but not fewer than 30 inpatient records. For small general hospitals (this reduction does not apply to surgical or other specialty hospitals) with an average daily census of 20 patients or less, the sample should not be fewer than 20 inpatient records, provided that number of records is adequate to determine compliance. Within the sample, select at least one patient from each nursing unit (e.g., med/surg, ICU, OB, pediatrics, specialty units, etc). In addition to the inpatient sample, select a sample of outpatients in order to determine compliance in outpatient departments, services, and locations. The sample size may be expanded as needed to assess the hospital's compliance with the CoP.

If a complaint is being investigated during the survey, include patients who have been identified as part of the complaint in the sample. Issues or concerns identified through complaints may be an area of focus when selecting the patient sample.

Give each patient in the sample a unique identifier. Appropriate identifiable information should be kept on a separate identifier list. Do not use medical record numbers, Social Security numbers, care unit or billing record numbers to identify patients.

To conduct an initial survey of a hospital there must be enough inpatients currently in the hospital and patient records (open and closed) for surveyors to determine whether the hospital can demonstrate compliance with all the applicable CoP. The number of current and discharged inpatients and outpatients in relation to the complexity of care provided to patients and the length of stay of those patients needs to be large enough for surveyors to evaluate the manner and degree to which the hospital satisfies all the standards within each CoP including any CoP applying to optional services offered by the hospital. Utilize the same sample size and selection methods as previously discussed.

Task 3 - Information Gathering/Investigation

General Objective

The objective of this task is to determine the hospital's compliance with the Medicare CoP through observations, interviews, and document review.

Guiding Principles

- Focus attention on actual and potential patient outcomes, as well as required processes.

- Assess the care and services provided, including the appropriateness of the care and services within the context of the regulations.
- Visit patient care settings, including inpatient units, outpatient clinics, anesthetizing locations, emergency departments, imaging, rehabilitation, remote locations, satellites, etc.
- Observe the actual provision of care and services to patients and the effects of that care, in order to assess whether the care provided meets the needs of the individual patient.
- Use the interpretive guidelines and other published CMS policy statements to guide the survey.
- Use Appendix Q for guidance if Immediate Jeopardy is suspected.

General Procedures

Survey Locations

For hospitals with either no or a small number of off-campus provider-based locations, survey all departments, services, and locations that bill for services under the hospital's provider number and are considered part of the hospital.

For hospitals with many provider-based locations survey:

- All hospital departments and services at the primary hospital campus and on the campuses of other remote locations of the hospital;
- All satellite locations of the hospital;
- All inpatient care locations of the hospital;
- All out-patient surgery locations of the hospital;
- All locations where complex out-patient care is provided by the hospital; and
- Select a sample of each type of other services provided at additional provider-based locations.

On any Medicare hospital survey, contracted patient care activities or patient services (such as dietary services, treatment services, diagnostic services, etc.) located on hospital campuses or hospital provider based locations should be surveyed as part of the hospital for compliance with the conditions of participation.

During the Survey

- Observe what activities are taking place and assess the CoP that represent the scope and complexity of the patient care services located at each location, as well as, any other CoP that apply to those locations. Expand the survey activities as necessary.

- The SA and surveyors have discretion whether to allow, or to refuse to allow, facility personnel to accompany the surveyors during a survey. Surveyors should make a decision whether to allow facility personnel to accompany them based on the circumstances at the time of the survey.

- The team should meet at least daily in order to assess the status of the survey, progress of completion of assigned tasks, areas of concern, and to identify areas for additional investigations. The team meetings should include an update by each surveyor that addresses findings and areas of concern that have been identified. If areas of concern are identified in the discussion, the team should coordinate efforts to obtain additional information. Additional team meetings can be called at any time during the survey to discuss crucial problems or issues.

- All significant issues or significant adverse events must be brought to the team coordinator's attention immediately.

- Maintain open and ongoing dialogue with the facility staff throughout the survey process. Conferences with facility staff may be held in order to inform them of survey findings. This affords facility staff the opportunity to present additional information or to offer explanations concerning identified issues. Survey information must not be discussed unless the investigation process and data collection for the specific concerns is completed.

- Surveyors should always maintain a professional working relationship with facility staff.

- Surveyors need to respect patient privacy and maintain patient confidentiality at all times during the survey.

- Surveyors should maintain their role as representatives of a regulatory agency. Although non-consultative information may be provided upon request, the surveyor is not a consultant.

Patient Review

A comprehensive review of care and services received by each patient in the sample should be part of the hospital survey. A comprehensive review includes observations of care/services provided to the patient, patient and/or family interview(s), staff interview(s), and medical record review. After obtaining the patient's permission, observe each sample patient receiving treatments (e.g., intravenous therapy, tube feedings, wound dressing

changes) and observe the care provided in a variety of treatment settings, as necessary, to determine if patient needs are met.

Observations

Observations provide first-hand knowledge of hospital practice. The regulations and interpretive guidelines offer guidance for conducting observations. Observation of the care environment provides valuable information about how the care delivery system works and how hospital departments work together to provide care. Surveyors are encouraged to make observations, complete interviews, and review records and policies/procedures by stationing themselves as physically close to patient care as possible. While completing a chart review, for instance, it may be possible to also observe the environment and the patients, as far as care being given, staff interactions with patients, safety hazards, and infection control practices. When conducting observations, particular attention should be given to the following:

- Patient care, including treatments and therapies in all patient care settings;
- Staff member activities, equipment, documentation, building structure, sounds and smells;
- People, care, activities, processes, documentation, policies, equipment, etc., that are present that should not be present, as well as, those that are not present that should be present;
- Integration of all services, such that the facility is functioning as one integrated whole;
- Whether quality assessment and performance improvement (QAPI) is a facility-wide activity, incorporating every service and activity of the provider and whether every facility department and activity reports to, and receives reports from, the facility's central organized body managing the facility-wide QAPI program; and
- Storage, security and confidentiality of medical records.

A surveyor should take complete notes of all observations and should document: the date and time of the observation(s); location; patient identifiers, individuals present during the observation, and the activity being observed (e.g., therapy, treatment modality, etc).

A surveyor should have observations verified by the patient, family, facility staff, other survey team member(s), or by another mechanism. For example, when finding an out-dated medication in the pharmacy, ask the pharmacist to verify that the drug is out-dated. In addition, a surveyor should integrate the data from observations with data gathered through interviews and document reviews.

Surveyors must not examine patients by themselves, although in certain circumstances, in order to determine a patient's health status and whether appropriate health care is being provided, especially to ensure a patient's welfare where he/she appears to be in immediate jeopardy, it is permissible and necessary to examine the patient. After obtaining permission from the patient, the surveyor should request that a staff member of the facility examine the patient in the surveyor's presence. The health and dignity of the patient is always of paramount concern. A surveyor must respect the patient's right to refuse to be examined.

Interviews

Interviews provide a method to collect information, and to verify and validate information obtained through observations. Informal interviews should be conducted throughout the duration of the survey. Use the information obtained from interviews to determine what additional observations, interviews, and record reviews are necessary. When conducting interviews, observe the following:

- Maintain detailed documentation of each interview conducted. Document the interview date, time, and location; the full name and title of the person interviewed; and key points made and/or topics discussed. To the extent possible, document quotes from the interviewee.

- Interviews with facility staff should be brief. Use a few well-phrased questions to elicit the desired information. For example, to determine if a staff member is aware of disaster procedures and his/her role in such events, simply ask, "If you smelled smoke, what would you do?"

- When interviewing staff, begin your interviews with staff that work most closely with the patient.

- Conduct patient interviews regarding their knowledge of their plan of care, the implementation of the plan, and the quality of the services received. Other topics for patient or family interview may include patient rights, advanced directives, and the facility's grievance/complaint procedure.

- Interviews with patients must be conducted in privacy and with the patient's prior permission.

- Use open-ended questions during your interview.

- Validate all information obtained.

- Telephone interviews may be conducted if necessary, but a preference should be made for in- person interviews.

- Integrate the data from interviews with data gathered through observations and document reviews.

Staff interviews should gather information about the staff's knowledge of the patient's needs, plan of care, and progress toward goals. Problems or concerns identified during a patient or family interview should be addressed in the staff interview in order to validate the patient's perception, or to gather additional information.

Patient interviews should include questions specific to the patient's condition, reason for hospital admission, quality of care received, and the patients knowledge of their plan of care. For instance, a surgical patient should be questioned about the process for preparation for surgery, the patient's knowledge of and consent for the procedure, pre-operative patient teaching, post-operative patient goals and discharge plan.

Document review

Document review focuses on a facility's compliance with the CoP. When conducting a document review, document the source and date of the information obtained. When making document copies, identify the original date of the document and indicate the date and time the copies were made. Once a document review is completed, integrate the data obtained with data gathered through observations and interviews to decide if the hospital is in compliance with the CoP. Documents reviewed may be both written and electronic and include the following:

- Patient's clinical records, to validate information gained during the interviews, as well as for evidence of advanced directives, discharge planning instructions, and patient teaching. This review will provide a broad picture of the patient's care. Plans of care and discharge plans should be initiated immediately upon admission, and be modified as patient care needs change. The record review for that patient who has undergone surgery would include a review of the pre-surgical assessment, informed consent, operative report, and pre-, inter-, and post-operative anesthesia notes. Although team members may have a specific area assigned during the survey, the team should avoid duplication of efforts during review of medical records and each surveyor should review the record as a whole instead of targeting the assigned area of concern. Surveyors should use open patient records rather than closed records, whenever possible;

- Closed medical records may be used to determine past practice, and the scope or frequency of a deficient practice. Closed records should also be reviewed to provide information about services that are not being provided by the hospital at the time of the survey. For example, if there are no obstetrical patients in the facility at the time of the survey, review closed OB records to determine care practices, or to evaluate past activities that cannot be evaluated using open records. In the review of closed clinical records, review all selected medical records for an integrated plan of care, timelines of implementation of the plan of care, and the patient responses to the interventions.

- Personnel files to determine if staff members have the appropriate educational requirements, have had the necessary training required, and are licensed, if it is required;

- Credential files to determine if the facility complies with CMS requirements and State law, as well as, follows its own written policies for medical staff privileges and credentialing;

- Maintenance records to determine if equipment is periodically examined and to determine if it is in good working order and if environmental requirements have been met;

- Staffing documents to determine if adequate numbers of staff are provided according to the number and acuity of patients;

- Policy and procedure manuals. When reviewing policy and procedure manuals, verify with the person in charge of an area that the policy and procedure manuals are current;

- Contracts, if applicable, to determine if patient care, governing body, QAPI, and other CoP requirements are included; and

Photocopies

Surveyors should make photocopies of all documents needed to support survey findings. The surveyor needs access to a photocopier where he/she can make their own photocopies of needed documents. If requested by the hospital, the surveyor should make the hospital a copy of all items photocopied. All photocopies need to be dated and timed as to when photocopied, and identified such as "hospital restraint policy- 2/17/04 page 3" or "Patient # 6, progress note- 2/17/04."

Completion of Hospital/CAH Medicare Database Worksheet

Arrange an interview with a member of the administrative staff to update and clarify information from the provider file. The Hospital/CAH Medicare Database Worksheet will be used to collect information about the hospital's services, locations, and staffing by Medicare surveyors during hospital surveys. The worksheet will be completed by the surveyors using observation, staff interviews, and document review. The worksheet will not be given to hospital staff to complete. The worksheet is used to collect information that will later be entered into the Medicare database. During the interview clarify any inconsistencies from prior information or information gathered during the survey.

Task 4 - Preliminary Decision Making and Analysis of Findings

General Objectives

The general objectives of this task are to integrate findings, review and analyze all information collected from observations, interviews, and record reviews, and to determine whether or not the hospital meets the Conditions of Participation found at 42 CFR Part 482 and, as appropriate, the PPS exclusionary criteria at 42 CFR Part 412 Subpart B, and the swing-bed requirements at 42 CFR §482.66. The team's preliminary decision-making and analysis of findings assist it in preparing the exit conference report. Based on the team's decisions, additional activities may need to be initiated.

General Procedures

Preparation

Prior to beginning this Task, each team member should review his/her notes, worksheets, records, observations, interviews, and document reviews to assure that all investigations are complete and organized for presentation to the team.

Discussion Meeting

At this meeting, the surveyors will share their findings, evaluate the evidence, and make team decisions regarding compliance with each requirement. Proceed sequentially through the requirements for each condition appropriate to the facility as they appear in regulation. For any issues of noncompliance, the team needs to reach a consensus. Decisions about deficiencies are to be team decisions, with each member having input. The team should document their decisions, the substance of the evidence, and the numbers of patients impacted, in order to identify the extent of facility noncompliance. The team must ensure that their findings are supported by adequate documentation of observations, interviews and document reviews and includes any needed evidence such as photocopies. Any additional documentation or evidence needed to support identified non compliance should be gathered prior to the exit conference but at a minimum, prior to exiting the hospital.

Determining the Severity of Deficiencies

The regulations at 42 CFR 488.26 state, "The decision as to whether there is compliance with a particular requirement, condition of participation, or condition for coverage, depends upon the manner and degree to which the provider or supplier satisfies the various standards within each condition." When noncompliance with a condition of participation is noted, the determination of whether a lack of compliance is at the Standard or Condition level depends upon the nature (how severe, how dangerous, how critical, etc.) and extent (how prevalent, how many, how pervasive, how often, etc.) of the lack of compliance. The cited level of the noncompliance is determined by the interrelationship between the nature and extent of the noncompliance.

A deficiency at the Condition level may be due to noncompliance with requirements in a single standard or several standards within the condition, or with requirements of

noncompliance with a single part (tag) representing a severe or critical health or safety breach. Even a seemingly small breach in critical actions or at critical times can kill or severely injure a patient, and represents a critical or severe health or safety threat.

A deficiency is at the Standard level when there is noncompliance with any single requirement or several requirements within a particular standard that are not of such character as to substantially limit a facility's capacity to furnish adequate care, or which would not jeopardize or adversely affect the health or safety of patients if the deficient practice recurred.

When a deficient practice (noncompliance) is determined to have taken place prior to the survey and the hospital states that it has corrected the deficient practice/issue (noncompliance), issues for the survey team to consider would include:

- Is the corrective action superficial or inadequate, or is the corrective action adequate and systemic?
- Has the hospital implemented the corrective intervention(s) or action(s)?
- Has the hospital taken a QAPI approach to the corrective action to ensure monitoring, tracking and sustainability?

The survey team uses their judgment to determine if any action(s) taken by the hospital prior to the survey is sufficient to correct the noncompliance and to prevent the deficient practice from continuing or recurring. If the deficient practice is corrected prior to the survey, do not cite noncompliance. However, if the noncompliance with any requirements is noted during the survey, even when the hospital corrects the noncompliance during the survey, cite noncompliance.

All noted noncompliance must be cited even when corrected on site during the survey. Citing noncompliance at the appropriate level is important to the integrity of the survey process. Citing too high a level is unfair to the hospital. Citing noncompliance at a level below the noted degree and manner of the noncompliance does not ensure that the hospital will develop acceptable plans of correction and implement corrective actions, and does not depict accurately whether the care provided adversely affects the health and safety of patients; and continued deficient practices may lead to adverse patient outcomes such as injury or death.

Gathering Additional Information

If it is determined that the survey team needs additional information to determine facility compliance or noncompliance, the team coordinator should decide the best way to conduct the additional review.

Task 5 - Exit Conference

General Objective

The general objective of this task is to inform the facility staff of the team's preliminary findings.

Prior to the Exit Conference

- The team coordinator is responsible for organization of the presentation of the exit.
- The team determines who will present the findings.
- If the team feels it may encounter a problem during the exit, they should contact their immediate supervisor.

Discontinuation of an Exit Conference

It is CMS' general policy to conduct an exit conference at the conclusion of each survey. However, there are some situations that justify refusal to continue or to conduct an exit conference. For example:

- If the provider is represented by counsel (all participants in the exit conference should identify themselves), surveyors may refuse to conduct the conference if the lawyer tries to turn it into an evidentiary hearing; or
- Any time the provider creates an environment that is hostile, intimidating, or inconsistent with the informal and preliminary nature of an exit conference, surveyors may refuse to conduct or continue the conference. Under such circumstances, it is suggested that the team coordinator stop the exit conference and call the State agency for further direction.

Recording the Exit Conference

If the facility wishes to audio tape the conference, it must provide two tapes and tape recorders, recording the meeting simultaneously. The surveyors should take one of the tapes at the conclusion of the conference. Video taping is also permitted if it is not disruptive to the conference, and a copy is provided at the conclusion of the conference. It is at the sole discretion of the surveyor(s) to determine if video taping is permitted.

General Principles

The following general principles apply when conducting an exit conference:

- The facility determines which hospital staff will attend the exit conference.

- The identity of an individual patient or staff member must not be revealed in discussing survey results. Identity includes not just the name of an individual patient or staff member, but also includes any reference by which identity might be deduced.

- Because of the ongoing dialogue between surveyors and facility staff during the survey, there should be few instances in which the facility is unaware of surveyor concerns or has not had an opportunity to present additional information prior to the exit conference.

Exit Conference Sequence

The following discusses the sequence of events in conducting an exit conference.

Introductory Remarks:

- Thank everyone for cooperation during the survey.

- Introduce all team members, mentioning any that have concluded their portion of the survey and have left the facility.

- Briefly mention the reason for the survey.

- Explain that the exit conference is an informal meeting to discuss preliminary findings.

- Indicate that official findings are presented in writing on the Form CMS-2567.

Ground Rules

- Explain how the team will conduct the exit conference and any ground rules.

- Ground rules may include waiting until the surveyor finishes discussing each deficiency before accepting comments from facility staff.

- State that the provider will have an opportunity to present new information after the exit conference for consideration after the survey.

Presentation of Findings

- Avoid referring to data tag numbers.

- Present the findings of noncompliance, explaining why the findings are a violation. If the provider asks for the regulatory basis, provide it.

- Refrain from making any general comments (e.g., "Overall the facility is very good"). Stick to the facts. Do not rank findings. Treat requirements as equal as possible.

- Do not identify unmet requirements as condition or standard level. Avoid statements such as, "the condition was not met" or "the standard was not met." It is better to state "the requirement is not met."

- If immediate jeopardy was identified, explain the significance and the need for immediate correction. Follow instructions in Appendix Q.

- Assure that all findings are discussed at the exit conference.

Closure

- Explain that a statement of deficiencies (Form CMS-2567) will be mailed within 10 working days to the hospital.

- Explain that the Form CMS-2567 is the document disclosed to the public about the facility's deficiencies and what is being done to remedy them. The Form CMS-2567 is made public no later than 90 calendar days following completion of the survey. It documents specific deficiencies cited, the facility's plans for correction and timeframes, and it provides an opportunity for the facility to refute survey findings and furnish documentation that requirements are met.

- Inform the facility that a written plan of correction must be submitted to the survey agency within 10 calendar days following receipt of the written statement of deficiencies.

- Explain the required characteristics of a plan of correction. The characteristics include:

    - Corrective action to be taken for each individual affected by the deficient practice, including any system changes that must be made;

    - The position of the person who will monitor the corrective action and the frequency of monitoring;

    - Dates each corrective action will be completed;

    - The administrator or appropriate individual must sign and date the Form CMS-2567 before returning it to the survey agency; and

    - The submitted plan of correction must meet the approval of the State agency, or in some cases the CMS Regional Office for it to be acceptable.

- If the exit conference was audio or video taped, obtain a copy of the tape in its entirety before leaving the facility.

All team members should leave the facility together immediately following the exit conference. If the facility staff provides further information for review, the team coordinator should decide the best way to conduct the further review. It is usually prudent for at least two individuals to remain.

Task 6 – Post-Survey Activities

General Objective

The general objective of this task is to complete the survey and certification requirements, in accordance with the regulations found at 42 CFR Part 488.

General Procedures

Each State agency and Federal Regional Office should follow directives in the State Operations Manual. The procedures include:

- Timelines for completing each step of the process;
- Responsibilities of the team coordinator and other team members to complete the Form CMS-2567, "Statement of Deficiencies," following the "Principles of Documentation";
- Notification to the facility staff regarding survey results;
- Additional survey activities based on the survey results (e.g., revisit, forwarding documents to the Regional Office for further action/direction);
- Completion of "Hospital Restraint/Seclusion Death Reporting Worksheet," as appropriate;
- Compilation of documents for the provider file;
- Signed letter of Authorization to obtain facilities most recent accreditation survey is forwarded to RO; and
- Enter the information collected on the Hospital/CAH Medicare Database Worksheet into the Medicare database.

Plan of Correction

Regulations at 42 CFR §488.28(a) allow certification of providers with deficiencies at the Standard or Condition level "only if the facility has submitted an acceptable plan of

Correction [POC] for achieving compliance within a reasonable period of time acceptable to the Secretary." Failure to submit a POC may result in termination of the provider agreement as authorized by 42 CFR §488.28(a) and §489.53(a)(1). After a POC is submitted, the surveying entity makes the determination of the appropriateness of the POC.

[. . .]

Rehabilitation Hospital Survey Module

When conducting a full survey of an accredited or non-accredited rehabilitation hospital, conduct a survey of the hospital's compliance with rehabilitation hospital excluded requirements using the survey methods in this module.

Surveys of the PPS excluded rehabilitation hospital requirements utilizing these methods will count as annual validation compliance surveys of the hospital's self-attestation of compliance with the excluded requirements.

Background

The term "exclusion" is a reimbursement term. Patient care in a PPS excluded rehabilitation hospital is reimbursed at the PPS rehabilitation hospital excluded rate rather than at the hospital PPS rate. In order for a hospital to receive the excluded rate for rehabilitation care provided, the hospital must comply with the excluded requirements found at 42 CFR §412.

A PPS excluded rehabilitation hospital is regulated by both the hospital CoP at 42 CFR §482 (also found in Appendix A of the SOM) and the PPS excluded rehabilitation hospital requirements at 42 CFR §412.

Regulatory Authority and Requirements for PPS Excluded Rehabilitation Hospitals

- 42 CFR §482 - Conditions of Participation for Hospitals;
- 42 CFR §412.22 - Excluded hospitals and hospital units: General rules; and
- 42 CFR §412.23 - Excluded hospitals: Classifications

Activities Conducted Prior to a Rehabilitation Hospital Survey

- Contact the RO to determine if the hospital has approval for a PPS excluded rehabilitation hospital.
- Contact the RO to determine the hospital's cost reporting period.
- Do not conduct the survey of the PPS excluded rehabilitation hospital requirements within 90 days of the end of the hospital's cost reporting period.

- Identify any satellite locations of the hospital.

- Verify with the RO that the hospital is in compliance with the inpatient population percent rule, and that each satellite, if any, is independently in compliance with the inpatient population percent rule.

- Review the "Rehabilitation Hospital Criteria Worksheet," Form CMS-437B.

Survey Tool

"Rehabilitation Hospital Criteria Worksheet," Form CMS-437B.

Survey Procedures for Determining Compliance with the PPS Excluded Rehabilitation Hospital Requirements

- Survey activities to determine hospital compliance with the PPS excluded rehabilitation hospital requirements should be conducted concurrently with the full survey of the hospital's compliance with the hospital CoP.

- Using the "Rehabilitation Hospital Criteria Worksheet," Form CMS-437B, verify whether the requirements have been met by checking the appropriate box marked "YES" or "NO." Under the column "Explanatory Statement," document specifics about the findings. Additional findings can be documented in a narrative note that should be attached to the worksheet.

- Select a minimum of two current inpatients for the patient sample.

- Select additional patients (open or closed records) as needed to determine compliance with the excluded rehabilitation hospital requirements.

- The selected patients should be included in the patient sample used for the full hospital survey.

- Identify if the rehabilitation hospital has remote locations, satellites, or other provider based locations. Record the location, name, address and telephone number for every remote location, satellite, or provider based location on the Hospital/CAH Medicare Database Worksheet for updating the Medicare database.

Exit Conference

- Inform the hospital of findings of noncompliance with the excluded rehabilitation hospital requirements.

- Inform the hospital that the SA will forward the completed Form CMS-437B to the hospital at the same time as the completed Form CMS-2567.

Post Survey Activities

- Do not include the survey findings for the PPS excluded rehabilitation hospital requirements on the Form CMS-2567.

- If there are PPS excluded hospital requirements that have not been met, notify the RO. Document survey findings of the PPS excluded rehabilitation hospital requirements on the CMS 437B. Submit the completed Form CMS-437B to the RO within the same time frame as the completion of the Form CMS-2567 and at least 60 days prior to the end of the hospital's cost reporting period.

- Follow the requirements in the SOM for post-survey activities.

Inpatient Rehabilitation Unit Survey Module

When conducting a full survey of an accredited or non-accredited hospital that has a PPS excluded rehabilitation unit, conduct a survey of the rehabilitation unit using the survey methods in this module to assess the hospital's compliance with the excluded rehabilitation unit requirements.

Surveys of the PPS excluded rehabilitation unit requirements utilizing these methods will count as annual validation compliance surveys of the hospital's self-attestation of compliance with the excluded requirements.

Background

The PPS excluded rehabilitation unit is part of the hospital and is included as part of the overall hospital survey. The term "exclusion" is a reimbursement term. Patient care in a PPS excluded rehabilitation unit is reimbursed at the PPS excluded rehabilitation unit rate rather than the hospital PPS rate. In order for a hospital to receive the excluded rate for rehabilitation care provided in its excluded unit, the unit must comply with the excluded rehabilitation unit requirements found at §412.

A PPS excluded rehabilitation unit is regulated by both the hospital CoP at 42 CFR §482 (also found in Appendix A of the SOM) and the PPS excluded rehabilitation unit requirements at 42 CFR §412.

Requirements for PPS Excluded Rehabilitation Units

- 42 CFR §482 - Conditions of Participation for hospitals;

- 42 CFR §412.25 - Excluded hospital units: Common Requirements;

- 42 CFR §412.29 - Excluded rehabilitation units: Additional Requirements; and

- State Operations Manual, Chapter 3, §3100.

Activities Conducted Prior to Rehabilitation Unit Survey

- Contact the RO to determine if the hospital has approval for a PPS excluded rehabilitation unit.

- Contact the RO to determine the unit's cost-reporting period.

- Do not conduct the survey of the PPS excluded rehabilitation unit requirements within 90 days of the end of the hospital's cost reporting period.

- Verify with the RO that the hospital is in compliance with the inpatient population percent rule for the unit and that each rehabilitation unit satellite, if any, is independently in compliance with the inpatient population percent rule.

- If possible, establish the location or locations of the rehabilitation unit. Determine if the unit has a satellite or satellites in other locations. Determination or verification of this information may have to wait until the survey team is onsite.

- Review the "Rehabilitation Unit Criteria Worksheet," Form CMS-437A.

Survey Tool

The "Rehabilitation Unit Criteria Worksheet," Form CMS-437A.

Survey Procedures for Determining Compliance with the PPS Excluded Rehabilitation Unit Requirements

- Survey activities to determine hospital compliance with the PPS excluded rehabilitation unit requirements should be conducted concurrently with the full survey of the hospital's compliance with the hospital CoP.

- Using the "Rehabilitation Hospital Criteria Worksheet," Form CMS-437A, verify whether the requirements have been met by checking the appropriate box marked "YES" or "NO." Under the column "Explanatory Statement," document specifics. about the findings. Additional findings can be documented in a narrative note that should be attached to the worksheet.

- Select 10 percent of the unit's average daily census or a minimum of two current patients for the patient sample.

- The selected patients should be included in the patient sample used for the full hospital survey.

- Select additional patients (open or closed records) as needed to determine compliance with the excluded rehabilitation unit requirements.

- If there are no patients on the unit at the time the survey is conducted, review closed patient records of unit patients treated within six months of the survey.

- Identify if the rehabilitation unit has a satellite or satellites. Record the location, name, address and telephone number for every satellite on the Hospital/CAH Medicare Database Worksheet for updating the Medicare database.

Exit Conference

- Inform the hospital of findings of noncompliance with the excluded rehabilitation unit requirements.

- Inform the hospital that the SA will forward the completed Form CMS-437A to the hospital at the same time as the completed Form CMS-2567.

Post Survey Activities

- Do not include the survey findings for the PPS excluded rehabilitation unit requirements on the Form CMS-2567.

- If there are PPS excluded unit requirements that have not been met, notify the RO. Document survey finding of the PPS rehabilitation unit requirements on the CMS-437A. Submit the completed Form CMS-437A to the RO within the same time frame as the completion of the Form CMS-2567 and at least 60 days prior to the end of the hospital's cost reporting period.

- Follow the requirements in the SOM for post-survey activities.

[. . .]

Regulations and Interpretive Guidelines

A-0001

§482.2 Provision of Emergency Services by Nonparticipating Hospitals

(a) The services of an institution that does not have an agreement to participate in the Medicare program may, nevertheless, be reimbursed under the program if--

(1) The services are emergency services; and

(2) The institution meets the requirements of section 1861(e)(1) through (5) and (7) of the Act. Rules applicable to emergency services furnished by non-participating hospitals are set forth in subpart G of part 424 of this chapter.

(b) Section 440.170(e) of this chapter defines emergency hospital services for purposes of Medicaid reimbursement.

Interpretive Guidelines §482.2

The statutory requirements that a hospital must meet are:

- The hospital is primarily engaged in providing, by or under the supervision of MD/DOs, to inpatients, diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled or sick persons, or rehabilitation services for the injured, disabled, or sick persons;
- The hospital maintains clinical records on all patients;
- The hospital has medical staff bylaws;
- The hospital has a requirement that every Medicare patient must be under the care of a MD/DO;
- The hospital provides 24-hour nursing services rendered or supervised by a registered professional nurse and has a licensed, practical or registered professional nurse on duty at all times; and
- The hospital is licensed or is approved as meeting the standards for licensing as a hospital as defined by the State.

A-0002

§482.11 Condition of Participation: Compliance With Federal, State and Local Laws

A-0003

§482.11(a) The hospital must be in compliance with applicable Federal laws related to the health and safety of patients.

Survey Procedures §482.11(a)

Interview the CEO, or appropriate individual designated by the hospital, to determine whether the hospital is in compliance with Federal laws related to patient health and safety. (e.g., if the hospital has been convicted of violating section 504 of the Rehabilitation Act of 1973 by denying people with disabilities access to care. If so, verify that satisfactory

corrections have been made to bring the hospital into compliance with that law.) Refer or report noted noncompliance with Federal laws and regulations to the appropriate agency having jurisdiction (e.g., accessibility issues, blood borne pathogens, universal precautions, TB control to OSHA; hazardous chemical/waste issues to EPA; etc.)

A-0004

§482.11(b) The hospital must be--

(1) Licensed; or

(2) Approved as meeting standards for licensing established by the agency of the State or locality responsible for licensing hospitals.

Survey Procedures §482.11(b)

Prior to the survey, determine whether the hospital is subject to licensure requirements and verify that the licensing agency has approved the hospital as meeting the standards for licensure as set forth by the agency of the State or locality responsible for licensing hospitals.

A-0005

§482.11(c) The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.
Interpretive Guidelines §482.11(c)

All staff that are required by the State to be licensed must possess a current license. The hospital must assure that these personnel are in compliance with the State's licensure laws. The laws requiring licensure vary from state to state. Examples of healthcare professionals that a state may require to be licensed could include: nurses, MD/DOs, physician assistants, dieticians, x-ray technologists, dentists, physical therapists, occupational therapists, respiratory therapists and hospital administrators.

All staff must meet all applicable standards required by State or local law for hospital personnel. This would include at a minimum:

- Certification requirements;
- Minimum qualifications;
- Training/education requirements; and
- Permits (such as food handlers permits).

When telemedicine is used and the practitioner and patient are located in different states, the practitioner providing the patient care service must be licensed and/or meet the other applicable standards that are required by State or local laws in both the state where the practitioner is located and the state where the patient is located.

Survey Procedures §482.11(c)

- Verify for those personnel required to be licensed, certified, and/or permitted by the State, that the hospital has established, and follows procedures for determining that personnel are properly licensed, certified, and/or permitted.

- Verify that staff and personnel are licensed, certified, and/or permitted in accordance with State and local requirements.

- Verify that staff and personnel meet all standards (such as continuing education, basic qualifications, etc.) required by State and local laws or regulations. Verify that the hospital has a mechanism established and enforced to ensure compliance.

- Review a sample of personnel files to verify that licensure and/or other required credentials information is up to date. Verify State licensure compliance of the direct care personnel as well as administrators and supervisory personnel.

A-0006

§482.12 Condition of Participation: Governing Body

The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.

Interpretive Guidelines §482.12

The hospital must have only one governing body and this governing body is responsible for the conduct of the hospital as an institution. In the absence of an organized governing body, there must be written documentation that identifies the individual or individuals that are responsible for the conduct of the hospital operations.

Survey Procedures §482.12

Verify that the hospital has an organized governing body or has written documentation that identifies the individual or individuals that are responsible for the conduct of the hospital operations.

A-0007

§482.12(a) Standard: Medical Staff

The governing body must:

A-0008

§482.12(a)(1) Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff;

Interpretive Guidelines §482.12(a)(1)

The governing body must determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff.

Survey Procedures §482.12(a)(1)

Review documentation and verify that the governing body has determined and stated the categories of practitioners that are eligible candidates for appointment to the medical staff.

A-0009

§482.12(a)(2) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff;

Interpretive Guidelines §482.12(a)(2)

It is the responsibility of the governing body to appoint, with the advice of the medical staff, the individual practitioners to the medical staff. After considering existing medical staff members recommendations, and in accordance with established hospital medical staff criteria and State and Federal laws and regulations, the governing body appoints new members or reappoints current members to the medical staff.

Survey Procedures §482.12(a)(2)

- Review records of medical staff appointments to determine that the governing body is involved in appointments of medical staff members.
- Confirm that the governing body appoints all members to the medical staff in accordance with established policies based on the individual practitioner's scope of clinical expertise and in accordance with Federal and State law.

A-0010

§482.12(a)(3) Assure that the medical staff has bylaws;

Interpretive Guidelines §482.12(a)(3)

The governing body must assure that the medical staff has bylaws and that those bylaws comply with State and Federal law and the requirements of the Medicare hospital Conditions of Participation.

Survey Procedures §482.12(a)(3)

Verify that the medical staff operates under current bylaws that are in accordance with Federal and State laws and regulations.

A-0011

§482.12(a)(4) Approve medical staff bylaws and other medical staff rules and regulations;

Interpretive Guidelines §482.12(a)(4)

The governing body decides whether or not to approve medical staff bylaws submitted by the medical staff. The medical staff bylaws and any revisions must be approved by the governing body before they are considered effective.

Survey Procedures and §482.12(a)(4)

- Verify that the medical staff operates under current bylaws, rules and policies that have been approved by the governing body.
- Verify that any revisions or modifications in the medical staff bylaws, rules and policies have been approved by the medical staff and the governing body, e.g., bylaws are annotated with date of last review and initialed by person(s) responsible.

A-0012

§482.12(a)(5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients;

Interpretive Guidelines §482.12(a)(5)

The governing body must ensure that the medical staff is accountable to the governing body for the quality of care provided to patients. The governing body is responsible for the conduct of the hospital and this conduct includes the quality of care provided to patients.

All hospital patients must be under the care of a member of the medical staff or under the care of a practitioner who is directly under the supervision of a member of the medical staff. All patient care is provided by or in accordance with the orders of a practitioner who meets the medical staff criteria and procedures for the privileges granted, who has been granted privileges in accordance with those criteria by the governing body, and who is working within the scope of those granted privileges.

Survey Procedures §482.12(a)(5)

- Verify that the governing body is periodically apprised of the medical staff evaluation of patient care services provided hospital wide, at every patient care location of the hospital.

- Verify that any individual providing patient care services is a member of the medical staff or is accountable to a member of the medical staff qualified to evaluate the quality of services provided, and in turn, is responsible to the governing body for the quality of services provided.

A-0013

§482.12(a)(6) Ensure the criteria for selection are individual character, competence, training, experience, and judgment; and

Interpretive Guidelines §482.12(a)(6)

The governing body ensures that the criteria for selection of both new medical staff members and selection of current medical staff members for continued membership must be based on:

- Individual character;

- Individual competence;

- Individual training;

- Individual experience; and

- Individual judgment.

Survey Procedures §482.12(a)(6)

- Verify that there are written criteria for staff appointments to the medical staff.
- Verify that selection of medical staff for membership, both new and renewal, is based upon an individual practitioner's compliance with the medical staff's membership criteria.
- Verify that at a minimum, criteria for selection to the medical staff are individual character, competence, training, experience, and judgment.

A-0014

§482.12(a)(7) Ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship or membership in a specialty body or society.

Interpretive Guidelines §482.12(a)(7)

The governing body must ensure that the hospital's rules and criteria for medical staff membership or the granting of privileges apply equally to all practitioners in each professional category of practitioners.

A hospital is not prohibited from requiring board certification when considering a MD/DO for medical staff membership. Rather, the regulation provides that a hospital may not rely solely on the fact that a MD/DO is or is not board certified in making a judgment on medical staff membership. In addition to matters of board certification, a hospital must also consider other criteria such as training, character, competence and judgment. After analysis of all of the criteria, if all criteria are met except for board certification, the hospital has the discretion to decide not to select that individual to the medical staff.

Survey Procedures §482.12(a)(7)

Verify that there are written criteria for staff appointments, and that these criteria are based on individual character, competence, training, experience, and judgment, and are not dependent solely upon certification, fellowship, or membership in a specialty body or society.

A-0015

§482.12(b) Standard: Chief Executive Officer

The governing body must appoint a chief executive officer who is responsible for managing the hospital.

Interpretive Guidelines §482.12(b)

The Governing Body must appoint one chief executive officer who is responsible for managing the entire hospital.

Survey Procedures §482.12(b)

- Verify that the hospital has only one chief executive officer for the entire hospital.
- Verify that the governing body has appointed the chief executive officer.
- Verify that the chief executive officer is responsible for managing the entire hospital.

A-0016

§482.12(c) Standard: Care of Patients

In accordance with hospital policy, the governing body must ensure that the following requirements are met:

A-0017

§482.12(c)(1) Every Medicare patient is under the care of:

(i) A doctor of medicine or osteopathy. (This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or a State's regulatory mechanism.);

(ii) A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State and who is acting within the scope of his or her license;

(iii) A doctor of podiatric medicine, but only with respect to functions which he or she is legally authorized by the State to perform;

(iv) A doctor of optometry who is legally authorized to practice optometry by the State in which he or she practices;

(v) A chiropractor who is licensed by the State or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist; and

(vi) A clinical psychologist as defined in §410.71 of this chapter, but only with respect to clinical psychologist services as defined in §410.71 of this chapter and only to the extent permitted by State law.

Interpretive Guidelines §482.12(c)(1)

Practitioners other than doctors of medicine or osteopathy may join the medical staff if the practitioners are appropriately licensed and medical staff membership is in accordance with State law.

Every Medicare or Medicaid patient must be under the care of a licensed practitioner as defined in this requirement.

Survey Procedures §482.12(c)(1)

Verify that Medicare patients are under the care of a licensed practitioner as defined by (c)(1).

A-0018

§482.12(c)(2) Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital.

Survey Procedures §482.12(c)(2)

- Verify that admitting privileges are limited to those categories of practitioners as allowed by State law.

- Verify that patients are admitted only by those practitioners who are currently licensed and have been granted admitting privileges by the governing body in accordance with State laws and medical staff bylaws.

A-0019

§482.12(c)(2) continued
If a Medicare patient is admitted by a practitioner not specified in paragraph (c)(1) of this section, that patient is under the care of a doctor of medicine or osteopathy.

Interpretive Guidelines §482.12(c)(2)

CMS hospital regulations do permit licensed practitioners (e.g., nurse practitioners, midwives, etc), as allowed by the State, to admit patients to a hospital, and CMS does not require these practitioners be employed by a MD/DO. However, CMS regulations do require that Medicare and Medicaid patients admitted by these practitioners be under the care of an MD/DO. Evidence of being under the care of an MD/DO must be in the patient's medical

record. If a hospital allows these practitioners to admit and care for patients, as allowed by State law, the governing body and medical staff would have to establish policies and bylaws to ensure that the requirements of 42 CFR §482 are met.

Survey Procedures §482.12(c)(2)

If the hospital grants admitting privileges to these practitioners, select patients that are admitted to the hospital by these practitioners. Determine if the patient is/was under the care of an MD/DO.

A-0020

§482.12(c)(3) A doctor of medicine or osteopathy is on duty or on call at all times.

Survey Procedures §482.12(c)(3)

- Verify the governing body has established and monitors the enforcement of policies that ensure a doctor of medicine or osteopathy is on duty or on call at all times to provide medical care and onsite supervision when necessary.

- Review the "call" register and documents that assure that a doctor of medicine or osteopathy is on duty or on call at all times.

- Interview nursing staff. How do they know who is on call? Are they able to call the on-call MD/DO and speak with him/her at all times? When appropriate, do on-call MD/DOs come to the hospital to provide needed care.

A-0021

§482.12(c)(4) A doctor of medicine or osteopathy is responsible for the care of each Medicare patient with respect to any medical or psychiatric problem that--

(i) Is present on admission or develops during hospitalization; and

(ii) Is not specifically within the scope of practice of a doctor of dental surgery, dental medicine, podiatric medicine, or optometry; a chiropractor; or clinical psychologist, as that scope is--

(A) Defined by the medical staff;

(B) Permitted by State law; and

(C) Limited, under paragraph (c)(1)(v) of this section, with respect to chiropractors.

Interpretive Guidelines §482.12(c)(4)

CMS hospital regulations do permit licensed practitioners (i.e., doctors of dental surgery, dental medicine, podiatric medicine, or optometry; chiropractors; or clinical psychologists), as allowed by the State, to admit patients to a hospital. However, CMS does require that Medicare and Medicaid patients who are admitted by a doctor of dental surgery, dental medicine, podiatric medicine, or optometry; a chiropractor; or clinical psychologist be under the care of a MD/DO with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization that is outside the scope of practice of the admitting practitioner. If a hospital allows a doctor of dental surgery, dental medicine, podiatric medicine, or optometry, a chiropractor or a clinical psychologist to admit and care for patients, as allowed by State law, the governing body and medical staff must establish policies and bylaws to ensure that the requirements of 42 CFR §482 are met. As applicable, the patient's medical record must demonstrate MD/DO responsibility/care.

Survey Procedures §482.12(c)(4)

- Verify that an assigned doctor of medicine or osteopathy is responsible for and is monitoring the care of each Medicare or Medicaid patient with respect to all medical or psychiatric problems during the hospitalization.

- If non-MD/DOs admit patients, verify that every Medicare/Medicaid patient is being monitored by an MD/DO who is responsible for any medical or psychiatric problem outside the scope of practice of the admitting practitioners.

A-0022

§482.12(d) Standard: Institutional Plan and Budget

The institution must have an overall institutional plan that meets the following conditions:

(1) The plan must include an annual operating budget that is prepared according to generally accepted accounting principles.

(2) The budget must include all anticipated income and expenses. This provision does not require that the budget identify item by item the components of each anticipated income or expense.

(3) The plan must provide for capital expenditures for at least a 3-year period, including the year in which the operating budget specified in paragraph (d)(2) of this section is applicable.

(4) The plan must include and identify in detail the objective of, and the anticipated sources of financing for, each anticipated capital expenditure in excess of $600,000 (or a

lesser amount that is established, in accordance with section 1122(g)(1) of the Act, by the State in which the hospital is located) that relates to any of the following:

(i) Acquisition of land;

(ii) Improvement of land, buildings, and equipment; or

(iii) The replacement, modernization, and expansion of buildings and equipment.

Survey Procedures §482.12(d)

Verify that an institutional plan and budget exist, includes items 1-4, and complies with all items in this standard. Do not review the specifics or format in the institutional plan or the budget.

A-0023

§482.12(d)(5) The plan must be submitted for review to the planning agency designated in accordance with section 1122(b) of the Act, or if an agency is not designated, to the appropriate health planning agency in the State. (See part 100 of this title.)

Survey Procedures §482.12(d)(5)

Determine that the hospital's plan for capital expenditures has been submitted to the planning agency designated to review capital expenditures. In certain cases facilities used by HMO and CMP patients are exempt from the review process.

A-0024

§482.12(d)(5) continued
A capital expenditure is not subject to section 1122 review if 75 percent of the health care facility's patients who are expected to use the service for which the capital expenditure is made are individuals enrolled in a health maintenance organization (HMO) or competitive medical plan (CMP) that meets the requirements of section 1876(b) of the Act, and if the Department determines that the capital expenditure is for services and facilities that are needed by the HMO or CMP in order to operate efficiently and economically and that are not otherwise readily accessible to the HMO or CMP because--

(i) The facilities do not provide common services at the same site;

(ii) The facilities are not available under a contract of reasonable duration;

(iii) Full and equal medical staff privileges in the facilities are not available;

(iv) Arrangements with these facilities are not administratively feasible; or

(v) The purchase of these services is more costly than if the HMO or CMP provided the services directly.

A-0025

§482.12(d)(6) The plan must be reviewed and updated annually

Survey Procedures §482.12(d)(6)

Verify that the plan and budget are reviewed and updated annually.

A-0026

§482.12(d)(7) The plan must be prepared--

(i) Under the direction of the governing body; and

(ii) By a committee consisting of representatives of the governing body, the administrative staff, and the medical staff of the institution.

Survey Procedures §482.12(d)(7)

Verify that the governing body, administrative staff, and medical staff have participated in the development of the institutional plan and budget.

A-0027

§482.12(e) Standard: Contracted Services

The governing body must be responsible for services furnished in the hospital whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services.

Interpretive Guidelines §482.12(e)

The governing body has the responsibility for assuring that hospital services are provided in compliance with the Medicare Conditions of participation and according to acceptable standards of practice, irrespective of whether the services are provided directly by hospital employees or indirectly by contract. The governing body must take actions through the hospital's QAPI program to: assess the services furnished directly by hospital staff and those services provided under contract, identify quality and performance problems, implement

appropriate corrective or improvement activities, and to ensure the monitoring and sustainability of those corrective or improvement activities. See §482.21 QAPI.

Survey Procedures §482.12(e)

Ascertain that all contractor services provided in the hospital are in compliance with the Conditions of Participation for hospitals.

A-0028

§482.12(e)(1) The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.

Interpretive Guidelines §482.12(e)(1)

Indirect arrangements may take into consideration services provided through formal contracts, joint ventures, informal agreements, shared services, or lease arrangements. The patient care services, and all other services, provided under contract are subject to the same hospital-wide quality assessment and performance improvement (QAPI) evaluation as other services provided directly by the hospital.

Survey Procedures §482.12(e)(1)

- Determine if the hospital has a mechanism to evaluate the quality of each contracted service and ensures that each contracted service is provided in a safe and effective manner.

- Review the QAPI plan to ensure that every contracted service is evaluated.

A-0029

§482.12(e)(2) The hospital must maintain a list of all contracted services, including the scope and nature of the services provided.

Survey Procedures §482.12(e)(2)

Review the list of contracted services and verify that there is a delineation of contractor responsibility.

A-0030

§482.12(f) Standard: Emergency Services

A-0031

§482.12(f)(1) If emergency services are provided at the hospital, the hospital must comply with the requirements of §482.55.

A-0032

§482.12(f)(2) If emergency services are not provided at the hospital, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

Interpretive Guidelines §482.12(f)(2)

This requirement applies hospital-wide (all on-campus and off-campus locations) to hospitals that do not provide emergency services.

The hospital must have and implement medical staff policies and procedures for the appraisal of emergencies, initial treatment, and referral when appropriate.

The hospital must have appropriate policies and procedures in place for dealing with emergency care situations at the hospital. This includes emergencies that occur to hospital patients, staff, visitors, and others at any hospital location and to individuals who come to the hospital or any of its off-campus locations seeking/needing emergency care. Hospital staff at all on-campus and off-campus locations must know what to do when a patient or other individual seeks/needs emergency care. Staff must know the hospital's policies and procedures and, as appropriate, be capable of appraising, providing initial care, and referring individuals who are seeking or needing emergency care.

Survey Procedures §482.12(f)(2)

- Verify that the medical staff has adopted written policies and procedures for the management of medical or psychiatric emergencies.

- Review emergency care policies and procedures. Do they address emergency procedures for all on-campus and off-campus locations?

- Interview hospital staff at various locations. Can they state their duties and what they are to do if an individual seeks or needs emergency care at their location?

A-0033

§482.12(f)(3) If emergency services are provided at the hospital but are not provided at one or more off-campus departments of the hospital, the governing body of the hospital must assure that the medical staff has written policies and procedures in effect with respect to the off-campus department(s) for appraisal of emergencies and referral when appropriate.

Interpretive Guidelines §482.12(f)(3)

This requirement applies to off-campus non-emergency departments/locations of hospitals that provide emergency services.

Hospital off-campus non-emergency departments/locations must have and implement medical staff policies and procedures for the appraisal of emergencies and referral when appropriate.

The hospital must have appropriate policies and procedures in place for dealing with emergency care situations at off-campus non-emergency departments and locations. This includes emergencies that occur to patients, staff, visitors or others at those locations or to individuals who come to those locations seeking/needing emergency care. Hospital staff at those locations must know what to do when any individual seeks/needs emergency care. Staff must know and be able to implement the hospital's policies and procedures for appraisal and referral of emergencies when appropriate.

Initial treatment and stabilization of patients needing emergency care must be provided in accordance with the complexity of services provided at that location, the type and qualifications of healthcare staff at that location and the other resources at that location. For example an off-campus cardiac rehabilitation clinic would be expected to have the appropriate qualified staff, equipment (such as a crash cart), and policies and procedures in place to appropriately provide appraisal, initial interventions, and referral of a patient who experiences a cardiac emergency.

The hospital's medical staff are responsible for the quality of the medical care provided to patients (See Governing Body and Medical Staff Conditions of Participation (CoP)). The Outpatient Services CoP requires that hospital outpatient services meet the needs of the patients in accordance with acceptable standards of practice, outpatient services must be appropriately organized and integrated with inpatient services, and outpatient services must have appropriate professional and nonprofessional personnel available. The Emergency Services CoP requires the hospital to meet the emergency needs of patients in accordance with accepted standards of practice. The Surgical Services CoP requires that outpatient surgical services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

See the hospital emergency services CoP (§482.55) for the emergency requirements for hospital locations with emergency services.

Survey Procedures §482.12(f)(3)

- Review emergency care policies and procedures. Determine if they address emergency procedures for all off-campus locations?
- Interview off-campus hospital department staff. Can they state their duties and what they are to do if an individual seeks emergency care?

A-0038

§482.13 Condition of Participation: Patients' Rights

A hospital must protect and promote each patient's rights.

Interpretive Guidelines §482.13

These requirements apply to all Medicare or Medicaid participating hospitals including short-term, acute care, surgical, specialty, psychiatric, rehabilitation, long-term, childrens' and cancer, whether or not they are accredited. This rule does not apply to critical access hospitals. (See Social Security Act (the Act) §1861(e)).

These requirements, as well as the other Conditions of Participation in 42 CFR §482, apply to all parts and locations (outpatient services, provider-based entities, inpatient services) of the Medicare participating hospital.

Survey Procedures §482.13

Survey of the Patients' Rights Condition of Participation (CoP) should be coordinated by one surveyor. However, each surveyor, as he/she conducts his/her survey assignments, should assess the hospital's compliance with the Patients' Rights CoP.

A-0039

§482.13(a) Standard: Notice of Rights

A-0040

§482.13(a)(1) A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

Interpretive Guidelines §482.13(a)(1)

This regulation requires that whenever possible, the hospital informs each patient of his or her rights in a language or method of communication that the patient understands. The hospital must notify all patients, both inpatients and outpatients of their rights. The hospital has the responsibility to establish and implement policies and procedures that effectively ensure that patients and/or their representatives have the information necessary to exercise their rights under the Act. This responsibility includes, and is not limited to, providing all notices required by statute and regulation regarding patients' rights. For example, the patient **must be given notice** of the rights afforded to him/her by the provider agreement, including the **right to formulate an advance directive, notice of beneficiary discharge rights, and notice of non-coverage rights** (See 42 CFR part 489), must be given notice of the beneficiary **right to appeal premature discharge**, as well as the other **rights discussed in this CoP**. Depending on other factors, the hospital may have existing mechanisms for notifying patients of their rights. The hospital may decide it is most effective to bundle the patients' rights and advance directives notice with these existing notices.

In providing this information, the hospital must be sensitive to the communication needs of its patients. As part of its provider agreement, the hospital agrees to comply with Civil Rights laws that assure that it will provide interpretation for certain individuals who speak languages other than English, use alternative communication techniques or aides for those who are deaf or blind, or take other steps as needed to effectively communicate with the patient. These civil rights laws and regulations also apply to the provision of this information.

The hospital's obligation to inform requires that the hospital presents information in a manner and form that can be understood, e.g., the use of large print materials, specialized programs to inform individuals who are deaf or blind, use of interpreters, etc.

This regulation does not require nor preclude documentation in the patient's record that this information has been provided. For example, as part of its admission procedure, the hospital may routinely provide this information with each admission packet. The method for achieving notification of patients' rights is determined by the hospital.

Survey Procedures §482.13(a)(1)

- Determine the hospital's policy for notifying all patients of their rights, both inpatient and outpatient.

- Review patient information that is provided to patients by the hospital. Determine if the provided information completely notifies the patient of their patient rights.

- Review records and interview staff to examine how the hospital meets the needs of diverse patients.

- Individuals who need assistive devices (e.g., magnifying glass, Braille, sign language), or have a communications challenge, such as deafness, low vision, blindness, or not being proficient in English, are at risk of not being informed of their rights. Include in the patient sample current patients who use assistive devices. Interview these patients, and/or their representatives to determine how the hospital assures that patients with these needs have been informed of their rights in a language and manner they understand.

- Ask patients to tell you what the hospital has told them about their rights.

- Does the hospital have alternative means, such as written materials, signs, or interpreters, to communicate patients' rights, when necessary?

- Do staff know what steps to take to inform a patient, if a patient has special communication needs?

A-0041

§482.13(a)(2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.

Interpretive guidelines §482.13(a)(2)

A "**patient grievance**" is a formal or informal written or verbal complaint that is made to the hospital by a patient, or the patient's representative, when a patient issue cannot be resolved promptly by staff present. If a complaint cannot be resolved promptly by staff present or is referred to a complaint coordinator, patient advocate, or hospital management, it is to be considered a grievance.

A patient issue is not a grievance if the patient issue can be resolved promptly, on the spot by staff present.

A patient issue could be a grievance if the patient (currently in the hospital) calls the Patient Representative first and has not tried to resolve the issue with the involved unit/department. If the Patient Representative can immediately call the patient's unit and if the patient care staff present are able to resolve the issue at that moment, then it is not a grievance. Issues that are not resolved on the spot by staff present are grievances.

If other staff must be called in (e.g., the Patient Representative) to resolve an issue that patient care staff cannot (or do not) resolve immediately, then it would be considered a grievance in most cases.

Billing issues are not considered grievances unless the complaint also contains elements addressing patient service or care issues.

Patient grievances would also include situations where patients or the patient's representative call or write to the hospital about concerns related to care or services, who were not able to resolve their concern during their stay or who did not wish to address their issue during their stay.

Additionally, whenever the patient or the patient's representative requests their complaint be handled as a formal complaint or grievance or when the patient requests a response from the hospital, then the complaint is a grievance and all the requirements apply.

The patient should have reasonable expectations of care and services and the facility should address those expectations in a timely, reasonable, and consistent manner. Although §482.13(a)(2)(ii) and (iii) address documentation of facility time frames for a response to a grievance, the expectation is that the facility will have a process to comply with a relatively minor request in a more timely manner than a written response. For example, a change in bedding, housekeeping of a room, and serving preferred food and beverages may be made relatively quickly and would not usually be considered a "grievance" and therefore would not require a written response.

The hospital must inform the patient and/or the patient's representative of the internal grievance process, including whom to contact to file a grievance (complaint). As part of its notification of patient rights, the hospital must inform the patient that he/she may lodge a grievance with the State agency (the State agency that has licensure survey responsibility for the hospital) directly, regardless of whether he/she has first used the hospital's grievance process. The hospital must provide the patient or the patient's representative a phone number and address for lodging a grievance with the State agency.

Survey Procedures §482.13(a)(2)

- Review the hospital's policies and procedures to assure that its grievance process encourages all personnel to alert appropriate staff concerning any patient grievance. Does the hospital adhere to its policy/procedure established for referrals?

- Interview patients or the patient's legal representative to determine if they know how to file a complaint (grievance) and who to contact if they have a complaint (grievance).

- Is the hospital following its grievance policies and procedures?

- Does the hospital's process assure that grievances involving situations or practices that place the patient in immediate danger, are resolved in a timely manner?

- Does the patient or the patient's representative know that he/she has the right to file a complaint with the State agency as well as or instead of utilizing the hospital's grievance process?

- Has the hospital provided the telephone number for the State agency to all patients/patient representatives?

- Are beneficiaries aware of their right to seek review by the QIO for quality of care issues, coverage decisions, and to appeal a premature discharge?

A-0042

§482.13(a)(2) continued
The hospital's governing body must approve and be responsible for the effective operation of the grievance process, and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee.

Survey Procedures §482.13(a)(2)

- Determine if the hospital's governing body approved the grievance process?

- Is the governing body responsible for the operation of the grievance process, or has the governing body delegated the responsibility in writing to a grievance committee?

- Determine how effectively the grievance process works. Are patient or the patient representative's concerns addressed in a timely manner? Are patients informed of any resolution to their grievances? Does the hospital apply what it learns from the grievance as part of its continuous quality improvement activities?

- Is the grievance process reviewed and analyzed through the hospital's QAPI process or some other mechanisms that provides oversight of the grievance process?

A-0043

§482.13(a)(2) continued
The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control, Quality Improvement Organization. At a minimum:

Interpretive Guidelines §482.13(a)(2)

Quality Improvement Organizations (QIO) are CMS contractors charged with reviewing the appropriateness and quality of care rendered to Medicare beneficiaries in the hospital setting. The QIOs are also tasked with reviewing utilization decisions. Part of this duty includes reviewing discontinuation of stay determinations based upon a beneficiary's request. The regulations mention the functions of the QIOs in order to make Medicare beneficiaries aware of the fact that if they have a **complaint regarding quality of care**, disagree with a **coverage decision**, or they wish to appeal a premature discharge, they may contact the QIO to lodge a complaint. The hospital is required to have procedures for referring Medicare beneficiary

concerns to the QIOs; additionally, CMS expects coordination between the grievance process and existing grievance referral procedures so that beneficiary complaints are handled timely and referred to the QIO at the beneficiary's request.

This regulation requires coordination between the hospital's existing mechanisms for utilization review notice and referral to QIOs for Medicare beneficiary concerns (See 42 CFR Part 489.27). This requirement does not mandate that the hospital automatically refer each Medicare beneficiary's grievance to the QIO; however, the hospital must inform all beneficiaries of this right, and comply with his or her request if the beneficiary asks for QIO review.

Survey Procedures §482.13(a)(2)

- Review patient discharge materials. Is the hospital in compliance with 42 CFR §489.27?
- Does the hospital grievance process include a mechanism for timely referral of Medicare patient concerns to the QIO? What time frames are established?
- Interview Medicare patients. Are they aware of their right to appeal premature discharge?

A-0044

§482.13(a)(2)(i) The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.

Interpretive Guidelines §482.13(a)(2)(i)

The hospital's procedure for a patient or the patient's representative to submit written or verbal grievances must be clearly explained. The patient or patient's representative should be able to clearly understand the procedure.

Survey Procedures §482.13(a)(2)(i)

- Review the information provided to patients explaining the hospital's grievance procedures. Does it clearly explain how the patient is to submit either a verbal or written grievance?
- Interview patients or patient representatives. Does the patient, or (if he/she is incapacitated) his/her representative, know about the grievance process and how to submit a grievance?

A-0045

§482.13(a)(2)(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.

Interpretive Guidelines §482.13(a)(2)(ii)

The hospital must review, investigate, and resolve each patient's grievance within a reasonable time frame. For example, grievances about situations that endanger the patient, such as neglect or abuse, should be reviewed immediately, given the seriousness of the allegations and the potential for harm to the patient(s). However, regardless of the nature of the grievance, the hospital should make sure that it is responding to the substance of each grievance while identifying, investigating, and resolving any deeper, systemic problems indicated by the grievance.

Most complaints are not complicated and should not require extensive investigation. Occasionally a complaint is complicated and may require an extensive investigation. A timeframe of 7 days for the provision of the response would be considered appropriate. We do not require that the grievance be resolved during the hospital's specified timeframe for the response, although most should be resolved. The Code of Federal Regulations at 42 CFR §482.13(a)(2)(iii) specifies information the hospital must include in their response. In most cases, the hospital includes the resolution of the grievance in their response. If the grievance is not resolved, if the investigation is not complete, or if the corrective action is still being evaluated, the hospital's response should address that the hospital is still working to resolve the complaint and states that the hospital will follow-up with another written response within so many days (depending on what actions the hospital may have to take). The hospital should attempt to resolve all grievances as soon as possible.

Survey Procedures §482.13(a)(2)(ii)

What time frames are established to review and respond to patient grievances? Are these time frames clearly explained in the information provided to the patient that explains the hospital's grievance process?

A-0046

§482.13(a)(2)(iii) In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

Interpretive Guidelines §482.13(a)(2)(iii)

The written notice of the hospital's determination regarding the grievance must be communicated to the patient or the patient's representative in a language and manner the patient or the patient's legal representative, when necessary, understands.

The hospital may use additional tools to resolve a grievance, such as meeting with the patient and his family, or other methods it finds effective. The regulatory requirements for the grievance process are minimum standards, and do not inhibit the use of additional effective approaches in handling patient grievances. However, in all cases the hospital must provide a written notice (response) to each patient's grievance(s). The written response must contain the elements listed in this requirement.

Survey Procedures §482.13(a)(2)(iii)

Review the hospital's copies of written notices (responses) to patients. Are all patients provided a written notice? Do the notices comply with the requirements?

A-0047

§482.13(b) Standard: Exercise of Rights

A-0048

§482.13(b)(1) The patient has the right to participate in the development and implementation of his or her plan of care.

Interpretive Guidelines §482.13(b)(1)

This regulation requires the hospital to actively include the patient in the development, implementation and revision of his/her plan of care. It requires the hospital to plan the patient's care, with patient participation, to meet the patient's psychological and medical needs.

The patient's (or patient's representatives, as allowed by State law) right to participate in the development and implementation of his or her plan of care includes at a minimum, the right to: participate in the **development and implementation** of his/her **inpatient treatment/care plan**, **outpatient treatment/care plan**, participate in the development and implementation of his/her **discharge plan**, and participate in the development and implementation of his/her **pain management plan**.

Survey Procedures §482.13(b)(1)

- Determine the extent to which the hospital initiates activities that involve the patient or the patient's legal representative in the patient's care. If the patient refused to participate, interview the patient to verify his/her refusal.

- What do you observe about the interactions between staff and patients?
- Is there evidence that the patient or the patient's legal representative was included or proactively involved in the development and implementation of the patient's plan of care?
- Were revisions in the plan of care explained to the patient?
- Have patients been notified of their right to be involved in their plan of care to include the development and implementation of their inpatient treatment/care plan, outpatient treatment/care plan, discharge plan, and pain management plan?

A-0049

§482.13(b)(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care.

Interpretive Guidelines §482.13(b)(2)

The right to make informed decisions means that the patient or patient's representative is given the information, explanations, consequences, and options needed in order to make "informed" decisions regarding his/her care. For example, the hospital needs to explain the options the patient has when post-hospital care is needed. For patients needing post-hospital hospice, home health or nursing home care, the patient must be given the choices of available Medicare participating post-hospital care providers such as Hospice Agencies, Home Health Agencies or Nursing Homes.

A patient may wish to delegate decision-making to specific persons, or the patient and family may have agreed among themselves on a decision-making process. To the degree permitted by State law, and to the maximum extent practicable, the hospital must respect the patient's wishes and follow that process. In some cases, the patient may be unconscious or otherwise incapacitated. If the patient is unable to make a decision, the hospital must consult the patient's advance directives. In the advance directive, the patient may provide guidance as to his/her wishes in certain situations, or may delegate decision-making to another individual as permitted by State law. If such an individual has been selected by the patient, relevant information should be provided to him/her so that informed health care decisions can be made for the patient. However, as soon as the patient is able to be informed of his/her rights, the hospital should provide that information to the patient.

The right to make informed decisions regarding care includes the right to make informed decisions about their care including the development of their plan of care, medical and surgical interventions (e.g., deciding whether to sign a surgical consent), pain management, patient care issues and discharge planning.

Section 1802 of the Social Security Act guarantees free choice by Medicare patients. It provides that any individual entitled to Medicare may obtain health services from any institution, agency, or person qualified to participate under Medicare law if the institution, agency, or person undertakes to provide him or her those services.

Survey Procedures §482.13(b)(2)

Is there evidence that patients/patient representatives are provided information and then allowed to make informed decisions about their care to include: inpatient treatment/care, clinical procedures and interventions, pain management, and discharge planning, and as appropriate, their selection of post-hospital extended care providers (hospice, HHA, and nursing homes)?

A-0050

§482.13(b)(2) continued
The patient's rights include being informed of his or her health status,

Interpretive Guidelines§482.13(b)(2)

The patient has the right to be informed of his/her health status. This would include being informed of his/her diagnosis and prognosis.

Survey Procedures §482.13(b)(2)

- Have patients been notified of their right to:
  - Be informed of his/her health status;
  - Be informed of his/her diagnosis;
  - Be informed of his/her prognosis.
- Have patients been informed in a language or method of communication that they understand?
- Have patients been informed of their health status, diagnosis and prognosis?

A-0051

§482.13(b)(2) continued
being involved in care planning and treatment,

Interpretive Guidelines §482.13(b)(2)

The patient's rights include being involved in care planning and treatment. The hospital must include the patient or the patient's representative in the development and any revisions to the patient's care plan and patient treatment decisions.

Survey Procedures §482.13(b)(2)

Conduct record reviews and interviews with staff and patients to determine what happens when staff and a patient disagree regarding the patient's plan of care. Is there evidence that patients or their representative are involved with care planning and treatment decisions?

A-0052

§482.13(b)(2) continued
and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

Interpretive Guidelines §482.13(b)(2)

The patient (or the patient's representative) has the right to request or refuse treatment. This regulation stresses, however, that the patient's right to make decisions about health care is not equivalent to an ability to demand treatment or services that are deemed medically inappropriate or unnecessary.

Survey Procedures §482.13(b)(2)

- Does evidence indicate the hospital respected a patient's request for or refusal of certain treatments?
- Does evidence indicate that a patient's request for treatment was denied? If so what was the reason for that denial?

A-0053

§482.13(b)(3) The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with §489.100 of this part (Definition), §489.102 of this part (Requirements for providers), and §489.104 of this part (Effective dates).

Interpretive Guidelines §482.13(b)(3)

The patient (inpatient or outpatient)has the right to formulate advance directives (as defined in §489.100), and to have hospital staff implement and comply with their advance directive.

The regulation at 42 CFR part 489.102 specifies the rights of a patient (as permitted by State law) to make medical care decisions (e.g., pain management) and to formulate an advance directive and requires the hospital to:

- Disseminate its policies regarding the implementation of advance directives, including a clear and precise statement of limitation if the hospital cannot implement an advance directive on the basis of conscience. At a minimum, a statement of limitation should:

- Clarify any differences between institution-wide conscience objections and those that may be raised by individual MD/DOs;

- Identify the State legal authority permitting such an objection; and

- Describe the range of medical conditions or procedures affected by the conscience objection.

The hospital must:

- Provide written information to patients at the time of admission concerning their rights under State law (whether statutory or recognized by the courts of the State) to make decisions concerning their medical care including their right to accept or refuse medical care and their right to formulate an advance directive. (Both inpatients and outpatients have the same rights under this requirement. However, the hospital is not required to provide written information concerning these rights to outpatients.);

- Document in a prominent part of the patient's medical record whether or not the patient has executed an advance directive;

- Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

- Ensure compliance with requirements of State law concerning advance directives and inform individuals that complaints concerning the advance directive requirements may be filed with the State survey and certification agency;

- Provide for the education of staff concerning its policies and procedures on advance directives. The right to formulate advance directives includes the right to formulate a psychiatric advance directive (as allowed by State law); and

- Provide community education regarding advance directives and the hospital must document its efforts.

An advance directive refers to instructions about the patient's medical care in the event that he/she becomes unable to communicate for himself/herself. An advance directive may take the form of a living will or a medical power of attorney. A **psychiatric advance directive** is

akin to a traditional advance directive for health care. This type of advance directive might be prepared by an individual who is concerned that at some time he or she may be subject to involuntary psychiatric commitment or treatment. The psychiatric advance directive may cover a range of subjects, and may name another person who is authorized to make decisions for the individual if he or she is determined to be legally incompetent to make his/her own choices. It may also provide the patient's instructions about hospitalization, alternatives to hospitalization, the use of medications, types of therapies, and the patient's wishes concerning restraint or seclusion. The patient may designate who should be notified upon his/her admission to the hospital, as well as who should not be permitted to visit him or her. State laws regarding the use of psychiatric advance directives vary.

In accordance with State law, a psychiatric advance directive should be accorded the same respect and consideration that a traditional advance directive for health care is given. Hospitals should carefully coordinate how the choices of a patient balance with the rights of other patients, staff, and individuals in the event that a dangerous situation arises.

However, even if State law has not explicitly spoken to the use of psychiatric advance directives, consideration should be given to them inasmuch as this regulation also supports the patient's right to participate in the development and implementation of his or her plan of care. When the patient is, for whatever reason, unable to communicate his/her wishes, the preferences expressed in the psychiatric advance directive can give critical insight to the MD/DOs, nurses, and other staff as they develop a plan of care and treatment for the patient.

Survey Procedures §482.13(b)(3)

- Review the records of a sample of patients for evidence of hospital compliance with advance directive notice requirements. Is there documentation of whether or not each patient has an advance directive? For those patients who have reported an advance directive, has the patient's advance directive been placed in the medical record? Is there evidence that the hospital provides written notice to inpatients or their representative of the patient's right to formulate an advance directive and to have hospital staff comply with the advance directive (in accordance with State law and stated conscientious objection)?

- What mechanism does the hospital have in place to allow patients to formulate an advance directive or to update their current advance directive? Is there evidence that the hospital is promoting and protecting each patient's right to formulate an advance directive?

- Determine to what extent the hospital educates its staff regarding advance directives.

- Interview staff to determine their knowledge of the advance directives of the patients in their care.

- Determine to what extent the hospital provides education for the patient population (inpatient and outpatient) regarding one's rights under State law to formulate advance directives.

A-0054

§482.13(b)(4) The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.

Survey Procedures §482.13(b)(4)

Is there evidence that the hospital has a system in place to assure that a patient's family and MD/DO are contacted as soon as can be reasonably expected after the patient is admitted (unless the patient requests that this not be done)?

A-0055

§482.13(c) Standard: Privacy and Safety

A-0056

§482.13(c)(1) The patient has the right to personal privacy.

Interpretive Guidelines §482.13(c)(1)

The underlying principle of this requirement is the patient's basic right to respect, dignity, and comfort. "The right to personal privacy" includes at a minimum, that patients have privacy during personal hygiene activities (e.g., toileting, bathing, dressing), during medical/nursing treatments, and when requested as appropriate. The right to personal privacy would also include limiting the release or disclosure of patient information such as the patient's presence in the facility or location in the hospital, or personal information such as name, age, address, income, health information without prior consent from the patient, as required by the Standards for Privacy of Individually Identifiable Health Information (the Privacy Rule). However, patients that are admitted due to emergency circumstances may not wish that family members or significant others be uninformed as to their presence or status. The hospital should have procedures in place, in accordance with State law, to provide appropriate information to patient families or significant others in those situations where the patient is unable to make their wishes known.

People not involved in the care of the patient should not be present without his/her consent while he/she is being examined or treated, nor should video or other electronic monitoring/recording methods be used while he/she is being examined without his/her consent. If an individual requires assistance during toileting, bathing, and other personal hygiene activities, staff should assist, giving utmost attention to the individual's need for

privacy. Privacy should be afforded when the MD/DO or other staff visits the patient to discuss clinical care issues or conduct any examination.

Additionally, audio/video monitoring (does not include recording) patients in medical-surgical intensive-care type units would not be considered violating the patient's privacy as long as patients/patient representatives are aware of the monitoring and the monitors or speakers are located so that the monitor screens are not visible or where speakers are not audible to visitors or the public. Staff must take appropriate precautions to provide patient privacy while patients are toileting, bathing, or being examined.

A patient's right to privacy may be limited in situations where a person must be continuously observed, such as when restrained or in seclusion when immediate and serious risk to harm self (such as when the patient is under suicide precautions or special observation status) or others exists. In most situations, security cameras in non-patient care areas such as stairwells, public waiting areas, outdoor areas, entrances, etc., are not generally affected by this requirements.

Survey Procedures §482.13(c)(1)

- Conduct observations to determine if patients are provided privacy during examinations, procedures, treatments, surgery, personal hygiene activities and discussions about their health status/care and other appropriate situations?

- Are patient names posted in public view?

- Is patient information posted in public view? Is the hospital promoting and protecting each patient's right to privacy?

A-0057

§482.13(c)(2) The patient has the right to receive care in a safe setting.

Interpretive Guidelines §482.13(c)(2)

The intention of this requirement is to specify that each patient receives care in an environment that a reasonable person would consider to be safe. For example, hospital staff should follow current standards of practice for patient environmental safety, infection control, and security. The hospital must protect vulnerable patients, including newborns and children. Additionally, this standard is intended to provide protection for the patient's emotional health and safety as well as his/her physical safety. Respect, dignity and comfort would be components of an emotionally safe environment.

Survey Procedures §482.13(c)(2)

- Review and analyze patient and staff incident and accident reports to identify any incidents or patterns of incidents concerning a safe environment. Expand your review if you suspect a problem with safe environment in the hospitals.

- Review QAPI, safety, infection control and security (or the committee that deals with security issues) committee minutes and reports to determine if the hospital is identifying problems, evaluating those problems and taking steps to ensure a safe patient environment.

- Observe the environment where care and treatment are provided.

- Observe and interview staff at units where infants and children are inpatients. Are appropriate security protections (such as alarms, arm banding systems, etc.) in place? Are they functioning?

- Review policy and procedures on what the facility does to curtail unwanted visitors or contaminated materials.

- Access the hospital's security efforts to protect vulnerable patients including newborns and children. Is the hospital providing appropriate security to protect patients? Are appropriate security mechanisms in place and being followed to protect patients?

A-0058

§482.13(c)(3) The patient has the right to be free from all forms of abuse or harassment.

Interpretive Guidelines §482.13(c)(3)

The intent of this requirement is to prohibit all forms of abuse, neglect (as a form of abuse) and harassment whether from staff, other patients or visitors. The hospital must ensure that patients are free from all forms of abuse, neglect, or harassment. The hospital must have mechanisms/methods in place that ensure patients are free of all forms of abuse, neglect, or harassment.

Abuse is defined as the willful infliction of injury, unreasonable confinement, intimidation, or punishment, with resulting physical harm, pain, or mental anguish. This includes staff neglect or indifference to infliction of injury or intimidation of one patient by another. Neglect, for the purpose of this requirement, is considered a form of abuse and is defined as the failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness.

The following components are suggested as necessary for effective abuse protection:

- **Prevent**. A critical part of this system is that there are adequate staff on duty, especially during the evening, nighttime, weekends and holiday shifts, to take care of the individual needs of all patients. (See information regarding meaning of adequate at those requirements that require the hospital to have adequate staff. Adequate staff would include that the hospital ensures that there are the number and types of qualified, trained, and experienced staff at the hospital and available to meet the care needs of every patient.)

- **Screen**. Persons with a record of abuse or neglect should not be hired or retained as employees.

- **Identify**. The hospital creates and maintains a proactive approach to identify events and occurrences that may constitute or contribute to abuse and neglect.

- **Train**. The hospital, during its orientation program, and through an ongoing training program, provides all employees with information regarding abuse and neglect, and related reporting requirements, including prevention, intervention, and detection.

- **Protect**. The hospital must protect patients from abuse during investigation of any allegations of abuse or neglect or harassment.

- **Investigate**. The hospital ensures, in a timely and thorough manner, objective investigation of all allegations of abuse, neglect or mistreatment.

- **Report/Respond**. The hospital must assure that any incidents of abuse, neglect or harassment are reported and analyzed, and the appropriate corrective, remedial or disciplinary action occurs, in accordance with applicable local, State, or Federal law.

As a result of the implementation of this system, changes to the hospital's policies and procedures should be made accordingly.

Survey Procedures §482.13(c)(3)

- Examine the extent to which the hospital has a system in place to protect patients from abuse, neglect and harassment of all forms, whether from staff, other patients, visitors or other persons. In particular, determine the extent to which the hospital addresses the following issues.

- Are staffing levels across all shifts sufficient to care for individual patient's needs?

- Does the hospital have a written procedure for investigating allegations of abuse and neglect including methods to protect patients from abuse during investigations of allegations?

- How does the hospital substantiate allegations of abuse and neglect?

- Do incidents of substantiated abuse and neglect result in appropriate action?
- Has the hospital implemented an abuse protection program? Does it comply with Federal, State and local laws and regulations? Is it effective?
- Are appropriate agencies notified in accordance with State and Federal laws regarding incidents of substantiated abuse and neglect?
- Can staff identify various forms of abuse or neglect?
- Do staff members know what to do if they witness abuse and neglect?
- What evidence is there that allegations of abuse and neglect are thoroughly investigated?
- Does the hospital conduct criminal background checks as allowed by State law for all potential new hires?
- Is there evidence the hospital employs people with a history of abuse, neglect or harassment?

A-0059

§482.13(d) Standard: Confidentiality of Patient Records

A-0060

§482.13(d)(1) The patient has the right to the confidentiality of his or her clinical records.

Interpretive Guidelines §482.13(d)(1)

The hospital has sufficient safeguards to ensure that access to all information regarding patients is limited to those individuals designated by law, regulation, and policy; or duly authorized as having a need to know. No unauthorized access or dissemination of clinical records is permitted. Clinical records are kept secure and are only viewed when necessary by those persons having a part in the patient's care.

The right to confidentiality means safeguarding the content of information, including patient paper records, video, audio, and/or computer stored information from unauthorized disclosure without the specific informed consent of the individual, parent of a minor child, or legal guardian. Hospital staff and consultants, hired to provide services to the individual, should have access to only that portion of information that is necessary to provide effective responsive services to that individual.

Confidentiality applies to both central records and clinical record information that may be kept at other locations in the hospital, such as, patient units, radiology, laboratories, patient clinics, record storage areas, data systems, etc.

Survey Procedures §482.13(d)(1)

Observe care units. Is patient information posted where it can be viewed by visitors or other non-hospital staff? Are medical records accessible to people not involved with the patient's care? Is it likely that unauthorized persons could read or remove the clinical record? Are patient clinical information/records available and accessible at the bedside or in the patient's room where people not involved in the patient's care could likely read the information.

A-0061

§482.13(d)(2) The patient has the right to access information contained in his or her clinical records within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.

Interpretive Guidelines §482.13(d)(2)

The requirements of the Department of Health and Human Services with regard to the confidentiality rights of individuals are set forth in the Privacy Rule at 42 CFR §164.500 et seq., pursuant to §264 of the Health Insurance Portability and Accountability Act of 1996." The regulation at 42 CFR §164.524 specifies that patients should be allowed to inspect and obtain a copy of health information about them that is held by providers; and that providers may not withhold information except under limited circumstances. These circumstances include:

- Psychotherapy notes;
- A correctional institution or a health care provider acting at the direction of a correctional institution may deny an inmate's request for access, if providing such access would jeopardize the health or security of the individual, other inmates, or officers or employees of the correctional institution;
- The information is about another person (other than a health care provider) and the hospital determines that the patient inspection is reasonably likely to cause sufficient harm to that person to warrant withholding;
- A licensed health care professional has determined that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person;

- The information contains data obtained under a promise of confidentiality (from someone other than a health care provider), and inspection could reasonably reveal the source;

- The information is collected in the course of research that includes treatment and the research is in progress, provided that the individual has agreed to the denial of access and the provider informs the individual that his or her right of access will be reinstated when the research is completed;

- The protected health information is subject to the Clinical Laboratory Improvements Amendments of 1988, 42 CFR §263a, to the extent that providing the requested access would be prohibited by law;

- The protected health information is exempt from the Clinical Laboratory Improvements Amendments of 1988, pursuant to 42 CFR §493.3(a)(2);

- The information is compiled in reasonable anticipation of, or for use in, a civil, criminal or administrative action or proceeding; and

- The request is made by an individual's personal representative (as allowed under state law) and a licensed health care professional has determined that access is reasonably likely to cause substantial harm to the individual or another person.

In general, each patient should be able to see and obtain a copy of his/her records. Record holders may not deny access except to a portion of the record that meets criteria specified above. In these cases, the record holder may decide to withhold portions of the record; however, to the extent possible, the patient should be given as much information as possible.

If the patient is incompetent, the patient record should be made available to his or her representative (as allowed under State law). Upon the patient's request, other designated individuals may access the patient's records.

The patient has the right to easily access his/her medical records. Reasonable cost-based fees may be imposed only to cover the cost of copying, postage, and/or preparing an explanation or summary of patient health information, as outlined in 42 CFR §164.524(c). The cost of duplicating a patient's record must not create a barrier to the individual's receiving his or her medical record.

Survey Procedures §482.13(d)(2)

- Does the hospital promote and protect the patient's right to access information contained in his/her clinical record?

- Does the hospital have a procedure for providing records to patients within a reasonable time frame?

- Does the hospital's system frustrate the legitimate efforts of individuals to gain access to their own medical record?

- Does the procedure include the method to identify what documents were not provided and the reason?

A-0062

§482.13(e) Standard: Restraint for Acute Medical and Surgical Care

Interpretive Guidelines §482.13(e)

Standards (e) and (f) concern the use of restraints in two situations: respectively, standard (e), use of restraints in medical and post-surgical care; and standard (f), **emergency use** of restraints in behavior management. For both situations, it is important to note that these requirements are not specific to any treatment setting, but to the situation the restraint is being used to address. Further, the decision to use a restraint is driven not by diagnosis, but by comprehensive individual assessment that concludes that for this patient at this time, the use of less intrusive measures poses a greater risk than the risk of using a restraint or seclusion.

The comprehensive assessment should include a physical assessment to identify medical problems that may be causing behavior changes in the patient. For example, temperature elevations, hypoxia, hypoglycemia, electrolyte imbalances, drug interactions, and drug side effects can cause confusion, agitation, and combative behaviors. Addressing these medical issues can often eliminate or minimize the need for the use of restraints.

For the purposes of this CoP, the phrase "seclusion and restraint for behavior management" applies to emergencies where the patient's behavior is violent or aggressive. The use of a restraint for a non-combative, otherwise cooperative individual is governed by standard (e) of the regulation. For example, a patient is displaying symptoms of Sundowner's Syndrome, is not acting out or behaving destructively or dangerously; however, the patient has an unsteady gait and continues to get out of bed even after staff have tried alternatives to keep him/her from getting out of bed. In the scenario described, the patient's behavior is not violent or aggressive.

We stress, however, that there is nothing inherently dangerous about a patient being able to walk or wander, even at night. The rationale that the patient should be restrained because he "might" fall is an inadequate basis for using a restraint for the purposes of this regulation. When assessing and care planning for the patient, the hospital should consider whether he/she has a medical condition or symptom that indicates a current need for a protective intervention to prevent the patient from walking or getting out of bed. A history of falling without a current clinical basis for a restraint intervention is inadequate to demonstrate the need for restraint. It is important to note that the regulation specifically states that convenience is not an acceptable reason to restrain a patient. A restraint must not serve as a substitute for adequate staffing to monitor patients.

In the case described in this question, assessment is critical. An assessment should minimally address the following questions: Are there safety interventions or precautions that can be taken to reduce the risk of the patient slipping, tripping, or falling if the patient gets out of bed? Is there a way to enable the patient to safely ambulate? Is there some assistive device that will improve his or her ability to self ambulate? Is a medication or a reversible condition causing this unsteady gait? Would the patient be content to walk with a staff person? Could the patient be brought closer to the nurse's station where he or she could be supervised?

If an assessment reveals a medical symptom or condition that indicates an intervention to protect the patient from harm, the regulation at §482.13(e)(3) requires that the hospital determine that less restrictive interventions are ineffective in protecting the patient from harm. Upon making this determination, the hospital may consider the use of a restraint; however, that consideration should weigh the risks of using a restraint (which are widely documented in research) against the risks presented by the patient's behavior. If the hospital chooses to use the restraint, it must meet the requirements of standard (e).

In the case of a patient with cognitive impairment, such as Alzheimer's Disease, which restraint standard (e) or (f) would apply? Two examples are offered for the sake of clarification.

- Example 1: A patient with Alzheimer's Disease has a catastrophic reaction where he/she becomes so agitated and aggressive that he/she physically attacks a staff member. He/she cannot be calmed by other mechanisms, and his/her behavior presents a danger to himself, and to staff and other patients. The use of restraint or seclusion in this situation is governed by the behavior management standard (§482.13(f)).

- Example 2: A patient diagnosed with Alzheimer's Disease has surgery for a fractured hip. Staff determines that it is necessary to immobilize the hip to prevent re-injury. The use of less restrictive alternatives has been evaluated or was unsuccessful. Restraint use in this situation is governed by the acute medical and surgical care standard (§482.13(e)).

If a patient has a diagnosed chronic medical or psychiatric condition such as those associated with Lesch-Nyhan Syndrome, and he/she engages in repetitive self-mutilating behavior, the use of restraint would need to meet the requirements of standard (e) for acute medical and surgical care rather than standard (f) for behavioral management. In these situations where the patient exhibits chronic self-injurious behavior, a PRN order that is applied in accordance with the specific parameters established in the treatment plan would be permitted (note than PRN application is not otherwise permitted with uses of restraint under standard (e)). Again, this use of restraint would need to be integrated into the plan for the patient's care and treatment. As always, the use of alternative interventions should be pursued when feasible, and use of restraint should be discontinued as quickly as possible. Since the use of restraints to prevent self-injury for these types of rare, severe medical and psychiatric conditions is

considered a standard (e) use of restraint for acute medical and surgical care, the requirement for face-to-face assessment within one hour and the limitation of length of orders (4, 2, or 1 hour(s) depending on the patient's age are not applicable).

Restraint must not be used unless it is to meet the patient's individual clinical needs. When used, restraints must be the least restrictive intervention that protects the patient's safety and alternatives have failed. Restraint use must end as soon as possible.

Patient care staff must be able to demonstrate that the restraints are the least restrictive intervention that protects the patient's safety. Patient care staff must demonstrate through their documentation that the use of restraint is based on individual assessments of the patient. The assessments and documentation of those assessments must be ongoing in order to demonstrate a continued need for restraint. Documentation by the physician or other staff once a day may not be adequate to support that the restraint intervention needs to continue and may not comply with the requirement to end the restraint as soon as possible. A patient's clinical needs often change as time passes or at differing times of the day.

The use of a protocol does not substitute for compliance with all the requirements nor does the use of a protocol necessarily demonstrate compliance with the requirements. All restraint interventions must be based on the individual clinical needs of a particular patient at a particular time as demonstrated by documented ongoing assessments of that patient.

Questions staff should ask (and surveyors will evaluate to determine compliance):

- Is the restraint intervention the least restrictive intervention that meets the patient's clinical needs/protects the patient's safety?

- Did the staff demonstrate that alternatives will not meet the patient's clinical needs/protects the patient's safety?

- Do ongoing documented assessments demonstrate that the restraint intervention is needed at this time (or at a time in the past) and that the restraint intervention remains the least restrictive way to protect the patient's safety?

CMS does not consider **the use of weapons** in the application of restraint as safe appropriate health care interventions. We consider the term "weapons" to include pepper spray, mace, nightsticks, Tazers, cattle prods, stun guns, pistols and other such devices. Security staff may carry weapons as allowed by hospital policy and State and Federal law. The use of weapons by security staff is considered as a law enforcement use and not a health care intervention. CMS does not approve the use of weapons by any hospital staff as a means of subduing a patient to place that patient in restraint/seclusion.

If a weapon is used by security or law enforcement personnel on a person in a hospital (patient, staff, visitor) to protect people or hospital property from harm, we would expect the situation to be handled as a criminal activity and the perpetrator be turned over to local law enforcement.

Again, CMS does not consider the use of weapons as safe appropriate "health care" interventions and their use is not appropriate in the application of patient restraint or initiation of seclusion.

Handcuffs, manacles, shackles, and other chain-type restraint devices are considered law enforcement restraint devices and would not be considered safe appropriate health care restraint interventions for use by hospital staff to restrain patients.

The use of such devices by non-hospital employed or contracted law enforcement officers is governed by Federal and State law and regulations. If non-hospital employed or contracted law enforcement officers bring a prisoner wearing handcuffs or other restraints, into the hospital for care, the officers are responsible for monitoring and maintaining the custody of their prisoner (the hospital's patient) and the officers will determine when their prisoner's restraint device can be removed in accordance with Federal and State law and regulations. This does not diminish the hospital's responsibility for appropriate assessment and provision of care for their patient (the officer's prisoner).

A-0063

§482.13(e)(1) The patient has the right to be free from restraints of any form that are not medically necessary or are used as a means of coercion, discipline, convenience, or retaliation by staff.

The term "restraint" includes either a physical restraint or a drug that is being used as a restraint.

A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body.

A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement, and is not a standard treatment for the patient's medical or psychiatric condition.

Interpretive Guidelines §482.13(e)(1)

The regulation states that patients have the right to be free from restraint/seclusion that is not medically necessary. Hospitals must ensure that this right is implemented. The hospital must take actions to comply with the requirements through its QAPI activities. Its hospital leadership should assess and monitor their use of restraint/seclusion, implement actions to ensure that only medically necessary restraints are used, and that when used the hospital complies with the requirements. One suggested method to assess and monitor restraint and seclusion use may be the use of a log to record restraint/seclusion use. Components of this log could include:

- Shift;
- Date, time of order;
- Staff who initiated the process;
- The length of each episode;
- Date and time each episode was initiated;
- Day of the week each episode was initiated;
- Type of restraint used;
- Whether injuries were sustained by the individual or staff;
- Age of individual;
- Gender of individual.

In acute medical and post-surgical care, a restraint may be necessary to ensure that (for example) an intravenous (IV) or feeding tube will not be removed, or that a patient who is temporarily or permanently incapacitated with a broken hip will not attempt to walk before it is medically appropriate. That is, medical restraint may be used to limit mobility or, temporarily immobilize a patient related to a medical, post-surgical or dental procedure.

If the intervention is undertaken because of an unanticipated outburst of severely aggressive, violent or destructive behavior that poses an imminent danger to the patient or others, standard (f) applies. Other uses of restraint for acute medical and post-surgical care should be considered under standard (e).

Risks associated with any intervention must be considered in the context of an ongoing process of assessment, intervention, evaluation, and re-intervention. A corollary principle is that the greater the risks associated with an intervention, the more careful and thorough the assessment must be.

The rationale that the patient should be restrained because he/she “might” fall is an inadequate basis for using a restraint. When assessing and care planning for the patient, the hospital should consider whether he/she has a history of falling or a medical condition or symptom that indicates a need for a protective intervention. It is important to note that the regulation specifically states that convenience is not an acceptable reason to restrain a patient. A restraint must not serve as a substitute for adequate staffing to monitor patients.

The use of a restraint intervention must never act as a barrier to the provision of safe and appropriate care, treatments, and other interventions to meet the needs of the patient.

Exceptions:

The **use of handcuffs or other restrictive devices applied by law enforcement officials who are not employed by or contracted by the hospital** is for custody, detention, and public safety reasons, and is not involved in the provision of health care. Therefore, the use of restrictive devices applied by and monitored by law enforcement officers who are not employed or contracted by the hospital, and who maintain custody and direct supervision of their prisoner, are not governed by §§482.13(e)(1)-482.13(e)(3) of the regulation. The individual may be the law enforcement officer's prisoner but he/she is also the hospital's patient. The hospital is still responsible for providing safe and appropriate care to their patient. The condition of the patient must be continually assessed, monitored, and re-evaluated.

A **voluntary mechanical support** used to achieve proper body position, balance, or alignment so as to allow greater freedom of mobility than would be possible without the use of such a mechanical support is not considered a restraint, (some patients lack the ability to walk without the use of leg braces, to sit upright without neck, head or back braces).

A medically necessary and voluntary **positioning or securing device** used to maintain the position, limit mobility or temporarily immobilize during medical, dental, diagnostic, or surgical procedures is not considered a restraint. Physically holding a patient during a **forced psychotropic medication procedure** is considered physical restraint and is not included in this exception. **Recovery from anesthesia** that occurs when the patient is in the intensive care unit or recovery room is considered part of the surgical procedure; therefore, medically necessary restraint use in this setting would not need to meet the requirements of the regulation. However, if the intervention is maintained when the patient is transferred to another unit, or recovers from the effects of the anesthesia (whichever occurs first), a restraint order would be necessary and the requirements of standard (e) must be followed.

Age or developmentally appropriate protective safety interventions (such as stroller safety belts, swing safety belts, high chair lap belts, raised crib rails, and crib covers) that a safety-conscious child care provider outside a health care setting would utilize to protect an infant, toddler, or preschool-aged child would not be considered restraint or seclusion for the purposes of this regulation. The use of these safety interventions needs to be addressed in the hospital's policies or procedures.

Devices That Serve Multiple Purposes

Devices that serve multiple purposes such as a Geri chair or side rails, when they have the effect of restricting a patient's movement and cannot be easily removed by the patient, constitute a restraint. Use of these restraints are not typically used to address violence or aggression, therefore their use would be governed by standard (e). Standard (f) would apply if used to address violent behavior.

The hospital should base its assessment for device use on what constitutes the least risk for the patient: the risk of what might happen if the device is not used versus the risk it poses as a restraint.

Evaluation of whether devices should be used as restraints must include how they benefit the patient, and whether a less restrictive device/intervention could offer the same benefit at less risk. In any case, a thorough evaluation of the patient and his/her needs is essential.

Side rails

If a patient is in a hospital bed with side rails raised, and the side rails restrict the patient's freedom to exit the bed, and the patient cannot easily remove or release the side rail, the side rail is a restraint and must meet the requirements of standard (e). Additionally, bed design varies. On some hospital beds, patients may be able to lower the side rail. If the patient is able to easily lower the side rail independently, it is not a restraint. Other types of hospital beds have divided side rails. One section may be raised or lowered independently. For example, the side rails are in sections and all but one section are raised and if the patient is able to easily get out of bed if he/she wishes then, for this patient, the side rail is not acting as a restraint.

Even when assessment indicates the presence of a clinical symptom that may warrant the use of a side rail, side rails present an inherent safety risk, particularly if the patient is elderly or disoriented. Even when a side rail is not intentionally used as a restraint, patients may become trapped between the mattress or bed frame and the side rail. Disoriented patients may view a raised side rail as a barrier to climb over, may slide between raised, segmented side rails, or may scoot to the end of the bed to get around a raised side rail. When attempting to leave the bed by any of these routes, the patient is at risk for entrapment, entanglement, or falling from a greater height posed by the raised side rail, with a possibility for sustaining greater injury or death than if he/she had fallen from the height of a lowered bed without raised side rails.

If the patient is on a **stretcher** (a narrow, elevated and highly mobile cart used to transport patients and to evaluate or treat patients), there is an increased risk of falling from a stretcher without raised side rails due to its narrow width and high mobility. Additionally, since stretchers are elevated platforms, the risk of patient injury due to a fall is significant. Therefore, the use of raised side rails on stretchers in emergency departments and when transporting patients are not considered restraint, but a prudent safety intervention. Such use would not require a MD/DO or LIP's order.

If the patient is being transported by stretcher or wheelchair to another area for a diagnostic or surgical procedure and must wait briefly, an order would not be required for raised side rails or a seatbelt. In the case of a patient who is awaiting a treatment or a procedure, we expect that even though an order is not required, as a matter of standard practice staff will assure that the patient is continuously monitored and not abandoned while he/she awaits treatment or care, and that his or her basic care needs are met.

Drugs Used as a Restraint

The regulation states, "A drug used as a restraint is a medication used to control behavior or to restrict the patient's movement, and is not a standard treatment for the patient's medical or psychiatric condition." The regulation is not intended to interfere with the clinical treatment of patients who are suffering from serious mental illness and who need appropriate therapeutic doses of psychotropic medication to improve their level of functioning so that they can more actively participate in their treatment. Similarly, the regulation is not intended to interfere with appropriate doses of sleeping medication prescribed for patients with insomnia or anti-anxiety medication prescribed to calm a patient who is anxious...hence the notation that medications that are a standard treatment for a patient's medical or psychiatric conditions are NOT subject to the requirements of the regulation.

Of course, as with any use of restraint, staff must engage in active patient assessment to determine whether there is some root cause or issue for the targeted problem that can be alleviated through other types of clinical or non-clinical interventions before using the drug intervention. A patient may be agitated because of pain, an adverse reaction to an existing medication, or an unmet care need or concern.

A "**standard treatment**" for a medication used to address a patient's medical or psychiatric condition would include all of the following:

- The medication is used within the pharmaceutical parameters approved for it by the Food and Drug Administration and the manufacturer, for the indications it is manufactured and labeled to address, listed dosage parameters, etc; and

- The use of the medication follows national practice standards established or recognized by the appropriate medical community and/or professional medical association or organization; and

- The use of the medication to treat a specific patient's clinical condition is based on that patient's target symptoms, overall clinical situation, and on the MD/DO's or other LIP's knowledge of that patient's expected and actual response to the medication.

- An additional component of "standard treatment" for a medication is the expectation that the standard use of a psychotherapeutic medication to treat the patient's condition enables the patient to more effectively or appropriately function in the world around him or her than would be possible without the use of the medication. Psychotherapeutic medications are to enable, not disable. If a psychotherapeutic medication reduces the patient's ability to effectively or appropriately interact with the world around him or her, then the psychotherapeutic medication is not being used as a "standard treatment" for the patient's condition.

If a medication is used as a standard treatment (as described above) to address the assessed symptoms and needs of a patient with a particular medical or psychiatric condition, its use is

NOT subject to the requirements of this regulation. The patient would still need to receive assessments, monitoring, interventions and care that are appropriate for that patient's needs.

A medication that is not being used as a standard treatment (as described above) for the patient's medical or psychiatric condition and that results in controlling the patient's behavior and/or in restricting his or her freedom of movement would be a drug used as a restraint.

The regulation supports existing State laws that provide more vigorous promotion of the patient's choice and rights. Therefore when a State's law prohibits the administration of drugs against the wishes of the patient without a court order, the State law applies.

Both standards (e) and (f) specify that a drug used as a restraint is a medication used to restrict the patient's freedom of movement in medical non-surgical situations (standard (e)) or for the emergency control of behavior (standard (f)), and is not a standard treatment for the patient's medical or psychiatric condition. A fundamental right is that the patient has the right to be free from restraints of any form that are imposed for coercion, discipline, convenience, or retaliation by staff, including drugs that are used as restraints. Two examples serve to clarify drugs as restraint in standards (e) and (f).

- **Example 1:** A patient has Sundowner's Syndrome. She gets out of bed in the evening and walks around the unit. The unit's staff find the patient's behavior bothersome, and ask the MD/DO to order a high dose of a sedative to "knock out" the patient and keep her in bed. The patient has no medical symptoms or conditions that indicate that she needs a sedative. In this case, for this patient, the drug is being used inappropriately as a restraint.

- **Example 2**: A patient is in a detoxification program. He becomes violent and aggressive one afternoon. Staff administer a PRN medication ordered by the patient's MD/DO or LIP to address this outburst of specific behaviors. The use of the medication enables the patient to better interact/function. In this case, the medication used for this patient is not considered a "drug used as a restraint." The availability of a PRN medication to manage outbursts of specific behaviors, such as, or aggressive, violent behavior is standard for this patient's medical condition (i.e., drug or alcohol withdrawal). Therefore, this patient's medication does not meet the definition of "drug used as a restraint" since it is "a standard treatment for his medical or psychiatric condition. The use of this medication for this patient is not affected by standard (e) or (f).

Physical Restraint

The definition of physical restraint is any manual method or physical or mechanical device that restricts freedom of movement or normal access to one's body, material, or equipment, attached or adjacent to the patient's body that he or she cannot easily remove. Holding a patient in a manner that restricts his/her movement (this would include **therapeutic holds**) constitutes restraint for that patient. Many deaths have involved these practices and they may be just as restrictive and potentially dangerous as restraining methods that involve devices.

Placing **hand mitts on infants** would not be considered restraint but pinning or otherwise attaching those same mitts to bedding would meet the definition of physical restraint and the requirements would apply.

For the purposes of this regulation a staff member picking up, redirecting, or holding an infant, toddler, or preschool-aged child is not considered restraint. Interventions that include the use of a **helmet** to protect a patient's head, and the patient is unable to easily remove the helmet, would meet the definition of physical restraint and the requirements would apply.

An object may be a restraint by functional definition; that is when an object restricts the patient's movement or access to his or her body, it is a restraint. Under this definition, all sorts of more commonly used hospital devices and practices could meet the definition of a restraint, such as:

- Tucking a patient's sheets in so tightly that he or she cannot move; or
- Using a side rail to prevent a patient from voluntarily getting out of bed.

The following questions need to be considered when defining an intervention as a physical restraint..

- Does the patient have the ability/skill to easily remove the intervention? **AND**
- Is the patient's freedom to move (or get out of bed) when the intervention is in place less than their freedom to move without the intervention, or is the patient's access to their body when the intervention is in place less than their access to their body without the intervention?

A restraint such as a soft wrist restraint, an arm restraint, wrapping or bundling, or some similar type of intervention to prevent an infant or toddler from removing invasive lines or reopening a surgical site, meets the definition of physical restraint and the requirements apply.

A functional definition does not name each device and situation that can be used to inhibit an individual's movement, and promotes looking at situations on a case-by-case basis. Therefore, if the effect of using an object fits the definition of restraint for that patient at that time, then for that patient at that time, the device is a restraint.

Survey Procedures §482.13(e)(1)

- Obtain a sample of patients who are currently in restraints or who have been in restraints during their hospital stay. Are inordinate numbers of patients restrained given the hospital's patient composition at that time?

- What evidence is there that hospital staff identified the reason for the restraint, and eliminated other less invasive measures before applying the restraint?

- Determine if there is a pattern of increased restraint use related to staff coverage.

- Are there patterns of applying the same type of restraint regardless of the medical condition of patients?

- Review patient incident/accident reports to determine the frequency (percent) of injured patients who were also restrained at the time of their injury. If record review indicates that restrained patients sustained injuries, determine what the hospital did to prevent additional injury while it investigated possible changes to its restraint protocol.

- Were the reasons for the use of a restraint in relation to the medical condition explained to the patient in understandable terms? Could the patient articulate his/her understanding?

A-0064

§482.13(e)(2) A restraint can only be used if needed to improve the patient's well being and less restrictive interventions have been determined to be ineffective.

Interpretive Guidelines §482.13(e)(2)

Restraint is only to be used when clinically necessary to improve the patient's well being and when other less restrictive measures have been found to be ineffective to protect the patient from harm. It is a last resort. Accordingly, when deciding whether a patient's condition is such that restraint is the only viable option, there needs to be a connection between the patient's condition and the necessity for restraint.

In restraint use, it is important to ask what is the patient doing that is a hazard. Hospital staff should be specific on this point.

Hospital staff should use concrete, objective observations in describing the behavior, encourage good assessment to determine the cause of the behavior (if determination is possible), and make the connection with why the patient's behavior is so hazardous for that patient that restraint is necessary.

Documentation in the patient's medical record should include:

- The patient's behavior and the intervention used;

- The rationale for the use of the restraint; and

- The patient's response to the use of restraint.

Documentation in the patient's record should indicate a clear progression in how techniques are implemented with less intrusive restrictive interventions attempted or determined to be ineffective prior to the introduction of more restrictive measures.

Survey Procedures §482.13(e)(2)

- Review hospital procedures for use of restraints.
- Examine patterns of restraints or seclusion use that may indicate that the intervention is not based on the patient's need, but on issues such as inadequate staffing or lack of training.
- Does the number of patients who are restrained increase on weekends, on holidays, at night, on certain shifts; where contract nurses are used; in one unit more than other units?
- Do MD/DO or other LIP orders specify the reason for restraint, the type of restraint and the duration?

A-0065

§482.13(e)(3) The use of a restraint must be--

(i) Selected only when other less restrictive measures have been found to be ineffective to protect the patient or others from harm.

Interpretive Guidelines §482.13(e)(3)(i)

A comprehensive assessment of the patient must determine that the risks associated with the use of the restraint are outweighed by the risk of not using it. Alternative interventions do not always need to be tried, but prior to the use of a restraint, alternative interventions must be found to be ineffective to protect the patient or others from harm.

Survey Procedures §482.13(e)(3)(i)

- Is there documentation in the medical record to explain the rationale for the use of restraints, including alternatives attempted?
- Were less intrusive measures considered first?

A-0066

§482.13(e)(3)(ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital or order a restraint. This order must--

Interpretive Guidelines §482.13(e)(3)(ii)

A protocol cannot serve as a substitute for obtaining a MD/DO or other LIP's order before initiating each episode of restraint use, and the requirements of the regulation must still be met. The philosophy that serves as a foundation for the regulation is that restraint use is an exceptional event, not a routine response to a certain condition or behavior. Each patient must be thoroughly assessed and interventions should be tailored to meet the individual patient's needs. The creation of a protocol can run counter to this philosophy if it sets up the expectation that restraint will be used as a normal part of care. The use of restraint is a last resort when less restrictive measures have been determined ineffective, not a standard response to a behavior or patient need.

The hospital should have a written policy, conforming to state law, indicating which LIP are permitted to order restraints in that facility.

The regulation requires an MD/DO or LIP to order restraint prior to the application of restraint. In some situations, the need for a restraint intervention may occur so quickly that an order cannot be obtained prior to the application of restraints. In these **emergency application situations** the order must be obtained either during the emergency application of the restraint or immediately (without time interval) after the restraint has been applied. The hospital should address this process in its restraint policies and procedures. This procedure should specify who can initiate the emergency application of restraint prior to obtaining an MD/DO's or LIP's order. The use of verbal orders should be addressed.

Licensed Independent Practitioner (LIP)

For the purpose of ordering restraint, a LIP is any practitioner permitted by State legislated law and hospital policy as having the authority to independently order restraints or seclusion for patients.

A resident who is authorized by State law and the hospital's residency program to practice as a MD/DO can carry out functions reserved for a MD/DO or LIP by the regulation. A medical school student holds no license, and his/her work is reviewed and must be countersigned by the attending MD/DO; therefore, he or she is not licensed or independent. A medical school student is not an LIP.

Survey Procedures §482.13(e)(3)(ii)

- Review hospital policy and medical by-laws to ascertain clinical practice guidelines that describe the responsibilities of medical staff and clinicians who are privileged in this area.

- Know what categories of practitioners the State recognizes as a LIP or as having the right to order restraints or seclusion.

A-0067

§482.13(e)(3)(ii)(A) Never be written as a standing or on an as needed basis (that is, PRN); and

Interpretive Guidelines §482.13(e)(3)(ii)(A)

This regulation prohibits the use of PRN orders for restraint use. If a patient was recently released from restraint and exhibits behavior that can only be handled by the reapplication of restraint, a new order would be required. Staff cannot discontinue an order and then re-start it under the same order because that would constitute a PRN order. Each episode of restraint use must be initiated in accordance with the order of a MD/DO or other LIP. However, a temporary release that occurs for the purpose of caring for a patient's needs--for example toileting, feeding, and range of motion--is not considered a discontinuation of the invention.

Survey Procedures §482.13(e)(3)(ii)(A)

- Verify in the patient's medical record, and/or the MD/DO's order, that the intent of the order is for the specific reason, and for the specified time period.

- Review the medical record including the progress notes, flow charts and nursing notes to evaluate any patterns of use and if orders were obtained.

- Is there evidence of restraints being implemented on a PRN basis?

A-0068

§482.13(e)(3)(ii)(B) Be followed by consultation with the patient's treating physician, as soon as possible, if the restraint is not ordered by the patient's treating physician;

Interpretive Guidelines §482.13(e)(3)(ii)(B)

The "treating" physician is the MD/DO who is responsible for the management and care of the patient. It is important to consult with the treating physician, as soon as possible, because

information regarding the patient's history may have a significant impact on selection of restraint intervention.

Survey Procedures §482.13(e)(3)(ii)(B)

Check the patient's medical record for documentation of contact with the treating physician if he/she did not order the restraint.

A-0069

§482.13(e)(3)(iii) In accordance with a written modification to the patient's plan of care;

Interpretive Guidelines §482.13(e)(3)(iii)

The use of restraints (including drugs used as restraints and physical restraints) should be referred to in the patient's "modified" plan of care or treatment plan.

Survey Procedures §482.13(e)(3)(iii)

- Determine whether the hospital's procedure followed the expectations of restraint requirements. Does the plan of care reflect a loop of assessment, intervention, evaluation, and re-intervention?
- Is there evidence of assessment of the identified problem or of individual patient assessment?
- Does the patient's plan of care reflect that assessment?
- What was the goal? Was it outcome oriented?
- What was the described intervention?
- Who is responsible for implementation?
- Did the MD/DO or other LIP write orders that included a time-limit? Were these orders incorporated into the plan of care?
- After the discontinuation of the restraint intervention, was this information documented in the update of the plan of care?

A-0070

§482.13(e)(3)(iv) Implemented in the least restrictive manner possible.

Interpretive Guidelines §482.13(e)(3)(iv)

A comprehensive assessment of the patient must determine that the risks associated with the use of the restraint are outweighed by the risk of not using it. Evaluation of whether devices should be used as restraints must include how they benefit the patient, and whether a less restrictive device/intervention could offer the same benefit at less risk. In any case, a thorough evaluation of the patient and his/her needs is essential.

Survey Procedures §482.13(e)(3)(iv)

- Is there clear documentation in the patient's medical record describing the steps or interventions used prior to the use of the needed restraint? That is, what documentation is in the medical record to explain the rationale for the use of restraint?
- Were less restrictive measures tried or considered first?
- Are those measures documented?
- Is there evidence of consideration of the patient's health needs/problems prior to implementation of the intervention?

A-0071

§482.13(e)(3)(v) In accordance with safe and appropriate restraining techniques, and

Interpretive guidelines §482.13(e)(3)(v)

Determine if the hospital's procedures reflect current standards of practice regarding appropriate restraining technique in that environment. Restraint use should not cause harm or pain to the patient.

Survey Procedures §482.13(e)(3)(v)

- Examine medical records of patients for whom restraints are used in the sample.
- After restraints were applied, was an assessment immediately made to ensure that restraints were properly and safely applied?
- Was nursing procedure and policy followed?
- What was the patient's response? If negative, were timely changes made?

- Was there any evidence of injury to the patient?

A-0072

§482.13(e)(3)(vi) Ended at the earliest possible time.

Interpretive Guidelines §482.13(e)(3)(vi)

The use of restraints should be frequently evaluated and ended at the earliest possible time based on the assessment and reevaluation of the patient's condition.

Staff should continually assess the patient to ascertain his/her condition and to determine whether restraint can be discontinued. The regulation requires that these interventions be ended as quickly as possible. However, the decision to discontinue the intervention should be based on the determination that the medical need for restraint is no longer present or the patient's needs can be met with less restrictive methods. When the physician continues the restraint, there must be documentation in the patient's medical record describing the patient's clinical needs and supporting the continued use of restraint.

Who is Authorized to Remove a Restraint?

The hospital should address in its policies and procedures, at a minimum:

- Who has the authority to discontinue restraints (based on a state law and hospital policies); and

- Under what circumstances restraints are to be discontinued.

Survey Procedures §482.13(e)(3)(vi)

- If the time of restraint use is lengthy, look for evidence that the symptoms necessitating the restraint use have persisted. Is there evidence to indicate that the staff have evaluated if the restraint can be safely removed?

- What are the hospital's policies and procedures for ending restraint use for medical and post surgical care?

A-0073

§482.13(e)(4) The condition of the restrained patient must be continually assessed, monitored, and reevaluated.

Interpretive Guidelines §482.13(e)(4)

The determination of frequency of monitoring should be made on an individual basis that includes a rationale that reflects consideration of the individual patient's medical needs and health status. Hospital policies and/or nursing policies should address: frequencies of assessment, assessment content (e.g., vital signs, circulation, hydration needs, elimination needs, level of distress and agitation, mental status, cognitive functioning, skin integrity), and provide for nutritional needs, range of motion, and elimination needs.

Standard (e) does not require one-to-one observation (a staff member constantly in the presence of the patient). We expect that the hospital will establish a policy and procedure (or guidelines for staff) to guide staff in how to determine an appropriate interval for assessment, monitoring, and re-evaluation based on the individual needs of the patient, his or her condition, and the type of restraint used. For example, placing staff at the bedside of a patient with an IV arm board may be unnecessary. However, for a more restrictive or risky intervention, staff may determine that constant one-to-one monitoring is needed.

Continuous face-to-face monitoring may be appropriate when the intervention leaves a patient vulnerable. Restraint limits an individual's ability to move or escape harm. Patients are vulnerable to assault or other abuse when they are immobilized in this manner. The hospital is responsible for providing monitoring and reassessment that will protect the patient's safety.

Survey Procedures §482.13(e)(4)

- Was there a valid rationale for the decision regarding the frequency of assessment/monitoring documented in the medical record?
- Was documentation consistent, relevant, and reflective of the patient's condition?
- If the patient's mental status, coordination, or gait improved, what actions did the staff take?
- What evidence do you find the hospital's/nursing assessment/monitoring policies are put into practice on all restrained patients?
- Do the patient's care needs dictate how frequently the reassessment is made, and is there documented evidence of the reassessment?

A-0074

§482.13(e)(5) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of restraints.

Interpretive Guidelines §482.13(e)(5)

Ongoing restraint education and training must be provided both as a part of the initial orientation of all new and contract staff and as a part of ongoing in-service training for all staff who have direct patient care responsibilities, responsibilities for application of restraint, or the monitoring or assessment of patients in restraint.

Survey Procedures §482.13(e)(5)

- Does the facility have a documented educational, instructional training program for the use of all restraint techniques used?
- Are all levels of staff that have direct patient care responsibilities or restraint application, monitoring, and/or assessment responsibilities, trained in the proper and safe application and use of restraints? Is this documented?
- Does the training require staff to demonstrate knowledge of the assessment loop and the safe application of restraints before they are allowed to apply restraints?
- Does the training review alternatives to the use of restraints?
- Do all contract/agency personnel with direct patient care responsibilities have documented training in the hospital's restraint/seclusion policies?

A-0075

§482.13(f) Standard: Seclusion and Restraint for Behavior Management

Interpretive Guidelines §482.13(f)

Standards (e) and (f) concern the use of restraints in two situations: respectively, standard (e), use of restraints in medical and post-surgical care; and standard (f), **emergency use** of restraints in behavior management. For both situations, it is important to note that these requirements are not specific to any treatment setting, but to the situation the restraint is being used to address. Further, the decision to use a restraint is driven not by diagnosis, but by comprehensive individual assessment that concludes that for this patient at this time, the use of less intrusive measures poses a greater risk than the risk of using a restraint or seclusion.

In the case of a patient with cognitive impairment, such as Alzheimer's disease, which restraint standard (e) or (f) would apply? Two examples are offered for the sake of clarification.

- **Example 1**: A patient with Alzheimer's disease has a catastrophic reaction where he/she becomes so agitated and aggressive that he/she physically attacks a staff member. He/she cannot be calmed by other mechanisms, and his/her behavior

presents a danger to him, and to staff and other patients. The use of restraint or seclusion in this situation is governed by the behavior management standard at §482.13(f).

- **Example 2**: A patient diagnosed with Alzheimer's disease has surgery for a fractured hip. Staff determines that it is necessary to immobilize the hip to prevent re-injury. The use of less restrictive alternatives has been evaluated or was unsuccessful. Restraint use in this situation is governed by the acute medical and surgical care standard (§482.13(e)).

The behavior management standard for restraints and seclusion should be followed in emergency or crisis situations if a patient's behavior becomes aggressive or violent, presenting an immediate, serious danger to his/her safety or that of others and the least restrictive measure that will assure the patient's or other's safety is restraint or seclusion. The behavior management standard governs the use of a restraint or seclusion in this type of a crisis situation whether it occurs on acute medical and surgical units, psychiatric units, Alzheimer's units, or in general, psychiatric, alcohol-drug, children's, rehabilitation, short-term, or long-term care hospitals. A restraint or seclusion for behavior management is used only as an emergency measure and is reserved for those occasions when severely aggressive, combative, or destructive behavior places the patient or others in imminent danger. While different factors may precipitate this type of psychiatric, behavioral, and physical outburst for an individual patient, the need for rapid assessment and continuous monitoring is applicable in each case.

The behavior management standard (Standard (f)) does not apply to situations where the hospital wishes to restrain a patient to address behavior where a confused patient is pulling at their central arterial lines, pulling at their intubation tube while on a ventilator, or attempting to get out of bed with an unstable fractured leg. The use of restraint for a non-violent or non-aggressive, otherwise cooperative patient may be governed by the Restraint for acute medical and surgical care (standard (e)). It is important to note that the regulation specifically states that convenience is not an acceptable reason to restrain or seclude a patient nor can restraint or seclusion use serve as a substitute for adequate staffing to monitor a patient.

The use of restraint or seclusion interventions must never act as a barrier to the provision of safe and appropriate care, treatments, and other interventions to meet the needs of the patient.

CMS does not consider the **use of weapons** in the application of restraint as safe appropriate health care interventions. We consider the term "weapons" to include pepper spray, mace, nightsticks, Tazers, cattle prods, stun guns, pistols and other such devices. Security staff may carry weapons as allowed by hospital policy and State law. The use of weapons by security staff is considered as a law enforcement use and not a health care intervention. CMS does not approve the use of weapons by any hospital staff as a means of subduing a patient to place that patient in patient restraint/seclusion.

If a weapon is used by security or law enforcement personnel on a person in a hospital (patient, staff, visitor) to protect people or hospital property from harm, we would expect the situation to be handled as a criminal activity and the perpetrator be turned over to local law enforcement.

Again, CMS does not consider the use of weapons as safe appropriate "health care" interventions and their use is not appropriate in the application of patient restraint or initiation of seclusion.

Handcuffs, manacles, shackles, and other chain-type restraint devices are considered **law enforcement restraint devices** and would not be considered safe appropriate health care restraint interventions for use by hospital staff to restraint patients in hospitals.

The use of such devices by non-hospital employed or contracted law enforcement officers is governed by Federal and State law and regulations. If non-hospital employed or contracted law enforcement officers bring a prisoner wearing handcuffs or other restraints, into the hospital for care, the officers are responsible for monitoring and maintaining the custody of their prisoner (the hospital's patient) and the officers will determine when their prisoner's restraint device can be removed in accordance with Federal and State law and regulations. This does not diminish the hospital's responsibility for appropriate assessment and provision of care for their patient (the officer's prisoner).

Restraint/seclusion must not be used unless it is to meet the patient's individual clinical needs. When used, restraints/seclusion must be the least restrictive intervention that protects the patient's safety and alternatives have failed. Restraint/seclusion use must end as soon as possible.

Patient care staff must be able to demonstrate that the restraint/seclusion is the least restrictive intervention that protects the patient's safety. Patient care must demonstrate through documentation that the use of restraint/seclusion is based on individual assessments of the patient. The assessments and documentation of those assessments must be ongoing in order to demonstrate a continued need for restraint/seclusion. Documentation by the physician or other staff once a day is not adequate to support that the restraint/seclusion intervention needs to continue and would not comply with the requirement to end the restraint/seclusion as soon as possible. A patient's clinical needs often change as time passes or at differing times of the day.

The use of a protocol does not substitute for compliance with all the requirements nor does the use of a protocol necessarily demonstrate compliance with the requirements. All restraint/seclusion interventions are to be based on the individual clinical needs of a particular patient at a particular time as demonstrated by documented ongoing assessments of that patient.

Questions staff should ask (and surveyors will evaluate to determine compliance):

- Is the restraint/seclusion intervention the least restrictive intervention that meets the patient's clinical needs/protects the patient's safety or the safety of others?

- Did the staff demonstrate that alternatives will not meet the patient's clinical needs/protect the patient's safety?

- Do ongoing documented assessments demonstrate that the restraint intervention is needed at this time (or at a time in the past) and that the restraint/seclusion intervention remains the least restrictive way to protect the patient's safety?

A-0076

§482.13(f)(1) The patient has the right to be free from seclusion and restraints, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff.

The term "restraint" includes either a physical restraint or a drug that is being used as a restraint.

A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body.

A drug used as a restraint is a medication used to control the behavior or to restrict the patient's freedom of movement and is not a standard treatment for the patient's medical or psychiatric condition.

Seclusion is the involuntary confinement of a person in a room or an area where the person is physically prevented from leaving.

Interpretive Guidelines §482.13(f)(1)

This regulation requires that patients have the right to be free from restraint or seclusion that is not clinically necessary. Hospitals must ensure that this right is implemented. The hospital must take actions to comply with the requirements through its QAPI activities. Its hospital leadership should assess and monitor their use of restraint/seclusion, implement actions to ensure that only clinically necessary restraints are used, and that when used the hospital complies with the requirements. One suggested method to assess and monitor restraint and seclusion use may be the use of a log to record restraint/seclusion use. Components of this log could include:

- Shift;

- Date and time of the order;

- Staff who initiated the process;

- The length of each episode;
- Date and time each episode was initiated;
- Day of the week each episode was initiated;
- Type of restraint/seclusion used;
- Whether injuries were sustained by the individual or staff;
- Age of individual;
- Gender of individual.

Seclusion

"Seclusion" does not include confinement on a locked unit or ward where the patient is with others. Seclusion is not just confining an individual to an area but involuntarily confining him/her alone in a room or area where he/she is physically prevented from leaving. A situation where a patient is restricted to a room alone and staff are physically intervening to prevent the patient from leaving the room or giving the perception that threatens the patient with physical intervention if the patient attempts to leave the room, is considered seclusion.

Seclusion is different from timeout. **Timeout** means the restriction of a patient for any period of time to a designated area from which the patient is not physically prevented from leaving and for the purpose of providing the patient an opportunity to regain self-control.

Physical Restraint

The definition of physical restraint is any manual method or physical or mechanical device that restricts freedom of movement or normal access to one's body, material, or equipment, attached or adjacent to the patient's body that he or she cannot easily remove. Holding a patient in a manner that restricts his/her movement (this would include **therapeutic holds**) constitutes restraint for that patient.

An object may be a restraint by functional definition; that is when an object restricts the patient's movement or access to his or her body, it is a restraint. Under this definition, all sorts of more commonly used hospital devices and practices could meet the definition of a restraint, such as:

- Tucking a patient's sheets in so tightly that he or she cannot move; or
- Using a side rail to prevent a patient from voluntarily getting out of bed.

Interventions that include the use of a **helmet** to protect a patient's head and the patient is unable to easily remove the helmet would meet the definition of physical restraint and the requirements would apply.

The following questions need to be considered when defining an intervention as a physical restraint:

- Does the patient have the ability/skill to easily remove the intervention? AND

- Is the patient's freedom to move when the intervention is in place less than their freedom to move without the intervention, or is the patient's access to their body when the intervention is in place less than their access to their body without the intervention?

A functional definition does not name each device and situation that can be used to inhibit an individual's movement, and promotes looking at situations on a case-by-case basis. Therefore, if the effect of using an object fits the definition of restraint for that patient at that time, then for that patient at that time, the device is a restraint.

Drugs Used as a Restraint

Both standards (e) and (f) specify that a drug used as a restraint is a medication used to restrict the patient's freedom of movement in medical or post-surgical situations (standard (e)) or for the emergency control of behavior (standard (f)), and is not a standard treatment for the patient's medical or psychiatric condition. A fundamental right that appears in both standards (e) and (f) is that the patient has the right to be free from restraints of any form that are imposed for coercion, discipline, convenience, or retaliation by staff, including drugs that are used as restraints. Two examples serve to clarify drugs as restraint in standards (e) and (f):

- **Example 1**: A patient has Sundowner's Syndrome. She gets out of bed in the evening and walks around the unit. The unit's staff finds the patient's behavior bothersome, and asks the MD/DO to order a high dose of a sedative to "knock out" the patient and keep her in bed. The patient has no medical symptoms or conditions that indicate that she needs a sedative. In this case, for this patient, the drug is being used inappropriately as a restraint.

- **Example 2**: A patient is in a detoxification program. He becomes violent and aggressive one afternoon. Staff administers a PRN medication ordered by the patient's MD/DO or LIP to address this outburst of specific behaviors. The use of the medication enables the patient to better interact/function. In this case, the medication used for this patient is not considered a "drug used as a restraint." The availability of a PRN medication to manage outbursts of specific behaviors, such as, or aggressive, violent behavior is standard for this patient's medical condition (i.e., drug or alcohol withdrawal). Therefore, this patient's medication does not meet the definition of "drug used as a restraint" since it is "a standard treatment for his medical or

psychiatric condition. The use of this medication for this patient is not affected by standard (e) or (f).

The regulation states, "A drug used as a restraint is a medication used to control behavior or to restrict the patient's movement, and is not a standard treatment for the patient's medical or psychiatric condition." The regulation is not intended to interfere with the clinical treatment of patients who are suffering from serious mental illness and who need appropriate therapeutic doses of psychotropic medication to improve their functioning state so that they can more actively participate in their treatment. Similarly, the regulation is not intended to interfere with appropriate doses of sleeping medication prescribed for patients with insomnia or anti-anxiety medication prescribed to calm a patient who is anxious...hence the notation that medications that are a standard treatment for a patient's medical or psychiatric conditions are NOT subject to the requirements of the regulation.

Of course, as with any use of restraint, staff must engage in active patient assessment to determine whether there is some root cause or issue for the targeted problem that can be alleviated through other types of clinical or non-clinical interventions before using the drug intervention. A patient may be agitated because of pain, an adverse reaction to an existing medication, or an unmet care need or concern.

A "**standard treatment**" for a medication used to address a patient's medical or psychiatric condition would include all of the following:

- The medication is used within the pharmaceutical parameters approved for it by the Food and Drug Administration and the manufacturer, for the indications it is manufactured and labeled to address, listed dosage parameters, etc.;

- The use of the medication follows national practice standards established or recognized by the appropriate medical community and/or professional medical association or organization; and

- The use of the medication to treat a specific patient's clinical condition is based on that patient's target symptoms, overall clinical situation, and on the MD/DO's or other LIP's knowledge of that patient's expected and actual response to the medication.

An additional component of "standard treatment" for a medication is the expectation that the standard use of a psychotherapeutic medication to treat the patient's condition enables the patient to more effectively or appropriately function in the world around him/her than would be possible without the use of the medication. Psychotherapeutic medications are to enable, not disable. If a psychotherapeutic medication reduces the patient's ability to effectively or appropriately interact with the world around him/her, then the psychotherapeutic medication is not being used as a "standard treatment" for the patient's condition.

If a medication is used as a standard treatment (as described above) to address the assessed symptoms and needs of a patient with a particular medical or psychiatric condition, its use is

NOT subject to the requirements of this regulation. The patient would still need to receive assessments, monitoring, interventions and care that are appropriate for that patient's needs.

A medication that is not being used as a standard treatment (as described above) for the patient's medical or psychiatric condition and that results in controlling the patient's behavior and/or in restricting his or her freedom of movement would be a drug used as a restraint.

The regulation supports existing State laws that provide more vigorous promotion of the patient's choice and rights. Therefore when a State's law prohibits the administration of drugs against the wishes of the patient without a court order, the State law applies.

Exceptions:

The use of handcuffs or other restrictive devices applied by law enforcement officials who are not employed by or contracted by the hospital is for custody, detention, and public safety reasons, and is not involved in the provision of health care. Therefore, the use of restrictive devices applied by and monitored by law enforcement officers who are not employed or contracted by the hospital, and who maintain custody and direct supervision of their prisoner, are not governed by §482.13(f)(1-3). The individual may be the law enforcement officer's prisoner but he/she is also the hospital's patient. The hospital is still responsible for providing safe and appropriate care to their patient. The condition of the patient must be continually assessed, monitored, and re-evaluated.

A **voluntary mechanical support** used to achieve proper body position, balance, or alignment so as to allow greater freedom of mobility than would be possible without the use of such a mechanical support is not considered a restraint, (some patients lack the ability to walk without the use of leg braces, to sit upright without neck, head or back braces).

A medically-necessary and voluntary **positioning or securing device** used to maintain the position, limit mobility or temporarily immobilize during medical, dental, diagnostic, or surgical procedures is not considered a restraint. Physically holding a patient during a **forced psychotropic medication procedure** is considered physical restraint and not included in this exception.

Age or developmentally appropriate protective safety interventions (such as stroller safety belts, swing safety belts, high chair lap belts, raised crib rails, and crib covers) that a safety-conscious child care provider outside a health care setting would utilize to protect an infant, toddler, or preschool-aged child would not be considered restraint or seclusion for the purposes of this regulation. The use of these safety interventions needs to be addressed in the hospital's policies or procedures. For the purposes of this regulation a staff member picking up, redirecting, or holding an infant, toddler, or preschool-aged child is not considered restraint.

A-0077

§482.13(f)(2) Seclusion or restraint can only be used in emergency situations if needed to ensure the patient's physical safety and less restrictive interventions have been determined to be ineffective.

Interpretive Guidelines §482.13(f)(2)

Emergency is defined as a situation where the patient's behavior is violent or aggressive and where the behavior presents an immediate and serious danger to the safety of the patient, other patients, staff, or others.

Restraint/seclusion is only to be used when clinically necessary to improve the patient's well-being and when other less restrictive measures have been found to be ineffective to protect the patient or others from harm. It is a last resort. Accordingly, when deciding whether a patient's condition is such that restraint or seclusion is the only viable option, there needs to be a connection between the patient's condition and the necessity for restraint or seclusion.

In restraint/seclusion use, it is important to ask what is the patient doing that is a hazard. Hospital staff should be specific on this point.

Hospital staff should use concrete, objective observations in describing the behavior, encourage good assessment to determine the cause of the behavior (if determination is possible), and make the connection with why the patient's behavior is so hazardous for that patient that restraint is necessary.

Documentation in the patient's medical record should include:

- The patient's behavior and the intervention used;
- The rationale for the use of the restraint or seclusion; and
- The patient's response to the use of restraint or seclusion.

Documentation in the patient's record should indicate a clear progression in how techniques are implemented with less intrusive restrictive interventions attempted (or considered prior to the introduction of more restrictive measures).

Survey Procedures §482.13(f)(2)

- Review hospital procedures for emergency use of restraints and seclusion.
- Look at incident and accident reports to determine if incidents and accidents are greater with restrained or secluded patients.

- Examine patterns of restraints or seclusion use that may indicate that the intervention is not based on the patient's need, but on issues such as inadequate staffing or lack of training.

- Does the number of patients who are restrained or secluded increase on weekends, on holidays, at night, on certain shifts; where contract nurses are used; in one unit more than other units?

- Do MD/DO or other LIP orders specify the reason for seclusion/restraint, the type of restraint and the duration?

- Does the severity of the behavior justify seclusion or restraint usage by identifying an immediate and serious danger to the physical safety of the patient or others?

- Is there evidence that the hospital considers factors other than the individual patient in determining causes for the need for restraints or seclusion (i.e., environmental factors)?

- Does the clinical record reflect assessment and/or a revision of the plan of care?

A-0078

§482.13(f)(3) The use of a restraint or seclusion must be--

(i) Selected only when less restrictive measures have been found to be ineffective to protect the patient or others from harm.

Interpretive Guidelines §482.13(f)(3)(i)

A comprehensive assessment of the patient must determine that the risks associated with the use of the restraint are outweighed by the risk of not using it. Alternative interventions do not always need to be tried, but prior to the use of a restraint or seclusion, must be found to be ineffective to protect the patient or others from harm. Alternatives attempted or the rationale for not using alternatives must be documented.

Survey Procedures §482.13(f)(3)(i)

- Does the clinical record reflect changes in behavior and staff concerns regarding potential danger on the unit/ward prompting use of seclusion or restraints?

- Did the patient's behavior place others/self at risk of harm?

- Were other behavior interventions tried and documented?

A-0079

§482.13(f)(3)(ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital to order seclusion or restraint.

The following requirements will be superseded by existing State laws that are more restrictive:

Interpretive Guidelines §482.13(f)(3)(ii)

The regulation requires a MD/DO or LIP to order restraint prior to the application of the restraint. Hospitals should have policies and procedures for the initiation of restraint or seclusion to manage violent, aggressive behavior that places the patient or others in danger.

In some emergency situations, the need for a restraint intervention may occur so quickly that an appropriate order cannot be obtained prior to the application of restraints. In these emergency situations the order must be obtained either during the **emergency application** of the restraint or immediately (without time interval) after the restraint has been applied. The hospital should address this process in its restraint policies and procedures. This procedure should specify who can initiate restraints or seclusion in an emergency prior to obtaining a MD/DO's or LIP's order. The use of verbal orders should be addressed.

A protocol cannot serve as a substitute for obtaining a MD/DO or other LIP's order before initiating each episode of restraint or seclusion use, and the requirements of the regulation must still be met. Restraint use is an exceptional event, not a routine response to a certain condition or behavior. Each patient must be thoroughly assessed. Interventions must be tailored to meet the individual patient's needs. The creation of a protocol can run counter to this philosophy if it sets up the expectation that restraint will be used as a normal part of care. The use of restraint is a last resort when less restrictive measures have been determined ineffective, not a standard response to a behavior or patient need.

Licensed Independent Practitioner (LIP)

For the purpose of ordering restraint or seclusion under Standard (f), a LIP is any practitioner permitted by State legislated law and hospital policy as having the authority to independently order restraints or seclusion for patients.

A resident who is authorized by State law and the hospital's residency program to practice as a MD/DO can carry out functions reserved for a MD/DO or LIP by the regulation. A medical school student holds no license, and his or her work is reviewed and must e countersigned by the attending MD/DO; there, he/she is not licensed or independent. A medical school student is not an LIP.

Survey Procedures §482.13(f)(3)(ii)

- Does the hospital have written policy indicating which practitioners are permitted to order seclusion or restraints in the facility?
- Do the hospital's written policies conform to State law?
- Does the hospital have written policies on the use of verbal orders?
- Does the hospital have established policies for who can initiate restraint and seclusion?

A-0080

§482.13(f)(3)(ii)(A) Orders for the use of seclusion or a restraint must never be written as a standing order or on an as needed basis (that is, PRN).

Interpretive Guidelines §482.13(f)(3)(ii)(A)

Ongoing authorization of restrictive techniques is not permitted. If a patient was recently released from restraint or seclusion and suddenly exhibits behavior that can only be handled by the reapplication of restraint or seclusion, a new order would be required. Staff cannot discontinue an order and then re-start it under the same order because that would constitute a PRN order. Restraints/seclusion instituted based on a contingent situation are considered PRN. PRN orders for restraint and seclusion are not permitted by the regulation. Accordingly, the same order cannot be used to reapply restraints or reinstitute seclusion if the patient's behavior escalates again after he or she has been released. Each episode of restraint or seclusion use must be initiated in accordance with the order of a MD/DO or other LIP. However, a temporary release that occurs for the purpose of caring for a patient's needs--for example, toileting, feeding, and range of motion--is not considered a discontinuation of the intervention.

In the case mentioned above, a new order is required, but another face-to-face assessment of the patient by a MD/DO or other LIP is not. In this situation, an RN can perform a thorough patient assessment and communicate his or her findings to the appropriate LIP when he or she obtains the new order. The LIP should conduct a face-to-face assessment if requested by the RN, or if in his or her judgment, the patient's condition warrants another in-person visit.

Survey Procedures §482.13(f)(3)(ii)(A)

Is there evidence of restraints or seclusion being implemented on a PRN basis?

A-0081

§482.13(f)(3)(ii)(B) The treating physician must be consulted as soon as possible, if the restraint or seclusion is not ordered by the patient's treating physician.

Survey Procedures §482.13(f)(3)(ii)(B)

- Determine the hospital's policies and procedures for prompt notification of treating physician when seclusion or restraint is ordered by someone other than the treating physician.
- Determine if medical records reflect hospital policies and procedures.

A-0082

§482.13(f)(3)(ii)(C) A physician or other licensed independent practitioner must see and evaluate the need for restraint or seclusion within 1 hour after the initiation of this intervention.

Interpretive Guidelines §482.13(f)(3)(ii)(C)

A MD/DO or LIP evaluation of a patient must be face-to-face. A telephone call or telemedicine methodology is not adequate. This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate the face-to-face assessment to a Nurse Practitioner or Physician's Assistant to the extent recognized under State law or a State's regulatory mechanism. The face-to-face assessment includes both a physical and psychological assessment of the patient. The MD/DO, other LIP, or delegated nurse practitioner or physician assistant who conducts the face-to-face assessment must be able to conduct both a physical and psychological assessment of the patient in accordance with State law, their scope of practice and hospital policy.

If a patient who is restrained for combative, assaultive or violent behavior quickly recovers and is released before the MD/DO or LIP arrives to perform the assessment, the MD/DO or LIP must still see the patient face-to-face to perform the assessment within 1 hour after the initiation of this intervention. The fact that the patient's behavior warranted the use of a restraint or seclusion indicates a serious medical or psychological need for prompt assessment of the incident/situation that led to the intervention, as well as the physiological and psychological condition of the patient at the time of the assessment. We expect that the assessment would also determine whether there is a continued need for the intervention, the cause of the incident, and whether the intervention was appropriate to address the behavior.

If a medication is being used as a restraint to address violent or aggressive patient behavior, the patient would need to be seen within one hour of the administration of the drug.

A-0083

§482.13(f)(3)(ii)(D) Each written order for a physical restraint or seclusion is limited to 4 hours for adults; 2 hours for children and adolescents ages 9 to 17; or 1 hour for patients under 9.

Interpretive Guidelines §482.13(f)(3)(ii)(D)

The use of physical restraint or seclusion must be limited to the duration of the emergency safety situation regardless of the length of the order. The time frames specified in these requirements are maximums. The MD/DO or LIP has the discretion to decide that the order should be written for a shorter period of time; and in the meantime, staff should be assessing, monitoring, and re-evaluating the patient so that he or she is released from the restraint or seclusion at the earliest possible time.

If restraints or seclusion are discontinued prior to the expiration of the original order, a new order must be obtained prior to reinitiating seclusion or reapplying the restraint and the requirements restart.

The MD/DO is not required to perform another face-to-face assessment of the adult patient after 4 hours (or 2 hours or 1 hour for younger patients). While we encourage MD/DO or LIP participation in the delivery of care and treatment, when the original order is about to expire, a qualified RN can telephone the MD/DO or LIP, report the results of his/her most recent assessment and request that the original order be renewed for another period of time (not to exceed the time limits established in the regulation).

A-0084

§482.13(f)(3)(ii)(D) continued
The original order may only be renewed in accordance with these limits for up to a total of 24 hours.

Interpretive Guidelines §482.13(f)(3)(ii)(D)

Orders for restraints must be renewed on a daily basis.

Survey Procedures §482.13(f)(3)(ii)(D)

Does the renewal for seclusion/restraint provide a rationale that is based on an individual assessment of the patient?

A-0085

§482.13(f)(3)(ii)(D) continued

After the original order expires, a physician or licensed independent practitioner (if allowed under State law) must see and assess the patient before issuing a new order.

Interpretive Guidelines §482.13(f)(3)(ii)(D)

At a minimum, if the patient has been in a restraint or in seclusion for 24 hours, the MD/DO or LIP (if allowed by State law) will at that point return to complete a face-to-face reevaluation. Twenty-four hours of restraint or seclusion is an extreme measure with the potential for serious harm to the patient.

Survey Procedures §482.13(f)(3)(ii)(D)

If patients are in seclusion or restraints for longer than 24 hours, is there evidence of a new written order and assessment documentation in the medical record that provides a reasonable rationale supporting the decision to continue with that intervention?

A-0086

§482.13(f)(3)(iii) In accordance with a written modification to the patient's plan of care;

Interpretive Guidelines §482.13(f)(3)(iii)

The use of restraints (including drugs used as restraints and physical restraints) should be referred to in the patient's "modified" plan of care or treatment plan.

Survey Procedures §482.13(f)(3)(iii)

- Determine whether the hospital's procedure followed the expectations of restraint requirements. Does the plan of care reflect a process of assessment, intervention, evaluation, and re-intervention?
- Is there evidence of assessment of the identified problem or of individual patient assessment?
- Does the patient's plan of care reflect that assessment?
- What was the goal? Was it outcome oriented?
- What was the described intervention?
- Who is responsible for implementation?
- Did the MD/DO or other LIP write orders that included a time-limit? Did these orders get incorporated into the plan of care?

- After the discontinuation of the restraint intervention, was this information documented in the update of the plan of care?

A-0087

§482.13(f)(3)(iv) Implemented in the least restrictive manner possible;

Interpretive Guidelines §482.13(f)(3)(iv)

A comprehensive assessment of the patient must determine that the risks associated with the use of the restraint are outweighed by the risk of not using it. Evaluation of whether devices should be used as restraints must include how they benefit the patient, and whether a less restrictive device/intervention could offer the same benefit at less risk. In any case, a thorough evaluation of the patient and his/her needs is essential.

Survey Procedures §482.13(f)(3)(iv)

- Is there clear documentation in the patient's medical record describing the steps or interventions used prior to the use of the needed restraint? What documentation is in the medical record to explain the rationale for the use of restraint?

- Were less restrictive measures tried or considered first?

- Are those measures documented?

- Is there evidence of consideration of the patient's health needs/problems prior to implementation of the intervention?

A-0088

§482.13(f)(3)(v) In accordance with safe appropriate restraining techniques; and

Interpretive Guidelines §482.13(f)(3)(v)

Restraint/seclusion use should not cause harm or pain to patient.

Survey Procedures §482.13(f)(3)(v)

- Examine and include patients for whom restraint is used in the sample.

- Determine if the hospital's procedures reflect current standards of practice regarding appropriate restraining techniques.

- Is there a clear description of the physical intervention utilized?

- Did staff do an immediate assessment of the patient to ensure that the restraints were safely and correctly applied?
- Was nursing procedure and policy followed?
- What was the patient's response? If negative, were changes made?
- Was there any evidence of injury to the patient?

A-0089

§482.13(f)(3)(vi) Ended at the earliest possible time.

Interpretive Guidelines §482.13(f)(3)(vi)

The use of restraints/seclusion should be frequently evaluated and ended at the earliest possible time based on the assessment and reevaluation of the patient's condition. Staff should continually assess the patient to ascertain his or her condition and to determine whether restraint or seclusion can be discontinued. The regulation requires that these interventions be ended as quickly as possible. However, the decision to discontinue the intervention should be based on the determination that the patient's behavior is no longer a threat to himself or herself. When the physician or LIP continues restraint or seclusion, there must be documentation in the medical record describing the patient's clinical needs and supporting the continued use of restraint or seclusion.

Who is Authorized to Remove a Restraint?

The hospital should address in its policies and procedures, at a minimum:

- Who has the authority to discontinue restraints (based on state law and hospital policies; and
- Under what circumstances restraints are to be discontinued.

Survey Procedures §482.13(f)(3)(vi)

- If the time of restraint use is lengthy, is there evidence that the symptoms necessitating the restraint use have persisted?
- What are the hospital policies and procedures for ending restraint use for behavior management?
- Does the evidence indicate that the staff have evaluated the patient's behavior so that the restraint can safely be removed?

A-0090

§482.13(f)(4) A restraint and seclusion may not be used simultaneously unless the patient is--

(i) Continually monitored face-to-face by an assigned staff member; or

Interpretive Guidelines §482.13(f)(4)(i)

When using both seclusion and restraints at the same time, continual monitoring is defined as uninterrupted monitoring. The monitoring must be face-to-face or by using both audio and video monitoring equipment.

An individual who is physically restrained alone in his or her room is not necessarily being simultaneously secluded. A key point to consider is that the individual's privacy and dignity should be protected to the greatest extent possible during any intervention. The purpose in restraining the individual alone in his or her room may be to promote privacy and dignity instead of simultaneously using seclusion and restraint. While this distinction may be difficult to make, it is helpful to consider whether the individual would, in the absence of the physical restraint, be able to voluntarily leave the room. If so, then he/she is not also being secluded. However, if the physical restraint was removed and yet the individual was still unable to leave the room because staff physically prevented him or her from doing so, then he or she is also being secluded.

Staff must take extra care to protect the safety of the patient when interventions that are more restrictive are used. Monitoring must be appropriate to the intervention chosen, so that the patient is protected from possible abuse, assault, or self injury during the intervention.

Survey Procedures §482.13(f)(4)(i)

- Conduct document review and staff interviews to determine if the hospital provides uninterrupted monitoring.
- Does the clinical record reflect uninterrupted monitoring?

A-0091

§482.13(f)(4)(ii) Continually monitored by staff using both video and audio equipment. This monitoring must be in close proximity to the patient.

Interpretive Guidelines §482.13(f)(4)(ii)

Continually monitored is defined as uninterrupted monitoring. The monitoring must be face-to-face monitoring or by using both video and audio monitoring equipment. The person

monitoring the patient using the audio and video equipment must be in close proximity to the patient and their monitoring must be uninterrupted.

The use of video and audio equipment does not eliminate the need for frequent assessment of the patient's needs and status. The hospital should ensure that staff that are assigned monitoring duties are competent to assess physical and psychological signs of distress. The basis for the requirement that the monitoring be in close proximity to the patient is to ensure that there are staff immediately available to intervene and render appropriate interventions to meet patient needs.

Survey Procedures §482.13(f)(4)(ii)

- Is the staff person monitoring the patient in close proximity to the patient so as to allow emergency intervention if a problem arises?

- Does the video equipment cover all areas of the room or location where the patient is restrained or secluded?

A-0092

§482.13(f)(5) The condition of the patient who is in a restraint or in seclusion must continually be assessed, monitored, and reevaluated.

Interpretive Guidelines §482.13(f)(5)

The frequency of monitoring will vary according to the type and design of the restraint device/intervention or seclusion; the patient's emotional, psychological and medical condition; and the patient's physical needs, clinical symptoms, and safety needs. We expect that the hospital will establish a policy and procedure (or guidelines for staff) to guide staff in how to determine an appropriate interval of assessment, monitoring, and re-evaluation based on the individual needs of the patient, his/her condition and the type of intervention used. When a more restrictive or higher risk intervention is required and/or a patient is suicidal, self injurious, or combative, staff may determine that one-to-one monitoring is needed.

Continuous face-to-face monitoring may be appropriate when the intervention leaves a patient vulnerable. For example, restraint limits an individual's ability to move or escape harm. Patients are vulnerable to rape or other abuse when they are immobilized in this manner. The hospital is responsible for providing monitoring and reassessment that will protect the patients' safety.

Survey Procedures §482.13(f)(5)

- Review the hospital's policy on restraints and seclusion to determine how the facility is assessing and monitoring patient medical and behavioral status. Obtain a sample of the patient population in restraints.

- Look for a cycle of removing restraints, then reapplying them without evaluating the patient.
- Does hospital policy describe which staff members are responsible for assessing and monitoring the patient?
- Are time frames described for how often a patient is monitored for vital signs, respiratory and cardiac status, and skin integrity checks?
- Is there documentation of ongoing patient assessment (e.g., skin integrity, circulation, respiration, intake and output, weight, hygiene, injury, etc)?
- Is the patient's mental status assessed? Is this documented in the medical record?
- Does the policy include frequent opportunities for offering fluids and nourishment, toileting/elimination, range of motion, exercise of limbs and systematic release of restrained limbs? Is this documented in the record?
- Is the patient assessed regarding continued need for use of seclusion or restraint? Is there adequate justification for continued use and is this documented?
- Did the patients understand the reasons for the use of restraints or seclusion?

A-0093

§482.13(f)(6) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of seclusion and restraint application and techniques and

Interpretive Guidelines §482.13(f)(6)

Ongoing restraint and seclusion education and training must be provided both as a part of the initial orientation of all new and contract staff and as a part of ongoing in-service training for all staff who have direct patient care responsibilities, responsibilities for the application of restraint, or the monitoring or assessment of patients in restraint or seclusion.

Hospitals are required to have appropriately trained staff for the proper and safe use of seclusion and restraint interventions. Appropriately trained staff would include both that the hospital has adequate numbers and types of trained staff, as well as, that those staff have been trained in the safe use and application of all the restraint and seclusion interventions used by the hospital. It would not be appropriate for a hospital to routinely or consistently call upon a law enforcement agency or agencies as a means of applying restraint or initiating seclusion on its patients.

Survey Procedures §482.13(f)(6)

Does the hospital have evidence that all staff that have direct patient care responsibilities and any other individuals who may be involved in the application of restraints (e.g., security guards, EMTs on the premises) have been trained and are able to demonstrate competency in the safe use of seclusion and the safe application and use of restraints?

A-0094

§482.13(f)(6) continued
[All staff who have direct patient contact must have ongoing education and training in] alternative methods for handling behavior, symptoms and situations that traditionally have been treated through the use of restraints or seclusion.

Interpretative Guidelines §482.13(f)(6)

Staff must not simply respond to the behavior but must work to understand what the behavior means. Direct care staff must be trained to intervene early in the escalation cycle with verbal and non-verbal de-escalation techniques. Restraint should only be used when alternatives have been tried and failed.

Trying less restrictive alternatives does not mean attempting a complex series of interventions or a lengthy checklist of steps to initiate before laying hands on the individual. Rather, a whole toolbox of possible interventions are implemented during the course of the interaction and modified based upon the assessment of the individual's response. Hospital staff must utilize least restrictive measures during the course of an interaction and modify them based upon the assessment of the individual's response.

Survey Procedures §482.13(f)(6)

- Are the staff members who are able to initiate restraint and seclusion trained in the safe use and application of restraint and seclusion and able to demonstrate competency?

- Is there evidence that staff are updated and trained on alternative interventions other than restraint/seclusion techniques?

- Determine if the hospital has experienced negative outcomes when handling these situations (through review of complaints, incident reports, and other available data). If there have been negative outcomes when handling these situations, has the hospital incorporated this problem into its QAPI program (See §482.21)? Has the hospital incorporated any needed changes into revisions of its policies/ procedures, training programs, and staff competency evaluations?

A-0095

§482.13(f)(7) The hospital must report to CMS any death that occurs while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion.

Interpretive Guidelines §482.13(f)(7)

In patient restraint/seclusion-associated deaths, when the patient was in seclusion or had been in seclusion, or when the restraint was applied or had been applied, to address violent, aggressive, assaultive, etc. behavior toward self or others, the death reporting requirements of the behavior management standard apply. In these restraint or seclusion situations (behavior management) the death of **any patient that dies, for any reason,** while in restraint or seclusion **must** be reported to the CMS Regional Office (RO). Also **any patient's death** that occurs after seclusion or restraint (that had been applied/used for the management of violent behavior) has been discontinued **and** where the patient's death could be **reasonably related** to that patient having been in restraint or seclusion **must** be reported to the RO. The hospital must report all patient deaths associated with the use of seclusion or restraint, by telephone, to their CMS-RO prior to the close of business the next business day after the patient's death.

CMS requires the hospital to report patient restraint or seclusion deaths to the hospital's RO for the circumstances and in the methods and times stated in the previous paragraphs. The hospital is **not** to postpone reporting the patient's death until after the hospital's investigation. The hospital is reporting to CMS that a patient died while in behavior management restraint or seclusion, or that the death could reasonably be related to the patient having been in seclusion or restraint; not the cause of the patient's death.

Survey Procedures §482.13(f)(7)

- Review the written hospital policy on reporting deaths that occur while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion.

- Interview patient care staff to determine their knowledge of the hospital's policy or protocol regarding the determination whether a death reasonably may have resulted from seclusion or restraint, and their knowledge of CMS reporting requirements.

- Is there evidence of deaths, associated with restraints or seclusion, not reported to CMS?

- If there have been deaths associated with seclusion or restraints, were they reported to CMS in a timely manner? Was this documented in the medical record?

- Does the hospital have a written policy on reporting deaths associated with seclusion or restraints to CMS in a timely manner?

- Do patient care staff know the CMS death reporting requirements?

A-0141

§482.21 Condition of Participation: Quality Assessment and Performance Improvement

The hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program.

The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.

The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.

A-0142

§482.21(a) Standard: Program Scope

A-0143

§482.21(a)(1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and

---

A-0144

§482.21(a)(1) continued
[The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will] identify and reduce medical errors.

A-0145

§482.21(a)(2) The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations.

A-0146

§482.21(b) Standard: Program Data

A-0147

§482.21(b)(1) The program must incorporate quality indicator data including patient care data, and other relevant data, for example, information submitted to, or received from, the hospital's Quality Improvement Organization.

A-0148

§482.21(b)(2) The hospital must use the data collected to--

(i) Monitor the effectiveness and safety of services and quality of care; and

A-0149

§482.21(b)(2)(ii) [The hospital must use the data collected to--] Identify opportunities for improvement and changes that will lead to improvement.

A-0150

§482.21(b)(3) The frequency and detail of data collection must be specified by the hospital's governing body.

A-0151

§482.21(c) Standard: Program Activities

A-0152

§482.21(c)(1) The hospital must set priorities for its performance improvement activities that--

(i) Focus on high-risk, high-volume, or problem-prone areas;

(ii) Consider the incidence, prevalence, and severity of problems in those areas; and

(iii) Affect health outcomes and quality of care.

A-0153

§482.21(c)(1) continued
[The hospital must set priorities for its performance improvement activities that--

(i) Focus on high-risk, high-volume, or problem-prone areas;

(ii) Consider the incidence, prevalence, and severity of problems in those areas; and]

(iv) Affect patient safety.

A-0154

§482.21(c)(2) Performance improvement activities must track medical errors and adverse patient events,

A-0155

§482.21(c)(2) continued
[Performance improvement activities must track medical errors and adverse patient events,] analyze their causes, and

A-0156

§482.21(c)(2) continued
[Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and] implement preventive actions and mechanisms that include feedback and learning throughout the hospital.

A-0157

§482.21(c) (3) The hospital must take actions aimed at performance improvement and,

A-0158

§482.21(c) (3) continued
after implementing those actions, the hospital must measure its success, and

A-0159

§482.21(c) (3) continued
track performance to ensure that improvements are sustained.

A-0160

§482.21(d) Standard: Performance Improvement Projects

As part of its quality assessment and performance improvement program, the hospital must conduct performance improvement projects.

A-0161

§482.21(d)(1) The number and scope of distinct improvement projects conducted annually must be proportional to the scope and complexity of the hospital's services and operations.

A-0162

§482.21(d)(2) A hospital may, as one of its projects, develop and implement an information technology system explicitly designed to improve patient safety and quality of care. This project, in its initial stage of development, does not need to demonstrate measurable improvement in indicators related to health outcomes.

A-0163

§482.21(d)(3) The hospital must document what quality improvement projects are being conducted.

A-0164

§482.21(d)(3) continued
[The hospital must document] the reasons for conducting these projects, and

A-0165

§482.21(d)(3) continued
[The hospital must document] the measurable progress achieved on these projects.

A-0166

§482.21(d)(4) A hospital is not required to participate in a QIO cooperative project, but its own projects are required to be of comparable effort.

A-0167

§482.21(e) Standard: Executive Responsibilities

The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:

A-0168

§482.21(e)(1) That an ongoing program for quality improvement [is defined, implemented, and maintained.]

A-0169

§482.21(e)(1) continued
[That an ongoing program for] patient safety, including the reduction of medical errors, [is defined, implemented, and maintained.]

A-0170

§482.21(e)(2) That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care, and that all improvement actions are evaluated.

A-0171

§482.21(e)(2) continued
[That the hospital-wide quality assessment and performance improvement efforts address priorities for improved] patient safety [and that all improvement actions are evaluated.]

A-0172

§482.21(e)(3) That clear expectations for safety are established.

A-0173

§482.21(e)(4) That adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and

A-0173

§482.21(e)(4) continued
[That adequate resources are allocated for] reducing risk to patients.

A-0174

§482.21(e)(5) That the determination of the number of distinct improvement projects is conducted annually.

A-0181

§482.22 Condition of Participation: Medical staff

The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital.

Interpretive Guidelines §482.22

The hospital may have only one medical staff for the entire hospital (including all campuses, provider -based locations, satellites, remote locations, etc.). The medical staff must be organized and integrated as one body that operates under one set of bylaws approved by the governing body. These medical staff bylaws must apply equally to all practitioners within each category of practitioners at all locations of the hospital and to the care provided at all locations of the hospital. The single medical staff is responsible for the quality of medical care provided to patients by the hospital.

A-0182

§482.22(a) Standard: Composition of the Medical Staff

The medical staff must be composed of doctors of medicine or osteopathy and, in accordance with State law, may also be composed of other practitioners appointed by the governing body.

A-0183

§482.22(a)(1) The medical staff must periodically conduct appraisals of its members.

Interpretive Guidelines §482.22(a)(1)

The purpose of the appraisal is for the medical staff to determine the suitability of individual members for continued membership on the medical staff and to determine if that individual

practitioner's clinical privileges should be continued, discontinued, revised, or otherwise changed.

The medical staff appraisal procedures must evaluate each individual member's training, experience, and demonstrated competence as established by the hospital QAPI program, credentialing process, and the member's adherence to medical staff bylaws and rules and regulations.

The medical staff bylaws must establish the frequency and other factors that determine when appraisals of medical staff members will be conducted.

After the medical staff conducts its appraisal of individual members, the medical staff makes recommendations to the governing body for continued medical staff membership that are specific to the type of appointment and extent of clinical privileges, and the governing body takes final appropriate action. A separate credentials file must be maintained for each medical staff member.

Survey Procedures §482.22(a)(1)

- Determine that the medical staff has a system in place that is used to periodically appraise its current members and their qualifications in accordance with approved medical staff bylaws and State law requirements.

- Determine that the medical staff bylaws specify the timeframes for the periodic appraisal.

- Verify that an outcome-oriented appraisal system is conducted for all individual members of the medical staff.

- Determine how the medical staff conducts the periodic appraisals of any current member of the medical staff who has not provided patient care at the hospital or who has not provided care for which he/she is privileged to patients at the hospital during the appropriate evaluation time frames. Is this method in accordance with State law and the hospital's written criteria for medical staff membership and for granting privileges?

A-0184

§482.22(a)(2) The medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates.

Interpretive Guidelines §482.22(a)(2)

There must be a mechanism established to examine credentials of individual prospective members(new appointments or reappointments) by the medical staff. The credentials examined include at least:

- A request for clinical privileges;
- Current licensure;
- Training and professional education;
- Documented experience; and
- Supporting references of competence.

The medical staff makes recommendations to the governing body for each new member and for reappointment of members that are specific to type of appointment and extent of the individual practitioner's specific rather than general clinical privileges, and then the governing body takes final appropriate action. A separate credentials file must be maintained for each individual medical staff member or applicant.

A-0185

§482.22(b) Standard: Medical Staff Organization and Accountability

The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to the patients.

(1) The medical staff must be organized in a manner approved by the governing body.

(2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.

(3)The responsibility for organization and conduct of the medical staff must be assigned only to an individual doctor of medicine or osteopathy or, when permitted by State law of the State in which the hospital is located, a doctor of dental surgery or dental medicine.

Interpretive Guidelines §482.22(b)

The medical staff must be accountable to the hospital's governing body for the quality of medical care provided to the patients. The organization of the medical staff must comply with these requirements.

Survey Procedures §482.22(b)

- Verify that the medical staff has a formalized organizational structure, that lines of function and responsibility are delineated between the governing body and other parts of the organization, and that the governing body has sanctioned its approval on the organizational structure and relationships.

- If there is an active executive committee, verify that a majority of the members are doctors of medicine or osteopathy.

- Verify that an individual doctor of medicine or osteopathy is responsible for the conduct and organization of the medical staff through review of the organizational structure and interviews with members of the medical staff.

A-0186

§482.22(c) Standard: Medical Staff Bylaws

The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:

Interpretive Guidelines §482.22(c)

The medical staff must develop and adopt bylaws, and after the hospital's governing body approves the bylaws, the medical staff must enforce its bylaws.

Survey Procedures §482.22(c)

- Verify that the medical staff have bylaws.

- Verify that the bylaws describe a mechanism for ensuring enforcement of its provisions along with rules and regulations of the hospital.

- Verify that the medical staff enforce the bylaws.

A-0187

§482.22(c)(1) Be approved by the governing body.

Interpretive Guidelines §482.22(c)(1)

The medical staff must regulate itself by bylaws, rules and regulations that are consistent with acceptable medical staff practices. The bylaws must be enforced and revised as necessary. Medical staff bylaws and any revisions of those bylaws must be submitted to the governing body for approval. The governing body has the authority to approve or disapprove

bylaws suggested by the medical staff. The bylaws and any revisions must be approved by the governing body before they are considered effective.

Survey Procedures §482.22(c)(1)

Verify the medical staff is operating under current medical staff bylaws, rules, and policies that are in accordance with Federal and State laws and regulations and accepted standards of practice and have been approved by the medical staff and the governing body.

A-0188

§482.22(c)(2) Include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, etc.)

Interpretive Guidelines §482.22(c)(2)

The medical staff bylaws must include a statement of the duties, responsibilities, and privileges of each category of medical staff.

Survey Procedures §482.22(c)(2)

Verify that the bylaws specify the roles and responsibilities of each category of practitioner on medical staff.

A-0189

§482.22(c)(3) Describe the organization of the medical staff.

Interpretive Guidelines §482.22(c)(3)

The medical staff bylaws must describe the organizational structure of the medical staff, and lay out the rules and regulations of the medical staff to make clear what are acceptable standards of patient care for all diagnostic, medical, surgical, and rehabilitative services.

Survey Procedures §482.22(c)(3)

- Verify that the bylaws specify the organization and structure of the medical staff, and a mechanism that delineates accountability to the governing body.

- Verify that the bylaws describe who is responsible for regularly scheduled review and evaluation of the clinical work of the members of the medical staff and describe the formation of medical staff leadership.

A-0190

§482.22(c)(4) Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.

Interpretive Guidelines §482.22(c)(4)

The medical staff bylaws must describe the qualifications to be met by a candidate for membership on the medical staff. The medical staff then recommends individual candidates that meet those requirements to the governing body for appointment to the medical staff.

Survey Procedures §482.22(c)(4)

Verify that the medical staff bylaws describe the qualifications such as licensure, specific training, experience, current competence, judgment, character, and health status to be met by an individual candidate for the medical staff to recommend appointment or reappointment.

A-0191

§482.22(c)(5) Include a requirement that a physical examination and medical history be done no more than 7 days before or 48 hours after an admission for each patient by a doctor of medicine or osteopathy, or, for patients admitted only for oromaxillofacial surgery, by an oromaxillofacial surgeon who has been granted such privileges by the medical staff in accordance with State law.

Interpretive Guidelines §482.22(c)(5)

The Medical Staff bylaws must include a requirement that a physical examination and medical history (H & P) must be performed on each patient by a MD, DO or for patients admitted only for oromaxillofacial surgery, by an oromaxillofacial surgeon. The practitioner who performs the H & P must have been granted such privileges by the medical staff in accordance with State law.

The H & P must be performed by an MD/DO or oromaxillofacial surgeon, for patients receiving oromaxillofacial surgery, no more than 7 days prior to hospital admission/outpatient surgery or 48 hours after hospital admission but prior to surgery/outpatient surgery.

Admission H & P

A H& P would meet the CMS requirements that a H & P be "performed no more than 7 days prior to admission or within 48 hours after admission," if:

- The H & P was performed within 30 days prior to the hospital admission; AND

- An appropriate assessment performed by the MD/DO, which must include a physical assessment of the patient to update any components of the patient's current medical status that may have changed since the prior H & P or to address any areas where more current data is needed, was completed within 7 days prior to admission or 48 hours after admission, but prior to surgery, confirming that the necessity for the procedure or care is still present and the H & P is still current. The physician uses his/her clinical judgment based on his/her assessment of the patient's condition, and any co-morbidities, in relation to the reason the patient was admitted or to the surgery to be performed, when deciding what depth of assessment needs to be performed and what information needs to be included in the update note; AND

- The physician or other individual qualified to perform the H & P writes an update note addressing the patient's current status and/or any changes in the patient's status, regardless of whether there were any changes in the patient's status, within 7 days prior to, or within 48 hours after admission, but prior to surgery. The update note must be on or attached to the H & P, AND

- The H & P, including all updates and assessments, must be included within 48 hours after admission, but prior to surgery (except in emergency situations), in the patient's medical record for this admission.

If a H & P meets all these requirements within 7 days prior to admission, or within 48 hours after admission, the H & P meets the provisions of the regulation with regard to justifying the admission and meeting the time restrictions on the currency of the H & P.

Outpatient Surgery H & P

Furthermore, a H & P would meet the CMS requirement at §482.51(b)(1) that "There must be a complete history and physical work-up in the chart of every patient prior to surgery…" if:

- The H & P was performed within 30 days prior to the outpatient surgery; AND

- An appropriate assessment performed by the MD/DO, which should include a physical examination of the patient to update any components of the patients current medical status that may have changed since the prior H & P or to address any areas where more current data is needed, was completed within 7 days prior to outpatient surgery confirming that the necessity for the procedure is still present and that the H & P is still current. The physician uses his/her clinical judgment based on his/her assessment of the patient's condition, and any co-morbidities, in relation to the surgery to be performed, when deciding what depth of assessment needs to be performed and what information needs to be included in the update note; AND

- The physician or other individual qualified to perform the H & P writes an update note addressing the patient's current status and/or changes in the patient's status, regardless of whether there were any changes in the patient's status, within 7 days prior to the outpatient surgery. The update note must be on or attached to the H & P; AND

- The H & P, including all updates and assessment, must be included in the patient's medical record, except in emergency situations, prior to surgery.

If a H & P meets all these requirements prior to outpatient surgery, the H & P meets all the provisions of the regulation with regard to meeting the time restrictions on the currency of the H & P.

An H & P performed more than 30 days prior to hospital admission/outpatient surgery does not comply with the currency requirements and a new H & P must be performed.

An H & P performed more than 7 days prior to admission/outpatient surgery that does not meet the above currency criteria does not comply with the requirements and a new H & P must be performed.

All or part of the H & P may be delegated to other practitioners in accordance with State law and hospital policy, but the MD/DO must sign the H & P and as applicable, the update note and assume full responsibility for the H & P. This means that a nurse practitioner or a physician assistant meeting these criteria may perform the H & P, and /or the update assessment and note. (Update assessments and update notes are considered part of the H & P.)

Survey Procedures §482.22(c)(5)

Determine that the medical staff bylaws require a physical examination and medical history be done for each patient by an MD or DO or where appropriate, an oromaxillofacial surgeon, no more than 7 days before admission/outpatient surgery or 48 hours after admission but prior to surgery/outpatient surgery. (However, the medical staff bylaws may allow the currency methodology and/or the delegation of this responsibility as discussed in the above interpretation.)

A-0192

§482.22(c)(6) Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.

Interpretive Guidelines §482.22(c)(6)

All patient care is provided by or in accordance with the orders of a practitioner who meets the medical staff criteria and procedures for the privileges granted, who has been granted

privileges in accordance with those criteria by the governing body, and who is working within the scope of those granted privileges.

Privileges are granted by the hospital's governing body to individual practitioners based on the medical staff's review of that individual practitioner's qualifications and the medical staff's recommendations for that individual practitioner to the governing body.

Survey Procedures §482.22(c)(6)

- Verify that the medical staff bylaws contain criteria for granting, withdrawing, and modifying clinical privileges to individual practitioners of the medical staff and that a procedure exists for applying these criteria.

- Verify that practitioners who provide care to patients are working within the scope of the privileges granted by the governing body.

A-0193

§482.22(d) Standard: Autopsies

The medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. The mechanism for documenting permission to perform an autopsy must be defined. There must be a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed.

Survey Procedures §482.22(d)

Verify that the medical staff has policies requiring the practitioners to attempt to secure permission to perform autopsies, that the mechanism for documenting permission to perform an autopsy is defined, and that there is a system for notifying the medical staff, specifically the attending practitioner, when an autopsy is performed.

A-0199

§482.23 Condition of Participation: Nursing Services

The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.

Interpretive Guidelines §482.23

The hospital must have an organized nursing service and must provide on premise nursing services 24 hours a day, 7 days a week with at least 1 registered nurse (RN) furnishing or

supervising the service 24 hours a day, 7 days a week (Exception: small rural hospitals operating under a waiver as discussed in §482.23(b)(1)).

The Social Security Act (SSA) at §1861(b) states that nursing services must be furnished to inpatients and **furnished by the hospital**. The SSA at §1861(e) further requires that the hospital have a **RN on duty at all times** (except small rural hospitals operating under a nursing waiver).

The nursing service must be a well-organized service of the hospital and under the direction of a registered nurse.

The nursing service must be integrated into the hospital-wide QAPI program.

Survey Procedures §482.23

- Determine if the nursing service is integrated into the hospital-wide QAPI program.
- Interview the director of the service. Request the following items:
  - Organizational chart(s) for nursing services for all locations where the hospital provides nursing services;
  - Job or position descriptions for all nursing personnel including the director's position description.
- Select at least one patient from every inpatient care unit. Observe the nursing care in progress to determine the adequacy of staffing and to assess the delivery of care. Other sources of information to use in the evaluation of the nursing services are: nursing care plans, medical records, patients, family members, accident and investigative reports, staffing schedules, nursing policies and procedures, and QAPI activities and reports. Interview patients for information relative to the delivery of nursing services.

A-0200

§482.23(a) Standard: Organization

The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

Interpretive Guidelines §482.23(a)

The hospital may have only one nursing service hospital-wide and the single nursing service must be under the direction of one RN.

The director of the nursing service must be a currently licensed RN and he/she is responsible for the operation of the nursing service. The operation of the nursing service would include the quality of the patient care provided by the nursing service.

The director of the nursing service must determine and provide the types and numbers of nursing care personnel necessary to provide nursing care to all areas of the hospital.

The organization will include various configurations of the following hospital personnel as determined necessary by the hospital and the Director of Nursing:

- Assistant/Associate Director(s);
- Supervisors/Coordinators;
- Head Nurses/Nurse Managers;
- Staff Nurses;
- Unit Secretaries/Clerks;
- Nurses Aide/Orderlies.

Survey Procedures §482.23(a)

- Review the organizational chart or plan for nursing services. Determine that the organizational chart(s) displays lines of authority that delegates responsibility within the department.
- Read the position description for the director of nursing (DON) to determine that it delegates to the DON specific duties and responsibilities for operation of the service.
- Verify that the director is currently licensed in accordance with state licensure requirements.
- Verify that the DON is involved with or approved the development of the nursing service staffing policies and procedures.
- Verify that the DON approves the nursing service patient care policies and procedures.

A-0201

§482.23(b) Standard: Staffing and Delivery of Care

The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.

Interpretive Guidelines §482.23(b)

The nursing service must ensure that patient needs are met by ongoing assessments of patients' needs and provides nursing staff to meet those needs. There must be sufficient numbers, types and qualifications of supervisory and staff nursing personnel to respond to the appropriate nursing needs and care of the patient population of each department or nursing unit.

There must be a RN physically present on the premises and on duty at all times. Every inpatient unit/department/location within the hospital-wide nursing service must have adequate numbers of RNs physically present at each location to ensure the immediate availability of a RN for the bedside care of any patient.

A RN would not be considered immediately available if the RN were working on more than one unit, building, floor in a building, or provider (distinct part SNF, RHC, excluded unit, etc.) at the same time.

Staffing schedules must be reviewed and revised as necessary to meet the patient care needs and to make adjustments for nursing staff absenteeism.

Survey Procedures §482.23(b)

- Determine that there are written staffing schedules which correlate to the number and acuity of patients. Verify that there is supervision of personnel performance and nursing care for each department or nursing unit. To determine if there are adequate numbers of nurses to provide nursing care to all patients as needed, take into consideration:
    - Physical layout and size of the hospital;
    - Number of patients;
    - Intensity of illness and nursing needs;

  - Availability of nurses' aides and orderlies and other resources for nurses, e.g., housekeeping services, ward clerks etc.;
  - Training and experience of personnel;
  - Do not count personnel assigned to areas other than bedside patient care.

- Review medical records to determine if patient care that is to be provided by nurses is being provided as ordered.

A-0202

§482.23(b)(1) The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times, except for rural hospitals that have in effect a 24-hour nursing waiver granted under §488.54 of this chapter.

Interpretive Guidelines §482.23(b)(1)

The hospital must provide nursing services 24 hours a day, 7 days a week. A LPN can provide nursing services if a RN, who is immediately available for the bedside care of those patients, supervises that care.

Exception: §488.54 set forth certain conditions under which rural hospitals of 50 beds or fewer may be granted a temporary waiver of the 24 hour registered nurse requirement by the regional office.

Rural is defined as all areas not delineated as "urbanized" areas by the Census Bureau, in the most recent census. Temporary is defined as a one year period or less and the waiver cannot be renewed.

Survey Procedures §482.23(b)(1)

- Review the nurse staffing schedule for a one-week period. If there are concerns regarding insufficient RN coverage, review the staffing schedules for a second week period to determine if there is a pattern of insufficient coverage. Document daily RN coverage for every unit of the hospital. Verify that there is at least one RN for each unit on each tour of duty, 7 days a week, 24 hours a day. Additional nurses may be required for vacation or absenteeism coverage.

- **Exception:** If the hospital has a temporary waiver of the 24-hour RN requirement in effect, verify and document the following:
  - 50 or fewer inpatient beds;

- The character and seriousness of the deficiencies do not adversely affect the health and safety of patients

- The hospital meets all the other statutory requirements in section 1861(e)(1-8).

- The hospital has made and continues to make a good faith effort to comply with the 24 hour nursing requirement. Determine the recruitment efforts and methods used by the hospitals' administration by requesting copies of advertisements in newspapers and other publications as well as evidence of contact with nursing schools and employment agencies. Document that the salary offered by the hospital is comparable to three other hospitals, located nearest to the facility.

- The hospital's failure to comply fully with the 24 hour nursing requirement is attributable to a temporary shortage of qualified nursing personnel in the area in which the hospital is located.

- A registered nurse is present on the premises to furnish the nursing service during at least the daytime shift, 7 days a week.

- On all tours of duty not covered by a registered nurse, a licensed practical (vocational) nurse is in charge.

A-0203

§482.23(b)(2) The nursing service must have a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licensure.

Interpretive Guidelines §482.23(b)(2)

The hospital's procedure must ensure that all nursing personnel have valid and current licensure that complies with State licensure laws. Furthermore, the Condition of Participation (CoP) Compliance with Federal, State and local laws (42 CFR §482.11) requires the hospital to assure that personnel meet applicable standards (such as continuing education, certification or training) required by State or local law.

Survey Procedures §482.23(b)(2)

- Review hospital personnel records or records kept by the nursing service to determine that RNs, LPNs, and other nursing personnel for whom licensure is required have current valid licenses.

- Review the nursing service licensure verification policies and procedures. Is licensure verified for each individual nursing services staff person for whom licensure is required?

A-0204

§482.23(b)(3) A registered nurse must supervise and evaluate the nursing care for each patient.

Interpretive Guidelines §482.23(b)(3)

A RN must supervise the nursing care for each patient. A RN must evaluate the care for each patient upon admission and when appropriate on an ongoing basis in accordance with accepted standards of nursing practice and hospital policy. Evaluation would include assessing the patient's care needs, patient's health status/conditioning, as well as the patient's response to interventions.

Survey Procedures §482.23(b)(3)

- Review staffing schedules and assignments.
- Determine that a RN is assigned to supervise and evaluate the nursing care furnished to each patient.

A-0205

§482.23(b)(4) The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient.

Interpretive Guidelines §482.23(b)(4)

Nursing care planning starts upon admission. It includes planning the patient's care while in the hospital as well as planning for discharge to meet post-hospital needs. A nursing care plan is based on assessing the patient's nursing care needs (not solely those needs related to the admitting diagnosis) and developing appropriate nursing interventions in response to those needs. The nursing care plan is kept current by ongoing assessments of the patient's needs and the patient's response to interventions, and updating or revising the patient's nursing care plan in response to assessments. The nursing care plan is part of the patient's medical record and must comply with the requirements for patient records and other patient information.

Survey Procedures §482.23(b)(4)

- Select a sample of nursing care plans. Approximately 6-12 plans should be reviewed.
    - Are they initiated as soon as possible after admission for each patient?

- Do they describe patient goals and as appropriate physiological and psychosocial factors and patient discharge planning?
- Is each plan consistent with the attending MD/DO's plan for medical care?
- Are they revised as the needs of the patient changes?
- Are nursing care plans implemented in a timely manner?

A-0206

§482.23(b)(5) A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.

Interpretive Guidelines §482.23(b)(5)

A RN must make all patient care assignments. The director of the nursing service and the hospital are to ensure that nursing personnel with the appropriate education, experience, licensure, competence and specialized qualifications are assigned to provide nursing care for each patient in accordance with the individual needs of each patient.

Survey Procedures §482.23(b)(5)

- Review the nursing assignments. Did an RN make the assignments? Determine that the assignments take into consideration the complexity of patient's care needs and the competence and specialized qualifications of the nursing staff.
- Ask a charge nurse what considerations are necessary when making staff assignments. Answers should include:
  - Patient needs;
  - Complexity of patients;
  - Any special needs of individual patients;
  - Competence of nursing personnel;
  - Qualifications of nursing personnel;
  - Education of nursing personnel;
  - Experience of nursing personnel.

A-0207

§482.23(b)(6) Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel that occur within the responsibility of the nursing services.

Interpretive Guidelines §482.23(b)(6)

The hospital must ensure that there are adequate numbers of clinical nursing personnel to meet its patients nursing care needs. In order to meet their patient's needs the hospital may supplement their hospital employed licensed nurses with volunteer and or contract non-employee licensed nurses.

The hospital and the director of the nursing service are responsible for the clinical activities of all nursing personnel. This would include the clinical activities of all non-employee nursing personnel (contract or volunteer).

Non-employee licensed nurses who are working at the hospital must adhere to the policies and procedures of the hospital. The hospital and the director of the nursing service are responsible for ensuring that non-employee nursing personnel know the hospital's policies and procedures in order to adhere to those policies and procedures.

The hospital and the director of the nursing service ensure that each non-employee nursing care staff person is adequately supervised and that their clinical activities are evaluated. This supervision and evaluation of the clinical activities of each non-employee nursing staff person must be conducted by an appropriately qualified hospital-employed RN.

Survey Procedures §482.23(b)(6)

- Review the method for orienting non-employee licensed nurses to hospital policies and procedures. The orientation should include at least the following:
    - The hospital and the unit;
    - Emergency procedures;
    - Nursing services policies and procedures; and
    - Safety policies and procedures.
- Determine if non-employee nursing personnel are appropriately oriented prior to providing care.

- If the hospital uses non-employee licensed nurses, are they supervised by a RN who is a regular employee of the hospital?
- Observe the care provided by non-employee nursing personnel.
    - Do they know and adhere to hospital policies?
    - Do they know appropriate emergency procedures?
    - Are they adequately supervised by an appropriately experienced hospital employed RN?
    - Are their clinical activities being evaluated adequately?
    - Are they licensed in accordance with State law?
- Confirm with the director of nurses that a non-employee nurse's performance is evaluated by the hospital at least once a year. If the performance evaluation is not considered confidential, review two evaluations.

A-0208

§482.23(c) Standard: Preparation and Administration of Drugs

Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice.

Interpretive Guidelines §482.23(c)

Drugs and biologicals must be prepared and administered in accordance with Federal and State laws.

Drugs and biologicals must be prepared and administered in accordance with the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c).

Drugs and biologicals must be prepared and administered in accordance with accepted standards of practice.

Accepted standards of practice include maintaining compliance with applicable Federal and State laws, regulations (including all the hospital Conditions of Participation (CoP) such as Pharmacy, Medical Records, Patients' Rights, QAPI), and guidelines governing drug and biological use in hospitals, as well as, any standards and recommendations promoted by nationally recognized professional organizations.

Survey Procedures §482.23(c)

- Select patients from the patient sample. Review their medication orders, medication administration records, and appropriate medication documentation in the medical record. Observe the preparation and administration of medications to those patients.

- Are medications prepared and administered in accordance with Federal and State laws, other hospital CoP, accepted national standards of practice, manufacturer's directions, and hospital policy?

A-0209

§482.23(c)(1) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

Survey Procedures §482.23(c)(1)

Verify that there is an effective method for the administration of drugs. Use the following indicators for assessing drug administration:

- Verify that there are policies and procedures approved by the medical staff covering who is authorized to administer medications, and that the policies are followed.

- Review a sample of medication administration records to see that they conform with the practitioner's order, that the order is current, and that drug and dosage are correct and administered as ordered.

- Observe the preparation of drugs and their administration to patients in order to verify that procedures are being followed. Are patients addressed by name and/or identiband checked? Does the nurse remain with the patient until medication is taken? Are drugs administered within 30 minutes of the scheduled time for administration?

- Verify that nursing or other personnel authorized by medical staff policy to administer drugs have completed appropriate training courses or are licensed or authorized to do so by State law and function under supervision as necessary.

- Check the QAPI activities to see if the administration of drugs is regularly monitored. The monitoring should include reports of medication irregularities or errors, their nature, frequency and the corrective action taken.

- Interview supervisory nursing personnel to determine how supervision is provided. Also interview personnel who administer medication to verify that the supervision is, in fact, provided.
    - Are personnel other than nursing personnel administering drugs or biologicals? If yes, determine if those personnel are administering drugs or biologicals in accordance with Federal and State laws and regulations. Use the above procedures to determine compliance.

A-0210

§482.23(c)(2) All orders for drugs and biologicals must be in writing and signed by the practitioner or practitioners responsible for the care of the patient as specified under §482.12(c) with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment for contraindications. When telephone or oral orders must be used, they must be--

Interpretive Guidelines §482.23(c)(2)

All entries in the medical record must be legible, timed, dated and authenticated. All orders for drugs and biologicals, including verbal orders, must be legible, timed, dated and authenticated with a signature by the practitioner or practitioners responsible for the care of the patient.

Verbal orders are orders for medications, treatments, interventions or other patient care that are communicated as oral, spoken communications between senders and receivers face to face or by telephone.

Verbal communication of orders should be limited to urgent situations where immediate written or electronic communication is not feasible.

Hospitals should establish policies and procedures that:

- Describe limitations or prohibitions on use of verbal orders;
- Provide a mechanism to ensure validity/authenticity of the prescriber;
- List the elements required for inclusion in a complete verbal order;
- Describe situations in which verbal orders may be used;
- List and define the individuals who may send and receive verbal orders; and
- Provide guidelines for clear and effective communication of verbal orders.

Hospitals should promote a culture in which it is acceptable, and strongly encouraged, for staff to question prescribers when there are any questions or disagreements about verbal orders. Questions about verbal orders should be resolved prior to the preparation, or dispensing, or administration of the medication.

Elements that should be included in any verbal medication order include:

- Name of patient;
- Age and weight of patient, when appropriate;
- Date and time of the order;
- Drug name;
- Dosage form (e.g., tablets, capsules, inhalants);
- Exact strength or concentration;
- Dose, frequency, and route;
- Quantity and/or duration;
- Purpose or indication;
- Specific instructions for use; and
- Name of prescriber.

The content of verbal orders must be clearly communicated. The entire verbal order should be repeated back to the prescriber. All verbal orders must be reduced immediately to writing and signed by the individual receiving the order. Verbal orders must be documented in the patient's medical record, and be reviewed and countersigned by the prescriber as soon as possible.

We recognize that in some instances, the ordering physician may not be able to authenticate his or her verbal order (e.g., the ordering physician gives a verbal order which is written and transcribed, and then is "off duty" for the weekend or an extended period of time). In such cases, it is acceptable for a covering physician to co-sign the verbal order of the ordering physician. The signature indicates that the covering physician assumes responsibility for his/her colleague's order as being complete, accurate and final. This practice must be addressed in the hospital's policy. However, a qualified practitioner such as a physician assistant or nurse practitioner may not "co-sign" a physician's verbal order or otherwise authenticate a medical record entry for the physician who gave the verbal order.

As noted above, CMS further requires that verbal orders, when used, be used infrequently (§482.23(c)(2)(iii)). Therefore, it is not acceptable to allow covering physicians to authenticate verbal orders for convenience or to make this common practice. When assessing compliance with this requirement, surveyors review the frequency and practice of using verbal orders within the hospital.

Survey Procedures §482.23(c)(2)

- Determine that all drug orders, including verbal orders, are written in the patient charts and signed by the practitioner caring for the patient.
- Read the hospital's policy for practitioner's orders. Does it require that orders must be in writing and signed by the attending practitioner?
- Verify that the prescriber has reviewed and authenticated the orders in accordance with medical staff policy and/or applicable State laws.

A-0211

§482.23(c)(2)(i) Accepted only by personnel that are authorized to do so by the medical staff policies and procedures, consistent with Federal and State law;

Interpretive Guidelines §482.23(c)(2)(i)

A telephone or verbal order must be written in the medical record by a nurse or other professional who is permitted by State law and hospital policy to accept verbal orders. The written verbal order must be legible and include the date, time, order, name of the ordering practitioner and the signature of the accepting individual. The ordering practitioner must date and time the order at the time that he or she signs the order.

Survey Procedures §482.23(c)(2)(i)

- Request to see several patient charts with telephone orders. Check to determine if they are taken by authorized hospital personnel, and are correctly countersigned by the practitioner. Ask several nurses if they are permitted to take telephone and oral orders and how frequently they do so.

A-0212

§482.23(c)(2)(ii) Signed or initialed by the prescribing practitioner as soon as possible; and

Interpretive Guidelines §482.23(c)(2)(ii)

As soon as possible would be the **earlier** of the following:

- The next time the prescribing practitioner provides care to the patient, assesses the patient, or documents information in the patient's medical record,
- The prescribing practitioner signs or initials the verbal order within time frames consistent with Federal and State law or regulation and hospital policy, or
- Within 48 hours of when the order was given.

Survey Procedures §482.23(c)(2)(ii)

Review verbal order entries in the medical record. Have verbal orders been signed or initialed by the prescribing practitioner as soon as possible as defined above?

A-0213

§482.23(c)(2)(iii) Used infrequently.

Interpretive Guidelines §482.23(c)(2)(iii)

Verbal orders, if used, must be used infrequently. This means that the use of verbal orders is not a common practice. Verbal orders pose an increased risk of miscommunication that could result in a patient adverse event (which includes medication errors). Verbal orders should be used only to meet the care needs of the patient when the ordering practitioner is unable to write the order himself/herself. Verbal orders are not to be used for the convenience of the ordering practitioner.

Survey Procedures §482.23(c)(2)(iii)

- Review patient medical records for the use of verbal orders.
    - Are verbal orders used infrequently?
    - Is there a pattern to the use of verbal orders?
    - Are verbal orders used frequently for certain situations?

- Do certain practitioners use verbal orders frequently?

A-0214

§482.23(c)(3) Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures. If blood transfusions and intravenous medications are administered by personnel other than doctors of medicine or osteopathy, the personnel must have special training for this duty.

Survey Procedures §482.23(c)(3)

- Review the transfusions and intravenous medications practices:
  - Does the hospital have special training for administering blood transfusions and intravenous medications?
  - Are blood transfusions and IVs administered in accordance with State law and approved hospital policies and procedures?
  - Are blood transfusions and IVs administered by personnel who are trained and working within their scope of practice in accordance with State law and hospital policies?
  - Review transfusion records. Determine the identity of practitioners who administered the blood. Do they have documented special training.
  - Review a sample of medical records to determine that only doctors of medicine or osteopathy or specially trained personnel perform this duty. If the nursing service trains personnel for IV administration, look at the content of the in-service course. It should include:
    - Fluid and electrolyte balance;
    - Blood components; and
    - Venipuncture techniques, demonstrations and supervised practice.

A-0215

§482.23(c)(4) There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

Survey Procedures §482.23(c)(4)

Request the hospital procedure for reporting adverse drug reactions and errors and transfusion reactions. Review the incident reports or other documentation that the procedure is being implemented and regularly monitored through hospital's QAPI program.

A-0221

§482.24 Condition of Participation: Medical Record Services

The hospital must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital.

Interpretive Guidelines §482.24

The term "hospital" includes all locations of the hospital.

The hospital must have one unified medical record service that has administrative responsibility for all medical records, both inpatient and out patient records. The hospital must create and maintain a medical record for every individual, both inpatient and out patient evaluated or treated in the hospital.

The term "**medical records**" includes at least written documents, computerized electronic information, radiology film and scans, laboratory reports and pathology slides, videos, audio recordings, and other forms of information regarding the condition of a patient.

Survey Procedures §482.24

- Review the organizational structure and policy statements and interview the person responsible for the medical records service to ascertain that the service is structured appropriately to meet the needs of the hospital and the patients.

- Review a sample of active and closed medical records for completeness and accuracy in accordance with Federal and State laws and regulations and hospital policy. The sample should be 10 percent of the average daily census and be no less than 30 records. Additionally, select a sample of outpatient records in order to determine compliance in outpatient departments, services, and locations.

A-0222

§482.24(a) Standard: Organization and Staffing

The organization of the medical record service must be appropriate to the scope and complexity of the services performed. The hospital must employ adequate personnel to ensure prompt completion, filing, and retrieval of records.

Interpretive Guidelines §482.24(a)

The medical records service must be organized, equipped, and staffed in accordance with the scope and complexity of the hospital's services and in such a manner as to comply with the requirements of this regulation and other Federal and State laws and regulations.

There must be an established medical record system that is organized and employs adequate personnel to ensure prompt:

- Completion of medical records;
- Filing of medical records; and
- Retrieval of medical records.

The term "employs adequate personnel" includes:

- That medical record personnel are employees of the hospital;
- That the hospital employs an adequate number of medical record personnel, employs adequate types of medical record personnel, and employs personnel who possess adequate education, skills, qualifications and experience to ensure the hospital complies with requirements of this regulation and other Federal and State laws and regulations.

Survey Procedures §482.24(a)

- Verify that there is an established system that addresses at least the following activities of the medical records services:
    - Timely processing of records;
    - Coding/indexing of records;
    - Retrieval of records;
    - Compiling and retrieval of data of quality assurance activities.

- Verify that the system is reviewed and revised as needed.
- Interview staff, if needed, review written job descriptions and staffing schedules to determine if staff is carrying out all designated responsibilities.
- Verify that the hospital employs adequate medical record personnel as previously described.
- Are medical records promptly completed in accordance with State law and hospital policy?
- Select a sample of past patients of the hospital (inpatient and/or outpatient). Request those patients' medical records. Can the hospital promptly retrieve those records?

A-0223

§482.24(b) Standard: Form and Retention of Record

The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.

Interpretive Guidelines §482.24(b)

The hospital must maintain a medical record for each inpatient and outpatient evaluated or treated in any part or location of the hospital.

All medical records must be **accurately written**. The hospital must ensure that all medical records accurately and completely document all orders, test results, evaluations, care plans, treatments, interventions, care provided and the patient's response to those treatments, interventions and care.

All medical records must be **promptly completed**. Every medical record must be complete with all documentation of orders, diagnosis, evaluations, treatments, test results, care plans, discharge plans, consents, interventions, discharge summary, and care provided along with the patient's response to those treatments, interventions, and care. The record must be completed promptly after discharge in accordance with State law and hospital policy but no later than 30 days after discharge.

The medical record must be **properly filed and retained**. The hospital must have a medical record system that ensures the prompt retrieval of any medical record, of any patient evaluated or treated at any location of the hospital within the past 5 years. [§482.24(b)(1) addresses the 5 year medical record retention requirement]

The medical record must be **accessible**. The hospital must have a medical record system that allows the medical record of any patient, inpatient or outpatient, evaluated and/or treated at any location of the hospital within the past 5 years to be accessible by appropriate staff, 24 hours a day, 7 days a week, whenever that medical record may be needed.

Medical records must be properly stored in secure locations where they are protected from fire, water damage and other threats.

Medical information such as consultations, orders, practitioner notes, x-ray interpretations, lab test results, diagnostic test results, patient assessments and other patient information must be accurately written, promptly completed and properly filed in the patients' medical record, and accessible to the physicians or other care providers when needed for use in making assessments of the patient's condition, decisions on the provision of care to the patient, and in planning the patient's care. This requirement applies to the medical records of current inpatients and outpatients of the hospital.

The hospital must have a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of **all** record entries. The medical record system must correctly identify the author of every medical record entry and must protect the security of all medical record entries. The medial record system must ensure that medical record entries are not lost, stolen, destroyed, altered, or reproduced in an unauthorized manner. Locations where medical records are stored or maintained must ensure the integrity, security and protection of the records. These requirements apply to both manual and electronic medical record systems.

Survey Procedures §482.24(b)

- Determine the location(s) where medical records are maintained.

- Verify that a medical record is maintained for each person treated or receiving care. The hospital may have a separate record for both inpatients and outpatients. However, when two different systems are used they must be appropriately cross referenced and accessible.

- Verify that procedures ensure the integrity of authentication and protect the security of patient records.

- Verify that medical records are stored and maintained in locations where the records are secure, that protects them from damage, flood, fire, etc., and limits access to only authorized individuals.

- Verify that records are accurate, completed promptly, easily retrieved and readily accessible, as needed, in all locations where medical records are maintained.

A-0224

§482.24(b)(1) Medical records must be retained in their original or legally reproduced form for a period of at least 5 years.

Interpretive Guidelines §482.24(b)(1)

Medical records are retained in their original or legally reproduced form in hard copy, microfilm, computer memory, or other electronic storage media. The hospital must be able to promptly retrieve the complete medical record of every individual evaluated or treated in any part or location of the hospital within the last 5 years.

In accordance with Federal and State law and regulations, certain medical records may have retention requirements that exceed 5 years (for example: FDA, OSHA, EPA).

Survey Procedures §482.24(b)(1)

- Determine that records are retained for at least 5 years, or more if required by State or local laws.

- Select a sample of patients, both inpatient and outpatient who were patients of the hospital between the previous 48-60 months. Request their medical record. Is it promptly retrieved? Is it complete? Is it in original or in a legally reproduced form?

A-0225

§482.24(b)(2) The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.

Survey Procedures §482.24(b)(2)

Verify that the hospital uses a coding and indexing system that permits timely retrieval of patient records by diagnosis and procedures.

A-0226

§482.24(b)(3) The hospital must have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals,

Interpretive Guidelines §482.24(b)(3)

The hospital has sufficient safeguards to ensure that access to all information regarding patients is limited to those individuals designated by law, regulation, and policy; or duly authorized as having a need to know. No unauthorized access or dissemination of clinical records is permitted. Clinical records are kept secure and are only viewed when necessary by those persons having a part in the patient's care.

The right to confidentiality means safeguarding the content of information, including patient paper records, video, audio, and/or computer stored information from unauthorized disclosure without the specific informed consent of the individual, parent of a minor child, or legal guardian. Hospital staff and consultants, hired to provide services to the individual, should have access to only that portion of information that is necessary to provide effective responsive services to that individual.

Confidentiality applies to both central records and clinical record information that may be kept at dispersed locations.

Survey Procedures §482.24(b)(3)

- Verify that only authorized persons are permitted access to records maintained by the medical records department.

- Verify that the hospital has a policy to grant patients direct access to his/her medical record if the responsible official (e.g., MD/DO responsible for patient's care) determines that direct access is not likely to have an adverse effect on the patient.

- Verify that medical records and other confidential patient information are released only for patient care evaluation, utilization review, treatment, quality assurance programs, in-house educational purposes, or in accordance with Federal or State law, court orders, or subpoenas.

- Verify that copies of medical records and other confidential patient information are released outside the hospital only upon written authorization of the patient, legal guardian, or person with an appropriate "power of attorney" to act on the patient's behalf, or only if there is a properly executed subpoena or court order, or as mandated by Federal and State law.

- Verify that precautions are taken to prevent unauthorized persons from gaining physical access or electronic access to information in patient records.

A-0227

§482.24(b)(3) continued
and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records.

Interpretive Guidelines §482.24(b)(3)

The hospital's patient record system must ensure the security of patient records. The hospital must ensure that unauthorized individuals cannot gain access to patient records and that individuals cannot alter patient records. Patient records must be secure at all times and in all locations. This includes open patient records for patients who are currently inpatients in the hospital and outpatients in outpatient clinics.

Survey Procedures §482.24(b)(3)

- Observe the hospital's security practices for patient records. Are patient records left unsecured or unattended? Are patient records unsecured or unattended in hallways, patient rooms, nurses stations, or on counters where an unauthorized person could gain access to patient records?

- Verify that there is an established system in place that addresses protecting the confidentiality of medical information.

- If the hospital uses electronic patient records, are appropriate security safeguards in place? Is access to patient records controlled?

- Verify that adequate precautions are taken to prevent physical or electronic altering, damaging or deletion/destruction of patient records or information in patient records.

A-0228

§482.24(b)(3) continued
original medical records must be released by the hospital only in accordance with Federal or State laws, court orders, or subpoenas.

A-0229

§482.24(c) Standard: Content of Record

The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.

Interpretive Guidelines §482.24(c)

The medical record must contain information such as notes, documentation, records, reports, recordings, test results, assessments etc. to:

- Justify admission;

- Justify continued hospitalization;
- Support the diagnosis;
- Describe the patient's progress;
- Describe the patient's response to medications; and
- Describe the patient's response to services such as interventions, care, treatments, etc.

The medical record must contain complete information/documentation regarding evaluations, interventions, care provided, services, care plans, discharge plans, and the patient's response to those activities.

Patient medical record information, such as, laboratory reports, test results, consults, assessments, radiology reports, dictated notes, etc. must be promptly filed in the patient's medical record in order to be available to the physician and other care providers to use in making assessments of the patient's condition, to justify continued hospitalization, to support the diagnosis, to describe the patient's progress, and to describe the patient's response to medications, interventions, and services, in planning the patient's care, and in making decisions on the provision of care to the patient`.

A-0230

§482.24(c)(1) All entries must be legible and complete, and must be authenticated and dated promptly by the person (identified by name and discipline) who is responsible for ordering, providing, or evaluating the service furnished.

Interpretive Guidelines §482.24(c)(1)

Entries in the medical record may be made only by individuals as specified in hospital and medical staff policies. All entries in the medical record must be timed, dated, and authenticated, and a method established to identify the author. The identification may include written signatures, initials, computer key, or other code.

When rubber stamps are authorized, the individual whose signature the stamp represents shall place in the administrative offices of the hospital a signed statement to the effect that he/she is the only one who has the stamp and uses it. There shall be no delegation to another individual.

A list of computer or other codes and written signatures must be readily available and maintained under adequate safeguards. There shall be sanctions for improper or unauthorized use of stamp, computer key, or other code signatures. The hospital must have policies and procedures in place and operational before an electronic medical record system would be deemed acceptable.

The parts of the medical record that are the responsibility of the MD/DO must be authenticated by this individual. When non-MD/DOs have been approved for such duties as taking medical histories or documenting aspects of MD/DO examination, such information shall be appropriately authenticated by the responsible MD/DO. Any entries in the medical record by house staff or non-MD/DOs that require counter signing by supervisory or attending medical staff members shall be defined in the medical staff rules and regulations.

All entries in the medical record must be legible. Orders, progress notes, nursing notes or other entries in the medical record that are not legible, that may be misread or misinterpreted could lead to medical errors or other adverse patient events. The hospital must ensure that entries in the medical record are legible.

All entries in the medical record must be complete.

All entries in the medical record must be authenticated.

Authentication would include at a minimum:

- The hospital has a method to establish the identify of the author of each entry. This would include verification of the author of faxed orders/entries or computer entries.

- The author takes a specific action to verify that the entry is his/her entry or that he/she is responsible for the entry, and that the entry is accurate.

- The timing of the entry is noted and correct. Timing documents the time and date of each entry (orders, reports, notes etc.). Timing establishes when an order was given, when an activity happened or when an activity is to take place. Timing and dating entries is necessary for patient safety and quality of care. Timing and dating of entries establishes a baseline for future actions or assessments and establishes a timeline of events. Many patient interventions or assessments are based on time intervals or time lines of various signs, symptoms, or events.

Failure to disapprove an entry within a specific time period is not acceptable as authentication.

A system of auto-authentication in which a MD/DO or other practitioner authenticates a report before transcription is not consistent with these requirements. There must be a method of determining that the practitioner did, in fact, authenticate the document after it was transcribed.

Survey Procedures §482.24(c)(1)

- Verify that entries are legible and complete and appropriately authenticated, timed and dated by the person who is responsible for ordering, providing, or evaluating the service provided.

- Verify that the department maintains a current list of authenticated signatures, written initials, codes, and stamps when such are used for authorship identification.

- Verify that the hospital's governing body authorizes computer or other code signatures and that a list of these codes is maintained under adequate safeguards by the hospital administration. Verify that the hospital's policies and procedures provide for appropriate sanctions for unauthorized or improper use of the computer codes.

- Examine the hospital's policies and procedures for using the system, and determine if documents are being authenticated after transcription.

A-0231

§482.24(c)(1)(i) The author of each entry must be identified and must authenticate his or her entry.

Interpretive Guidelines §482.24(c)(1)(i)

The hospital must have a system in place that ensures that the identity of the author of each entry is correct. The author of every entry must take a specified action to identify himself/herself as the author (or responsible person) of the entry, the time and dating of the entry, that the entry is accurate, and that he/she takes responsibility for accuracy of the entry.

A-0232

§482.24(c)(1)(ii) Authentication may include signatures, written initials or computer entry.

Interpretive Guidelines §482.24(c)(1)(ii)

For the purposes of this regulation, electronic signatures comply with the signature requirement for medical record entries that include a requirement for a signature.

A-0233

§482.24(c)(2) All records must document the following, as appropriate:

A-0234

§482.24(c)(2)(i) Evidence of a physical examination, including a health history, performed no more than 7 days prior to admission or within 48 hours after admission.

Interpretive Guidelines §482.24(c)(2)(i)

The medical record must contain a history and physical examination (H & P). The H & P must be performed by an MD/DO or oromaxillofacial surgeon, for patients receiving oromaxillofacial surgery, no more than 7 days prior to hospital admission/outpatient surgery or 48 hours after hospital admission but prior to surgery/outpatient surgery.

Admission H & P

A H& P would meet the CMS requirements that a H & P be "performed no more than 7 days prior to admission or within 48 hours after admission," if:

- The H & P was performed within 30 days prior to the hospital admission; AND
- An appropriate assessment performed by the MD/DO, which must include a physical assessment of the patient to update any components of the patient's current medical status that may have changed since the prior H & P or to address any areas where more current data is needed, was completed within 7 days prior to admission or 48 hours after admission, but prior to surgery, confirming that the necessity for the procedure or care is still present and the H & P is still current. The physician uses his/her clinical judgment based on his/her assessment of the patient's condition, and any co-morbidities, in relation to the reason the patient was admitted or to the surgery to be performed, when deciding what depth of assessment needs to be performed and what information needs to be included in the update note; AND
- The physician or other individual qualified to perform the H & P writes an update note addressing the patient's current status and/or any changes in the patient's status, regardless of whether there were any changes in the patient's status, within 7 days prior to, or within 48 hours after admission, but prior to surgery. The update note must be on or attached to the H & P, AND
- The H & P, including all updates and assessments, must be included within 48 hours after admission, but prior to surgery (except in emergency situations), in the patient's medical record for this admission.

If a H & P meets all these requirements within 7 days prior to admission, or within 48 hours after admission, the H & P meets the provisions of the regulation with regard to justifying the admission and meeting the time restrictions on the currency of the H & P.

Outpatient Surgery H & P

Furthermore, a H & P would meet the CMS requirement at §482.51(b)(1) that "There must be a complete history and physical work-up in the chart of every patient prior to surgery…" if:

- The H & P was performed within 30 days prior to the outpatient surgery; AND

- An appropriate assessment performed by the MD/DO, which should include a physical examination of the patient to update any components of the patients current medical status that may have changed since the prior H & P or to address any areas where more current data is needed, was completed within 7 days prior to outpatient surgery confirming that the necessity for the procedure is still present and that the H & P is still current. The physician uses his/her clinical judgment based on his/her assessment of the patient's condition, and any co-morbidities, in relation to the surgery to be performed, when deciding what depth of assessment needs to be performed and what information needs to be included in the update note; AND

- The physician or other individual qualified to perform the H & P writes an update note addressing the patient's current status and/or changes in the patient's status, regardless of whether there were any changes in the patient's status, within 7 days prior to the outpatient surgery. The update note must be on or attached to the H & P; AND

- The H & P, including all updates and assessment, must be included in the patient's medical record, except in emergency situations, prior to surgery.

If a H & P meets all these requirements prior to outpatient surgery, the H & P meets all the provisions of the regulation with regard to meeting the time restrictions on the currency of the H & P.

An H & P performed more than 30 days prior to hospital admission/outpatient surgery does not comply with the currency requirements and a new H & P must be performed.

An H & P performed more than 7 days prior to admission/outpatient surgery that does not meet the above currency criteria does not comply with the requirements and a new H & P must be performed.

All or part of the H & P may be delegated to other practitioners in accordance with State law and hospital policy, but the MD/DO must sign the H & P and as applicable, the update note and assume full responsibility for the H & P. This means that a nurse practitioner or a physician assistant meeting these criteria may perform the H & P, and /or the update assessment and note. (Update assessments and update notes are considered part of the H & P.)

Survey Procedures §482.24(c)(2)(i)

Determine that the medical records contain a physical examination and medical history completed for each patient by an MD or DO or where appropriate, an oromaxillofacial surgeon, no more than 7 days before admission/outpatient surgery or 48 hours after admission but prior to surgery/outpatient surgery. (Or, the medical staff bylaws may allow the currency methodology and/or the delegation as discussed in the above interpretation.)

A-0235

§482.24(c)(2)(ii) Admitting diagnosis.

Interpretive Guidelines §482.24(c)(2)(ii)

All inpatient medical records must contain the admitting diagnosis.

Survey Procedures §482.24(c)(2)(ii)

Verify in a sample of medical records that the patient's admitting diagnosis is documented in each medical record.

A-0236

§482.24(c)(2)(iii) Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.

Interpretive Guidelines §482.24(c)(2)(iii)

All patient records, both inpatient and outpatient, must contain the results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient. This information must be promptly filed in the patient's medical record in order to be available to the physician or other care providers to use in making assessments of the patient's condition, to justify treatment or continued hospitalization, to support or revise the patient's diagnosis, to support or revise the plan of care, to describe the patient's progress and to describe the patient's response to medications, treatments, and services.

Survey Procedures §482.24(c)(2)(iii)

Review a sample of medical records of patients who have orders for consultative evaluations. Are the results/reports and other clinical findings of those consultative evaluations included in the patient's medical record?

A-0237

§482.24(c)(2)(iv) Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia.

Interpretive Guidelines §482.24(c)(2)(iv)

All patient medical records, both inpatient and outpatient, must document:

- Complication;
- Hospital-acquired infections;
- Unfavorable reactions to drugs; and
- Unfavorable reactions to anesthesia.

Survey Procedures §482.24(c)(2)(iv)

Through observations, interviews, and reviews of hospital reports and documentation, determine if patient complications, hospital-acquired infections, unfavorable reactions to drugs/anesthesia have been documented in the applicable patient's medical record.

A-0238

§482.24(c)(2)(v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.

Interpretive Guidelines §482.24(c)(2)(v)

All inpatient and outpatient medical records must contain a properly executed and completed written informed consent form for all procedures and treatments specified by the hospital's medical staff, or State or Federal laws or regulations.

Informed consent means the patient or patient representative is given (in a language or means of communication he/she understands) the information, explanations, consequences, and options needed in order to consent to a procedure or treatment. Informed consent would include that the patient is informed as to who will actually perform surgical interventions that are planned. When practitioners other than the primary surgeon will perform important parts of the surgical procedures, even when under the primary surgeon's supervision, the patient must be informed of who these other practitioners are, as well as, what important tasks each will carry out. We recognize that at the time of the surgery, unforeseen circumstances may require changing which individual practitioners actually are involved in conducting the surgery.

A properly executed informed consent form contains at least the following:

- Name of patient, and when appropriate, patient's legal guardian;
- Name of hospital;

- Name of specific procedure(s);
- Name of practitioner(s) performing the procedure(s) or important aspects of the procedures, as well as the name(s) and specific significant surgical tasks that will be conducted by practitioners other than the primary surgeon/practitioner. (Significant surgical tasks include: harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues.);
- Risks;
- Alternative procedures, treatments or therapies;
- Signature of patient or legal guardian;
- Date and time consent is obtained;
- Statement that procedure was explained to patient or guardian;
- Signature of professional person witnessing the consent;
- Name/signature of person who explained the procedure to the patient or guardian.

Situations where the patient consents to a procedure and information was withheld from the patient, where if the patient had been informed of that information, the patient may not have consented to the procedure or made the same decisions would not be considered **informed consent**.

Survey Procedures §482.24(c)(2)(v)

- Verify that the medical staff have specified which procedures or treatments require a written informed consent.
- Verify that medical records contain consent forms for all procedures or treatments are required by hospital policy.
- Verify that consent forms are properly executed and contain at least the information identified above.

A-0239

§482.24(c)(2)(vi) All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.

Interpretive Guidelines §482.24(c)(2)(vi)

The requirement means that the stated information is necessary to monitor the patient's condition and that this and other necessary information must be in the patient's medical record. In order for necessary information to be used it must be promptly filed in the medical record so that health care staff involved in the patient's care can access/retrieve this information in order to monitor the patient's condition and provide appropriate care.

The medical record must contain:

- All practitioner's orders (properly authenticated);
- All nursing notes (including nursing care plans);
- All reports of treatment (including complications and hospital-acquired infections);
- All medication records (including unfavorable reactions to drugs);
- All radiology reports;
- All laboratory reports;
- All vital signs; and
- All other information necessary to monitor the patient's condition.

Survey Procedures §482.24(c)(2)(vi)

- Verify that the patient records contain appropriate documentation of practitioners' orders, interventions, findings, assessments, records, notes, reports and other information necessary to monitor the patient's condition.
- Is necessary information included in patient records in a prompt manner so that health care staff involved in the care of the patient have access to the information necessary to monitor the patient's condition?

A-0240

§482.24(c)(2)(vii) Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow-up care.

Interpretive Guidelines §482.24(c)(2)(vii)

All patient medical records must contain a discharge summary. A discharge summary discusses the outcome of the hospitalization, the disposition of the patient, and provisions for follow-up care. Follow-up care provisions include any post hospital appointments, how post hospital patient care needs are to be met, and any plans for post-hospital care by providers such as home health, hospice, nursing homes, or assisted living.

The MD/DO or other qualified practitioner with admitting privileges in accordance with State law and hospital policy, who admitted the patient is responsible for the patient during the patient's stay in the hospital. This responsibility would include developing and entering the discharge summary.

Other MD/DOs who work with the patient's MD/DO and who are covering for the patient's MD/DO and who are knowledgeable about the patient's condition, the patient's care during the hospitalization, and the patient's discharge plans may write the discharge summary at the responsible MD/DO's request.

In accordance with hospital policy, and 42 CFR part 482.12(c)(1)(i) the MD/DO may delegate writing the discharge summary to other qualified health care personnel such as nurse practitioners and MD/DO assistants to the extent recognized under State law or a State's regulatory mechanism.

Whether delegated or non-delegated, we would expect the person who writes the discharge summary to authenticate, date, and time their entry and additionally for delegated discharge summaries we would expect the MD/DO responsible for the patient during his/her hospital stay to co-authenticate and date the discharge summary to verify its content.

The discharge summary requirement would include outpatient records. For example:

- The outcome of the treatment, procedures, or surgery;
- The disposition of the case;
- Provisions for follow-up care for an outpatient surgery patient or an emergency department patient who was not admitted or transferred to another hospital.

Survey Procedures §482.24(c)(2)(vii)

- Verify that a discharge summary is included to assure that proper continuity of care is required.
- For patient stays under 48 hours, the final progress notes may serve as the discharge summary and must contain the outcome of hospitalization, the case disposition, and any provisions for follow-up care.
- Verify that a final diagnosis is included in the discharge summary.

A-0241

§482.24(c)(2)(viii) Final diagnosis with completion of medical records within 30 days following discharge.

Interpretive Guidelines §482.24(c)(2)(viii)

All medical records must contain a final diagnosis. All medical records must be complete within 30 days of discharge or outpatient care.

Survey Procedures §482.24(c)(2)(viii)

Select a sample of patients who have been discharged for more than 30 days. Request their medical records. Are those records complete? Does each record have the patient's final diagnosis?

A-0247

§482.25 Condition of Participation: Pharmaceutical Services

The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

Interpretive Guidelines §482.25

Provision of pharmaceutical services must meet the needs of the patients' therapeutic goal by promoting a safe medication use process that ensures optimal selection of medications, dose, dosage form, frequency, route, duration of therapy and that substantially reduces or eliminates adverse drug events and duplication of treatment.

The hospital's pharmacy must be directed by a registered pharmacist. If a drug storage area is used instead of a pharmacy at any location providing pharmacy services, that storage area must be under competent supervision in accordance with State and Federal law.

Pharmaceutical Services would include:

- The procuring, manufacturing, compounding, packaging, dispensing, ordering, distributing, disposition, use, and administering of all medications, biologicals, chemicals and the use of medication related devices.

- Provision of medication-related information to hospital health care professionals and patients necessary to optimize therapeutic outcomes.

- Provision of pharmaceutical care. Pharmaceutical care is defined as the direct, responsible provision of medication-related care for the purpose of achieving definite outcomes that improve a patient's quality of life while minimizing patient risk.

Functions of Pharmaceutical Care are the:

- Collection and organization of patient-specific information;

- Determination of the presence of medication-therapy problems both potential and actual;

- Summary of the patient's medication related health care needs;

- Identification and specification of pharmacotherapeutic goals;

- Development of a pharmacotherapeutic regimen;

- Implementation of a monitoring plan in collaboration with the patient, if applicable, and other health care professionals;

- Monitoring the effects of the pharmacotherapeutic regimen; and

- Redesigning the regimen and monitoring plan as indicated.

Medication errors are a substantial source of morbidity and mortality in the hospitalized setting. Therefore, the development of policies and procedures to minimize medication

errors should be based on accepted professional principles; external alerts and proactive review of facility reported and reviewed adverse drug events. It is important to flag new types of mistakes and continually improve and refine things, based on what went wrong.

The hospital's medical staff must develop policies and procedures to minimize drug errors, but may delegate this function to the hospital's organized pharmaceutical service.

Policies and procedures to minimize drug errors should include:

- High-alert medications - dosing limits, administration guidelines, packaging, labeling and storage;
- Limiting the variety of medication-related devices and equipment. For Example limit the types of general-purpose infusion pumps to one or two;
- Availability of up-to-date medication information;
- Availability of pharmacy expertise. Pharmacist available on-call when pharmacy does not operate 24 hours a day;
- Standardization of prescribing and communication practices to include:
    - Avoidance of dangerous abbreviations;
    - All elements of the order – dose, strength, units (metric), route, frequency, and rate;
    - Alert systems for look-like and sound-alike drug names;
    - Use of facility approved pre-printed order sheets whenever possible.
- That orders to "resume previous orders" are prohibited;
- A voluntary, non-punitive, reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions);
- The preparation, distribution, administration and proper disposal of hazardous medications;
- Drug recalls;
- That patient-specific information is readily accessible to all individuals involved in provision of pharmaceutical care. The patient information must be sufficient to properly order, prepare, dispense, administer and monitor medications as appropriate;
- Identification of when weight-based dosing for pediatric populations is required; and

- Requirements for review and revision based on facility-generated reports of adverse drug events and QAPI activities.

The hospital should have policies and procedures to actively identify potential and actual adverse drug events. Proactive identification could include; direct observation of medication administration, review of patient's clinical records, identification of patient signals that would warrant immediate review of patient's medication therapy and implementation of medication use evaluation studies.

The hospital should have a means to incorporate external alerts and/or recommendations from national associations and governmental agencies for review and facility policy and procedure revision consideration. National associations could include Institute for Safe Medications Practice, National Coordination Council for Medication Error Reporting and Prevention and Joint Commission for Accreditation of Health Care Facilities, Sentinel Event Reports. Governmental agencies may include: Food and Drug Administration, Med Watch Program, and Agency for Health Care Research and Quality.

The hospital's pharmacy services must be integrated into its hospital-wide QAPI program.

Survey Procedures §482.25

- Interview the chief pharmacist or the individual delegated to fulfill the chief pharmacist's functions. Determine that either the medical staff has developed policies and procedures regarding the management of pharmaceuticals or that this function is fulfilled by the pharmacy service.

- Verify that the purpose of pharmaceutical policies and procedures is to minimize drug errors. Review the pharmaceutical policies and procedures, the hospital's formulary and, if there is a pharmacy and therapeutic committee, the minutes of the committee meetings.

- Does a multidisciplinary committee composed of representatives from nursing, pharmacy, administration and medicine develop policies and procedures?

- Are there policies and procedures to minimize drug errors?

- Are policies and procedures reviewed and amended based on:

    - Facility-generated reports of adverse drug events;

    - Facility QAPI activities pertaining to pharmaceutical care;

    - Evaluation of external alerts and/or recommendations from national associations;

  - Evaluation of literature for new technologies or successful practices that have demonstrated enhanced medication safety in other organizations.

- Is the staff familiar with the medication-related policies and procedures?

- Is there a method to periodically review and evaluate the actual implementation of pharmaceutical policies and procedures by staff?

- Upon review of patient clinical record are issues with regard to provision of pharmaceutical services identified? Is the facility aware of the issues? Was there a failure to implement a policy and procedure?

- Are pharmacists an integral component of pharmaceutical care?

- Verify that the hospital's pharmacy services is integrated into its hospital-wide QAPI program.

A-0248

§482.25(a) Standard: Pharmacy Management and Administration

The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

Interpretive Guidelines §482.25(a)

The hospital may utilize a unit dose system, individual prescription, floor stock system or a combination of these systems, properly stored.

Pharmaceutical services must be administered in accordance with accepted professional principles. Accepted professional principles includes compliance with applicable Federal and State laws, regulations, and guidelines governing pharmaceutical services, as well as, standards or recommendations promoted by nationally recognized professional organizations. Agencies and organizations could include FDA, NIH, American Society of Health-System Pharmacists, etc.

A fundamental purpose of pharmaceutical services is to ensure the safe and appropriate use of medications and medication-related devices. The pharmacy director, with input from appropriate hospital staff and committees, develops, implements and periodically reviews and revises policies and procedures governing provision of pharmaceutical services.

Methods a hospital may use to maintain professional principles include:

- Policies and procedures have been developed and are being followed;

- Drugs and biologicals are stored in accordance with manufacturer's directions and State and Federal requirements;
- Employees provide pharmaceutical services within their scope of license and education;
- Pharmacy records have sufficient detail to follow the flow of pharmaceuticals from their entry into the hospital through dispensation/administration;
- Maintaining controls over drugs and medications including the floor stock and those of the pharmacy or drug room;
- Maintaining pharmacy and accounting records pertaining to the requisitioning and dispensing of drugs and pharmaceutical supplies;
- Ensuring that drugs are being dispensed only by a licensed pharmacist;
- Only pharmacists or pharmacy-supervised personnel compound, label and dispense drugs or biologicals.

Survey Procedures §482.25(a)

- Are the policies and procedures consistent with accepted professional principles?
- Determine that professional principles are maintained by verifying that:
    - Policies and procedures have been developed and are being followed;
    - Drugs and biologicals are stored in accordance with manufacturers directions and State and Federal requirements;
    - Records have sufficient detail to follow the flow of control from entry through dispensation; and
    - Employees provide pharmaceutical services within their scope of license and education.
- Does the hospital have a means to incorporate external alerts and/or recommendations from national associations and governmental agencies for review and facility policy and procedure revision consideration?
- Are policies developed to promote consistent application of pharmaceutical services and care throughout the hospital?
- Is the pharmacy director periodically monitoring implementation of policies and procedures?

- Are policies and procedures reviewed and revised as warranted?
- Are services provided in a manner consistent with accepted professional principles?
- Is the pharmacy responsible for the procurement, distribution and control of all medication products used in the hospital (including medication-related devices) for inpatient and outpatient care?

A-0249

§482.25(a)(1) A full-time, part-time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

Interpretive Guidelines §482.25(a)(1)

Direction of pharmaceutical services may not require continuous on-premise supervision at the hospital's single pharmacy or at any pharmacy location but may be accomplished through regularly scheduled visits, and/or telemedicine in accordance with Federal and State law and regulation and accepted professional principles.

A single pharmacist must be responsible for the overall administration of the pharmacy service and must be responsible for developing, supervising, and coordinating all the activities of the hospital wide pharmacy service.

The job description or the written agreement for the responsibilities of the pharmacist should be clearly defined and include development, supervision and coordination of all the activities of pharmacy services.

A professional, competent, legally qualified pharmacist must manage the pharmacy. The Director of pharmacy service must be thoroughly knowledgeable about hospital pharmacy practice and management.

Pharmacists and pharmacy technicians must perform their duties within scope of their license and education.

The Pharmacy Director should be actively involved in those committees responsible for establishing medication-related policies and procedures.

Survey Procedures §482.25(a)(1)

- Determine whether the pharmacist is a full-time, or part-time employee or employed on a consultative basis.

- Review the implementation of the chief pharmacist's responsibilities by:
    - Reviewing written status reports;
    - Reviewing minutes of meetings (if any) with facility staff regarding pharmaceutical services;
    - Reviewing schedules, time logs, etc.;
    - Reviewing the job description or the written agreement to see that the responsibilities of the pharmacist are clearly defined and include development supervision and coordination of all the activities of pharmacy services;
    - Determining whether the Pharmacy Director routinely evaluates the performance and competency of pharmacy personnel? Do performance evaluations include high-risk activities such as the compounding of hazardous medications, pharmacy-based prescriptive activities (e.g. aminoglycoside protocols) and pharmaceutical care for high-risk patients (pediatric, ICU, geriatric etc)?
- Determine whether the pharmacy director is actively involved in those committees responsible for establishing medication-related policies and procedures?

A-0250

§482.25(a)(2) The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.

Interpretive Guidelines §482.25(a)(2)

There must be sufficient personnel to respond to the pharmaceutical needs of the patient population being served.

The pharmaceutical services staff must be sufficient in types, numbers, and training to provide quality services, including 24 hour, 7-day emergency coverage, or there is an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff.

The number of pharmacists and/or the number of hours of services provided by pharmacists at the hospital, or at each location of the hospital that provides pharmaceutical services, must meet and be in accordance with the needs of its patients and accepted professional principles (as previously defined), and reflect the scope and complexity of the hospital's pharmaceutical services.

There must be sufficient numbers and types of personnel to provide accurate and timely medication delivery, ensure accurate and safe medication administration and to provide

appropriate clinical services as well as the participation in continuous quality improvement programs that meet the needs of the patient population being served.

Survey Procedures §482.25(a)(2)

- Determine that the pharmaceutical services staff is sufficient in number and training to provide quality services, including 24 hour, 7-day emergency coverage, or there is an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff.

- Determine if there are sufficient personnel to provide accurate and timely medication delivery, ensure accurate and safe medication administration and to provide appropriate clinical services as well as the participation in continuous quality improvement programs that meet the needs of the patient population being served.

A-0251

§482.25(a)(3) Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.

Interpretive Guidelines §482.25(a)(3)

Components of a record system to maintain current and accurate records of the receipt and disposition of scheduled drugs would include:

- Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs.

- Records of the receipt and disposition of all scheduled drugs must be current and must be accurate.

- Records trace the movement of scheduled drugs throughout the service.

- The pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled.

- The record system, delineated in policies and procedures, tracks movement of all scheduled drugs from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacture. This system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

- All drug records are in order and an account of all scheduled drugs is maintained and any discrepancies in count are reconciled promptly.

- The hospital system is capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion?

- Facility policies and procedures should minimize scheduled drug diversion.

Survey Procedures §482.25(a)(3)

- Determine if there is a record system in place that provides information on controlled substances in a readily retrievable manner.

- Review the records to determine that they trace the movement of scheduled drugs throughout the service.

- Determine if there is a system, delineated in policies and procedures, that tracks movement of all scheduled drugs from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacture. Determine if this system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

- Determine if the pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and periodically reconciled.

- Is the hospital system capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual losses or diversion to the time of detection and determination of the extent of loss or diversion?

- Determine if facility policy and procedures minimize scheduled drug diversion.

A-0252

§482.25(b) Standard: Delivery of Services

In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

Interpretive Guidelines §482.25(b)

Drugs and biologicals must be controlled and distributed in accordance with applicable Federal and State laws and regulations, and in accordance with applicable standards of

practice. Applicable standards of practice include compliance with all Federal and State laws, regulations, and guidelines, as well as, standards and recommendations promoted by nationally recognized professional organizations, that apply to pharmaceutical care and the control and distribution of drugs and biologicals.

The procedures established to prevent unauthorized usage and distribution must provide for an accounting of the receipt and disposition of drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970.

The pharmacist, in consultation with appropriate hospital staff and committees, is to develop and implement guidelines, protocols, policies and procedures for the provision of pharmaceutical services that ensure patient safety through the appropriate control and distribution of medications, medication-related devices and biologicals.

For high risk medications and high-risk patients (pediatric, geriatric or patients with renal or hepatic impairment) there should be systems in place to minimize adverse drug events. Such systems could include but not limited to; checklists, dose limits, pre-printed orders, special packaging, special labeling, double-checks and written guidelines. "**High risk medications**" are those medications involved in a high percentage of medication errors and/or sentinel events and medications that carry a higher risk for abuse, errors, or other adverse outcomes. Lists of high-risk or high-alert drugs are available from such organizations as the Institute for Safe Medication Practices (ISMP) and the United States Pharmcopoeia (USP). Examples of high-risk drugs may include investigational drugs, controlled medications, medications not on the approved FDA list, medications with a narrow therapeutic range, psychotherapeutic medications and look-alike/sound-alike medications and those new to the market or new to the hospital.

All medication orders (except in emergency situations) should be reviewed for appropriateness by a pharmacist before the first dose is dispensed.

Review of medication orders should include:

- Therapeutic appropriateness of a patient's medication regimen;
- Therapeutic duplication in the patient's medication regimen;
- Appropriateness of the drug, dose, frequency, route and method of administration;
- Real or potential medication-medication, medication-food, medication-laboratory test and medication-disease interactions;
- Real or potential allergies or sensitivities;
- Variation from organizational criteria for use
- Other contraindications;

The effects of medication(s) on patients are monitored to assure medication therapy is appropriate and minimizes the occurrence of adverse events. That monitoring process includes:

- Clinical and laboratory data to evaluate the efficacy of medication therapy to anticipate or evaluate toxicity and adverse effects;
- Physical signs and clinical symptoms relevant to the patient's medication therapy;
- Assessing the patient's own perceptions about side effects, and, when appropriate, perceived efficacy.

Sterile products should be prepared and labeled in a suitable environment by appropriately trained and qualified personnel.

The pharmacy should participate in hospital decisions about emergency medication kits. The supply and provision of emergency medications stored in the kits must be consistent with standards of practice and appropriate for a specified age group or disease treatment as well as consistent with applicable Federal and State laws.

The pharmacy should be involved in the evaluation, use and monitoring of drug delivery systems, administration devices and automated drug-dispensing machines? The evaluation and monitoring should include the potential for medication errors.

There must be a process to report serious adverse drug reactions to the FDA in accordance with the MedWatch program?

There is a policy that addresses the use of medications brought into the hospital by patients or their families.

There is a process and policy to ensure that investigational medications are safety controlled and administered. Procedures for the use of investigational medications include the following: A written process for reviewing, approving, supervising and monitoring investigational medications specifying that when pharmacy services are provided, the pharmacy controls the storage, dispensing, labeling, and distribution of the investigational medication.

Medications dispensed by the hospital are retrieved when recalled or discontinued by the manufacturer or the Food and Drug Administration (FDA) for safety reasons.

The hospital pharmacy must ensure that medication orders are accurate and that medications are administered as ordered. The pharmacy should have a system to reconcile medications that are not administered, that remain in the patient's medication drawer, slot, etc., when the pharmacy inventories patient medications or restocks patient medications. The pharmacy should determine the reason the medications were not used. For example, did the patient

refuse the medication, was there a clinical or treatment reason the medication was not used, or was the medication not used due to an error?

Survey Procedures §482.25(b)

- Are there limits on the number of possible concentrations for a medication, particularly high-alert drugs like morphine and heparin?
- Is access to concentrated solutions (e.g. potassium chloride, sodium chloride solutions greater than 0.9%) restricted?
- Are questions regarding the order resolved with the prescriber and a written notation of these discussions documented in the patient's medical record or pharmacy copy of the prescriber's order?
- Identify and assess the quality assurance procedures for the preparation of sterile products.
- Is appropriate monitoring of medication therapy being conducted?
- Is the pharmacy involved in the evaluation, use and monitoring of drug delivery systems, administration devices and automated drug dispensing machines? The evaluation and monitoring should include the potential for medication errors.
- Is there a process to report serious adverse drug reactions to the Federal MedWatch program?
- Review the procedures established to prevent unauthorized usage and distribution. These procedures must provide for an accounting of the receipt and disposition of drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970.
- Are medication storage areas periodically inspected to make sure medications are properly stored?
- Does the hospital retrieve and remove medications available or patient use when the hospital has been informed of a drug recall? Does the recall include notification of patients that have been impacted and those that would order, dispense or administer the medication?

A-0253

§482.25(b)(1) All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.

Interpretive Guidelines §482.25(b)(1)

All compounding, packaging, and dispensing of drugs and biologicals must be conducted by a registered pharmacist or under the supervision of a registered pharmacist and performed consistent with State and Federal laws.

Medications must be prepared safely. Safe preparation procedures could include:

- Only the pharmacy compounds or admixes all sterile medications, intravenous admixtures, or other drugs except in emergencies or when not feasible (for example, when the product's stability is short).

- Whenever medications are prepared, staff uses safety materials and equipment while preparing hazardous medications.

- Wherever medications are prepared, staff uses techniques to assure accuracy in medication preparation.

- Whenever medications are prepared, staff uses appropriate techniques to avoid contamination during medication preparation, which include but are not limited to the following:

    - Using clean or sterile technique as appropriate;

    - Maintaining clean, uncluttered, and functionally separate areas for product preparation to minimize the possibility of contamination;

    - Using a laminar airflow hood or other appropriate environment while preparing any intravenous (IV) admixture in the pharmacy, any sterile product made from non-sterile ingredients, or any sterile product that will not be used with 24 hours; and

    - Visually inspecting the integrity of the medications.

Medications should be dispensed in a manner that is safe and meets the needs of the patient:

- Quantities of medications are dispensed which minimize diversion and potential adverse events while meeting the needs of the patient;

- Medications are dispensed in a timely manner. The hospital must have a system that ensures that medication orders get to the pharmacy and medications get back to patients promptly.

- Whenever possible, medications are dispensed in the most ready to administer form available from the manufacturer or, if feasible, in unit dose that have been repackaged by the pharmacy;

- The hospital consistently uses the same dose packaging system, or, if a different system is used, provides education about the use of the dose packaging system; and

- All concerns, issues or questions are clarified with the individual prescriber before dispensing.

Survey Procedures §482.25(b)(1)

- Determine that only pharmacists or pharmacy supervised personnel compound, label and dispense drugs or biologicals in accordance with State and Federal laws and regulations and as accepted national principles by:

    - Reviewing policies and procedures;

    - Interviewing pharmacy and hospital staff to determine how drugs and biologicals are prepared and dispensed;

    - Observing on site dispensing and compounding operations (if applicable);

    - Reviewing records of drugs and biologicals removed from the pharmacy by non-pharmacy personnel; and

    - Inspecting drug storage areas.

- Verify through interviews of pharmacy and hospital staff, observation of on-site dispensing operations, inspection and review of hospital records that compounding, dispensing and packaging of drugs and biologicals are performed under the supervision of a pharmacist, in accordance with applicable laws and in a manner to promote patient safety.

A-0254

§482.25(b)(2) Drugs and biologicals must be kept in a locked storage area.

Interpretive Guidelines §482.25(b)(2)

All drugs and biologicals must be kept in a locked room or container. If the container is mobile or readily portable, when not in use, it must be stored in a locked room, monitored location, or secured location that will ensure the security of the drugs or biologicals.

All drugs and biologicals must be stored in a manner to prevent access by non-authorized individuals.

Persons without legal access to drugs and biologicals cannot have unmonitored access to drugs or biologicals.

Persons without legal access to drugs or biologicals cannot have keys to medication storage rooms, carts, cabinets, or containers. Whenever persons without legal access to the drugs or biologicals have unmonitored access to or could gain access to the drugs or biologicals stored in an area, the hospital is not in compliance with the requirement to store all drugs and biologicals in a locked storage area.

Nursing Medication Carts, Anesthesia Carts, and Other Medication Carts

When not in use, nursing medication carts, anesthesia carts, and other medication carts (hereafter referred to as "carts") containing drugs or biologicals must be locked or stored in a locked storage room. However, due to the mobility of carts, when not in use, locked carts that contain drugs or biologicals must be stored in a locked room or secure location. If a cart containing drugs or biologicals is in use and unlocked, someone with legal access to the drugs and biologicals in the cart must be close by and directly monitoring the cart. That person could be a nurse, a physician, or other individual who in accordance with State and Federal law and hospital policy has legal access to the drugs and biologicals in the cart. That person must monitor the cart and be aware of other people's activities near the cart. He/she is responsible for the security of the drugs and biologicals in the cart.

Survey Procedures §482.25(b)(2)

- Determine that there is a policy for the safeguarding, transferring and availability of keys to the locked storage area.
- Determine by inspection whether all medications are stored in a manner that prevents unauthorized access.
- Determine if the facility identifies what personnel may have access to medications.

A-0255

§482.25(b)(3) Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.

Interpretive Guidelines §482.25(b)(3)

The hospital must have a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable drugs and biologicals are not available for patient use.

Survey Procedures §482.25(b)(3)

- Spot-check the labels of individual drug containers to verify that they conform to State laws, and/or contain the following minimal information:
    - Each patient's individual drug container bears his/her full name, the prescriber's name, and strength and quantity of the drug dispensed. Appropriate accessory and cautionary statements are included as well as the expiration date.
    - Each floor stock container bears the name and strength of the drug, lot and control number of equivalent, expiration date.
- If the unit dose system is utilized, verify that each single unit dose package bears name and strength of the drug, lot and control number equivalent, and expiration date.
- Inspect patient-specific and floor stock medications to identify expired, mislabeled or unusable medications.

A-0256

§482.25(b)(4) When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law.

Interpretive Guidelines §482.25(b)(4)

Routine after-hours access to the pharmacy by non-pharmacists for access to medication should be minimized and eliminated as much as possible. The use of well-designed night cabinets, after-hours medication carts, and other methods may preclude the need for non-pharmacist to enter the pharmacy. Policies and procedures should be consistent with Federal and State Law.

If an urgent or emergent patient need occurs, the hospital must be able to provide medications to the patients in its facility.

The hospital must have a process for providing medications to meet patient needs when the pharmacy is closed.

When non-pharmacist health care professionals are allowed by law and regulation to obtain medications after the pharmacy is closed, the following safeguards are applied:

- Access is limited to a set of medications that has been approved by the hospital. These medications can be stored in a night cabinet, automated storage and distribution device, or a limited section of the pharmacy.

- Only trained, designated prescribers and nurses are permitted access to medications.
- Quality control procedures (such as an independent second check by another individual or a secondary verification built into the system, such as bar coding) are in place to prevent medication retrieval errors.
- The hospital arranges for a qualified pharmacist to be available either on-call or at another location (for example, at another organization that has 24-hour pharmacy service) to answer questions or provides medications beyond those accessible to non-pharmacy staff.
- This process is evaluated on an on-going basis to determine the medications accessed routinely and the causes of accessing the pharmacy after hours.
- Changes are implemented as appropriate to reduce the amount of times non-pharmacist health care professionals are obtaining medications after the pharmacy is closed.

Survey Procedures §482.25(b)(4)

- Determine through pharmacy records that when the pharmacist is not available, drugs are removed from the pharmacy (drug storage area) only by a designated individual (in accordance with State law if applicable) and only in amounts sufficient for immediate therapeutic needs.
- Review policies and procedures to determine who is designated to remove drugs and biologicals from the pharmacy or storage area and the amount a non-pharmacist may remove in the absence of a pharmacist. The individual(s) designated should be identified by name and qualifications.
- Determine that a system is in place that accurately documents the removal of medications (type and quantity) from either the pharmacy or the after hours supply.
- Determine that the pharmacist reviews all medication removal activity and correlates the removal with current medication orders in the patient medication profile.
- Determine if the pharmacist routinely reviews the contents of the after-hours supply to determine if it is adequate to meet the after-hours needs of the hospital.

A-0257

§482.25(b)(5) Drugs and biologicals not specifically prescribed as to time or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.

Interpretive Guidelines §482.25(b)(5)

In accordance with accepted standards of practice, the medical staff, in coordination and consultation with the pharmacy service, determines and establishes the reasonable time to automatically stop orders for drugs and biologicals not specifically prescribed as to time or number of doses. The hospital must implement, monitor, and enforce this automatic stop system.

Survey Procedures §482.25(b)(5)

Review policies and procedures to determine that there is a protocol established by the medical staff to discontinue and review patients' medical records to determine compliance with stop-order policy.

A-0258

§482.25(b)(6) Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital-wide quality assurance program.

Interpretive Guidelines §482.25(b)(6)

Drug administration errors, adverse drug reactions, and drug incompatibility must be immediately reported to the patient's attending physician, or when appropriate the covering physician. When the covering physician is notified due to the attending physician not being available, the patient's attending physician must be notified as soon as he/she is available. Additionally in accordance with the regulation and 482.21, the hospital must report drug administrative errors, adverse drug reactions and drug incompatibilities to its hospital wide QAPI program.

Reduction of medication errors and adverse reactions can be achieved by effective reporting systems that proactively identify causative factors and are used to implement corrective actions to reduce or prevent reoccurrences. To facilitate reporting, the facility should adopt a medication error and adverse drug reaction (ADR) definition that is broad enough in scope to capture "near misses" and suspected ADRs as well as actual medication errors and ADRs.

An example is the use of the National Coordinating Council Medication Error Reporting and Prevention definition of a medication error.

> "Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature;

compounding; dispensing; distribution; administration; education; monitoring; and use."

When compared to the traditional definition of a medication error (right patient, right drug, right route, right time, right dose) all errors secondary to any aspect of medication utilization (including purchasing, ordering, dispensing, administrative, preparation, compounding, etc.) would be reported versus only those that occurred in the administration phase of medication utilization.

In addition to broad scope definitions, the facility must also proactively identify medication errors and adverse drug reactions. Reliance solely on incident reporting fails to identify the majority of adverse drug events. Proactive identification includes observation of medications passes, concurrent and retrospective review of patient's clinical records, ADR surveillance team, implementation of medication usage evaluations for high-alert drugs and identification of indicator drugs or "patient signals" that, when ordered, or noted automatically generate a drug regimen review for a potential adverse drug event.

The facility must have a method by which to measure the effectiveness of their reporting system so as to identify whether or not their system(s) is identifying as many medication errors and adverse drug reactions that would be expected for the size and scope of services provided by their hospital. Such methods could include use of established benchmarks or studies on reporting rates published in peer-reviewed journals.

To improve incident reporting the facility should adopt a non-punitive system with the focus on the system and not the involved health care professionals.

Survey Procedures §482.25(b)(6)

- Determine that the hospital has an effective procedure that ensures drug administration errors, adverse drug reactions, and drug incompatibilities are immediately reported to the attending physician.

- Review records of medication errors and adverse drug reactions to determine that they are reported immediately in accordance with written procedures, and that medications administered and/or drug reactions are promptly recorded in the patient's medical record.

- Is the facility's definition of an adverse drug reaction and medication error based on established benchmarks or studies on report rates published in peer-review journals? Is it identifying as many medication errors and adverse drug reactions as would be expected for the size and scope of services provided by the hospital?

- If upon review of patient's clinical records, a suspected ADR or medication error is identified, determine if it was reported immediately to the attending or on-call physician, in accordance, with written procedures and that it was promptly recorded in the patient's medical record.

- Review QAPI activities for medication errors and adverse reaction reports to determine if upon analyses of the reports that potential corrective actions are identified and implemented, if appropriate.

- Determine if the number of medication errors and adverse drug reactions reported is consistent with the size and scope of services provided by the hospital.

- Interview facility staff (nursing, pharmacy and medicine) to ascertain awareness of the facility's policy on reporting and documentation of medication errors and adverse drug reactions

---

A-0259

§482.25(b)(7) Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

Survey Procedures §482.25(b)(7)

- Interview the pharmacists, or pharmacy employees to determine their understanding of the controlled drug policies.

- Conduct a spot check of drug use and other inventory records to ensure that drugs are properly accounted for.

- Review reports of pharmaceutical services to determine if there are reported problems with controlled drugs and what actions have been taken to correct the situation.

- Interview the Pharmacy Director, pharmacist and pharmacy employees to determine their understanding of the controlled drug policies. Is there a policy and procedure for handling controlled drug discrepancies?

- Review reports of pharmaceutical services to determine if there are reported problems with controlled drugs and what actions have been taken to correct the situation.

- Determine if controlled drug losses were reported to appropriate authorities in accordance with State and Federal laws.

A-0260

§482.25(b)(8) Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff.

Interpretive Guidelines §482.25(b)(8)

The facility has immediately available sufficient texts and other resources on drug therapy. The pharmacist also should be readily available by telephone or other means to discuss drug therapy, interactions, side effects, dosage etc., with practitioners to assist in drug selection and with nursing personnel to assist in the identification of drug-induced problems.

Survey Procedures §482.25(b)(8)

- Examine the sources of drug information available at the nursing station and/or drug storage area and determine if they are current.

- Determine whether staff development programs on drug therapy are available to facility staff to cover such topics as new drugs added to the formulary, how to resolve drug therapy problems, and other general information as the need arises.

A-0261

§482.25(b)(9) A formulary system must be established by the medical staff to assure quality pharmaceuticals at reasonable costs.

Interpretive Guidelines §482.25(b)(9)

The medical staff must establish a formulary system. The formulary lists medications for dispensing or administration that the hospital maintains or that are readily available. In accordance with accepted standards of practice, the medical staff, in consultation with the pharmacy service, should develop written criteria for determining what medications are available for dispensing or administration. At a minimum, the criteria include the indication for use, effectiveness, risks (including propensity for medication errors, abuse potential, and sentinel events), and costs.

Processes and mechanisms should be established to monitor patient responses to a newly added medication before the medication is made available for dispensing or administration within the hospital.

Medications designated as available for dispensing or administration are reviewed periodically based on emerging safety and efficacy information.

The hospital should have processes to approve and procure medications that are not on the hospital's medication list.

The hospital should have processes to address medication shortages and outages, including the following:

- Communicating with appropriate prescribers and staff;

- Developing approved substitution protocols;
- Educating appropriate LIPs, appropriate health care professionals, and staff about these protocols; and
- Obtaining medications in the event of a disaster.

Survey Procedures §482.25(b)(9)

- Interview the pharmacist to determine that the medical staff has established a formulary that lists drugs that actually are available in the hospital.
- Interview the Pharmacy Director to determine that there is a process for creation and periodic review of a formulary system.
- Determine that the formulary lists drugs that are available.

A-0267

§482.26 Condition of Participation: Radiological Services

The hospital must maintain, or have available, diagnostic radiological services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet the professionally approved standards for safety and personnel qualifications.

Interpretive Guidelines §482.26

The hospital must maintain, or have available, diagnostic radiological services according to the needs of their patients. These services must be maintained or available at all times. All radiological services provided by the hospital, including diagnostic and, if offered, therapeutic, must be provided in accordance with acceptable standards of practice and must meet professionally approved standards for safety and personnel qualifications. The scope and complexity of radiological services offered should be specified in writing and approved by the medical staff and governing body.

Acceptable standards of practice include maintaining compliance with applicable Federal and State laws, regulations and guidelines governing radiological services, including facility licensure and/or certification requirements, as well as any standards and recommendations promoted by nationally recognized professional organizations (e.g., the American Medical Association, American College of Radiology, etc).

Radiological services may be provided by the hospital directly or through a contractual arrangement. The same standards apply whether the service is provided by the hospital directly or under contract. Diagnostic radiology services provided under contract may be

provided either on the hospital premises or in an adjacent or other nearby, readily accessible facility.

The hospital's radiological services, including any contracted services, must be integrated into its hospital-wide QAPI program.

Survey Procedures §482.26

Verify that radiological services are integrated into the hospital-wide QAPI program.

A-0268

§482.26(a) Standard: Radiology Services

The hospital must maintain, or have available, radiology services according to the needs of the patients.

Interpretive Guidelines §482.26(a)

The scope and complexity of radiology services provided must meet the needs of the patients.

Radiological services may be provided by the hospital directly or through a contractual arrangement. The same standards apply whether the service is provided by the hospital directly or under contract. Diagnostic radiology services provided under contract may be provided either on the hospital premises or in an adjacent or other nearby, readily accessible facility.

Survey Procedures §482.26(a)

Verify that the hospital maintains, or has available, organized radiology services that meet the needs of the patients, are provided in accordance with accepted standards of practice, and are maintained or available at all times to meet the patient needs.

A-0269

§482.26(b) Standard: Safety for Patients and Personnel

The radiological services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

Interpretive Guidelines §482.26(b)

The hospital must adopt and implement policies and procedures that provide safety for patients and personnel.

Survey Procedures §482.26(b)

Observe locations where radiological services are provided. Are they safe for patients and personnel? Are any hazards to patients or personnel observed?

A-0270

§482.26(b)(1) Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use and disposal of radioactive materials.

Interpretive Guidelines §482.26(b)(1)

The hospital policies must contain safety standards for at least:

- Adequate shielding for patients, personnel and facilities;
- Labeling of radioactive materials, waste, and hazardous areas;
- Transportation of radioactive materials between locations within the hospital;
- Security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials;
- Testing of equipment for radiation hazards;
- Maintenance of personal radiation monitoring devices;
- Proper storage of radiation monitoring badges when not in use;
- Storage of radio nuclides and radio pharmaceuticals as well as radioactive waste; and
- Disposal of radio nuclides, unused radio pharmaceuticals, and radioactive waste.
- Methods of identifying pregnant patients.

The hospital must implement and ensure compliance with its established safety standards.

Survey Procedures §482.26(b)(1)

- Verify that patient shielding (aprons, etc) are properly maintained and routinely inspected by the hospital.
- Verify that hazardous materials are stored properly in a safe manner.

- Observe areas where testing is done for violations in safety precautions.

A-0271

§482.26(b)(2) Periodic inspection of equipment must be made and hazards identified must be properly corrected.

Interpretive Guidelines §482.26(b)(2)

The hospital must have policies and procedures in place to ensure that periodic inspections of radiology equipment are conducted, current and that problems identified are corrected in a timely manner. The hospital must ensure that equipment is inspected in accordance with manufacturer's instructions, Federal and State laws, regulations, and guidelines, and hospital policy. The hospital must have a system in place, qualified employees or contracts, to correct hazards. The hospital must be able to demonstrate current inspection and proper correction of all hazards.

Survey Procedures §482.26(b)(2)

- Review the inspection records (logs) to verify that periodic inspections are conducted in accordance with manufacturer's instructions, Federal and State laws, regulations, and guidelines and hospital policy.

- Determine that any problems identified are properly corrected in a timely manner.

A-0272

§482.26(b)(3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

Interpretive Guidelines §482.26(b)(3)

The requirement that "radiation workers must be checked periodically, by use of exposure meters or badge tests, for amount of radiation exposure" would include radiological services personnel, as well as, other hospital employees who may be regularly exposed to radiation due to working near radiation sources. This could include personnel such as certain nursing and maintenance staff.

Survey Procedures §482.26(b)(3)

- Verify that the hospital requires periodic checks on all radiology personnel and any other hospital staff exposed to radiation and that the personnel are knowledgeable about radiation exposure for month, year, and cumulative/entire working life.

- Observe that appropriate staff have a radiation-detecting device and that they appropriately wear their radiation detecting device.

- Review records to verify that periodic tests of radiology personnel by exposure meters or test badges are performed.

A-0273

§482.26(b)(4) Radiology services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.

Survey Procedures §482.26(b)(4)

Review medical records to determine that radiological services are provided only on the orders of practitioners with clinical privileges and to practitioners outside the hospital who have been authorized by the medical staff and the governing body to order radiological services, consistent with State law.

A-0274

§482.26(c) Standard: Personnel

A-0275

§482.26(c)(1) A qualified full-time, part-time or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiological tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

Interpretive Guidelines §482.26(c)(1)

The medical staff must establish, in accordance with this regulation and other Federal and State laws, regulations and guidelines, the qualifications necessary for radiologist appointment to the medical staff.

There must be written policies developed and approved by the medical staff to designate which radiological tests require interpretation by a radiologist.

When telemedicine is used, and the radiologist who interprets radiological tests and the patient are located in different states, the radiologist interpreting the radiological test must be licensed and/or meet the other applicable standards that are required by State or local laws in both the state where the practitioner is located and the state where the patient is located.

Supervision of the radiology services may only be performed by a radiologist who is a member of the medical staff. Supervision should include at least the following:

- Ensuring that radiology reports are signed by the practitioner who interpreted them;
- Assigning duties to radiology personnel appropriate to their level of training, experience, and licensure if applicable;
- Enforcing infection control standards;
- Ensuring that emergency care is provided to patients who experience an adverse reaction to diagnostic agents in the radiology service;
- Ensuring that files, scans, and other image records are kept in a secure area and are readily retrievable; and
- Training radiology staff on how to operate the equipment safely, perform tests offered by the facility and on the management of emergency radiation hazards and accidents.

Survey Procedures §482.26(c)(1)

- Review the radiologist's credentialing file to verify that he/she meets the qualifications established by the medical staff for appointment.
- Review records to determine that a radiologist interprets those tests that have been designated by the medical staff to require interpretation by a qualified radiologist.
- Verify that supervision of the radiology services is restricted to a radiologist who is a member of the medical staff.

A-0276

§482.26(c)(2) Only personnel designated as qualified by the medical staff may use the radiological equipment and administer procedures.

Interpretive Guidelines §482.26(c)(2)

There should be written policies, developed and approved by the medical staff, consistent with State law, to designate which personnel are qualified to use the radiological equipment and administer procedures.

Survey Procedures §482.26(c)(2)

Determine which staff are using differing pieces of radiological equipment and/or administering patient procedures. Review their personnel folders to determine they meet the qualifications established by the medical staff for the tasks they perform.

A-0277

§482.26(d) Standard: Records

Records of radiology services must be maintained.

Interpretive Guidelines §482.26(d)

The hospital must maintain records for all radiology procedures performed. At a minimum, the records should include copies of reports and printouts, and any films, scans or other image records, as appropriate. The hospital should have written policies and procedures that ensure the integrity of authentication and protect the privacy of radiology records. Patient radiology records are considered patient medical records and the hospital must comply with the medical records CoP (§482.24). The medical records CoP requires that medical records, which would include radiology films, image records, scans, reports, and printouts must be secure, properly stored, be accessible and promptly retrievable for any care, procedure, treatment, or test provided or conducted within the past 5 years.

Survey Procedures §482.26(d)

Determine the hospital's procedures for maintaining radiology records.

A-0278

§482.26(d)(1) The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.

Survey Procedures §482.26(d)(1)

Review radiological records to determine that reports are signed by the practitioner who reads and evaluates the roentgenogram.

A-0279

§482.26(d)(2) The hospital must maintain the following for at least 5 years:

Copies of reports and printouts
Films, scans, and other image records, as appropriate.

Interpretive Guidelines §482.26(d)(2)

Patient radiology records are a type of patient medical record. The hospital must maintain radiology records in compliance with the medical records CoP and this CoP. Medical records, including radiology records, must be maintained for 5 years.

Survey Procedures §482.26(d)(2)

- Verify that the hospital maintains records for at least 5 years.
- Verify that radiology records are maintained in the manner required by the Medical Records CoP.

A-0284

§482.27 Condition of Participation: Laboratory Services

(a) The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with Part 493 of this chapter.

Interpretive Guidelines §482.27(a)

The hospital must maintain or have available laboratory services whenever its patients need those services. The hospital may maintain laboratory services at the hospital, or for other than emergency lab services, may make laboratory services available through contractual agreements. The scope and complexity of the hospital laboratory service must be adequate to meet the needs of its patients. All laboratory services, whether direct or contractual, whether conducted in a lab or in another location, must be provided in accordance with Clinical Laboratory Improvement Act (CLIA) requirements. Every hospital laboratory service must be operating under a current CLIA certificate appropriate to the level of services performed.

The hospital's laboratory services, including any contracted services, must be integrated into its hospital-wide QAPI program.

Patient laboratory results and all other laboratory clinical patient records are considered patient medical records and the hospital must comply with the requirements of the Medical Records CoP.

Survey Procedures §482.27(a)

- Determine the total number of laboratories, the location of each laboratory, and every location where laboratory procedures are performed.
- Verify that the laboratory service and all laboratory locations are integrated into the hospital-wide QAPI program.
- If laboratory services are contracted, verify that the review of the quality of those services is integrated into the hospital-wide QAPI program.

A-0285

§482.27(b) Standard: Adequacy of Laboratory Services

The hospital must have laboratory services available, either directly or through a contractual agreement with a certified laboratory that meets requirements of Part 493 of this chapter.

Interpretive Guidelines §482.27(b)

The CLIA certification may be accomplished by having one certificate for the entire hospital's laboratory services, by having one certificate for each laboratory, or by the hospital having a mixture. Whatever the arrangement, all laboratory services must be provided in accordance with CLIA requirements and under a current CLIA certificate, even when those laboratory services take place outside of a lab.

Survey Procedures §482.27(b)

- Determine which services are provided directly by the facility and which are provided through contractual agreements.
- Determine if the referral laboratory is CLIA certified for the appropriate test specialty.
- If the hospital provides laboratory services in multiple locations, verify that all laboratory services are operating under a current CLIA certificate.
- Examine records and determine if the services, including emergency services, are provided in accordance with the hospital's policies.

A-0286

§482.27(b)(1) Emergency laboratory services must be available 24 hours a day.

Interpretive Guidelines §482.27(b)(1)

The hospital must provide emergency laboratory services 24 hours a day, 7 days a week. The medical staff must determine which laboratory services are to be immediately available to meet the emergency laboratory needs of patients who may be currently at the hospital or those patients who may arrive at the hospital in an emergency condition. The emergency laboratory services (procedures, tests, personnel) available should reflect the scope and complexity of the hospital's operation and be provided in accordance with Federal and State law, regulations and guidelines and acceptable standards of practice.

Survey Procedures §482.27(b)(1)

Review the written description of the emergency laboratory services. Review records (including accession records, worksheets, and test reports) to verify the 24- hour availability of emergency services and that those services are provided when required.

A-0287

§482.27(b)(2) A written description of services provided must be available to the medical staff.

Survey Procedures §482.27(b)(2)

Verify the existence of a written description of the laboratory services provided, including those furnished on routine and stat basis (either directly or under an arrangement with an outside facility). Verify that the description of services is accurate and current.

A-0288

§482.27(b)(3) The laboratory must make provision for proper receipt and reporting of tissue specimens.

Interpretive Guidelines §482.27(b)(3)

The laboratory must have written instructions for the collection, preservation, transportation, receipt, and reporting of tissue specimen results.

Survey Procedures §482.27(b)(3)

Review tissue records (accession records, worksheets, and test reports) to determine whether the laboratory follows the written protocol.

A-0289

§482.27(b)(4) The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.

Interpretive Guidelines §482.27(b)(4)

Laboratory written policies, approved by the medical staff and a pathologist, must state which tissue specimens require a macroscopic examination and which tissue specimens require both macroscopic and microscopic examination.

Survey Procedures §482.27(b)(4)

- Verify that the hospital has a written policy for examination requirements.
- Review the written policies and tissue reports to assure that tissue specimens are examined in accordance with the written policies.
- Verify that the policies are in accordance with these requirements and other Federal and State laws, regulations, and guidelines.

A-0290

§482.27(c) Standard: Potentially Infectious Blood and Blood Products

(1) Potentially HIV infectious blood and blood products are prior collections from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to the human immunodeficiency virus (HIV) on a later donation, and the FDA-licensed, more specific test or other follow up testing recommended or required by FDA is positive and the timing of seroconversion cannot be precisely estimated.

(2) Services furnished by an outside blood bank. If a hospital regularly uses the services of an outside blood bank, it must have an agreement with the blood bank that governs the procurement, transfer, and availability of blood and blood products. The agreement must require that the blood bank promptly notify the hospital of the following:

(i) If it supplied blood and blood products collected from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to HIV on a later donation; and

(ii) The results of the FDA-licensed, more specific test or other follow up testing recommended or required by FDA completed within 30 calendar days after the donor's repeatedly reactive screening test. (FDA regulations concerning HIV testing and look back procedures are set forth at 21 CFR §610.45-et seq.)

(3) Quarantine of blood and blood products pending completion of testing. If the blood bank notifies the hospital of the repeatedly reactive HIV screening test results as required by paragraph (c)(2)(i) of this section, the hospital must determine the disposition of the blood or blood product and quarantine all blood and blood products from previous donations in inventory.

(i) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other follow up testing recommended or required by FDA is negative, absent other informative test results, the hospital may release the blood and blood products from quarantine.

(ii) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other follow up testing recommended or required by FDA is positive, the hospital must dispose of the blood and blood products in accordance with 21 CFR §606.40 and notify all patients in accordance with paragraph (c)(4) of this section.

(4) Patient notification. If the hospital has administered potentially HIV infectious blood or blood products (either directly through its own blood bank or under an agreement described in paragraph (c)(2) of this section) or released such blood or blood products to another entity or appropriate individual, the hospital must take the following actions:

(i) Promptly make at least three attempts to notify the patient's attending physician (that is, the physician of record) or the physician who ordered the blood or blood product that potentially HIV infectious blood or blood products were transfused to the patient.

(ii) Ask the physician to immediately notify the patient, or other individual as permitted under paragraph (c)(8) of this section, of the need for HIV testing and counseling.

(iii) If the physician is unavailable, declines to make the notification, or later informs the hospital that he or she was unable to notify the patient, promptly make at least three attempts to notify the patient, or other individual as permitted under paragraph (c)(8) of this section, of the need for HIV testing and counseling

(iv) Document in the patient's medical record the notification or attempts to give the required notification.

(5) Timeframe for notification. The notification effort begins when the blood bank notifies the hospital that it received potentially HIV infectious blood and blood products and continues for 8 weeks unless--

(i) The patient is located and notified; or

(ii) The hospital is unable to locate the patient and documents in the patient's medical record the extenuating circumstances beyond the hospital's control that caused the notification timeframe to exceed 8 weeks.

(6) Content of notification. The notification given under paragraphs (c)(4) (ii) and (iii) of this section must include the following information:

(i) A basic explanation of the need for HIV testing and counseling.

(ii) Enough oral or written information so that the transfused patient can make an informed decision about whether to obtain HIV testing and counseling.

(iii) A list of programs or places where the patient can obtain HIV testing and counseling, including any requirements or restriction the program may impose.

(7) Policies and procedures. The hospital must establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for confidentiality and medical records.

(8) Notification to legal representative or relative. If the patient has been adjudged incompetent by a State court, the physician or hospital must notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or hospital must notify the patient or his or her legal representative or relative. If the patient is deceased, the physician or hospital must continue the notification process and inform the deceased patient's legal representative or relative.

Interpretive Guidelines §482.27(c)

This regulation requires the hospital to have a system in place to take appropriate action when notified that blood or blood products it received are at increased risk of transmitting HIV.

The "**window period**" is defined as that period early in infection when the antibody to HIV is not detectable by the screening test. (Currently, the average infectious window period, when a person may be infected with HIV, but the HIV antibody is not detectable by current screening test methods, is approximately 22 to 25 days.)

The term "**repeatedly reactive**" means that the initial HIV antibody screening test is reactive, re-tested in duplicate, and one or both of the duplicate tests are reactive. If repeatedly reactive, a licensed, more specific (confirmatory) test, e.g., Western Blot, is used to confirm the presence of HIV.

"**Look back**" is considered to include: the quarantine of products from a window period donor; notification of consignees (facilities having received such window period products) to quarantine those products; and on completion of the licensed, more specific (confirmatory) test, notification of any transfusion recipient.

Despite the best practices of blood banks, a person may have donated blood during the window period. If the donor attempts to donate blood at a later date, the screening test for the antibody to HIV may, at that time, be repeatedly reactive. Under such circumstances, previously collected blood and blood products would be at increased risk for transmitting HIV and a recipient of blood or blood products collected during the window period would not know whether the donor was infected with HIV at the time of the previous donations.

CMS regulations apply only to transfusion services in hospitals that participate in Medicare, where the transfusion service does not include more than the performance of compatibility testing, i.e., the hospital receives blood and blood products from an outside source and only performs compatibility (cross match) testing in preparation for transfusion to patients. Most hospitals that do not draw donors or process donor blood would fall under CMS' regulations.

FDA's regulations apply to facilities collecting, processing, and storing (manufacturing) blood and blood products, e.g., collecting donor blood, washing, or freezing red blood cells, and irradiating blood components. FDA's regulations also apply to facilities that do not participate in Medicare, such as Indian Health Services and Veteran's Administration hospitals. An independent laboratory performing compatibility testing and issuing blood and blood products directly to a non-hospital entity, i.e., home health agency, nursing facility, or ambulatory surgery center, would come under the jurisdiction of the FDA's rule as well, since it is considered a transfusion service that is not subject to the conditions of Medicare participation for hospitals.

FDA's companion regulation to these requirements (21 CFR §§610.45), also published 9/9/96, requires that, within 72 hours, blood banks notify the hospital (the consignee) for which it supplied whole blood, blood components, source plasma, or source leukocytes that are at increased risk for transmitting HIV infection and follow up this notification within 30 days of the results of the more specific (confirmatory) test for HIV.

A blood bank that is part of a hospital and collects, processes, and stores (manufactures) blood products for that hospital is not required to have an agreement with the hospital administration. It would be required to meet the aforementioned FDA regulations and requirements as well as those of other regulatory and accrediting bodies.

Details of agreements or practice policies are worked out between the hospital and blood bank and are consistent with applicable Federal, State, and local laws, but can be written

flexibly so that any changes in FDA or CMS requirements can be incorporated into operating procedures rather than by constructing a new agreement.

Under certain circumstances, such as during blood emergencies. hospitals may receive blood from a source other than the contracted blood bank. FDA regulations require a blood bank to notify the hospital in the event it furnished the hospital with potentially HIV-infected blood.

No release of quarantined blood or blood products is permitted before the results of further testing are available. If a blood bank fails to notify the hospital of the more specific (confirmatory) test results within the 30-day limit, immediate destruction of quarantined units is not required because further testing and notification was not completed within the 30 days. The blood shall not be released until the subsequent, more specific (confirmatory) test result, when reported, is negative.

The hospital's policy should reflect that release (from quarantine) of potentially HIV-infected blood is possible only if the more specific (confirmatory) test is negative, and the blood bank's (the facility that notified the hospital) records show the donor has no other informative test results that show evidence of HIV infection. "Other" informative tests are tests that a blood bank may voluntarily perform, i.e., HIV antigen tests, viral cultures, etc. If these tests are positive, the blood and blood products are disposed of if still available. The blood bank will communicate this information to the hospital. If no other informative test results exist, the hospital may release the blood and blood products from quarantine. If other informative test results exist that indicate possible HIV infection, the hospital must dispose of the blood and blood products.

The reference to 21 CFR §606.40 refers to the requirements for facilities, such as hospitals, that perform blood compatibility testing. Specifically "the facility must provide for the safe and sanitary disposal of blood and blood components not suitable for use or distribution." (21 CFR §606.40(d)(2)).

The hospital retains flexibility to develop its own policies and procedures in order to meet notification requirements. The physician of record is the first choice to notify the patient that he or she received potentially HIV-infectious blood. If the physician declines, then the notification responsibility falls to the hospital. The hospital may designate an appropriate, competent hospital representative to inform the patient. This may be another physician, such as the medical director of the transfusion service, an infection control officer, a nurse, a clinical laboratory scientist, a social worker, or a non-physician with medical expertise.

This requirement also applies when the hospital transfusion service furnishes blood or blood products to another facility, such as an ambulatory surgery center, clinic, nursing facility, or home setting (via a home health agency). The hospital retains responsibility for patient notification.

If the physician who orders the transfusion is not the same as the physician of record, e.g., the physician identified on the admitting form, the hospital may ask either physician to

perform the notification. It is recommended that the hospital make 3 attempts within one week to notify the physician.

If the hospital is unable to locate the physician, or the physician does not agree to notify the patient, the hospital should promptly make efforts to locate the patient. In this way, it is reasonable to expect the hospital to locate and notify the patient in the remaining 7 weeks. If after 3 attempts, the hospital is not able to locate the patient within the 8-week notification period, it is not expected to continue its search. However, there is no limit on how much time a hospital may choose to expend on this effort.

Documentation related to notification, e.g., contacting physician, telephone log, return receipt from a certified or registered letter, becomes part of the patient's medical record. Policies and procedures for the notification process must conform to all Federal, State, and local laws regarding confidentiality. There are no Federal penalties imposed on physicians who decline to notify the patient.

When the physician accepts the responsibility for notification, the hospital is not required to follow up with the physician to determine whether notification occurred. It is expected that the physician would inform the hospital if notification did not occur, but this is part of professional relationships and not a requirement.

If the physician accepts responsibility for notification, and later informs the hospital that the patient was not notified, or the hospital otherwise learns that no follow up occurred, it must attempt notification, regardless of the time that elapsed after the hospital first notified the physician. Once a hospital is notified of a potentially HIV-infectious product, there is never a time that patient notification need not be attempted. It is only when, after the hospital has made a good faith effort of at least 3 attempts but is not able to locate the patient within 8 weeks, that the notification process may come to an end.

This regulation does not require the hospital to provide HIV testing or counseling, but merely to refer the patient for testing and counseling. Referral for testing and counseling will be made to a physician or organization that provides high quality HIV testing and has extensive experience in providing HIV counseling. In addition, the patient should be told about any requirements or restrictions the programs may impose, such as, whether the program requires a fee, a physician request form, identification or public assistance cards, or a residency requirement. The CDC National AIDS Hotline operates a toll-free number (1-800-342-2437) 24 hours a day that the hospital or physician can give to the patient for more assistance.

A hospital that delegates notification must ensure that the notification, which includes referral for counseling, is performed in accordance with these requirements.

Hospital requirements for confidentiality in record keeping exist at §482.24. Documents related to notification become part of the patient's medical record and are subject to the normal safeguards for access, information release, patient consent, and other precautions for confidential information. Hospitals must retain notification records for 5 years.

Hospitals should contact their State concerning special statutes regarding HIV status, testing, and confidentiality. Messages should not be left on telephone answering machines about the need for HIV testing. Any written correspondence would also need to be conducted with confidentiality in mind.

If the patient in question is competent, but the physician believes the information should not be given to the patient, and State law permits a legal representative or relative to receive information on the patient's behalf, then the physician must notify the patient's representative or relative. Upon learning of the death of the transfused patient, the hospital must pursue the notification process to inform the patient's family. It would not be appropriate for a physician or hospital to determine that neither the patient nor someone acting on his or her behalf need be informed.

Survey Procedures §482.27(c)

- In a hospital, investigation of an incident related to look back or the lack of look back policy will most likely occur in response to an allegation of a hospital patient receiving HIV-infected blood or blood products. However, on a routine certification or validation survey, without a specific case to investigate, the surveyor should inquire about how the hospital plans to meet the requirements of §482.27(c**).** If a specific case is identified, determine if the hospital has developed and effectively implemented its look back plan.

- Review the written agreement for notification expectations and approval by an appropriate hospital representative.

- If the hospital receives notification from the blood bank of receipt of potentially HIV-infected blood, review how and where the follow up confirmatory test results are documented. How does the hospital handle the situation where confirmatory test results are not received from the blood bank within 30 days?

- What is the hospital's policy for quarantining potentially HIV-infected blood and blood products?

- Does it include documentation of the quarantine, follow up testing (required of the blood bank to be communicated to the hospital within 30 days), and disposal of infected blood products, if warranted?

- If the hospital was notified that it had received potentially infectious blood and blood products, what did it do?

- Was the potentially HIV-infectious blood quarantined according to policy? If not, why not?

- Was the potentially HIV-infectious blood disposed of when confirmatory testing showed evidence of HIV infection? How was it disposed?

- How does hospital policy address notification of potentially HIV-infectious blood or blood products?
- Ask the hospital representative to explain what the hospital did (or would do) in the event it received such notification.
- Has the hospital ever been notified that it received potentially HIV-infectious blood or blood products? If so, was follow up according to the hospital's policy? Were there any negative outcomes attributed to a breakdown in the notification process?
- How does the hospital ensure that the notification process is carried out within the 8-week timeframe specified in this requirement?
- If the hospital had a look back incident, is there documentation of notification efforts in the patient's medical record, including any extenuating circumstances that prevented patient notification within the 8-week timeframe?
- If the three attempts at notification extended beyond the 8-week timeframe, what would the hospital do differently should notification be necessary in a future incident?
- What system does the hospital have in place to assist the patient in seeking testing and counseling?
- What role does the patient's physician play in explaining the need for testing and counseling?
- What information does the hospital make available to the patient transfused with potentially HIV-infectious blood or blood products?
- Review the hospital's notification procedures. Was notification performed in such a manner as to ensure that names of patients requiring notification and records relating to the notification were kept confidential?
- Under what circumstances does the hospital determine it necessary to notify someone other than the patient who received potentially HIV infectious blood or blood products?

A-0295

§482.28 Condition of Participation: Food and Dietetic Services

The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel. However, a hospital that has a contract with an outside food management company may be found to meet this Condition of Participation if the

company has a dietician who serves the hospital on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.

Interpretative Guidelines §482.28

The hospital's food and dietetic services must be organized, directed and staffed in such a manner to ensure that the nutritional needs of the patients are met in accordance with practitioners' orders and acceptable standards of practice.

The hospital should have written policies and procedures that address at least the following:

- Availability of a diet manual and therapeutic diet menus to meet patients' nutritional needs;
- Frequency of meals served;
- System for diet ordering and patient trays delivery;
- Accommodation of non-routine occurrences (e.g., parenteral nutrition (tube feeding), total parenteral nutrition, peripheral parenteral nutrition, change in diet orders, early/late trays, nutritional supplements, etc);
- Integration of the food and dietetic service into the hospital-wide QAPI and Infection Control programs;
- Guidelines for acceptable hygiene practices of food service personnel; and
- Guidelines for kitchen sanitation.

The same standards apply whether the food and dietetic services are provided by the hospital directly, through a contractual agreement, or by off-site vendor.

The hospital must be in compliance with Federal and State licensure requirements for food and dietary personnel as well as food service standards, laws and regulations.

A-0296

§482.28(a) Standard: Organization

A-0297

§482.28(a)(1) The hospital must have a full-time employee who–

(i) Serves as director of the food and dietetic services;

(ii) Is responsible for daily management of the dietary services; and

(iii) Is qualified by experience or training

Interpretive Guidelines §482.28(a)(1)

The service director must be a full-time employee who has been granted the authority and delegated responsibility by the hospital's governing body and medical staff for the operation of the dietary services. This authority and delegated responsibility includes, the daily management of the service, implementing training programs for dietary staff, and assuring that established policies and procedures are maintained that address at least the following:

- Safety practices for food handling;
- Emergency food supplies;
- Orientation, work assignments, supervision of work and personnel performance;
- Menu planning, purchasing of foods and supplies, and retention of essential records (e.g., cost, menus, personnel, training records, QAPI reports, etc);
- Service QAPI program.

Additionally, the service director must demonstrate, through education, experience and/or specialized training, the qualifications necessary to manage the service, appropriate to the scope and complexity of the food service operations.

Survey Procedures §482.28(a)(1)

- Verify that the director of the food and dietetic services is a full-time employee.
- Review the service director's job description to verify that it is position-specific and that responsibility and authority for the direction of the food and dietary service has been clearly delineated.

- Review the service director's personnel file to verify that he/she has the necessary education, experience, and training to manage the service, appropriate to the scope and complexity of food service operations.

A-0298

§482.28(a)(2) There must be a qualified dietitian, full-time, part-time or on a consultant basis.

Interpretive Guidelines §482.28(a)(2)

A qualified dietitian must supervise the nutritional aspects of patient care. Responsibilities of a hospital dietitian may include, but are not limited to:

- Approving patient menus and nutritional supplements;
- Patient, family, and caretaker dietary counseling;
- Performing and documenting nutritional assessments and evaluating patient tolerance to therapeutic diets when appropriate;
- Collaborating with other hospital services (e.g., medical staff, nursing services, pharmacy service, social work service, etc) to plan and implement patient care as necessary in meeting the nutritional needs of the patients;
- Maintaining pertinent patient data necessary to recommend, prescribe, or modify therapeutic diets as needed to meet the nutritional needs of the patients.

Qualification is determined on the basis of education, experience, specialized training, State licensure or registration when applicable, and maintaining professional standards of practice.

If the qualified dietitian does not work full-time, and when the dietitian is not available, the hospital must make adequate provisions for dietary consultation that meets the needs of the patients. The frequency of consultation depends on the total number of patients, their nutritional needs and the number of patients requiring therapeutic diets or other nutritional supplementation.

Survey Procedures §482.28(a)(2)

- Review the dietitian's personnel file to determine that he/she is qualified based on education, experience, specialized training, and, if required by State law, is licensed, certified, or registered by the State.

- If the dietitian is not full-time, determine that the number of hours spent working is appropriate to serve the nutritional needs of the patients, and that the hospital makes adequate provisions for a qualified consultant coverage when the dietitian is not available.

A-0299

§482.28(a)(3) There must be administrative and technical personnel competent in their respective duties.

Interpretive Guidelines §482.28(a)(3)

Administrative and technical personnel must be competent in their assigned duties. This competency is demonstrated through education, experience and specialized training appropriate to the task(s) assigned. Personnel files should include documentation that the staff member(s) is competent in their respective duties.

Survey Procedures §482.28(a)(3)

Review personnel files for administrative and technical staff to determine they have appropriate credentials as required and have received adequate training and are competent in their respective duties.

A-0300

§482.28(b) Standard: Diets

Menus must meet the needs of the patients.

Interpretive Guidelines §482.28(b)

Menus provided by the hospital must be nutritionally balanced and meet the special needs of the patients. Current menus should be posted in the hospital kitchen. In order to ensure that the hospital is meeting the nutritional needs of its patients, screening criteria should be developed to identify patients at nutritional risk. Once a patient is identified as at altered nutritional status, a nutritional assessment should be performed on the patient. In addition to the initial nutritional assessment, the patient should be re-evaluated as necessary to ensure their ongoing nutritional needs are met. Examples of patients who may require a nutritional assessment include:

- All patients requiring artificial nutrition by any means (i.e., enteral nutrition (tube feeding), total parenteral nutrition, or peripheral parenteral nutrition);

- Patients whose medical condition, surgical intervention, or physical status interferes with their ability to ingest, digest or absorb nutrients;

- Patients whose diagnosis or presenting signs/symptoms indicates a compromised nutritional status (e.g., anorexia nervosa, bulimia, electrolyte imbalances, dysphagia, malabsorption, end stage organ diseases, etc);

- Patients whose medical condition can be adversely affected by their nutritional intake (e.g., diabetes, congestive heart failure, patients taking certain medications, renal diseases, etc).

Patients who refuse the food served should be offered substitutes that are of equal nutritional value in order to meet their basic nutritional needs.

A-0301

§482.28(b)(1) Therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the patients.

Interpretive Guidelines §482.28(b)(1)

Therapeutic diets should be:

- Prescribed in writing by a qualified practitioner or a qualified dietitian;

- Documented in the patient's medical record including information about the patient's tolerance to the therapeutic diet as ordered; and

- Evaluated for nutritional adequacy.

Survey Procedures §482.28(b)(1)

Verify that therapeutic diet orders are prescribed and authenticated by the practitioner(s) responsible for the care of the patient.

A-0302

§482.28(b)(2) Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the patients.

Interpretive Guidelines §482.28(b)(2)

Recognized dietary practices include following current national standards for recommended dietary allowances, i.e., the current Recommended Dietary Allowances (RDA) or the Dietary Reference Intake (DRI) of the Food and Nutrition Board of the National Research Council.

Survey Procedures §482.28(b)(2)

- Ask the hospital to show you what national standard they are following in their menus to meet the nutritional needs of their patients.
- Review patient records to verify that diet orders are provided as prescribed by the practitioner(s) responsible for the care of the patient.
- From the sample patient records, identify patients with special nutritional needs to determine:
    - If their nutritional needs have been met;
    - If appropriate therapeutic diets have been ordered; and
    - As appropriate, if their dietary intake and nutritional status is being monitored.

A-0304

§482.28(b)(3) A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.

Interpretive Guidelines §482.28(b)(3)

The therapeutic diet manual must be approved by the dietitian and the medical staff. The publication or revision date of the approved therapeutic diet manual must not be more than 5 years old. The therapeutic diet manual (or copies of it) must be available to all medical, nursing and food service personnel.

Survey Procedures §482.28(b)(3)

- Determine that the therapeutic diet manual is current, and:
    - Has been approved by both the medical staff and a qualified dietitian;
    - Is readily available to MD/DOs, nursing and food service personnel;
    - Is in accordance with the current national standards, such as RDA or DRI;
    - Includes the different types of therapeutic diets routinely ordered at the hospital; and
    - Is consistently used as guidance for ordering and preparing patient diets.

A-0308

§482.30 Condition of Participation: Utilization Review

The hospital must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs.

Interpretive Guidelines §482.30

The hospital UR plan should include a delineation of the responsibilities and authority for those involved in the performance of UR activities. It should also establish procedures for the review of the medical necessity of admissions, the appropriateness of the setting, the medical necessity of extended stays, and the medical necessity of professional services.

Survey Procedures §482.30

- Determine that the hospital has a utilization review plan for those services furnished by the hospital and its medical staff to Medicare and Medicaid patients.
- Verify through review of records and reports, and interviews with the UR chairman and/or members that UR activities are being performed as described in the hospital UR plan.
- Review the minutes of the UR committee to verify that they include dates, members in attendance, extended stay reviews with approval or disapproval noted in a status report of any actions taken.

A-0309

§482.30(a) Standard: Applicability

The provisions of this section apply except in either of the following circumstances:

(1) A Utilization and Quality Control Quality Improvement Organization (QIO) has assumed binding review for the hospital.

(2) CMS has determined that the UR procedures established by the State under title XIX of the Act are superior to the procedures required in this section, and has required hospitals in that State to meet the UR plan requirements under §§456.50 through 456.245 of this chapter.

Interpretive Guidelines §482.30(a)

Under Medicare, a QIO must perform UR functions for a hospital, the hospital must have a contract with their QIO to perform UR functions. Under Medicaid, the State must undertake review of UR activities in participating hospitals either directly or optionally by a QIO or other contractor. If a QIO contract exists, the State Plan must comply with 42 CFR §431.630.

Survey Procedures §482.30(a)

- Do not apply these UR requirements if **any** of the following situations apply:
  - A QIO has assumed binding review for the hospital, or
  - The State has entered into a contract with a QIO that is deemed under section 431.630, or
  - CMS has determined that the UR procedures established by the State under Medicaid are superior to these requirements and has required hospitals in that State to meet them. In these cases, the State requirements are applied to both Medicare and the Medicaid patients. The State requirements will then be used for survey in those States.

A-0310

§482.30(b) Standard: Composition of Utilization Review Committee

A UR committee consisting of two or more practitioners must carry out the UR function. At least two of the members of the committee must be doctors of medicine or osteopathy. The other members may be any of the other types of practitioners specified in §482.12(c)(1).

(1) Except as specified in paragraphs (b)(2) and (3) of this section, the UR committee must be one of the following:

(i) A staff committee of the institution;

(ii) A group outside the institution--

(A) Established by the local medical society and some or all of the hospitals in the locality; or

(B) Established in a manner approved by CMS.

(2) If, because of the small size of the institution, it is impracticable to have a properly functioning staff committee, the UR committee must be established as specified in paragraph (b)(1)(ii) of this section.

(3) The committee or group's reviews may not be conducted by any individual who--

(i) Has a direct financial interest (for example, an ownership interest) in that hospital; or

(ii) Was professionally involved in the care of the patient whose case is being reviewed.

Survey Procedures §482.30(b)

- Determine the composition of the UR committee;
- Determine that the governing body has delegated to the UR committee the authority and responsibility to carry out the UR function;
- Verify that small hospitals delegate the UR function to an outside group if it is impractical to have a staff committee;
- Ascertain that committee members are not financially involved in the hospital (ownership of 5 percent or greater) nor participants in the development or execution of the patient's treatment plan.

A-0311

§482.30(c) Standard: Scope and Frequency of Review

(1) The UR plan must provide for review for Medicare and Medicaid patients with respect to the medical necessity of--

(i) Admissions to the institution;

(ii) The duration of stays; and

(iii) Professional services furnished including drugs and biologicals.

(2) Review of admissions may be performed before, at, or after hospital admission.

(3) Except as specified in paragraph (e) of this section, reviews may be conducted on a sample basis.

(4) Hospitals that are paid for inpatient hospital services under the prospective payment system set forth in Part 412 of this chapter must conduct review of duration of stays and review of professional services as follows:

(i) For duration of stays, these hospitals need review only cases that they reasonably assume to be outlier cases based on extended length of stay, as described in §412.80(a)(1)(i) of this chapter; and

(ii) For professional services, these hospitals need review only cases that they reasonably assume to be outlier cases based on extraordinarily high costs, as described in §412.80(a)(1)(ii) of this chapter.

Interpretive Guidelines §482.30(c)

Admissions may be reviewed before, during, or after hospital admission as stated in the hospital's UR plan.

Reviews may be conducted on a sample basis, except for reviews of extended stay cases.

In a PPS hospital, to determine outlier review compliance, "reasonably assumes" is a good faith test. The question to ask is whether the hospital is reviewing outlier cases. In instances where there was no other review of outlier cases, the question is whether it was reasonable for the hospital not to have known that the cases were in fact outliers. Some medical judgment might be required to determine whether it is reasonable for the hospital to have assumed that a patient fell into a DRG other than the one eventually assigned by the intermediary. This would be an issue in long stay outlier cases where the hospital did not review because the hospital erroneously assumed that the patient was in a DRG under which the case would not have been an outlier.

Survey Procedures §482.30(c)

- Examine the UR plan and other documentation to determine that the medical necessity for Medicare and Medicaid patients is reviewed with respect to admission, duration of the stay, and the professional services furnished.

- Determine if the hospital is reimbursed under PPS. This requirement does not apply to PPS excluded hospitals or units.

- Verify that in a PPS hospital the following are being reviewed:

    - Duration of stay in cases reasonably assumed to be outlier cases; and

    - Professional services in cases reasonably assumed to be outlier cases.

A-0312

§482.30(d) Standard: Determination Regarding Admissions or Continued Stays

(1) The determination that an admission or continued stay is not medically necessary-

(i) May be made by one member of the UR committee if the practitioner or practitioners responsible for the care of the patient, as specified of §482.12(c), concur with the determination or fail to present their views when afforded the opportunity; and

(ii) Must be made by at least two members of the UR committee in all other cases.

(2) Before making a determination that an admission or continued stay is not medically necessary, the UR committee must consult the practitioner or practitioners responsible for the care of the patient, as specified in §482.12(c), and afford the practitioner or practitioners the opportunity to present their views.

(3) If the committee decides that admission to or continued stay in the hospital is not medically necessary, written notification must be given, no later than 2 days after the determination, to the hospital, the patient, and the practitioner or practitioners responsible for the care of the patient, as specified in §482.12(c);

Interpretive Guidelines §482.30(d)

When other than a doctor of medicine or osteopathy makes an initial finding that the written criteria for extended stay are not met, the case must be referred to the committee, or subgroup thereof which contains at least one physician. If the committee or subgroup agrees after reviewing the case that admissions, or extended stay is not medically necessary or appropriate, the attending physician is notified and allowed an opportunity to present his views and any additional information relating to the patient's needs for admissions or extended stay. When a physician member of the committee performs the initial review instead of a non-physician reviewer, and he finds that admissions or extended stay is not necessary no referral to the committee or subgroup is necessary and he may notify the attending practitioner directly.

If the attending practitioner does not respond or does not contest the findings of the committee or subgroup or those of the physician who performed the initial review, then the findings are final.

If the attending physician contests the committee or subgroup findings, or if he presents additional information relating to the patient's need for extended stay, at least one additional physician member of the committee must review the case. If the two physician members determine that the patient's stay is not medically necessary or appropriate after considering all the evidence, their determination becomes final. Written notification of this decision must

be sent to the attending physician, patient (or next of kin), facility administrator, and the single State agency (in the case of Medicaid) no later than 2 days after such final decision and in no event later than 3 working days after the end of the assigned extended stay period.

There are only 5 working days in a given week. Normally these days are Monday through Friday, however, the institution has the option to establish 5 other days as working days. When a holiday falls on a working day, that day is not counted as a working day.

In no case may a non-physician make a final determination that a patient's stay is not medically necessary or appropriate.

If, after referral of a questioned case to the committee or subgroup thereof, the physician reviewer determines that an admission or extended stay is justified, the attending physician shall be so notified and an appropriate date for subsequent extended stay review will be selected and noted on the patient's record.

Written notification of this final determination must be sent to the attending physician, the patient (or next of kin), the facility administrator and the single State agency (in the case of Medicaid) no later than 2 days after such final determination and in no event later than 3 working days after the end of the assigned extended stay period.

Where possible, the written notification should be received by all involved parties within the stated time period. Where appropriate and desired, verbal notification may precede written notification.

Survey Procedures §482.30(d)

- Review a sample of "medically unnecessary" decisions involving admissions or continued stay that are not medically necessary and determine that these decisions are made by:
    - One member of the UR committee, if the practitioner(s) responsible for the patient's care concurs with the determination or fails to present his/her views. The practitioner must be one of those specified in §482.12(c), or
    - At least two members of the UR committee in all cases not qualified under the above.
- Review a sample of "medically unnecessary" decisions and verify that the physician or practitioners, as specified in §482.12(c), were informed of the committees expected decision and were given an opportunity to comment.
- Review a sample of "medically unnecessary" cases and verify that all involved parties are notified of the decision that care is medically not necessary no later than two days following the decision.

A-0313

§482.30(e) Standard: Extended Stay Review

(1) In hospitals that are not paid under the prospective payment system, the UR committee must make a periodic review, as specified in the UR plan, or each current inpatient receiving hospital services during a continuous period of extended duration.

The scheduling of the periodic reviews may--

(i) Be the same for all cases; or

(ii) Differ for different classes of cases.

(2) In hospitals paid under the prospective payment system, the UR committee must review all cases reasonably assumed by the hospital to be outlier cases because the extended length of stay exceeds the threshold criteria for the diagnosis, as described in §412.80(a)(1)(i). The hospital is not required to review an extended stay that does not exceed the outlier threshold for the diagnosis.

(3) The UR committee must make the periodic review no later than 7 days after the day required in the UR plan.

Survey Procedures §482.30(e)

- Review the facility's definition of extended stay in the UR plan.
- Verify that the hospital's UR plan requires a periodic review of each current Medicare/Medicaid inpatient receiving hospital services of extended duration and that the review is carried out at the specified time stated in the facility's UR plan.
- The review may be the same for all cases or be different for different classes of care.
- If the committee uses a different number of days for different diagnosis or functional categories for the period of extended stay, the surveyor must verify that there is a written list with lengths of stay designated for each diagnosis of functional category.
- Determine if the hospital is under PPS. Hospitals under PPS need only review cases reasonably assumed to be outlier cases, and extended stay that exceeds the outlier threshold for the diagnosis.
- Review minutes of the UR committee. Determine that the periodic reviews of extended stay are carried out on or before the expiration of the stated period or no later than 7 days after the day required in the hospital's plan.

A-0314

§482.30(f) Standard: Review of Professional Services

The committee must review professional services provided, to determine medical necessity and to promote the most efficient use of available health facilities and services.

Interpretive Guidelines §482.30(f)

"**Professional**" services includes the aspects of care rendered by laboratory personnel, physical therapists, nurses, and others, as well as services provided by MD/DOs.

The review includes medical necessity and efficient use of available health facilities and services. Examples of topics a committee may review are:

- Availability and use of necessary services - underused, overuse, appropriate use
- Timeliness of scheduling of services - operating room, diagnostic
- Therapeutic procedures

Survey Procedures §482.30(f)

Determine that the committee performs a review of professional services.

A-0317

§482.41 Condition of Participation: Physical Environment

The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.

Interpretive Guidelines §482.41

This CoP applies to all locations of the hospital, all campuses, all satellites, all provider-based activities, and all inpatient and outpatient locations.

The hospital's Facility Maintenance and hospital departments or services responsible for the hospital's buildings and equipment (both facility equipment and patient care equipment) must be incorporated into the hospital's QAPI program and be in compliance with the QAPI requirements.

Survey Procedures §482.41

Survey of the Physical Environment CoP should be conducted by one surveyor. However, each surveyor as he/she conducts his/her survey assignments should assess the hospital's compliance with the Physical Environment CoP. The Life Safety Code survey may be conducted separately by a specialty surveyor.

A-0318

§482.41(a) Standard: Buildings

The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well being of patients are assured.

Interpretive Guidelines §482.41(a)

The hospital must ensure that the condition of the physical plant and overall hospital environment is developed and maintained in a manner to ensure the safety and well being of patients. This includes ensuring that routine and preventive maintenance and testing activities are performed as necessary, in accordance with Federal and State laws, regulations, and guidelines and manufacturer's recommendations, by establishing maintenance schedules and conducting ongoing maintenance inspections to identify areas or equipment in need of repair. The routine and preventive maintenance and testing activities should be incorporated into the hospital's **QAPI** plan.

Assuring the safety and well being of patients would include developing and implementing appropriate **emergency preparedness** plans and capabilities. The hospital must develop and implement a comprehensive plan to ensure that the safety and well being of patients are assured during emergency situations. The hospital must coordinate with Federal, State, and local emergency preparedness and health authorities to identify likely risks for their area (e.g., natural disasters, bioterrorism threats, disruption of utilities such as water, sewer, electrical communications, fuel; nuclear accidents, industrial accidents, and other likely mass casualties, etc.) and to develop appropriate responses that will assure the safety and well being of patients. The following issues should be considered when developing the comprehensive emergency plans(s):

- The differing needs of each location where the certified hospital operates;
- The special needs of patient populations treated at the hospital (e.g., patients with psychiatric diagnosis, patients on special diets, newborns, etc.);
- Security of patients and walk-in patients;
- Security of supplies from misappropriation;

- Pharmaceuticals, food, other supplies and equipment that may be needed during emergency/disaster situations;
- Communication to external entities if telephones and computers are not operating or become overloaded (e.g., ham radio operators, community officials, other healthcare facilities if transfer of patients is necessary, etc.);
- Communication among staff within the hospital itself;
- Qualifications and training needed by personnel, including healthcare staff, security staff, and maintenance staff, to implement and carry out emergency procedures;
- Identification, availability and notification of personnel that are needed to implement and carry out the hospital's emergency plans;
- Identification of community resources, including lines of communication and names and contact information for community emergency preparedness coordinators and responders;
- Provisions if gas, water, electricity supply is shut off to the community;
- Transfer or discharge of patients to home, other healthcare settings, or other hospitals;
- Transfer of patients with hospital equipment to another hospital or healthcare setting; and
- Methods to evaluate repairs needed and to secure various likely materials and supplies to effectuate repairs.

Survey Procedures §482.41(a)

- Verify that the condition of the hospital is maintained in a manner to assure the safety and well being of patients (e.g., condition or ceilings, walls, and floors, presence of patient hazards, etc.).
- Review the hospital's routine and preventive maintenance schedules to determine that ongoing maintenance inspections are performed and that necessary repairs are completed.
- Verify that the hospital has developed and implemented a comprehensive plan to ensure that the safety and well being of patients are assured during emergency situations.

A-0319

§482.41(a)(1) There must be emergency power and lighting in at least the operating, recovery, intensive care, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available.

Interpretive Guidelines §482.41(a)(1)

The hospital must comply with the applicable provisions of the Life Safety Code, National Fire Protection Amendments (NFPA) 101, 2000 Edition and applicable references, such as, NFPA-99: Health Care Facilities, for emergency lighting and emergency power.

Survey Procedures §482.41(a)(1)

Use the Life Safety Code Survey Report Form (CMS-2786) to evaluate compliance with this item.

A-0320

§482.41(a)(2) There must be facilities for emergency gas and water supply.

Interpretive Guidelines §482.41(a)(2)

The hospital must have a system to provide emergency gas and water as needed to provide care to inpatients and other persons who may come to the hospital in need of care. This includes making arrangements with local utility companies and others for the provision of emergency sources of water and gas. The hospital should consider nationally accepted references or calculations made by qualified staff when determining the need for at least water and gas. For example, one source for information on water is the Federal Emergency Management Agency (FEMA).

Emergency gas includes fuels such as propane, natural gas, fuel oil, liquefied natural gas, as well as any gases the hospital uses in the care of patients such as oxygen, nitrogen, nitrous oxide, etc.

The hospital should have a plan to protect these limited emergency supplies, and have a plan for prioritizing their use until adequate supplies are available. The plan should also address the event of a disruption in supply (e.g., disruption to the entire surrounding community).

Survey Procedures §482.41(a)(2)

- Review the system used by hospital staff to determine the hospital's emergency needs for gas and water. Verify that the system accounts for not only inpatients, but also staff and other persons who come to the hospital in need of care during emergencies.

- Determine the source of emergency gas and water, both the quantity of these supplies readily available at the hospital, and that are needed within a short time through additional deliveries.

- Verify that arrangements have been made with utility companies and others for the provision of emergency sources of critical utilities, such as water and gas.

A-0321

§482.41(b) Standard: Life Safety From Fire

A-0322

§482.41(b)(1) Except as otherwise provided in this section, the hospital must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA101 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD, and at the Office of the Federal Register, 800 North Capital Street N.W., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes.

(i) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the Life Safety Code does not apply to hospitals.

Interpretive Guidelines §482.41(b)(1)(i)

Medicare-participating hospitals, regardless of size or number of beds, must comply with the hospital/healthcare Life Safety Code requirements for all inpatient care locations. Hospital departments and locations such as emergency departments, outpatient care locations, etc. must comply with hospital/healthcare Life Safety Code Requirements. Additionally, the hospital must be in compliance with all applicable codes referenced in the Life Safety Code, such as, NFPA-99: Health Care Facilities.

Survey Procedures §482.41(b)(1)(i)

There is a separate survey form, (Form CMS-2786) used by the Fire Authority surveyor to evaluate compliance with the Life Safety Code.

A-0323

§482.41(b)(1)(ii) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of patients.

Interpretive Guidelines §482.41(b)(1)(ii)

Life Safety Code waivers may be recommended by the State survey agency but only CMS (at the regional office level) may grant those waivers for Medicare or Medicaid- participating hospitals.

Survey Procedures §482.41(b)(1)(ii)

Consideration, assessment, and recommendation for waivers of specific Life Safety Code provisions are handled by the Fire Authority surveyor as part of the Life Safety Code survey process.

A-0324

§482.41(b)(1)(iii) If CMS finds that the State has a fire and safety code imposed by State law that adequately protects patients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the LSC.

A-0325

§482.41(b)(1)(iv) A hospital must be in compliance with the following provisions beginning on March 13, 2006:

(A) Chapter 19.3.6.3.2 exception number 2.

(B) Chapter 19.2.9 Emergency Lighting.

Interpretive Guidelines §482.41(b)(1)(iv)

§482.41(b)(1)(i) states "Chapter 19.3.6.3.2, exception number 2 of the adopted Life Safety Code does not apply to hospitals." The wording in §482.41 (b)(1)(i) and §482.41 (b)(1)(i)(iv)(A) when used together means that after March 13, 2006 a hospital may no longer continue to keep in service existing roller latches even when those roller latches are demonstrating the ability to keep the door closed against 5 lbf.

Beginning March 13, 2003, Medicare-participating hospitals must be in compliance with chapter 19.3.6.3.2 of the 2000 Edition of NFPA 101. Beginning March 13, 2006, Exception number 2 of chapter 19.3.6.3.2 **will not be allowed** in Medicare-participating hospitals.

Hospitals should develop plans for compliance with this requirement so that in all applicable locations roller latches have been replaced by positive latches **prior to** March 13, 2006.

Beginning March 13, 2006, Medicare-participating hospitals **must be in compliance** with Chapter 19.2.9 of the 2000 Edition of NFPA 101.

This section gives hospitals until March 31, 2006, to replace roller latches and to replace 1 hour batteries with 1 ½ hour batteries in emergency lighting systems that use batteries as power sources. After March 13, 2006 a hospital with doors in service with roller latches or with emergency lighting systems with less than 1 ½ hour batteries will not be in compliance and will be cited at §482.41(b)(1)(i).

A-0326

§482.41(b)(2) The hospital must have procedures for the proper routine storage and prompt disposal of trash.

Interpretive Guidelines §482.41(b)(2)

The term trash refers to common garbage as well as biohazardous waste. The storage and disposal of trash must be in accordance with Federal, State and local laws and regulations (i.e., EPA, OSHA, CDC, State environmental, health and safety regulations). The Conditions of Participation for Radiology and Nuclear Medicine Services address handling and storage of radioactive materials.

Survey Procedures §482.41(b)(2)

Verify that the hospital has developed and implemented policies for the proper storage and disposal of trash. Verify through observation that staff adhere to these policies and that the hospital has signage, as appropriate.

A-0327

§482.41(b)(1)(3) The hospital must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities.
Survey Procedures §482.41(b)(3)

- Review the hospital's written fire control plans to verify they contain the required provisions of the Life Safety Code or State law.

- Verify that hospital staff reported all fires as required to State officials.

- Interview staff throughout the facility to verify their knowledge of their responsibilities during a fire (this is usually done during the LSC survey, but health surveyors may also verify staff knowledge).

A-0328

§482.41(b)(4) The hospital must maintain written evidence of regular inspection and approval by State or local fire control agencies.

Survey Procedures §482.41(b)(4)

Examine copies of inspection and approval reports from State and local fire control agencies.

A-0329

§482.41(c) Standard: Facilities

The hospital must maintain adequate facilities for its services.

Interpretive Guidelines §482.41(c)

Adequate facilities means the hospital has facilities that are:

- Designed and maintained in accordance with Federal, State and local laws, regulations and guidelines; and

- Designed and maintained to reflect the scope and complexity of the services it offers in accordance with accepted standards of practice.

Survey Procedures §482.41(c)

- Observe the facility layout and determine if the patient's needs are met. Toilets, sinks, specialized equipment, etc. should be accessible.

- Review the facility's water supply and distribution system to ensure that the water quality is acceptable for its intended use (drinking water, irrigation water, lab water, etc.). Review the facility water quality monitoring and, as appropriate, treatment system.

A-0330

§482.41(c)(1) Diagnostic and therapeutic facilities must be located for the safety of patients.

Interpretive Guidelines §482.41(c)(1)

Diagnostic and therapeutic facilities must be in rooms or areas specifically designed for the purpose intended.

Survey Procedures §482.41(c)(1)

Determine that x-ray, physical therapy, and other specialized services are provided in areas appropriate for the service provided.

A-0331

§482.41(c)(2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

Interpretive Guidelines §482.41(c)(2)

Facilities must be maintained to ensure an acceptable level of safety and quality.

Supplies must be maintained to ensure an acceptable level of safety and quality.

This would include that supplies are stored in such a manner to ensure the safety of the stored supplies (protection against theft or damage, contamination, or deterioration), as well as, that the storage practices do not violate fire codes or otherwise endanger patients (storage of flammables, blocking passageways, storage of contaminated or dangerous materials, safe storage practices for poisons, etc.).

Additionally, "supplies must be maintained to ensure an acceptable level of safety" would include that the hospital identifies the supplies it needs to meet its patients' needs for both day-to-day operations and those supplies that are likely to be needed in likely emergency situations such as mass casualty events resulting from natural disasters, mass trauma, disease outbreaks, etc.; and that the hospital makes adequate provisions to ensure the availability of those supplies when needed.

Equipment must be maintained to ensure an acceptable level of safety and quality.

Equipment includes both facility equipment (e.g., elevators, generators, air handlers, medical gas systems, air compressors and vacuum systems, etc.) and medical equipment (e.g., biomedical equipment, radiological equipment, patient beds, stretchers, IV infusion equipment, ventilators, laboratory equipment, etc.).

There must be a regular periodical maintenance and testing program for medical devices and equipment. A qualified individual such as a clinical or biomedical engineer, or other qualified maintenance person must monitor, test, calibrate and maintain the equipment periodically in accordance with the manufacturer's recommendations and Federal and State laws and regulations. Equipment maintenance may be conducted using hospital staff, contracts, or through a combination of hospital staff and contracted services.

"Equipment must be maintained to ensure an acceptable level of safety" would include that the hospital identifies the equipment it needs to meet its patients' needs for both day-to-day operations and equipment that is likely to be needed in likely emergency/disaster situations such as mass casualty events resulting from natural disasters, mass trauma, disease outbreaks, internal disasters, etc.; and that the hospital makes adequate provisions to ensure the availability of that equipment when needed.

Survey Procedures §482.41(c)(2)

- Interview the person in charge of medical equipment and determine if there is an adequate repair/periodical maintenance program.
- Verify that all medical devices and equipments are routinely checked by a clinical or biomedical engineer.
- Review maintenance logs for significant medical equipment (e.g., cardiac monitors, IV infusion pumps, ventilators, etc.).
- Are supplies maintained in such a manner as to ensure that safety?
- Are supplies stored as recommended by the manufacturer?
- Are supplies stored in such a manner as to endanger patient safety?
- Has the hospital identified supplies and equipment that are likely to be needed in emergency situations?
- Has the hospital made adequate provisions to ensure the availability of those supplies and equipment when needed?

A-0332

§482.41(c)(3) The extent and complexity of facilities must be determined by the services offered.

Interpretive Guidelines §482.41(c)(3)

Physical facilities must be large enough, numerous enough, appropriately designed and equipped, and of appropriate complexity to provide the services offered in accordance with Federal and State laws, regulations and guidelines and accepted standards of practice for that location or service.

Survey Procedures §482.41(c)(3)

Verify through observation that the physical facilities are large enough and properly equipped for the scope of services provided and the number of patients served.

A-0333

§482.41(c)(4) There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

Interpretive Guidelines §482.41(c)(4)

There must be proper ventilation in at least the following areas:

- Areas using ethylene oxide, nitrous oxide, guteraldehydes, xylene, pentamidine, or other potentially hazardous substances;
- Locations where oxygen is transferred from one container to another;
- Isolation rooms and reverse isolation rooms (both must be in compliance with Federal and State laws, regulations, and guidelines such as OSHA, CDC, NIH, etc.);
- Pharmaceutical preparation areas (hoods, cabinets, etc.); and
- Laboratory locations.

There must be adequate lighting in all the patient care areas, and food and medication preparation areas.

Temperature, humidity and airflow in the operating rooms must be maintained within acceptable standards to inhibit bacterial growth and prevent infection, and promote patient comfort. Excessive humidity in the operating room is conducive to bacterial growth and

compromises the integrity of wrapped sterile instruments and supplies. Each operating room should have separate temperature control. Acceptable standards such as from the Association of Operating Room Nurses (AORN) or the American Institute of Architects (AIA) should be incorporated into hospital policy.

The hospital must ensure that an appropriate number of refrigerators and/or heating devices are provided and ensure that food and pharmaceuticals are stored properly and in accordance with nationally accepted guidelines (food) and manufacturer's recommendations (pharmaceuticals).

Survey Procedures §482.41(c)(4)

- Verify that all food and medication preparation areas are well lighted.
- Verify that the hospital is in compliance with ventilation requirements for patients with contagious airborne diseases, such as tuberculosis, patients receiving treatments with hazardous chemical, surgical areas, and other areas where hazardous materials are stored.
- Verify that food products are stored under appropriate conditions (e.g., time, temperature, packaging, location) based on a nationally-accepted sources such as the United States Department of Agriculture, the Food and Drug Administration, or other nationally-recognized standard.
- Verify that pharmaceuticals are stored at temperatures recommended by the product manufacturer.
- Verify that each operating room has temperature and humidity control mechanisms.
- Review temperature and humidity tracking log(s) to ensure that appropriate temperature and humidity levels are maintained.

A-0338

§482.42 Condition of Participation: Infection Control

The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

Interpretive Guidelines §482.42

This regulation requires the hospital to develop, implement and maintain an infection control program for the prevention, control, and investigation of infections (which includes, but is not limited to nosocomial infections) and communicable diseases of patients and personnel (which includes, but is not limited to patient care staff).

The hospital must have an active surveillance program that includes specific measures for prevention, early detection, control, education, and investigation of **infections and communicable diseases** in the hospital. There must be a mechanism to evaluate the effectiveness of the program(s) and take corrective action when necessary. The program must include implementation of nationally recognized systems of infection control guidelines to avoid sources and transmission of infections and communicable diseases (e.g., the Centers for Disease Control and Prevention (CDC) Guidelines for Prevention and Control of Nosocomial Infections, the CDC Guidelines for Preventing the Transmission of Tuberculosis in Health Care Facilities, the Occupational Health and Safety Administration (OSHA) regulations, and the Association for Professionals in Infection Control and Epidemiology (APIC) infection control guidelines, etc).

The active infection control program should have policies that address the following:

- Definition of nosocomial infections and communicable diseases;
- Measures for identifying, investigating, and reporting nosocomial infections and communicable diseases;
- Measures for identifying, investigations and controlling post-operative infections in outpatient surgery patients and post-operative infections in inpatients who are discharged soon after surgery;
- Measures for assessing and identifying patients and health care workers, including hospital personnel, contract staff (e.g., agency nurses, housekeeping staff) and volunteers, at risk for infections and communicable diseases;
- Methods for obtaining reports of infections and communicable diseases on inpatients, outpatients, and health care workers, including all hospital personnel, contract staff (e.g., agency nurses, housekeeping staff, etc) and volunteers, in a timely manner;
- Measures for the prevention of infections, especially infections caused by organisms that are antibiotic-resistant or in other ways epidemiologically important; device related infections e.g., those associated with intravascular devices, ventilators, tube feeding, indwelling urinary catheters, etc, surgical site infections; and those infections associated with tracheostomy care, respiratory therapy, burns, immunosuppressed patients, and other factors which compromise a patient's resistance to infection;
- Measures for prevention of communicable disease outbreaks, such as airborne diseases (TB, SARS, etc.), food borne diseases (Hepatitis A, Salmonella, etc.), blood borne diseases (HIV, Hepatitis B, etc.), and others (VRE, MRSA, pseudomonas, etc.).
- Provision of a safe environment consistent with nationally recognized infection control precautions, such as the current CDC recommendations for the identified infection and/or communicable disease;

- Isolation procedures and requirements for infected or immunosuppressed patients;
- Use and techniques for standard precautions;
- Education of patients, family members and caregivers about infections and communicable diseases;
- Methods for monitoring and evaluating practices of asepsis;
- Techniques for hand washing, respiratory protections, asepsis, sterilization, disinfection, food sanitation, housekeeping, fabric care, liquid and solid waste disposal, needle disposal, separation of clean items from dirty items, as well as other means for limiting the spread of contagion;
- Authority and indications for obtaining microbiological cultures from patients;
- A requirement that disinfectants, antiseptics, and germicides be used in accordance with the manufacturers' instructions to avoid harming patients, particularly central nervous system effects on children;
- Orientation of all new hospital personnel to infections, communicable diseases, and to the infection control program;
- Measures for the screening and evaluation of health care workers, including all hospital staff, contract workers (e.g., agency nurses, housekeeping staff, etc), and volunteers, for communicable diseases, and for the evaluation of staff and volunteers exposed to patients with non-treated communicable diseases;
- Employee health policies regarding infectious diseases and when infected or ill employees, including contract workers and volunteers, must not render patient care and/or must not report to work;
- A procedure for meeting the reporting requirements of the local health authority;
- Procedures for working with local, State, and Federal health authorities in emergency preparedness situations;
- Policies and procedures developed in coordination with Federal, State, and local emergency preparedness and health authorities to address communicable disease threats and outbreaks; and
- Provision for program evaluation and revision of the program, when indicated.

The hospital infection control program must be hospital-wide, include all locations, all campuses, all departments and services. It must include a program for the prevention, control, and investigation of infections and communicable diseases in patients and staff, including both patient care and non-patient care staff. In many circumstances, non-patient care staff can readily serve as a reservoir or a means of transmission of infections or communicable disease within the hospital environment.

The hospital's infection control program must be integrated into its hospital-wide QAPI program.

Survey Procedures §482.42

- Survey of the Infection Control CoP should be coordinated by one surveyor. However, each surveyor as he/she conducts his/her survey assignments should assess the hospital's compliance with the Infection Control CoP.

- Verify that there is a system (policies) for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and hospital personnel, including contract workers and volunteers.

- Determine that this system is an active program, that it is both hospital-wide and program-specific, and that it is implemented correctly.

- Throughout the hospital, observe the environment of care, noting the cleanliness of horizontal surfaces, bedside equipment, and air inlets, etc, because infectious organisms may spread from these places.

- Verify that the hospital's infection control program is integrated into its hospital-wide QAPI program.

A-0339

§482.42(a) Standard: Organization and Policies

A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases.

Interpretive Guidelines §482.42(a)

The hospital must designate in writing an individual or group of individuals, qualified through education, training, experience, and certification or licensure, as an infection control officer or officers.

The infection control officer or officers must develop and implement policies governing the control of infections and communicable diseases.

Survey Procedures §482.42(a)

- Interview the infection control officer regarding the hospital's infection control program, hospital issues regarding infection control, and to verify and evaluate integration of the hospital infection control program into the hospital's QAPI program.

- Verify that an infection control officer (or officers) is designated and has the responsibility for the infection control program.

- Review the personnel file of the infection control officer(s) to verify that he/she is qualified through education, training, experience, and certification or licensure to oversee the infection control program.

- Verify that appropriate policies and procedures have been developed and implemented governing the control of infections and communicable diseases.

A-0340

§482.42(a)(1) The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

Interpretive Guidelines §482.42(a)(1)

The infection control officer(s) is responsible for:

- Implementing policies governing asepsis, sterilization, and infection control;

- Developing a system for identifying, investigating, reporting, and preventing the spread of infections and communicable diseases among patients and hospital personnel, including contract staff and volunteers;

- Identifying, investigating and reporting infections and outbreaks of communicable diseases among patients and hospital personnel, including contract staff and volunteers, especially those occurring in clusters;

- Preventing and controlling the spread of infections and communicable diseases among patients and staff;

- Cooperating with hospital-wide orientation and in-service education programs;

- Cooperating with other departments and services in the performance of quality assurance activities;

- Cooperating with disease control activities of the local health authority; and
- Cooperating with Federal, State and local emergency preparedness and public health officials to develop and implement emergency preparedness programs regarding bioterrorism and communicable disease threats.

Survey Procedures §482.42(a)(1)

- Determine that the infection control officer(s) is responsible for the elements specified in the interpretive guidelines.
- Determine if the hospital has an infection control committee. Review committee minutes to evaluate compliance with requirements.

A-0341

§482.42(a)(2) The infection control officer or officers must maintain a log of incidents related to infections and communicable diseases.

Interpretive Guidelines §482.42(a)(2)

The infection control officer or officers must maintain a **log of all incidents related to infections and communicable diseases**, including those identified through employee health services. The log is not limited only to nosocomial infections. All incidents of infection and communicable disease must be included in the log. The log documents infections and communicable diseases of patients and all staff (patient care, non patient care, employees, contract staff and volunteers). This would include incidents of post-operative infections in inpatients who are discharged soon after surgery or outpatients who received outpatient surgery.

Survey Procedures §482.42(a)(2)

Verify that the infection control officer(s) maintains a log of all incidents related to infections and communicable diseases, including those identified through employee health services.

A-0342

§482.42(b) Standard: Responsibilities of Chief Executive Officer, Medical Staff, and Director of Nursing Services

The chief executive officer, the medical staff, and the director of nursing must--

(1) Ensure that the hospital-wide quality assurance program and training programs address problems identified by the infection control officer or officers; and

(2) Be responsible for the implementation of successful corrective action plans in affected problem areas.

Interpretive Guidelines §482.42(b)

The chief executive officer (CEO), the medical staff and the director of nursing (DON) must ensure that the hospital-wide Quality Assessment and Performance Improvement (QAPI) program and staff in-service training programs address problems identified through the infection control program.

The CEO, the medical staff, and the DON are responsible for implementing corrective action plans to address problems identified by the infection control officer(s). These plans should be evaluated for effectiveness and revised if needed, and documentation concerning corrective actions and outcomes should be maintained.

Survey Procedures §482.42(b)

- Determine that the hospital's QAPI program and staff in-service training programs address problems identified by the infection control officer(s).

- Determine that problems identified are reported to the medical staff, nursing and administration, and addressed in the hospital's quality assurance and in-service training programs.

A-0349

§482.43 Condition of Participation: Discharge Planning

The hospital must have in effect a discharge planning process that applies to all patients. The hospital's policies and procedures must be specified in writing.

Interpretive Guidelines §482.43

This CoP applies to all types of hospitals and requires all hospitals to conduct appropriate discharge planning activities for all inpatients. It applies to patients who are admitted to the hospital as inpatients. This CoP does not apply to patients who appear in a hospital emergency department but are not admitted as hospital inpatients.

The written discharge planning process must reveal a thorough, clear, comprehensive process that is understood by the hospital staff.

Adequate discharge planning is essential to the health and safety of all patients. Patients may suffer adverse health consequences upon discharge without benefit of appropriate planning. Such planning is vital to mapping a course of treatment aimed at minimizing the likelihood of having any patient rehospitalized for reasons that could have been prevented.

Survey Procedures §482.43

- Review hospital written policies and procedures to determine the existence of a discharge planning process.
- Review patient care plans for discharge planning interventions.
- Interview a sample of hospital staff that are involved in direct patient care. Ask the following questions:
    - How is discharge planning conducted at this hospital?
    - How are you kept apprised of the hospital's policies and procedures for discharge planning?
    - How is this communicated and integrated into a plan of care?

A-0350

§482.43(a) Standard: Identification of Patients in Need of Discharge Planning

The hospital must identify at an early stage of hospitalization all patients who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning.

Interpretive Guidelines §482.43(a)

Medicare participating hospitals are afforded great flexibility in setting the criteria for identifying patients who are likely to suffer adverse health consequences upon discharge without adequate discharge planning. Presently there is no nationally accepted tool or criteria for identifying these individuals. However, the following factors have been identified as important: functional status, cognitive ability of the patient, and family support. Patients at high-risk of requiring post-hospital services must be identified through a screening process. The hospital should reevaluate the needs of the patients on an ongoing basis, and prior to discharge, as they may change based on the individual's status.

There is no set time frame for identification of patients requiring a discharge planning evaluation other than it must be done as early as possible. The timing is left up to the hospital, its staff, and attending MD/DO.

Survey Procedures §482.43(a)

- Interview staff. How are the patients who are in need discharge planning identified?

- Review the hospital's high-risk screening procedure.
    - Does it identify patients who need discharge planning evaluations?
    - How does the hospital's high-risk screening procedure work?
    - What staff are involved? Who is ultimately accountable?
    - Who evaluates the procedure to make sure patients are appropriately evaluated and that patients do not suffer adverse consequences due to lack of or insufficient discharge planning?

A-0351

§482.43(b) Standard: Discharge Planning Evaluation

(1) The hospital must provide a discharge planning evaluation to the patients identified in paragraph (a) of this section, and to other patients upon the patient's request, the request of a person acting on the patient's behalf, or the request of the physician.

Interpretive Guidelines §482.43(b)(1)

The needs assessment can be formal or informal. A needs assessment generally includes an assessment of factors that impact on a patient's needs for care after discharge from the acute care setting. These may include assessment of biopsychosocial needs, the patient's and caregiver's understanding of discharge needs, and identification of post-hospital care resources.

At the present time, there is no nationally accepted standard for the evaluation. The purpose of a discharge planning evaluation is to determine continuing care needs after the patient leaves the hospital setting. It is not intended to be a care-planning document. The hospital may develop an evaluation tool or protocol.

Survey Procedures §482.43(b)(1)

- Interview a sample of hospital staff and ask: How are patients and caregivers made aware of their rights to request a discharge plan?
- Talk to a sample of patients and family members who are expecting a discharge soon and ask:
    - Did the hospital staff assist them in planning for post-hospital care? Does the patient/family express that they feel prepared for discharge?
    - Are you given the pamphlet, "Important Message from Medicare?"

- Are you aware that you may request assistance with discharge planning?

A-0352

§482.43(b)(2) A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, the evaluation.

Interpretive Guidelines §482.43(b)(2)

The responsibility for discharge planning is often multidisciplinary. It is not restricted to a particular discipline. The hospital has flexibility in designating the responsibilities of the registered nurse, social worker, or other appropriate qualified personnel for discharge planning. The responsible personnel should have experience in discharge planning, knowledge of social and physical factors that affect functional status at discharge, and knowledge of community resources to meet post-discharge clinical and social needs.

Ideally, discharge planning will be an interdisciplinary process, involving disciplines with specific expertise, as dictated by the needs of the patient. For example, for a patient with emphysema, the discharge planner could coordinate respiratory therapy and nursing care, and financial coverage for home care services and oxygen equipment, and patient/caregiver education utilizing cost effective, available community services in an expedient manner.

Survey Procedures §482.43(b)(2)

- Review the written policy and procedure that designates discharge-planning responsibilities.

- Determine who is responsible for discharge planning. Ask the designated personnel to describe their qualifications for and experience with discharge planning and evaluate whether they are familiar with the community standard of practice. If needed, review the job descriptions of the designated personnel for discharge planning expectations. If licensing is required, current credentials must be on file.

A-0353

§482.43(b)(3) The discharge planning evaluation must include an evaluation of the likelihood of a patient needing post-hospital services and of the availability of the services.

Interpretive Guidelines §482.43(b)(3)

The hospital is responsible for developing the discharge plan for patients who need a plan and for arranging its initial implementation. The hospital's ability to meet discharge planning requirements is based on the following:

- Implementation of a needs assessment process with identified high risk criteria;
- Evidence of a complete, timely, and accurate assessment;
- Maintenance of a complete and accurate file on community-based services and facilities including long term care, sub acute care, home care or other appropriate levels of care to which patients can be referred; and
- Coordination of the discharge planning evaluation among various disciplines responsible for patient care.

Survey Procedures §482.43(b)(3)

- What is the process the hospital uses to identify patients who need a discharge plan?
- Does the hospital use its QAPI program to determine whether the discharge planning process effectively identifies patients in need of plans, and whether the plans are adequate and appropriately executed?
- Ascertain whether various disciplines are involved with discharge planning, including physical, speech, occupational, and respiratory therapists and dietitians, in addition to MD/DOs, nurses, and social workers.

A-0354

§482.43(b)(4) The discharge planning evaluation must include an evaluation of the likelihood of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the hospital.

Interpretive Guidelines §482.43(b)(4)

The capacity for self-care includes the ability and willingness for such care. The choice of a continuing care provider depends on the self-care components, as well as, availability, willingness, and ability of family/caregivers and the availability of resources. The hospital must inform the patient or family as to their freedom to choose among providers of post-hospital care. Patient preferences should also be considered; however, preferences are not necessarily congruent with the capacity for self- care.

Patients should be evaluated for return to the pre-hospital environment, but also should be offered a range of realistic options to consider for post-hospital care. This includes patients admitted to a hospital from a SNF, who should be evaluated to determine an appropriate discharge site.

Hospital staff should incorporate information provided by the patient and/or caregivers to implement the process.

The Social Security Act (SSA) at §1861(ee) requires Medicare participating hospitals, as part of their discharge planning evaluations, share with each patient, as appropriate, a list of Medicare-certified home health agencies (HHA) that serve the geographic area in which the patient resides and that request to be included on the list. In addition the SSA prohibits hospitals from limiting or steering patients to any particular HHA and must identify those HHA to whom the patient is referred in which the hospital has a disclosable financial interest or which has such an interest in the hospital.

The SSA, section 1861(ee) requires a hospital's discharge plan to include an evaluation of the patient's likely need for hospice care and post-hospital extended care services and to provide a list of the available Medicare certified hospice and SNFs that serve the geographic area requested by the patient. In addition, the discharge plan shall not specify or limit qualified hospice or SNFs and must identify those entities to whom the patient is referred in which the hospital has a disclosable financial interest or which has such an interest in the hospital.

Therefore, we expect hospitals to provide a list of Hospice, HHAs or SNFs that are available to the patient, that participate in the Medicare program, and that serve the geographic area that the patient requests. The list must be presented only to patients for whom post-hospital Hospice services, HHA services or SNF extended care services are indicated and appropriate as determined by the discharge planning evaluation. It is not expected that patients without a need for post-hospital Hospice services, HHA services, or SNF extended care services would receive the list. The hospital must document in the patient's medical record that a list of Hospices, HHAs or SNFs was presented to the patient or individual acting on the patient's behalf. This serves as documentation that the requirement was met. Finally, the hospital has the flexibility to develop and maintain its own list of Hospices or SNFs; or in the case of SNF, simply print a list from the Nursing Home Compare site on the CMS Web site, http://www.medicare.gov/ based on the geographic area that the patient requests.

Survey Procedures §482.43(b)(4)

- Review a sample of discharge planning evaluations.
    - Gather information about the patient's self-care capacity from the clinical record, direct clinical observation, and information obtained from the patient, caregiver, and staff involved in the care of the patient; judge appropriateness of discharge disposition.
    - Note if appropriate interdisciplinary input is documented.
    - Did the patient and/or caregiver participate in the needs assessment and decision for post-hospital care resources?
- Is a patient who was admitted from a home or another setting given a full-range of realistic options for post-hospital continuation of care?

- Interview patients who the discharge evaluation identified as needing home health services. Was a list of Medicare certified HHA providers that serve the geographic area in which the patient resides presented to the patient or the individual acting on the patient's behalf? Was the patient's choice of HHA respected, when possible? Was the choice of HHA limited? Was the patient inappropriately steered to a particular HHA? Was the patient informed of any HHA in which the hospital has a financial interest?

- Interview patients who the discharge evaluation identified as needing hospice care or post-hospital extended care SNF services. Was a list of Medicare certified Hospice or skilled nursing facilities that serve the geographic area in which the patient resides presented to the patient or individual acting on the patient's behalf? Was the patient's choice of Hospice or SNF respected, when possible? Was the choice of Hospice or SNF limited? Was the patient inappropriately steered to a particular Hospice or SNF? Was the patient informed of any Hospice or SNF in which the hospital has a financial interest?

A-0355

§482.43(b)(5) The hospital personnel must complete the evaluation on a timely basis so that appropriate arrangements for post-hospital care are made before discharge, and to avoid unnecessary delays in discharge.

Interpretive Guidelines §482.43(b)(5)

Patient hospital length of stay varies widely. The timing of the discharge evaluation should be relative to the patient's clinical condition and anticipated length of stay. Assessment should start as soon after admission as possible and be updated periodically during the episode of care.

Information about the patient's age and sex could be collected on admission while functional ability data is best collected closer to discharge, indicating more accurately a patient's continuing care requirements.

Survey Procedures §482.43(b)(5)

- Review several patients' discharge plans for the appropriate coordination of health and social care resources based on the individual patient and caregiver's expected post-hospital needs.

- Is there a pattern of prolonged length of stay for certain patient populations because the evaluation for post-hospital care was delayed? If so, is the delay due to circumstances beyond the hospital's control (e.g., inability to reach the beneficiary's responsible person(s), continuing change in the patient's condition, and/or is the delay due to poor hospital planning for timely post-hospital arrangements)?

A-0356

§482.43(b)(6) The hospital must include the discharge planning evaluation in the patient's medical record for use in establishing an appropriate discharge plan and must discuss the results of the evaluation with the patient or individual acting on his or her behalf.

Interpretive Guidelines §482.43(b)(6)

The hospital must demonstrate its development of discharge plan evaluation for patients in need and then must discuss the results of the evaluation with the patient or individual acting on his/her behalf. Documentation of these activities is expected.

The discharge plan evaluation is generally found in the clinical notes if there is no dedicated form. The hospital will be expected to document its decision about the need for a plan, document the existence of plans when needed, and indicate what steps were taken to implement the plans initially. Evidence of an ongoing evaluation of the discharge planning needs of the patient is the important factor.

Documented evidence of discussion of the discharge planning evaluation with the patient, if possible, and interested persons should exist in the medical record. Although not mandated by this CoP, it is preferable that the hospital staff seek information from the patient and family to make the discharge planning evaluation as realistic and viable as possible. The Patients' Rights CoP (§482.13) does provide the patient the right to participate in the development of their plan of care. Discharge planning is considered a part of the plan of care.

Survey Procedures §482.43(b)(6)

- Review several clinical records for evidence of a discharge planning evaluation.
- Through review of the clinical record notes and questioning of the patient and/or caregiver and staff, verify discussion of the evaluation with the involved persons.

A-0357

§482.43(c) Standard: Discharge Plan

A-0358

§482.43(c)(1) A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, a discharge plan if the discharge planning evaluation indicates a need for a discharge plan.

Interpretive Guidelines §482.43(c)(1)

It is a management function of the hospital to ensure proper supervision of its employees. Existing training and licensing requirements of a registered nurse and social worker in discharge planning are sufficient. "Other appropriately qualified personnel" may include an MD/DO. The hospital should determine who has the requisite knowledge and skills to do the job regardless of how these were acquired. However, because post-hospital services and, ultimately, the patient's recovery and quality of life can be affected by the discharge plan, the plan should be supervised by qualified personnel to ensure professional accountability.

The hospital CoP at §482.13(b): Patients' Rights states that "The patient has the right to participate in the development and implementation of his or her plan of care." (CMS views discharge planning as part of the patient's plan of care). "The patient or his/her representative (as allowed under State law) has the right to make informed decisions regarding his/her care" and "The patient's rights include...being involved in care planning and treatment."

Survey Procedures §482.43(c)(1)

- Examine patients' clinical records for references to a registered nurse, social worker, or other designated qualified personnel or their signature on a written discharge plan notation.

- Ask staff to describe who oversees the development of a discharge plan.

A-0359

§482.43(c)(2) In the absence of a finding by the hospital that a patient needs a discharge plan, the patient's physician may request a discharge plan. In such a case, the hospital must develop a discharge plan for the patient.

Interpretive Guidelines §482.43(c)(2)

The physician can make the final decision as to whether a discharge plan is necessary. The hospital will develop a plan if a physician requests one even if the interdisciplinary team had determined one to be unnecessary.

Survey Procedures §482.43(c)(2)

- Review the hospital policy and procedure to determine who may request a discharge plan.

- Is there reference to or existence of a discharge plan in the clinical record when requested by a physician?

- Ask a physician involved with discharge planning about experiences with requesting development of discharge plans when the interdisciplinary team does not recommend a plan.

A-0360

§482.43(c)(3) The hospital must arrange for the initial implementation of the patient's discharge plan.

Interpretive Guidelines §482.43(c)(3)

The hospital is required to arrange for the initial implementation of the discharge plan. This includes arranging for necessary post-hospital services and care, and educating patient/family/caregivers/community providers about post-hospital care plans.

Survey Procedures §482.43(c)(3)

- Review a sample of patient records. Determine if there is documented evidence of implementation of the discharge plan, including contact and transmission of information to the patient (when possible) and the next caregiver. Ask staff responsible for the patient's care to describe the steps taken to implement the plan initially for the patients.

- Interview the patient or caregiver regarding implementation of the plan by facility staff.

A-0361

§482.43(c)(4) The hospital must reassess the patient's discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan.

Interpretive Guidelines §482.43(c)(4)

The discharge plan should be initiated as soon as possible after admission. As changes in the patient's condition and needs occur, the discharge plan must be reassessed and updated to address those changes.

Survey Procedures §482.43(c)(4)

- Review the hospital's policy on reassessment of discharge plans.

- Review several clinical records for evidence of reassessment of the patient and related changes with regard to the care plan/critical pathway(s) in the discharge plan when warranted.

- Ask staff involved with discharge planning to discuss the reassessment process and/or present a clinical record that documents reassessment.

A-0362

§482.43(c)(5) As needed, the patient and family members or interested persons must be counseled to prepare them for post-hospital care.

Interpretive Guidelines §482.43.(c)(5)

Evidence should exist that the patient and/or family and/or caregiver is/are provided information and instructions in preparation for post-hospital care and kept informed of the progress. It is important that the patient and caregivers who are expected to provide the care know, and as appropriate, can demonstrate or verbalize the care needed by the patient.

Use of family caregivers in providing post-hospital care should occur when the family is both willing and able to do so. It is appropriate to use community resources with or without family support whenever necessary.

Survey Procedures §482.43(c)(5)

Where possible, interview patients and their family members to determine whether they have been instructed in post-hospital care. Potential training could include the timing and dosage of medications, the wide effects of medications, treatments, and therapy regimens.
If the patient is being transferred to an alternate care delivery setting, has this information been shared with the patient?

A-0363

§482.43(d) Standard: Transfer or Referral

The hospital must transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for follow-up or ancillary care.

Interpretive Guidelines §482.43(d)

The hospital must ensure that patients receive proper post-hospital care within the constraints of a hospital's authority under State law and within the limits of a patient's right to refuse discharge-planning services. If a patient exercises the right to refuse discharge planning or to comply with a discharge plan, documentation of the refusal is recommended.

"Medical information" may be released only to authorized individuals according to provision §482.24(b)(3). Examples of necessary information include functional capacity of the patient, requirements for health care services procedures, discharge summary, and referral forms.

"Appropriate facilities" refers to facilities that can meet the patient's assessed needs on a post-discharge basis and that comply with Federal and State health and safety standards.

Survey Procedures §482.43(d)

- Ask staff involved with discharge planning to describe the process of transfer of patient information from the hospital to a post-discharge facility.
- Does the process assure continuity of care?
- Are the patient's rights, such as for confidentiality, refusal, and preference considered?
- If required, is there evidence of written authorization by the patient before release of information?
- Is there documentation that care instruction has been communicated to the post hospital care setting?

A-0364

§483.43(e) Standard: Reassessment

The hospital must reassess its discharge planning process on an on-going basis. The reassessment must include a review of discharge plans to ensure that they are responsive to discharge needs.

Interpretive Guidelines §483.43(e)

The hospital's discharge planning process must be integrated into its QAPI program.

The hospital must have a mechanism in place for ongoing reassessment of its discharge planning process. Although specific parameters or measures that would be included in a reassessment are not required, the hospital should assure the following factors in the reassessment process:

- Time effectiveness of the criteria to identify patients needing discharge plans;
- The quality and timeliness for discharge planning evaluations and discharge plans;
- The hospital discharge personnel maintain complete and accurate information to advise patients and their representatives of appropriate options; and
- The hospital has a coordinated discharge planning process that integrates discharge planning with other functional departments, including the quality assurance and utilization review activities of the institution and involves various disciplines.

Survey Procedures §482.43(e)

- Review hospital policies and procedures to determine how often the discharge planning process is reassessed.
- Does the hospital's QAPI program determine whether its discharge planning process effectively identifies patients who need discharge planning, whether the plans are adequate and whether the plans are effectively executed?
- Ask hospital staff how often the discharge planning process is reassessed. What data is examined to determine how well the process is working in providing for continued care of the patient?

A-0369

§482.45 Condition of Participation: Organ, Tissue and Eye Procurement

---

A-0370

§482.45(a) Standard: Organ Procurement Responsibilities

The hospital must have and implement written protocols that:

Interpretive Guidelines §482.45(a)

The hospital must have written policies and procedures to address its organ procurement responsibilities.

A-0371

§482.45(a)(1) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose;

Interpretive Guidelines §482.45(a)(1)

The hospital must have a written agreement with an Organ Procurement Organization (OPO), designated under 42 CFR Part 486. At a minimum, the written agreement must address the following:

- The criteria for referral, including the referral of all individuals whose death is imminent or who have died in the hospital;
- Includes a definition of "imminent death";
- Includes a definition of "timely notification";
- Addresses the OPO's responsibility to determine medical suitability for organ donation;
- Specifies how the tissue and/or eye bank will be notified about potential donors using notification protocols developed by the OPO in consultation with the hospital-designated tissue and eye bank(s);
- Provides for notification of each individual death in a timely manner to the OPO (or designated third party) in accordance with the terms of the agreement;
- Ensures that the designated requestor training program offered by the OPO has been developed in cooperation with the tissue bank and eye bank designated by the hospital;
- Permits the OPO, tissue bank, and eye bank access to the hospital's death record information according to a designated schedule, e.g., monthly or quarterly;
- Includes that the hospital is not required to perform credentialing reviews for, or grant privileges to, members of organ recovery teams as long as the OPO sends only "qualified, trained individuals" to perform organ recovery; and
- The interventions the hospital will utilize to maintain potential organ donor patients so that the patient organs remain viable.

Hospitals must notify the OPO of every death or imminent death in the hospital. When death is imminent, the hospital must notify the OPO both before a potential donor is removed from a ventilator and while the potential donor's organs are still viable. The hospital should have a written policy, developed in coordination with the OPO and approved by the hospital's medical staff and governing body, to define "imminent death." The definition for "imminent death" should strike a balance between the needs of the OPO and the needs of the hospital's care givers to continue treatment of a patient until brain death is declared or the patient's family has made the decision to withdraw supportive measures. Collaboration between

OPOs and hospitals will create a partnership that furthers donation, while respecting the perspective of hospital staff.

The definition for "imminent death" might include a patient with severe, acute brain injury who:

- Requires mechanical ventilation;
- Is in an intensive care unit (ICU) or emergency department; **AND**
- Exhibits clinical findings consistent with a Glascow Coma Score that is less than or equal to a mutually-agreed-upon threshold; **or**
- MD/DOs are evaluating a diagnosis of brain death; **or**
- An MD/DO has ordered that life sustaining therapies be withdrawn, pursuant to the family's decision.

Hospitals and their OPO should develop a definition of "imminent death" that includes specific triggers for notifying the OPO about an imminent death.

In determining the appropriate threshold for the Glascow Coma Score (GCS), it is important to remember that if the threshold is too low, there may be too many "premature" deaths or situations where there is a loss of organ viability. Standards for appropriate GCS thresholds may be obtained from the hospital's OPO or organizations such as The Association of Organ Procurement Organizations.

Note that a patient with "severe, acute brain injury" is not always a trauma patient. For example, post myocardial infarction resuscitation may result in a patient with a beating heart and no brain activity.

The definition agreed to by the hospital and the OPO may include all of the elements listed above or just some of the elements. The definition should be tailored to fit the particular circumstances in each hospital.

Hospitals may not use "batch reporting" for deaths by providing the OPO with periodic lists of patient deaths, even if instructed to do so by the OPO. If the patient dies during a transfer from one hospital to another, it is the receiving hospital's responsibility to notify the OPO.

"**Timely notification**" means a hospital must contact the OPO by telephone as soon as possible after an individual has died, has been placed on a ventilator due to a severe brain injury, or who has been declared brain dead (ideally within 1 hour). That is, a hospital must notify the OPO while a brain dead or severely brain-injured, ventilator-dependent individual is still attached to the ventilator and as soon as possible after the death of any other individual, including a potential non-heart-beating donor. Even if the hospital does not

consider an individual who is not on a ventilator to be a potential donor, the hospital must call the OPO as soon as possible after the death of that individual has occurred.

Referral by a hospital to an OPO is timely if it is made:

- As soon as it is anticipated that a patient will meet the criteria for imminent death agreed to by the OPO and hospital or as soon as possible after a patient meets the criteria for imminent death agreed to by the OPO and the hospital (ideally, within one hour); **AND**

- Prior to the withdrawal of any life sustaining therapies (i.e., medical or pharmacological support).

Whenever possible, referral should be made early enough to allow the OPO to assess the patient's suitability for organ donation before brain death is declared and before the option of organ donation is presented to the family of the potential donor. Timely assessment of the patient's suitability for organ donation increases the likelihood that the patient's organs will be viable for transplantation (assuming there is no disease process identified by the OPO that would cause the organs to be unsuitable), assures that the family is approached only if the patient is medically suitable for organ donation, and assures that an OPO representative is available to collaborate with the hospital staff in discussing donation with the family.

It is the OPO's responsibility to determine medical suitability for organ donation, and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose.

Survey Procedures §482.45(a)(1)

- Review the hospital's written agreement with the OPO to verify that it addresses all required information.

- Verify that the hospital's governing body has approved the hospital's organ procurement policies.

- Review a sample of death records to verify that the hospital has implemented its organ procurement policies.

- Interview the staff to verify that they are aware of the hospital's policies and procedures for organ, tissue and eye procurement.

- Verify that the organ, tissue and eye donation program is integrated into the hospital's QAPI program.

A-0372

§482.45(a)(2) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

Interpretative Guidelines §482.45(a)(2)

The hospital must have an agreement with at least one tissue bank and at least one eye bank. The OPO may serve as a "gatekeeper" receiving notification about every hospital death and should notify the tissue bank or eye bank chosen by the hospital about potential tissue and eye donors.

It is not necessary for a hospital to have a separate agreement with a tissue bank if it has an agreement with its OPO to provide tissue procurement services; nor is it necessary for a hospital to have a separate agreement with an eye bank if its OPO provides eye procurement services. The hospital is not required to use the OPO for tissue or eye procurement but is free to have an agreement with the tissue bank or eye bank of its choice. The tissue banks and eye banks define "usable tissues" and "usable eyes."

The requirements of this regulation may be satisfied through a single agreement with an OPO that provides services for organ, tissue and eye, or by a separate agreement with another tissue and/or eye bank outside the OPO, chosen by the hospital. The hospital may continue current successful direct arrangements with tissue and eye banks as long as the direct arrangement does not interfere with organ procurement.

Survey Procedures §482.45(a)(2)

Verify that the hospital has an agreement with at least one tissue bank and one eye bank that specifies criteria for referral of all potential tissue and eye donors, or an agreement with an OPO that specifies the tissue bank and eye bank to which referrals will be made. The agreement should also acknowledge that it is the OPO's responsibility to determine medical suitability for tissue and eye donation, unless the hospital has an alternative agreement with a different tissue and/or eye bank.

A-0373

§482.45(a)(3) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its options to donate organs, tissues, or eyes, or to decline to donate.

Interpretive Guidelines §482.45(a)(3)

It is the responsibility of the OPO to screen for medical suitability in order to select potential donors. Once the OPO has selected a potential donor, that person's family must be informed of the family's donation options.

Ideally, the OPO and the hospital will decide together how and by whom the family will be approached.

Survey Procedures §482.45(a)(3)

- Verify that the hospital ensures that the family of each potential donor is informed of its options to donate organs, tissues, or eyes, including the option to decline to donate.

- Does the hospital have QAPI mechanisms in place to ensure that the families of all potential donors are informed of their options to donate organs, tissues, or eyes, or to decline to donate?

A-0374

§482.45(a)(3) continued
The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

Interpretive Guidelines §482.45(a)(3)

The individual designated by the hospital to initiate the request to a family must be an organ procurement representative, an **organizational representative of a tissue or eye bank**, or a designated requestor. Any individuals involved in a request for organ, tissue, and eye donation must be formally trained in the donation request process.

The individual designated by the hospital to initiate the request to the family must be an OPO, tissue bank, or eye bank representative or a designated requestor. A "**designated requestor**" is defined as a hospital-designated individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community.

Ideally, the OPO and the hospital will decide together how and by whom the family will be approached. If possible, the OPO representative and a designated requestor should approach the family together.

The hospital must ensure that any "designated requestor" for organs, tissues or eyes has completed a training course either offered or approved by the OPO, which addresses methodology for approaching potential donor families.

Survey Procedures §482.45(a)(3)

- Review training schedules and personnel files to verify that all designated requestors have completed the required training.
- How does the hospital ensure that only OPO, tissue bank, or eye bank staff or designated requestors are approaching families to ask them to donate?

A-0375

§482.45(a)(4) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

Interpretive Guidelines §482.45(a)(4)

Using discretion does not mean a judgment can be made by the hospital that certain families should not be approached about donation. Hospitals should approach the family with the belief that a donation is possible and should take steps to ensure the family is treated with respect and care. The hospital staff's perception that a family's grief, race, ethnicity, religion or socioeconomic background would prevent donation should never be used as a reason not to approach a family.

All potential donor families must be approached and informed of their donation rights.

Survey Procedures §482.45(a)(4)

- Interview a hospital-designated requestor regarding approaches to donation requests.
- Review the designated requestor training program to verify that it addresses the use of discretion.
- Review the hospital's complaint file for any relevant complaints.

A-0376

§482.45(a)(5) Ensure that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues;

Interpretive Guidelines §482.45(a)(5)

Appropriate hospital staff, including all patient care staff, must be trained on donation issues. The training program must be developed in cooperation with the OPO, tissue bank and eye bank, and should include, at a minimum:

- Consent process;
- Importance of using discretion and sensitivity when approaching families;
- Role of the designated requestor;
- Transplantation and donation, including pediatrics, if appropriate;
- Quality improvement activities; and
- Role of the organ procurement organization.

Training should be conducted with new employees annually, whenever there are policy/procedure changes, or when problems are determined through the hospital's QAPI program.

Those hospital staff who may have to contact or work with the OPO, tissue bank and eye bank staff must have appropriate training on donation issues including their duties and roles.

Survey Procedures §482.45(a)(5)

- Review in-service training schedules and attendance sheets.
- How does the hospital ensure that all appropriate staff has attended an educational program regarding donation issues and how to work with the OPO, tissue bank, and eye bank?

A-0377

§482.45(a)(5) continued
Reviewing death records to improve identification of potential donors; and

Interpretive Guidelines §482.45(a)(5)

Hospitals must cooperate with the OPOs, tissue banks and eye banks in regularly or periodically reviewing death records. This means that the hospital must develop policies and procedures which permit the OPO, tissue bank, and eye bank access to death record information that will allow the OPO, tissue bank and eye bank to assess the hospital's donor potential, assure that all deaths or imminent deaths are being referred to the OPO in a timely manner, and identify areas where the hospital, OPO, tissue bank and eye bank staff performance might be improved. The policies must address how patient confidentiality will be maintained during the review process.

Survey Procedures §482.45(a)(5)

- Verify by review of policies and records that the hospital works with the OPO, tissue bank, and eye bank in reviewing death records.
- Verify that the effectiveness of any protocols and policies is monitored as part of the hospital's quality improvement program.
- Validate how often the reviews are to occur. Review the protocols that are in place to guide record reviews and analysis.
- Determine how confidentiality is ensured.

A-0378

§482.45(a)(5) continued
Maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.

Interpretive Guidelines §482.45(a)(5)

The hospital must have policies and procedures, developed in cooperation with the OPO, that ensure that potential donors are maintained in a manner that maintains the viability of their organs. The hospital must have policies in place to ensure that potential donors are identified and declared dead within an acceptable time frame by an appropriate practitioner.

Survey Procedures §482.45(a)(5)

- Determine by review, what policies and procedures are in place to ensure that potential donors are identified and declared dead by an appropriate practitioner within an acceptable timeframe.

- Verify that there are policies and procedures in place to ensure the coordination between facility staff and OPO staff in maintaining the potential donor.

A-0379

§482.45(b) Standard: Organ Transplantation Responsibilities

(1) A hospital in which organ transplants are performed must be a member of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274) and abide by its rules. The term "rules of the OPTN" means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS Act which are enforceable under 42 CFR 121.10. No hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act, or with the requirements of this paragraph, unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing.

(2) For purposes of these standards, the term "organ" means a human kidney, liver, heart, lung, or pancreas.

(3) If a hospital performs any type of transplants, it must provide organ transplant related data, as requested by the OPTN, the Scientific Registry, and the OPOs. The hospital must also provide such data directly to the Department when requested by the Secretary.

Interpretive Guidelines §482.45(b)

If you have questions concerning the facility membership in the Organ Procurement and Transplantation Network; you may verify the membership by contacting the CMS regional office or by calling the United Network for Organ sharing (UNOS) at 1-804-330-8500.

Survey Procedures §482.45(b)

Verify by review, one year of reports submitted by the facility to the OPTN, the Scientific Registry, the OPOs, and any data submitted to the Department per request of the Secretary.

A-0384

§482.51 Condition of Participation: Surgical Services

If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

Interpretive Guidelines §482.51

The provision of surgical services is an optional hospital service. However, if a hospital provides any degree of surgical services to its patients, the hospital must comply with all the requirements of this Condition of Participation (CoP).

If surgical services are provided, they must be organized and staffed in such a manner to ensure the health and safety of patients.

Acceptable standards of practice include maintaining compliance with applicable Federal and State laws, regulations and guidelines governing surgical services or surgical service locations, as well as, any standards and recommendations promoted by or established by nationally recognized professional organizations (e.g., the American Medical Association, American College of Surgeons, Association of Operating Room Nurses, Association for Professionals in Infection Control and Epidemiology, etc.)

Outpatient surgical services must be in compliance with all hospital CoPs including the surgical services CoP. Outpatient surgical services must be provided in accordance with acceptable standards of practice. Additionally, the hospital's outpatient surgical services must be consistent in quality with the hospital's inpatient surgical services. Post-operative care planning, coordination for the provision of needed post-operative care and appropriate provisions for follow-up care of outpatient surgery patients must be consistent in quality with inpatient care in accordance with the complexity of the services offered and the needs of the patient.

The hospital's inpatient and outpatient surgical services must be integrated into its hospital-wide QAPI program.

Survey Procedures §482.51

- Inspect all inpatient and outpatient operative rooms/suites. Request the use of proper attire for the inspection. Observe the practices to determine if the services are provided in accordance with acceptable standards of practice. Observe:
    - That access to the operative and recovery area is limited to authorized personnel and that the traffic flow pattern adheres to accepted standards of practice;
    - The conformance to aseptic and sterile technique by all individuals in the surgical area;
    - That there is appropriate cleaning between surgical cases and appropriate terminal cleaning applied;
    - That operating room attire is suitable for the kind of surgical case performed, that persons working in the operating suite must wear only clean surgical costumes, that surgical costumes are designed for maximum skin and hair coverage;
    - That equipment is available for rapid and routine sterilization of operating room materials;
    - That equipment is monitored, inspected, tested, and maintained by the hospital's biomedical equipment program and in accordance with Federal and State law, regulations and guidelines and manufacturer's recommendations;
    - That sterilized materials are packaged, handled, labeled, and stored in a manner that ensures sterility e.g., in a moisture and dust controlled environment and policies and procedures for expiration dates have been developed and are followed in accordance with accepted standards of practice.
    - That temperature and humidity are monitored and maintained within accepted standards of practice;
    - That medical/surgical devices and equipment are checked and maintained routinely by clinical/biomedical engineers.
- Verify that all surgical service activities and locations are integrated into the hospital-wide QAPI program.

A-0385

§482.51(a) Standard: Organization and Staffing

The organization of the surgical services must be appropriate to the scope of the services offered.

Interpretive Guidelines §482.51(a)

When the hospital offers surgical services, the hospital must provide the appropriate equipment and the appropriate types and numbers of qualified personnel necessary to furnish the surgical services offered by the hospital in accordance with acceptable standards of practice.

The scope of surgical services provided by the hospital should be defined in writing and approved by the medical staff.

Survey Procedures §482.51(a)

Review the hospital's organizational chart displaying the relationship of the operating room service to other services. Confirm that the operating room's organization chart indicates lines of authority and delegation of responsibility within the department or service.

A-0386

§482.51(a)(1) The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.

Interpretive Guidelines §482.51(a)(1)

The operating room (inpatient and outpatient) must be supervised by an experienced RN or MD/DO. The RN or MD/DO supervising the operating room must demonstrate appropriate education, background working in surgical services, and specialized training in the provision of surgical services/management of surgical service operations. The hospital should address its required qualifications for the supervisor of the hospital's operating rooms in its policies and the supervisor's personnel file should contain information demonstrating compliance with the hospital's established qualifications.

Survey Procedures §482.51(a)(1)

- Verify that an RN or a doctor of medicine or osteopathy is assigned responsibility for supervision of the operating rooms.

- Request a copy of the supervisor's position description to determine that it specifies qualifications, duties and responsibilities of the position. Verify that the supervisor is experienced and competent in the management of surgical services.

A-0387

§482.51(a)(2) Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as "scrub nurses" under the supervision of a registered nurse.

Interpretive Guidelines §482.51(a)(2)

If the hospital utilizes LPN or operating room technicians as "scrub nurses," those personnel must be under the supervision of an RN who is immediately available to physically intervene and provide care.

Survey Procedures §482.51(a)(2)

- Determine that an RN is available for supervision in the department or service. Validate the availability by requesting and reviewing a staffing schedule for the OR.

- Review staffing schedules to determine adequacy of staff and RN supervision.

A-0388

§482.51(a)(3) Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies.

Interpretive Guidelines §482.51(a)(3)

The circulating nurse must be an RN. An LPN or surgical technologist may assist an RN in carrying out circulatory duties (in accordance with applicable State laws and medical-staff approved hospital policy) but the LPN or surgical technologist must be under the supervision of the circulating RN who is in the operating suite and who is available to immediately and physically respond/intervene to provide necessary interventions in emergencies. The supervising RN would not be considered immediately available if the RN was located outside the operating suite or engaged in other activities/duties which prevent the RN from immediately intervening and assuming whatever circulating activities/duties that were being provided by the LPN or surgical technologist. The hospital, in accordance with State law and acceptable standards of practice, must establish the qualifications required for RNs who perform circulating duties and LPNs and surgical technologists who assist with circulating duties.

Survey Procedures §482.51(a)(3)

- If LPNs and surgical technologists (STs) are assisting with circulating duties, verify that they do so in accordance with applicable State laws and medical-staff approved policies and procedures.

- Verify in situations where LPNs and STs are permitted to assist with circulating duties that a qualified RN supervisor is immediately available to respond to emergencies.

- Verify that RNs working as circulating nurses are working in accordance with applicable State laws and medical-staff approved policies and procedures.

A-0389

§482.51(a)(4) Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.

Interpretive Guidelines §482.51(a)(4)

Surgical privileges should be reviewed and updated at least every 2 years. A current roster listing each practitioner's specific surgical privileges must be available in the surgical suite and area/location where the scheduling of surgical procedures is done. A current list of surgeons suspended from surgical privileges or whose surgical privileges have been restricted must also be retained in these areas/locations.

The hospital must delineate the surgical privileges of all practitioners performing surgery and surgical procedures. The medical staff is accountable to the governing body for the quality of care provided to patients. The medical staff bylaws must include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. Surgical privileges are granted in accordance with the competencies of each practitioner. The medical staff appraisal procedures must evaluate each individual practitioner's training, education, experience, and demonstrated competence as established by the hospital's QAPI program, credentialing process, the practitioner's adherence to hospital policies and procedures, and in accordance with scope of practice and other State laws and regulations.

The hospital must specify the surgical privileges for each practitioner that performs surgical tasks. This would include practitioners such as MD/DO, dentists, oral surgeons, podiatrists, RN first assistants, nurse practitioners, surgical physician assistants, surgical technicians, etc. When a practitioner may perform certain surgical procedures under supervision, the specific tasks/procedures and the degree of supervision (to include whether or not the supervising practitioner is physically present in the same OR, in line of sight of the practitioner being

supervised) be delineated in that practitioner's surgical privileges and included on the surgical roster.

If the hospital utilizes RN First Assistants, surgical PA, or other non-MD/DO surgical assistants, the hospital must establish criteria, qualifications and a credentialing process to grant specific privileges to individual practitioners based on each individual practitioner's compliance with the privileging/credentialing criteria and in accordance with Federal and State laws and regulations. This would include surgical services tasks conducted by these practitioners while under the supervision of an MD/DO.

When practitioners whose scope of practice for conducting surgical procedures requires the direct supervision of an MD/DO surgeon, the term "supervision" would mean the supervising MD/DO surgeon is present in the same room, working with the same patient.

Surgery and all surgical procedures must be conducted by a practitioner who meets the medical staff criteria and procedures for the privileges granted, who has been granted specific surgical privileges by the governing body in accordance with those criteria, and who is working within the scope of those granted and documented privileges.

Survey Procedures §482.51(a)(4)

- Review the hospital's method for reviewing the surgical privileges of practitioners. This method should require a written assessment of the practitioner's training, experience, health status, and performance.

- Determine that a current roster listing each practitioner's specific surgical privileges is available in the surgical suite and the area where the scheduling of surgical procedures is done.

- Determine that a current list of surgeons suspended from surgical privileges or who have restricted surgical privileges is retained in these areas/locations.

A-0390

§482.51(b) Standard: Delivery of Service

Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

Interpretive Guidelines §482.51(b)

Policies governing surgical care should contain:

- Aseptic and sterile surveillance and practice, including scrub techniques;

- Identification of infected and non-infected cases;
- Housekeeping requirements/procedures;
- Patient care requirements:
    - Preoperative work-up;
    - Patient consents and releases;
    - Clinical procedures;
    - Safety practices;
    - Patient identification procedures;
- Duties of scrub and circulating nurse;
- Safety practices;
- The requirement to conduct surgical counts in accordance with accepted standards of practice;
- Scheduling of patients for surgery;
- Personnel policies unique to the O.R.;
- Resuscitative techniques;
- DNR status;
- Care of surgical specimens;
- Malignant hyperthermia
- Appropriate protocols for all surgical procedures performed. These may be procedure-specific or general in nature and will include a list of equipment, materials, and supplies necessary to properly carry out job assignment;
- Sterilization and disinfection procedures;
- Acceptable operating room attire;
- Handling infections and biomedical/medical waste; and

- Outpatient surgery post-operative care planning and coordination, and provisions for follow-up care.

Policies and procedures must be written, implemented and enforced. Surgical services' policies must be in accordance with acceptable standards of medical practice and surgical patient care.

Survey Procedures §482.51(b)

Review policies and procedures, ascertain whether they contain the minimum policies specified in the interpretive guidelines.

A-0391

§482.51(b)(1) There must be a complete history and physical work-up in the chart of every patient prior to surgery, except in emergencies. If this has been dictated, but not yet recorded in the patient's chart, there must be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient.

Interpretive Guidelines §482.51(b)(1)

There must be a complete history and physical examination (H & P) in the medical record of every patient prior to surgery, except in emergencies.

In all circumstances, when an H & P has been conducted, but is not present on the chart prior to surgery, or in emergency situations where a complete H & P cannot be conducted prior to surgery, a brief admission note on the chart is necessary. The note should include at a minimum critical information about the patient's condition including pulmonary status, cardiovascular status, BP, vital signs, etc.

An H & P must be performed by an MD/DO or oromaxillofacial surgeon, for patients receiving oromaxillofacial surgery, no more than 7 days prior to hospital admission/outpatient surgery or 48 hours after hospital admission but prior to surgery/outpatient surgery.

Admission H & P

A H& P would meet the CMS requirements that a H & P be "performed no more than 7 days prior to admission or within 48 hours after admission," if:

- The H & P was performed within 30 days prior to the hospital admission; AND

- An appropriate assessment performed by the MD/DO, which must include a physical assessment of the patient to update any components of the patient's current medical status that may have changed since the prior H & P or to address any areas where more current data is needed, was completed within 7 days prior to admission or 48

hours after admission, but prior to surgery, confirming that the necessity for the procedure or care is still present and the H & P is still current. The physician uses his/her clinical judgment based on his/her assessment of the patient's condition, and any co-morbidities, in relation to the reason the patient was admitted or to the surgery to be performed, when deciding what depth of assessment needs to be performed and what information needs to be included in the update note; AND

- The physician or other individual qualified to perform the H & P writes an update note addressing the patient's current status and/or any changes in the patient's status, regardless of whether there were any changes in the patient's status, within 7 days prior to, or within 48 hours after admission, but prior to surgery. The update note must be on or attached to the H & P, AND

- The H & P, including all updates and assessments, must be included within 48 hours after admission, but prior to surgery (except in emergency situations), in the patient's medical record for this admission.

If a H & P meets all these requirements within 7 days prior to admission, or within 48 hours after admission, the H & P meets the provisions of the regulation with regard to justifying the admission and meeting the time restrictions on the currency of the H & P.

Outpatient Surgery H & P

Furthermore, a H & P would meet the CMS requirement at §482.51(b)(1) that "There must be a complete history and physical work-up in the chart of every patient prior to surgery…" if:

- The H & P was performed within 30 days prior to the outpatient surgery; AND

- An appropriate assessment performed by the MD/DO, which should include a physical examination of the patient to update any components of the patients current medical status that may have changed since the prior H & P or to address any areas where more current data is needed, was completed within 7 days prior to outpatient surgery confirming that the necessity for the procedure is still present and that the H & P is still current. The physician uses his/her clinical judgment based on his/her assessment of the patient's condition, and any co-morbidities, in relation to the surgery to be performed, when deciding what depth of assessment needs to be performed and what information needs to be included in the update note; AND

- The physician or other individual qualified to perform the H & P writes an update note addressing the patient's current status and/or changes in the patient's status, regardless of whether there were any changes in the patient's status, within 7 days prior to the outpatient surgery. The update note must be on or attached to the H & P; AND

- The H & P, including all updates and assessment, must be included in the patient's medical record, except in emergency situations, prior to surgery.

If a H & P meets all these requirements prior to outpatient surgery, the H & P meets all the provisions of the regulation with regard to meeting the time restrictions on the currency of the H & P.

An H & P performed more than 30 days prior to hospital admission/outpatient surgery does not comply with the currency requirements and a new H & P must be performed.

An H & P performed more than 7 days prior to admission/outpatient surgery that does not meet the above currency criteria does not comply with the requirements and a new H & P must be performed.

All or part of the H & P may be delegated to other practitioners in accordance with State law and hospital policy, but the MD/DO must sign the H & P and as applicable, the update note and assume full responsibility for the H & P (update assessments and update notes are considered part of the H & P). This means that a nurse practitioner or a physician assistant meeting these criteria may perform the H & P and/or the update assessment and note.

Survey Procedures §482.51(b)(1)

Review a minimum of six medical records of surgical patients to determine if a complete history and physical examination by a doctor of medicine or osteopathy is completed prior to surgery, except in an emergency, and in accordance with the methodology described above.

A-0392

§482.51(b)(2) A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies.

Interpretive Guidelines §482.51(b)(2)

A properly executed informed consent form contains at least the following:

- Name of patient, and when appropriate, patient's legal guardian;
- Name of hospital;
- Name of procedure(s);
- Name of practitioner(s) performing the procedure(s) or important aspects of the procedure(s), as well as the name(s) and specific significant surgical tasks that will be conducted by practitioners other than the primary surgeon/practitioner. (Significant surgical tasks include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues);

- Risks;
- Alternative procedures and treatments;
- Signature of patient or legal guardian;
- Date and time consent is obtained;
- Statement that procedure was explained to patient or guardian;
- Signature of professional person witnessing the consent; and
- Name/signature of person who explained the procedure to the patient or guardian.

The responsible practitioner must disclose to the patient information necessary to enable the patient to evaluate a proposed medical or surgical procedure before submitting to it. Informed consent requires that a patient have a full understanding of that to which he or she has consented. An authorization from a patient who does not understand what he/she is consenting to is not informed consent.

Consent would not be considered informed consent in situations where the patient consents to a procedure and information was withheld from the patient, where if the patient had been informed of the withheld information, the patient may not have consented to the procedure or made the same decisions.

Patients must be given sufficient information to allow them to make intelligent choices from among the alternative courses of available treatment for their specific ailments. Informed consent must be given despite a patient's anxiety or indecisiveness.

The responsible practitioner must provide as much information about treatment options as is necessary based on a patient's personal understanding of the practitioner's explanation of the risks of treatment and the probable consequences of the treatment.

Informed consent means the patient or patient representative is given (in a language or means of communication he/she understands) the information needed in order to consent to a procedure or treatment.

An informed consent would include at least: an explanation of the nature and purpose of the proposed procedures, risks and consequences of the procedures, risks and prognosis if no treatment is rendered, the probability that the proposed procedure will be successful, and alternative methods of treatment (if any) and their associated risks and benefits. Furthermore, informed consent would include that the patient is informed as to who will actually perform surgical interventions that are planned. When practitioners other than the primary surgeon will perform important parts of the surgical procedures, even when under

the primary surgeon's supervision, the patient must be informed of who these other practitioners are, as well as, what important tasks each will carry out.

Survey Procedures §482.51(b)(2)

Review a minimum of six random medical records of surgical patients to verify that they contain consent forms. Ascertain that the completed forms contain at least the information specified in the interpretive guidelines.

A-0393

§482.51(b)(3) The following equipment must be available to the operating room suites: call-in system, cardiac monitor, resuscitator, defibrillator, aspirator, and tracheotomy set.

Survey Procedures §482.51(b)(3)

- Check to determine that the operating room suite has available the items listed:
    - On-call system;
    - Cardiac monitor;
    - Resuscitator;
    - Defibrillator;
    - Aspirator (suction equipment);
    - Tracheotomy set (a cricothyroidotomy set is not a substitute)

Verify that all equipment is working and, as applicable, in compliance with the hospital's biomedical equipment inspection, testing, and maintenance program.

A-0394

§482.51(b)(4) There must be adequate provisions for immediate post-operative care.

Interpretive Guidelines §482.51(b)(4)

Adequate provisions for immediate post-operative care means:

- Post operative care must be in accordance with acceptable standards of practice.
- The post-operative care area or recovery room is a separate area of the hospital. Access is limited to authorized personnel.

- Policies and procedures specify transfer requirements to and from the recovery room. Depending on the type of anesthesia and length of surgery, the post-operative check before transferring the patient from the recovery room should include some of the following:
    - Level of activity;
    - Respirations;
    - Blood pressure;
    - Level of consciousness;
    - Patient color;
- If the patients are not transferred to the recovery room, determine that provisions are made for close observation until they have regained consciousness, e.g., direct observation by a qualified RN in the patient's room.

Survey Procedures §482.51(b)(4)

- Verify that the hospital has provisions for post-operative care.
- Determine that there are policies and procedures that govern the recovery room area.

A-0395

§482.51(b)(5) The operating room register must be complete and up to date.

Interpretive Guidelines §482.51(b)(5)

The register includes at least the following information:

- Patient's name;
- Patient's hospital identification number;
- Date of the operation;
- Inclusive or total time of the operation;
- Name of the surgeon and any assistant(s);
- Name of nursing personnel (scrub and circulating);

- Type of anesthesia used and name of person administering it;
- Operation performed;
- Pre and post-op diagnosis;
- Age of patient.

Survey Procedures §482.51(b)(5)

Examine the OR register or equivalent record which lists all surgery performed by the surgery service. Determine that the register includes items specified in the interpretive guidelines.

A-0396

§482.51(b)(6) An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.

Interpretive Guidelines §482.51(b)(6)

The operative report includes at least:

- Name and hospital identification number of the patient;
- Date and times of the surgery;
- Name(s) of the surgeon(s) and assistants or other practitioners who performed surgical tasks (even when performing those tasks under supervision);
- Pre-operative and post-operative diagnosis;
- Name of the specific surgical procedure(s) performed;
- Type of anesthesia administered;
- Complications, if any;
- A description of techniques, findings, and tissues removed or altered;
- Surgeons or practitioners name(s) and a description of the specific significant surgical tasks that were conducted by practitioners other than the primary surgeon/practitioner

(significant surgical procedures include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues); and

- Prosthetic devices, grafts, tissues, transplants, or devices implanted, if any.

Survey Procedures §482.51(b)(6)

Review a minimum of six random medical records of patients who had a surgical encounter. Verify that they contain a surgical report that is dated and signed by the responsible surgeon and includes the information specified in the interpretive guidelines.

A-0416

§482.52 Condition of Participation: Anesthesia Services

If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.

Interpretive Guidelines §482.52

The provision of anesthesia services is an optional hospital service. However, if a hospital provides any degree of anesthesia service to its patients, the hospital must comply with all the requirements of this Condition of Participation (CoP).

The hospital's anesthesia services must be integrated into the hospital-wide QAPI program.

The anesthesia services must be under the direction of a qualified MD/DO. The hospital's medical staff establishes criteria for the qualifications for the director of the anesthesia services in accordance with State laws and acceptable standards of practice. A single anesthesia director must be responsible for the single hospital-wide anesthesia service.

The single anesthesia service is responsible for all anesthesia administered in the hospital. The anesthesia service must be organized and staffed in such a manner as to ensure the health and safety of patients.

Survey Procedures §482.52

- Request a copy of the organizational chart for anesthesia services. Determine that a doctor of medicine or osteopathy has the authority and responsibility for directing the administration of all anesthesia throughout the hospital.

- Request evidence of the director's appointment. Review the position description. Confirm that the director's responsibilities include at least the following:

    - Planning, directing, and supervising all activities of the service

  - Establishing staffing schedules, including written on-call schedule for anesthesia coverage when the department is normally closed
  - Monitoring of the quality and appropriateness of the anesthesia patient care
- Evidence of responsibility for anesthesia services delivered in all areas of the hospital where applicable:
  - Operating room suite(s), both inpatient and outpatient;
  - Obstetrical suite(s);
  - Radiology department;
  - Clinics;
  - Outpatient surgery areas.
- Verify that anesthesia services is integrated into the hospital-wide QAPI program.

A-0417

§482.52(a) Standard: Organization and Staffing

The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered only by --

(1) A qualified anesthesiologist;

(2) A doctor of medicine or osteopathy (other than an anesthesiologist);

(3) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;

(4) A certified registered nurse anesthetist (CRNA), as defined in §410.69(b) of this chapter, who, unless exempted in accordance with paragraph (c) of this section, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or

§482.52(c) Standard: State Exemption

(1) A hospital may be exempted from the requirement for MD/DO supervision of CRNAs as described in paragraph (a)(4) of this section, if the State in which the hospital is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting

exemption from MD/DO supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current MD/DO supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.]

(5) An anesthesiologist's assistant, as defined in Sec. 410.69(b) of this chapter, who is under the supervision of an anesthesiologist who is immediately available if needed.

Interpretive Guidelines §482.52(a)

The medical staff bylaws must include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. The hospital must specify the anesthesia privileges for each practitioner that administers anesthesia, or who supervises the administration of anesthesia by another practitioner. The privileges granted must be in accordance with State law and hospital policy. The type and complexity of procedures for which the practitioner may administer anesthesia, or supervise another practitioner supervising anesthesia, must be specified in the privileges granted to the individual practitioner.

A dentist, oral surgeon, or podiatrist may administer anesthesia in accordance with State law, their scope of practice and hospital policy. The anesthesia privileges of each practitioner must be specified. Anesthesia privileges are granted in accordance with the practitioner's scope of practice, State law, the individual competencies, education and training of the practitioner and the practitioner's compliance with the hospital's credentialing criteria.

When a hospital permits operating practitioners to supervise CRNA administering anesthesia, the medical staff must specify in the statement of privileges for each category of operating practitioner, the type and complexity of procedures they may supervise.
A CRNA may administer anesthesia when under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed (unless supervision is exempted in accordance with §482.52(c)). An anesthesiologist's assistant may administer anesthesia when under the supervision of an anesthesiologist who is immediately available if needed. " Immediately available" to intervene includes at a minimum, that the supervising anesthesiologist or operating practitioner, as applicable, is:

- Physically located within the operative suite or in the labor and delivery unit;
- Prepared to immediately conduct hands-on intervention if needed; and
- Not engaged in activities that could prevent the supervising practitioner from being able to immediately intervene and conduct hands-on interventions if needed.

Survey Procedures §482.52(a)

- Review the qualifications of individuals authorized to deliver anesthesia.
- Determine that there is documentation of current licensure or current certification status for all persons administering anesthesia.

A-0418

§482.52(b) Standard: Delivery of Services

Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of pre-anesthesia and post-anesthesia responsibilities. The policies must ensure that the following are provided for each patient:

Interpretive Guidelines §482.52(b)

Policies at a minimum address:

- The qualifications, responsibilities and supervision required of all personnel who administer anesthesia;
- Patient consent;
- Infection control measures;
- Safety practices in all anesthetizing areas;
- Protocol for supportive life functions, e.g., cardiac and respiratory emergencies;
- Reporting requirements;
- Documentation requirements;
- Equipment requirements, as well as the monitoring, inspection, testing and maintenance of anesthesia equipment in the hospital's biomedical equipment program.

Survey Procedures §482.52(b)

Review the policies developed on anesthesia procedures. Determine that the anesthesia service incorporates the minimum policies identified in interpretive guidelines.

A-0419

§482.52(b)(1) A pre-anesthesia evaluation by an individual qualified to administer anesthesia under paragraph (a) of this section performed within 48 hours prior to surgery.

Interpretive Guidelines §482.52(b)(1)

The pre-anesthesia evaluation must be performed within 48 hours of inpatient or out-patient surgery. An individual qualified to administer anesthesia in accordance with §482.52(a) must perform the pre-anesthesia evaluation. At a minimum, the pre-operative anesthetic evaluation includes:

- Notation of anesthesia risk;
- Anesthesia, drug and allergy history;
- Any potential anesthesia problems identified;
- Patient's condition prior to induction of anesthesia

Survey Procedures §482.52(b)(1)

Review records to determine that each patient has a pre-anesthesia evaluation by an individual qualified to administer anesthesia. The evaluation must be performed within 48 hours prior to surgery.

A-0420

§482.52(b)(2) An intraoperative anesthesia record.

Interpretive Guidelines §482.52(b)(2)

The intraoperative anesthesia record includes at a minimum:

- Name and hospital identification number of the patient;
- Name of practitioner who administered anesthesia, and as applicable, the name and profession of the supervising anesthesiologist or operating practitioner;
- Name, dosage, route and time of administration of drugs and anesthesia agents;
- IV fluids;

- Blood or blood products, if applicable;
- Oxygen flow rate;
- Continuous recordings of patient status noting blood pressure, heart and respiration rate; and
- Any complications or problems occurring during anesthesia, including time and description of symptoms, vital signs, treatments rendered, and patient's response to treatment.

Survey Procedures §482.52(b)(2)

Review records to determine that each patient has an intraoperative anesthesia record documenting all pertinent events taking place during anesthesia.

A-0421

§482.52(b)(3) With respect to inpatients, a post-anesthesia follow-up report by the individual who administers the anesthesia that is written within 48 hours after surgery.

Interpretive Guidelines §482.52(b)(3)

The post-anesthesia follow-up report must be written within 48 hours after the inpatient surgery. The follow-up report must be written by the individual who administered the anesthesia or in accordance with §482.12(c)(1)(i), an MD/DO may delegate the post-anesthesia assessment and writing the post-anesthesia follow-up report to practitioners qualified to administer anesthesia in accordance with State law and hospital policy. When delegation of the post-anesthesia follow-up report is permitted, the medical staff must address its delegation requirements and methods in its bylaws. At a minimum, the post-anesthesia follow-up report documents the following:

- Cardiopulmonary status;
- Level of consciousness;
- Any follow-up care and/or observations;
- Any complications occurring during post-anesthesia recovery

Survey Procedures §482.52(b)(3)

Review records to determine that a post-anesthesia follow-up report is written for each patient by the individual who administered the anesthesia, or by a delegated practitioner who is qualified to administer anesthesia, within 48 hours after surgery. Documentation should include those items specified in interpretive guidelines.

A-0422

§482.52(b)(4) With respect to outpatients, a post-anesthesia evaluation for proper anesthesia recovery performed in accordance with policies and procedures approved by the medical staff.

Interpretive Guidelines §482.52(b)(4)

A post-anesthesia evaluation must be conducted on patients who have had outpatient surgery. The evaluation must be documented in the patient's medical record. The evaluation must be performed in accordance with policies and procedures approved by the medical staff and in accordance with State law and acceptable standards of practice.

At a minimum, the outpatient surgery post-anesthesia evaluation includes and documents:

- Cardiopulmonary status;
- Level of consciousness;
- Any complications occurring during post-anesthesia recovery; and
- Any follow-up care needed or patient instructions given.

Survey Procedures §482.52(b)(4)

Review records to determine that outpatients have a post-anesthesia evaluation for proper anesthesia recovery in accordance with hospital policies and procedures. Depending on the type of anesthesia and length of surgery, the post-operative check should include the items listed in the interpretive guidelines.

A-0428

§482.53 Condition of Participation: Nuclear Medicine Services

If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.

Interpretative Guidelines §482.53

This is an optional hospital service. However, if a hospital provides any degree of nuclear medicine services to its patients, the hospital must comply with the requirements of this Condition of Participation.

The hospital's nuclear medicine services must be integrated into its hospital-wide QAPI program.

If nuclear medicine services are provided under arrangement, the governing body must ensure that the services are provided in a safe and effective manner, in accordance with §482.12(e).

Nuclear medicine services must be provided in accordance with acceptable standards of practice. Acceptable standards of practice include maintaining compliance with applicable Federal and State laws, regulations and guidelines governing the use of nuclear medicine, including facility licensure and/or certification requirements, as well as any standards and recommendations promoted by nationally recognized professional organizations (e.g., the American Medical Association, American College of Radiology, etc).

Survey Procedures §482.53

- Determine if the hospital provides nuclear medicine services. If nuclear medicine services are offered, determine the type(s) of services provided and the location where each service is provided.

- Determine if the hospital's nuclear medicine services are integrated into its hospital-wide QAPI program.

A-0429

§482.53(a) Standard: Organization and Staffing

The organization of the nuclear medicine service must be appropriate to the scope and complexity of the services offered.

Interpretive Guidelines §482.53(a)

The hospital must provide the appropriate equipment and types and numbers of qualified personnel necessary to furnish the services offered by the hospital in accordance with acceptable standards of practice.

The scope of nuclear medicine services offered by the hospital should be defined in writing, and approved by the Medical staff.

Survey Procedures §482.53(a)

Review the hospital policies & procedures to verify that the scope of the nuclear medicine services offered is defined in writing.

A-0430

§482.53(a)(1) There must be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.

Interpretive Guidelines §482.53(a)(1)

The nuclear medicine service director must be a doctor of medicine or osteopathy and must demonstrate through education, experience and specialized training that he/she is qualified in nuclear medicine, appropriate to the scope and complexity of services offered.

Survey Procedures §482.53(a)(1)

Review the service director's credentialing file to verify that he/she is a M.D. or D.O. and has the necessary education, experience and specialized training in nuclear medicine, appropriate to the scope and complexity of services offered.

A-0431

§482.53(a)(2) The qualifications, training, functions and responsibilities of the nuclear medicine personnel must be specified by the service director and approved by the medical staff.

Interpretive Guidelines §482.53(a)(2)

The hospital must have written policies, developed and approved by the nuclear medicine service director and medical staff, that specify the qualifications, training, functions and experience of personnel responsible for performing each type of nuclear medicine procedure. Qualifications include at a minimum, job title, education, experience, specialized training, and licensure/certification, consistent with Federal and State law.

Survey Procedures §482.53(a)(2)

- Review personnel files for nuclear medicine staff to verify that they meet the necessary qualifications, specified by the medical staff, to perform their specified duties and responsibilities.

- Verify that the qualifications, training, functions and responsibilities of nuclear medicine staff are specified by the director and approved by the medical staff.

A-0432

§482.53(b) Standard: Delivery of Service

Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.

Interpretive Guidelines §482.53(b)

The hospital must establish, in writing, safety standards for radioactive materials that address, at a minimum:

- Handling of equipment and radioactive materials;
- Protection of patients and personnel from radiation hazards;
- Labeling of radioactive materials, waste, and hazardous areas;
- Transportation of radioactive materials between locations within the hospital;
- Security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials;
- Testing of equipment for radiation hazards;
- Maintenance of personal radiation monitoring devices;
- Storage of radio nuclides and radio pharmaceuticals as well as radioactive waste; and
- Disposal of radio nuclides, unused radio pharmaceuticals, and radioactive waste.

The hospital must implement and ensure compliance with its established safety standard

Survey Procedures §482.53(b)

- Verify that safety precautions are followed in the functioning of the nuclear medicine service and that personnel and patients wear appropriate body shielding (e.g., lead aprons or lead gloves) when appropriate.
- Verify that radioactive materials are prepared, labeled, used, transported, stored and disposed of in accordance with Federal and State laws and regulations and acceptable standards of practice.

A-0433

§482.53(b)(1) In-house preparation of radio pharmaceuticals is by, or under, the direct supervision of an appropriately trained registered pharmacist or doctor of medicine or osteopathy.

Interpretive Guidelines §482.53(b)(1)

In-house preparation of radio pharmaceuticals must be performed by, or directly supervised by, a registered pharmacist or MD/DO who is qualified through education, experience and training, in the preparation of radio pharmaceuticals, consistent with Federal and State law.

Survey Procedures §482.53(b)(1)

If radio pharmaceuticals are prepared in-house, determine that the preparation is performed by, or directly supervised by, a registered pharmacist or MD/DO who is qualified through education, experience and training, consistent with Federal and State law.

A-0434

§482.53(b)(2) There is proper storage and disposal of radioactive material.

Survey Procedures §482.53(b)(2)

- Verify through observation and document review that radioactive materials, including radioactive waste, have appropriate storage and disposal.
- Determine how the hospital disposes of unneeded radio nuclides and radio pharmaceuticals.
    - Are these methods in accordance with Federal and State laws, regulations and guidelines?
    - Are the methods described in hospital policy?

A-0435

§482.53(b)(3) If laboratory tests are performed in the nuclear medicine service, the service must meet the applicable requirement for laboratory services specified in §482.27.

Interpretive Guidelines §482.53(b)(3)

Refer to the guidelines under §482.27 for independent laboratory if laboratory tests are performed in the nuclear medicine service.

All in vitro tests and all in vivo procedures classified under radio bioassay must be performed in accordance with the requirements of §482.27 including quality control calibration and record retention, etc.

A-0436

§482.53(c) Standard: Facilities

Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance.

Interpretive Guidelines §482.53(c)

The nuclear medicine service must function in accordance with applicable Federal and State regulations and guidelines governing radiation safety. For more information, see 21 CFR Subpart J, "Radiological Health," and 10 CFR, Chapter 1, Part 20, "U.S. Nuclear Regulatory Commission Standards for Protection Against Ionizing Radiation."

Reagents must be labeled to ensure proper identification, use, storage and safe handling and date of preparation and assay.

A-0437

§482.53(c) The equipment must be--

(1) Maintained in safe operating condition; and

(2) Inspected, tested and calibrated at least annually by qualified personnel.

Interpretive Guidelines §482.53(c)(1-2)

The hospital must develop and implement a preventive maintenance schedule to ensure that nuclear medicine equipment is maintained in safe operating condition to ensure accurate results and patient, staff, and public safety.
Nuclear medicine equipment must be inspected, tested and calibrated at least annually by qualified personnel in accordance with Federal and State laws, regulations and guidelines.

Survey Procedures §482.53(c)(1-2)

Verify that the nuclear medicine service follows its preventive maintenance schedule and that any problems identified are corrected in a timely manner.

Review preventive maintenance records to verify that equipment is inspected, tested and calibrated at least annually by qualified personnel.

A-0438

§482.53(d) Standard: Records

The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.

Interpretive Guidelines §482.53(d)

The hospital must maintain records for all nuclear medicine procedures performed. At a minimum, the records must include signed and dated reports of nuclear medicine interpretations, consultations, and procedures. Nuclear medicine patient records, including interpretations, consultations, and procedures are patient medical records and the hospital must comply with the Medical Records CoP (§482.24).

A-0439

§482.53(d)(1) The hospital must maintain copies of nuclear medicine reports for at least 5 years.

Interpretive Guidelines §482.53(d)(1)

Nuclear medicine patient records, like all patient medical records, must be maintained in accordance with the Medical Records CoP (§482.24).

Survey Procedures §482.53(d)(1)

Verify that copies of nuclear medicine reports are maintained for at least 5 years.

A-0440

§482.53(d)(2) The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretation of these tests.

Survey Procedures §482.53(d)(2)

Verify that reports of nuclear medicine interpretations are signed and dated only by practitioners authorized by the medical staff to perform these interpretations.

A-0441

§482.53(d)(3) The hospital must maintain records of the receipt and distribution of radio pharmaceuticals.

Survey Procedures §482.53(d)(3)

Verify that the hospital maintains accurate records of the receipt and distribution of radio pharmaceuticals. Request to see the most recent documentation for the delivery of radio pharmaceuticals.

A-0442

§482.53(d)(4) Nuclear medicine services must be ordered only by practitioners whose scope of Federal or State licensure and whose defined staff privileges allow such referrals.

Survey Procedures §482.53(d)(4)

Verify that nuclear medicine services are ordered only by practitioners authorized to do so by the medical staff, consistent with Federal and State law.

A-0446

§482.54 Condition of Participation: Outpatient Services

If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.

Interpretive Guidelines §482.54

This is an optional hospital service, however, if a hospital provides any degree of outpatient care to its patients, the hospital must comply with the requirements of this Condition of Participation (CoP).

The Medicare Hospital CoP apply to both inpatient and outpatient services of the hospital. The hospital must be in compliance with the CoP in 42 CFR §482 in all on-campus and off-campus outpatient service locations.

All outpatient services provided by the hospital, both on campus and at any provider-based clinics, must meet the needs of the patients, in accordance with acceptable standards of practice. The hospital must ensure that services, equipment, staff, and facilities are adequate to provide the outpatient services offered at each location in accordance with acceptable standards of practice.

If the hospital offers outpatient surgical services, the Surgical Services CoP (§482.5) requires that the offered services must be consistent in quality with inpatient care in accordance with the services offered.

The hospital's outpatient services must be integrated into its hospital-wide QAPI program.

Acceptable standards of practice include standards that are set forth in Federal or State laws, regulations or guidelines, as well as standards and recommendations promoted by nationally recognized professional organizations (e.g., the American Medical Association, American College of Radiology, American College of Surgeons, etc).

Survey Procedures §482.54

- Verify that equipment, staff and facilities are adequate to provide the outpatient services offered at each location are in accordance with acceptable standards of practice.
- Verify that outpatient services at all locations are in compliance with the hospital CoP.
- Determine locations and type(s) of outpatient services provided.
- Verify that the hospital's outpatient services are integrated into its hospital-wide QAPI program.

A-0447

§482.54(a) Standard: Organization

Outpatient services must be appropriately organized and integrated with inpatient services.

Interpretive Guidelines §482.54(a)

The organization of the hospital's outpatient services must be appropriate to the scope and complexity of services offered.

The hospital's outpatient services, at all locations, must be integrated with inpatient services (e.g., medical records, radiology, laboratory, surgical services, anesthesia (including pain management) services, other diagnostic services, etc), as appropriate to the outpatient services offered. The hospital must have written policies in place to assure the integration of outpatient services, including an established method of communication between outpatient service departments to corresponding inpatient services.

The hospital must coordinate the care, treatment and services provided to a patient. In order to provide continuity of care, it should have an established method of communication between inpatient services and outpatient care in order to provide continuity of care to its patients.

Survey Procedures §482.53(a)

- Verify that the outpatient services are organized in a manner appropriate to the scope and complexity of services offered.
- Verify that the hospital has an established method of communication and established procedures to assure integration with inpatient services to provide continuity of care.
- Review medical records of outpatients who were later admitted to the hospital in order to determine that pertinent information from the outpatient record has been included in the inpatient record.
- Determine that each outpatient service location is integrated with the appropriate hospital inpatient services in accordance with the needs of the patient care provided at each of those locations.

A-0448

§482.54(b) Standard: Personnel

The Hospital must:

(1) Assign an individual to be responsible for outpatient services; and

(2) Have appropriate professional and nonprofessional personnel available.

Interpretive Guidelines §482.54(b)

The outpatient services department must be accountable to a single individual who directs the overall operation of the hospital's entire outpatient services (all locations, all outpatient services). The hospital should define in writing the qualifications and competencies necessary to direct the outpatient services. Qualifications include necessary education, experience and specialized training consistent with State law and acceptable standards of practice.

Adequate types and numbers of qualified professional and nonprofessional personnel must be available to provide patients with the appropriate level of care and services offered by the hospital's outpatient department. The types and numbers of qualified personnel are based on the scope and complexity of outpatient services offered and the number and types of patients treated as outpatients.

Survey Procedures 482.54(b)

- Verify that one person is assigned to manage and be responsible for outpatient services.
- Review the organization's policies and procedures to determine the person's responsibility.
- Review the position description and personnel file of the individual responsible for the outpatient services to ensure that he/she meets the qualifications, in accordance with State law, acceptable standards of practice and hospital policy.
- Review personnel files to verify that the staff qualifications including education, experience, certifications, current licensure where appropriate, and competencies are appropriate for assigned responsibilities.
- Compare duty rosters to patient log to verify that sufficient MD/DOs, nurses and other staff are available to provide care to verify that the types and number of qualified personnel are appropriate for the types and numbers of patients receiving care, and the frequency, duration, and complexity of services offered.
- Review policies and contracts, if services provided are under an arrangement.

A-0452

§482.55 Condition of Participation: Emergency Services

The hospital must meet the emergency needs of patients in accordance with acceptable standards of practice.

Interpretive Guidelines §482.55

The hospital must meet the emergency needs of its patients in accordance with §482.12(f) even if it chooses not to provide emergency services in a dedicated emergency department. The provision of emergency services is an optional service for Medicare participation, but may be required by State law or regulation or the State's hospital licensing requirements.

If the hospital provides emergency services, the hospital must comply with all the requirements of this Condition of Participation (CoP) and provide those services in accordance with acceptable standards of practice.

"Acceptable standards of practice" includes maintaining compliance with applicable Federal and State laws, regulations, and guidelines regarding hospital emergency services, as well as any standards or recommendations promoted by or established by nationally recognized

professional organizations (e.g., American Medical Association, American Nurses Association, American College of Emergency Medicine, etc.).

The hospital's emergency services must be integrated into the hospital-wide QAPI program.

The medical staff is responsible for the quality of care provided to its patients. Appropriate provisions for follow-up care for emergency patients, who are not admitted to the hospital or transferred to another hospital, must be made.

Survey Procedures §482.55

Verify that the hospital's emergency services is integrated into the hospital-wide QAPI program.

A-0453

§482.55(a) Standard: Organization and Direction

If emergency services are provided at the hospital--

A-0454

§482.55(a)(1) The services must be organized under the direction of a qualified member of the medical staff;

Interpretive Guidelines §482.55(a)(1)

The hospital's emergency services must be under the direction of a qualified member of the hospital's medical staff. The hospital's medical staff establishes criteria for the qualifications for the director of the hospital's emergency services in accordance with State law and acceptable standards of practice. A single emergency services director must be responsible for the hospital's emergency services.

Survey Procedures §482.55(a)(1)

Verify that emergency services are organized under the direction of a qualified member of the medical staff.

A-0455

§482.55(a)(2) The services must be integrated with other departments of the hospital;

Interpretive Guidelines §482.55(a)(2)

The hospital's emergency service/department must be integrated with the other departments of the hospital such as surgical services, lab, ICU, diagnostic services, etc. The hospital must demonstrate that its emergency services are truly integrated into its other departments. The integration must be such that the hospital can immediately make available the full extent of its patient care resources to assess and render appropriate care for an emergency patient.

Emergency Services integration would include at a minimum:

- Coordination and communication between the Emergency Department and other hospital services/departments;
- Physical access for emergency department patients to the services, equipment, personnel, and resources of other hospital departments/services;
- The immediate availability of services, equipment, personnel, and resources of other hospital departments/services to emergency patients; and
- That the provision of services, equipment, personnel and resources of other hospital departments/services to emergency department patients is within timeframes that protect the health and safety of patients and is within acceptable standards of practice, including:
    - The length of time it takes to transport the emergency patient from the ED to another hospital department where needed interventions or diagnostic services will be rendered.
    - The length of time it takes to deliver equipment or supplies, or for the staff from other departments to travel from their location to the emergency department in order to provide needed interventions, tests, care, or services.

Time is critical in the provision of emergency care. The hospital must be able to demonstrate how the hospital's other departments provide emergency patients the care and services needed within safe and appropriate times.

In emergency care situations, the time needed to provide the patient with appropriate diagnostic and care interventions can have a significant effect on the patient. Delays in diagnosis and the provision of needed interventions is likely to adversely affect the health and safety of patients who require emergency care. Therefore, a hospital that cannot demonstrate integration of its emergency services with its other departments (including radiological services, OR, intensive care, laboratory, etc) would not be in compliance with the Emergency Services CoP.

Many hospitals offer urgent care services on the hospital campus or in provider-based clinics in the communities they serve. Those clinics must be in compliance with the hospital CoP.

Hospitals may organize their **urgent care clinics** as part of their outpatient department or emergency services department. An urgent care clinic that:

- The hospital holds out to the public as providing only urgent care services and possibly other services;
- Clearly advises the public that the urgent care clinic is not an emergency services department; and
- Does not meet the EMTALA definition of dedicated emergency department;

would be evaluated for compliance with the integration requirement in the Outpatient Services CoP (§482.54(a)) rather than the integration requirement in the Emergency Services CoP. In most urgent care situations, the time, qualified personnel, equipment, and other resources needed to provide the patient with appropriate diagnostic and care interventions are less than needed in emergency situations.

Survey Procedures §482.55(a)(2)

Verify that there are established procedures to assure integration with either hospital services including laboratory, radiology, and operating services to provide continuity of care.

A-0456

§482.55(a)(3) The policies and procedures governing medical care provided in the emergency service or department are established by and are a continuing responsibility of the medical staff.

Interpretive Guidelines §482.55(a)(3)

The hospital's medical staff must establish policies and procedures governing the medical care provided in the emergency service or emergency department. The medical staff must have had ongoing/continuing assessment of the medical care provided in the emergency service or department. Emergency service or emergency department policies must be current and revised as necessary based on the ongoing monitoring conducted by the medical staff and the emergency service or department QAPI activities.

Survey Procedures §482.55(a)(3)

Verify that procedures and policies for emergency medical services (including triage of patients) are established, evaluated, and updated on an ongoing basis.

A-0457

§482.55(b) Standard: Personnel

A-0458

§482.55(b)(1) The emergency services must be supervised by a qualified member of the medical staff.

Interpretive Guidelines §482.55(b)(1)

A qualified member of the medical staff must be on premises and available to supervise the provision of emergency services at all times the hospital offers emergency services. A qualified member of the medical staff must be physically present in the emergency department and available to directly supervise the provision of emergency care to a patient.

The medical staff must establish criteria, in accordance with State law, regulations, and guidelines, delineating the qualifications a medical staff member must possess in order to be granted privileges for the supervision of the provision of emergency care services. Qualifications include necessary education, experience and specialized training, consistent with State law and acceptable standards of practice.

Survey Procedures §482.55(b)(1)

Verify that a qualified member of the medical staff is designated to supervise emergency services.

A-0459

§482.55(b)(2) There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.

Interpretive Guidelines §482.55(b)(2)

The hospital must staff the emergency department with the appropriate numbers and types of professionals and other staff who possess the skills, education, certifications, specialized training and experience in emergency care to meet the written emergency procedures and needs anticipated by the facility.

The hospital must determine the categories and numbers of MD/DOs, specialists, RNs, EMTs, and emergency department support staff the hospital needs to met its anticipated emergency needs.

The medical staff must establish criteria, in accordance with State law and regulations and acceptable standards of practice delineating the qualifications required for each category of emergency services staff (e.g., emergency physicians, specialist MD/DO, RNs, EMTs, mid-level practitioners, etc.).

As a suggested prudent practice the hospital should conduct periodic assessments of its emergency needs in order to anticipate the policies, procedures, staffing, training, and other resources that may be needed to address likely demands.

Additionally, the hospital should work cooperatively with Federal, State and local emergency preparedness agencies and officials in order to identify likely risks to the community (e.g., natural disasters, mass casualties, terrorist acts, etc.), to anticipate demands and resources needed by the hospital emergency services, and to develop plans, methods and coordinating networks to address those anticipated needs.

Survey Procedures §482.55(b)(2)

- Verify that there are sufficient medical and nursing personnel qualified in the needs anticipated by the facility and that there are specific assigned duties for emergency care personnel and a clear chain of command.
- Interview staff to determine that they are knowledgeable, within their own level of participation in emergency care including:
    - Parenteral administration of electrolytes, fluids, blood and blood components;
    - Care and management of injuries to extremities and central nervous system;
    - Prevention of contamination and cross infection.

A-0463

§482.56 Condition of Participation: Rehabilitation Services

If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients.

Interpretive Guidelines §482.56

This is an optional hospital service. However, if a hospital provides any degree of rehabilitative services to its patients, the hospital must comply with the requirements of the Condition of Participation.

If rehabilitative services are provided, they must be organized and staffed in such a manner to ensure the health and safety of patients. This includes providing rehabilitative services in accordance with practitioner orders and acceptable standards of practice.
Acceptable standards of practice include compliance with any applicable Federal or State laws, regulations or guidelines, as well as standards and recommendations promoted by nationally recognized professional organizations (e.g., American Physical Therapy Association, American Speech and Hearing Association, American Occupational Therapy Association, American College of Physicians, American Medical Association, etc.).

The hospital's rehabilitation services must be integrated into its hospital-wide QAPI program.

Survey Procedures §482.56

- Determine if the hospital provides any degree of rehabilitation services.
- Determine if the hospital's rehabilitation services are integrated into its hospital-wide QAPI program.

A-0464

§482.56(a) Standard: Organization and Staffing

The organization of the service must be appropriate to the scope of the services offered.

Interpretive Guidelines §482.56(a)

The hospital must provide the appropriate equipment and types and numbers of qualified personnel necessary to furnish the rehabilitation services offered by the hospital in accordance with acceptable standards of practice.

The scope of rehabilitation services offered by the hospital should be defined in written policies and procedures, and approved by the Medical staff.

Each service, whether provided through a single discipline department or within a multi-discipline department, must function with established lines of authority and responsibility to ensure the health and safety of patients. There must be an adequate number of qualified staff available when needed to evaluate each patient, initiate the plan of treatment, and supervise supportive personnel when they furnish rehabilitation services. The number of qualified staff is based on the type of patients treated and the frequency, duration, and complexity of the treatment required.

Survey Procedures §482.56(a)

- Review the hospital's policies and procedures to verify that the scope of rehabilitation services offered is defined in writing.

- If services are provided under an arrangement, review policies and contracts.
- For each service, determine that adequate types and numbers of qualified staff are available to ensure safe and efficient provision of treatment.
- Review medical records to verify that a qualified professional evaluates the patient and initiates each treatment episode.
- Review a sample of personnel files to verify current licensure, certifications and ongoing training, consistent with applicable State laws.

A-0465

§482.56(a)(1) The director of the services must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

Interpretive Guidelines §482.56(a)(1)

Each service must be accountable to an individual that directs the overall hospital-wide operation of that service. An individual may serve as the director of a multi-service department or as director of single service departments.

The service director must demonstrate through education, experience, and/or specialized training that he/she has the necessary knowledge, experience and capabilities to properly supervise and administer the service(s).

The director may be part-time or full time. In all situations the director retains professional and administrative responsibility for personnel providing the service. If the director is part-time, the time spent directing the service should be appropriate to the scope of the services provided.

Survey Procedures §482.56(a)(1)

- Verify that each service is accountable to an individual who directs the overall operation of that service.
- Review the service director's position description to verify that he/she has been granted the authority and responsibility for operation of the service, consistent with hospital policies, State law, and accepted standards of practice.
- If the director does not work full-time, determine that the number of hours (review timesheets) spent working is appropriate to the scope of services provided.

- Review the director's personnel file to determine that he/she has the necessary education, experience and specialized training to properly supervise and administer the service. This includes maintaining current licensure and certifications as required by State law.

- Interview the director to determine if he/she has the necessary knowledge, experience and capabilities to properly supervise and administer the service.

A-0466

§482.56(a)(2) Physical therapy, occupational therapy, or speech therapy or audiology services, if provided, must be provided by staff that meets the qualifications specified by the medical staff, consistent with State law.

Interpretive Guidelines §482.56(a)(2)

The Medical staff must define in writing the required qualifications and competencies for rehabilitation staff in each program or service offered, (e.g., physical therapists, physical therapy assistants, occupational therapists, occupational therapy assistants, speech-language pathologists, and audiologists, etc). Qualifications should include the necessary education, experience, specialized training, and if applicable, licensure requirements appropriate for assigned responsibilities consistent with State law.

A qualified professional, of the applicable discipline, must:

- Perform an initial evaluation of each patient for whom rehabilitative services were ordered;

- Perform periodical evaluations as applicable and in accordance with accepted standards of practice and State laws;

- Initiate the plan of treatment based on the initial evaluation, input from family/caregivers and in accordance with the orders of the practitioner responsible for the care of the patient; and

- Supervise supportive personnel when they furnish services as appropriate and consistent with State law.

For the purposes of this requirement, "qualified professional" means a physical therapist, an occupational therapist, or a speech language pathologist, who is licensed in accordance with State law and credentialed in accordance with the hospital medical staff criteria.

Survey Procedures §482.56(a)(2)

- Review medical staff documentation to determine that specific qualifications have been established for all rehabilitation staff.

- Review documentation indicating the services provided and the various levels of personnel permitted to provide the services.

- Verify the hospital has a procedure for periodically reviewing the qualifications of staff and for keeping informed of changes in State law regarding personnel qualifications/requirements.

- Review personnel files to determine that staff meets the qualifications specified by the Medical staff as demonstrated through education, experience, current licensure, certifications, and competency as appropriate for their assigned responsibilities.

A-0467

§482.56(b) Standard: Delivery of Services

Services must be furnished in accordance with a written plan of treatment. Services must be given in accordance with orders of practitioners who are authorized by the medical staff to order the services, and the orders must be incorporated in the patient's record.

Interpretive Guidelines §482.56(b)

Each patient must have an individualized plan of treatment, based on the patient's specific rehabilitation needs, input from family/caregivers and therapeutic treatment goals, that are established in writing prior to the initiation of treatment. At a minimum, the treatment plan must:

- Be established by the practitioner ordering the service in collaboration with individuals qualified to provide the service(s);

- Be based on the patient's individualized assessment;

- Include the type, amount, frequency and duration of services;

- Include measurable short-term and long-term goals; incorporate patient, family and caregiver goals; and

- Be reviewed and revised, as necessary, to reflect changes in the patient's response to therapeutic intervention. Updated treatment goals should reflect the changes the patient's status.

Changes to the treatment plan must be documented in writing and supported by clinical record information such as evaluation, test results, interdisciplinary staff conferences or MD/DO orders.

The activities described in the written plan of treatment must be within the scope of practice, State licensure, or certifications of the individual performing the activity.

Verbal orders for the provision of treatment may be accepted and must be authenticated in accordance with the requirements in §482.23 and with Federal and State Laws.

Survey procedures §482.56(b)

- Review patient records to verify that rehabilitation services are provided only in accordance with practitioner orders and that those orders are incorporated into the medical record.
- Verify that each patient has a plan of treatment established in writing prior to the beginning of treatment.
- Verify that the plan is established by the practitioner ordering the service in collaboration with individual(s) qualified to provide the service(s).
- Verify that changes in the treatment plan are documented in writing, supported by clinical record information such as evaluation, test results, or orders, and that changes have been approved by the practitioner.

A-0471

§482.57 Condition of Participation: Respiratory Services

The hospital must meet the needs of the patients in accordance with acceptable standards of practice. The following requirements apply if the hospital provides respiratory care services.

Interpretive Guidelines §482.57

If a hospital provides care to patients who require respiratory care services, the hospital must meet the needs of those patients, in accordance with acceptable standards of practice. This is an optional hospital service. However, if a hospital provides any degree of respiratory care to its patients, the hospital must comply with the requirements of this Condition of Participation.

Acceptable standards of practice include compliance with applicable standards that are set forth in Federal or State laws, regulations or guidelines, as well as standards and recommendations promoted by nationally recognized professional organizations (e.g., American Medical Association, American Association for Respiratory Care, American Thoracic Association, etc).

The hospital's respiratory services must be integrated into its hospital-wide QAPI program.

Survey Procedures §482.57

- Determine if the hospital provides any degree of respiratory care services.

- Determine that the type and amount of respiratory care provided meets the needs of the patients and is delivered in accordance with acceptable standards of practice.
- Determine if the hospital's respiratory services are integrated into its hospital-wide QAPI program.

A-0472

§482.57(a) Standard: Organization and Staffing

The organization of the respiratory care services must be appropriate to the scope and complexity of the services offered.

Interpretive Guidelines §482.57(a)

The hospital must provide the appropriate equipment and types and numbers of qualified personnel necessary to furnish the services offered by the hospital in accordance with acceptable standards of practice.

The scope of diagnostic and/or therapeutic respiratory services offered by the hospital should be defined in writing, and approved by the Medical staff.

Survey Procedures §482.57(a)

- Review the hospital's organizational chart to determine the relationship of respiratory care services to other services provided by the hospital.

- Review the hospital policies and procedures to verify that the scope of the diagnostic and/or therapeutic respiratory care services provided is defined in writing.

A-0473

§482.57(a)(1) There must be a director of respiratory care services who is a doctor of medicine or osteopathy with the knowledge, experience and capabilities to supervise and administer the service properly. The director may serve on either a full-time or part-time basis.

Interpretive Guidelines §482.57(a)(1)

The service director must be a doctor of medicine or osteopathy and must demonstrate through education, experience and specialized training that he/she has the qualifications

necessary to supervise and administer the service properly, appropriate to the scope and complexity of services offered.

If the director serves on a part-time basis, the time spent directing the department should be appropriate to the scope and complexity of services provided.

Survey Procedures §482.57(a)(1)

- Verify that a director has been appointed and that he/she has fixed lines of authority and delegated responsibility for operation of the service.
- Interview staff regarding the role and oversight activities conducted by the director.
- Review the service director's credentialing file to determine that he/she is a M.D. or D.O. and has the necessary education, experience and specialized training to supervise and administer the service properly.

A-0474

§482.57(a)(2) There must be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with State law.

Interpretive Guidelines §482.57(a)(2)

There must be sufficient personnel available to respond to the respiratory care needs of the patient population being served.

Survey Procedures §482.57(a)(2)

- Interview respiratory care staff regarding: services provided, schedules, and availability of respiratory care staff throughout the day and week to determine that the number and type of staff available is appropriate to the volume and types of treatments furnished. If needed, review staffing and on-call schedules.
- Review a sample of personnel files for respiratory care staff to determine that the personnel meet the qualifications specified by the medical staff, consistent with State law.

A-0475

§482.57(b) Standard: Delivery of Services

Services must be delivered in accordance with medical staff directives.

Interpretive Guidelines §482.57(b)

There should be written policies for the delivery of respiratory care services that are developed and approved by the medical staff. Appropriate to the scope of services provided, the written policies should address at least the following:

- Equipment assembly, operation, and preventive maintenance;
- Safety practices, including infection control measures for equipment, sterile supplies, biohazardous waste, posting of signs, and gas line identification;
- Handling, storage, and dispensing of therapeutic gases to both inpatients and outpatients;
- Cardiopulmonary resuscitation;
- Procedures to follow in the advent of adverse reactions to treatments or interventions;
- Pulmonary function testing;
- Therapeutic percussion and vibration;
- Bronchopulmonary drainage;
- Mechanical ventilatory and oxygenation support;
- Aerosol, humidification, and therapeutic gas administration;
- Storage, access, control, administration of medications and medication errors; and
- Procedures for obtaining and analyzing blood samples (e.g., arterial blood gases).

A-0476

§482.57(b)(1) Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures must be designated in writing.

Interpretive Guidelines §482.57(b)(1)

The hospital must have written policies to address, at a minimum:

- Each type of respiratory care service provided by the hospital;

- The qualifications, including job title, licensure consistent with State law, education, training and experience of personnel authorized to perform each type of respiratory care service and whether they may perform it without supervision; and
- The type of personnel qualified to provide the direct supervision.

Survey Procedures §482.57(b)(1)

- Review treatment logs, job descriptions of respiratory care staff, and policies and procedures to determine the following:
    - Duties and responsibilities of staff;
    - Qualifications and education required, including licensure, consistent with State law;
    - Specialized training or experience needed to perform specific duties.

A-0477

§482.57(b)(2) If blood gases or other clinical laboratory tests are performed in the respiratory care unit, the unit must meet the applicable requirements for laboratory services specified in §482.27.

Interpretive Guidelines §482.57(b)(2)

Refer to the guidelines under §482.27 for independent laboratory if blood gases and laboratory tests are performed in the respiratory care unit.

A-0478

§482.57(b)(3) Services must be provided only on, and in accordance with, the orders of a doctor of medicine or osteopathy.

Survey Procedures §482.57(b)(3)

Review the medical records of patients receiving respiratory services to verify that those services are provided only upon the orders of a doctor of medicine or osteopathy, and that the services are provided in accordance with those orders.

17.2 Sections 3100–3112

17.2: Excerpts from *SOM* Section 3100

The excerpts in this *Manual* section pertain to free-standing rehabilitation hospitals and rehabilitation units in acute care hospitals that are excluded from the Medicare hospital Inpatient Prospective Payment System (IPPS). These excerpts discuss the initial verification and annual self-attestation procedures.

The purpose of excerpting was to consolidate information on inpatient rehabilitation facilities (IRFs) for the *Rehabilitation Reference Manual.* In the future, such consolidated information will be inserted into a revised *SOM* Section 3100.

Please note that the flowcharts that follow the excerpts in the *Rehabilitation Reference Manual* do not appear in the current Internet-only *SOM.* The flowcharts were designed specifically for the *Rehabilitation Reference Manual* and depict the responsibilities of the IRF providers, State agencies (SAs), Fiscal Intermediaries (FIs) and Regional Offices (ROs).

Due to some survey and certification differences between the critical access hospital (CAH) and the IRF, the CAH rehabilitation DPU was not discussed in this section. A new section for the CAH DPU will be drafted when Section 3100 is revised and will include responsibilities of the providers, SAs, FIs and ROs.

Excerpts from *State Operations Manual (SOM)* Section 3100

Initial Verification and Annual Self-Attestation Procedures for Rehabilitation Hospitals and Rehabilitation Units of Acute Care Hospitals That Are Excluded from the Medicare Hospital Inpatient Prospective Payment System

A limited group of hospitals and special hospital units are excluded from the Medicare Hospital *Inpatient Prospective Payment System (IPPS)* that determines Medicare payment for operating costs and capital-related costs of inpatient hospital services. IPPS-excluded hospitals and units have their own specific reimbursement criteria. Title 42 of the Code of Federal Regulations (CFR), Sections 412.20 through 412.30, describes the criteria under which these facilities are excluded. IPPS-excluded status is not optional. In the past, the *State agencies* (SAs) have been required to conduct annual onsite surveys of these hospitals and units to verify that they continue to meet certain IPPS-exclusion criteria. This procedure is revised as follows:

- Annual onsite verification surveys for *all IPPS-excluded* rehabilitation hospitals and units are **not required,** and these hospitals or units may self-attest on an annual basis that they continue to meet certain IPPS-exclusion criteria.

- *IPPS*-excluded hospitals *or* units are required to report any change in operations (e.g., expansion or *inclusion of* an offsite *IPPS*-excluded unit) to the appropriate *Regional Office* (RO), *Fiscal Intermediary* (FI), and SA. This report should be submitted two months prior to the beginning of the next cost reporting period.

- ***IPPS-excluded hospitals or units that are planning to downsize during the current cost reporting period are required to report this in writing to the RO and the FI at least 30 days before the date of the decrease.*** Any decrease in the number of beds or square footage (considered to be part of an excluded unit) made during a cost reporting period must remain in effect for the rest of that cost reporting period.

- *Each year,* the SA *is to* conduct onsite verification surveys of a sample of *five percent* of all currently excluded hospitals *and* units, *selected* at random. These verification surveys may be conducted concurrently with a *recertification survey, complaint survey or validation compliance (if deemed)* hospital survey.

- The SA continues to conduct complaint surveys at IPPS-excluded hospitals or units.

- The SA continues to conduct *onsite* verification surveys for first-time IPPS exclusion for hospitals and units.

FIs continue to verify, on an annual basis, compliance with the current compliance percentage threshold (commonly known as the "75 percent rule") for free-standing rehabilitation hospitals, rehabilitation units in acute care hospitals, and critical access hospital (CAH) rehabilitation distinct part units (42 CFR 412.23 (b)(2) and 412.30); age criterion for

children's hospitals (42 CFR 412.23(d)(2)); length-of-stay criterion for long-term hospitals (42 CFR 412.23(e)(2); and the requirement that all excluded units are separate cost centers for cost finding and apportionment (42 CFR 412.29(a)(9)).

3102 - General Information on IPPS Exclusion

The following hospitals and hospital units are excluded from *the* regular *I*PPS:

- Psychiatric hospitals;
- Rehabilitation hospitals;
- Children's hospitals;
- Long-term hospitals;
- Distinct part psychiatric and rehabilitation units of acute care hospitals that are subject to IPPS and distinct part psychiatric and rehabilitation units of CAHs; and
- Cancer hospitals.

Certain kinds of hospitals are paid under special provisions and are never subject to IPPS. These hospitals need not be evaluated for compliance with the *IPPS*-exclusion criteria:

- Department of Veterans Affairs (formerly, Veterans Administration) hospitals;
- Hospitals paid under State cost control systems approved by CMS;
- Hospitals paid under demonstration projects approved by CMS;
- Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries; and
- Hospitals outside the 50 States, the District of Columbia, or Puerto Rico.

When a hospital is excluded from IPPS, the exclusion extends to all components of the hospital. No unit or other component of an excluded hospital can be considered separately for exclusion.

Hospitals (except those now certified as psychiatric hospitals) and hospitals containing units meeting the criteria of §3106 (based on the hospital's self-identification) are to notify the RO that they qualify. Such notification *is to* include the following: name of hospital, type of hospital *or* unit(s), address, current provider identification number, name of contact person *and* FI, and a statement that the hospital/unit meets the criteria for exclusion. A notice relating to a unit is to identify the particular areas designated as the unit and specify the

number of beds and square footage included in the unit. *Hospitals should be encouraged to include a floor plan, with room numbers and the number of beds, to identify the designated space (this helps to determine whether hospital beds are co-located or separate)*. Room numbers or the number of beds must be used to identify the designated space. When possible, the notification is to be made no later than **five months** before the date the hospital would otherwise become subject to prospective payment. After receipt of this notification, the **RO** asks the **SAs** to verify that certain criteria are met for psychiatric units of acute care hospitals or CAHs, for rehabilitation hospitals and rehabilitation units of acute care hospitals, and *for* rehabilitation units of CAHs.

Excluded or nonexcluded status for a hospital or hospital unit remains in effect for the entire cost reporting period for which the determination is made. If a change in meeting applicable criteria occurs during a cost reporting period or the hospital requests IPPS exclusion after the start of its cost reporting period, the status determined for that period remains for the duration of the period.

If a unit is added to a hospital after the start of a cost reporting period, it cannot be excluded from IPPS before the start of the hospital's next cost reporting period. A CAH cannot add a rehabilitation *or psychiatric* distinct part unit until the start of their next cost reporting period.

For purposes of *IPPS* exclusion, increases or decreases in the number of beds and square footage assigned to an IPPS-excluded unit are recognized only at the start of a hospital's cost reporting period.

3104 - Criteria for IPPS-Excluded Hospitals

3104B - Rehabilitation Hospitals

A hospital is an IPPS-excluded rehabilitation hospital if:

- It has in effect a provider agreement to participate as a hospital**;**
- During the most recent, consecutive, and appropriate 12-month time period (as defined by CMS or the FI) the hospital treated an inpatient population that met or exceeded the current compliance percentage threshold and *that* required intensive rehabilitative services for one or more of the following medical conditions:

    - Stroke;
    - Spinal cord injury;
    - Congenital deformity;

  - Amputation;
  - Major multiple trauma;
  - Fracture of femur (hip fracture);
  - Brain injury;
  - Neurological disorders, including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson's disease;
  - Burns;
  - Active, polyarticular rheumatoid arthritis, psoriatric arthritis, and seronegative arthropathies;
  - Systemic vasculidities with joint inflammation;
  - Severe or advanced osteoarthritis (osteoarthrosis or degenerative joint disease); or
  - Knee or hip joint replacement, or both.

- It has in effect a preadmission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient hospital rehabilitation program or assessment;
- It ensures that patients receive close medical supervision, rehabilitation nursing, physical therapy and occupational therapy, plus, as needed, speech therapy, social services or psychological services, and orthotic and prosthetic services;
- It has, for each inpatient, a plan of treatment that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient;
- It uses a coordinated, multidisciplinary team approach in the rehabilitation of each inpatient, as documented by periodic clinical entries to the patient's medical record noting the patient's status in relationship to goal attainment, and team conferences are held at least every two weeks to determine the appropriateness of treatment; *and*
- It has a director of rehabilitation who:
  - Provides services to the hospital and its inpatients on a full-time basis;

- Is a Doctor of Medicine or Osteopathy licensed under State law to practice medicine or surgery; and

- Has had, after completing a one-year hospital internship, at least two years of training in the medical management of inpatients requiring intensive rehabilitation services.

Note: In order to be paid under the IRF PPS, the facility agrees to use, collect and transmit data using the Inpatient Rehabilitation Facilities - Patient Assessment Instrument (IRF-PAI).

For purposes of determining whether the current compliance percentage threshold is met, the FI considers the medical condition of all patients (i.e., Medicare and non-Medicare) treated in the hospital. The FI uses either the number of admissions or the number of discharges during a cost reporting period.

The current compliance percentage threshold is applied to the 12-month cost reporting period immediately preceding the cost reporting period for which exclusion is sought. The cost reporting period need not be complete when this evaluation takes place. The RO requests the servicing FI to make the determination concerning the current compliance percentage threshold.

EXCEPTION: A hospital that seeks classification as a rehabilitation hospital for the first full l2-month cost reporting period that occurs after it becomes a Medicare participating hospital *may provide* a written certification that the inpatient population it intends to serve **will meet** the current compliance percentage threshold.

The written certification described above is effective for any cost reporting period of not less than one month and not more than 11 months occurring between the date the hospital began participating in Medicare and the start of the hospital's regular 12-month cost reporting period. This exception is available only once, when the facility first *seeks IPPS*-excluded status.

If a new rehabilitation hospital is excluded from IPPS for a cost reporting period, but the inpatient population treated in the hospital during the period does not actually meet the current compliance percentage threshold, a retroactive adjustment of payments to the hospital for the period is needed. Where this occurs, the FI advises the RO of the identity of the hospital and of the dates of the cost reporting period involved.

3104E - Hospitals within Hospitals

An IPPS-excluded hospital that occupies space in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital, must meet the criteria at 42 CFR 412.22(e) as follows:

- The hospital has a governing body that is separate from the governing body occupying space in the same building or campus, and the governing body is not controlled by the host facility or any third entity that controls both hospitals;

  NOTE: For purposes of this section, "control" exists if an individual or an organization has the power, directly or indirectly, to significantly influence or direct the actions or policies of an organization or institution. *The SA should conduct a review to verify that there are separately operating governing bodies for each hospital or entity. The FIs can review Form CMS-855A for any indication of sharing of ownership or control.*

- The hospital has a chief medical officer who reports directly to the governing body, is responsible for all medical staff activities of the hospital, and is not employed or under contract with the host facility or any third party that controls both hospitals;

- The hospital has a medical staff that is separate from that of the host facility, reports directly to the hospital's governing body, and adopts and enforces bylaws governing medical care provided in the hospital and medical staff activities, including the granting of privileges to individual practitioners;

- The hospital has a single chief executive officer through whom all administrative authority flows, who exercises control and surveillance over all administrative activities at the hospital, and who is not employed by or under contract to the host facility or any third party that controls both hospitals; and

- The hospital meets **one** of the following criteria:

  - The hospital performs the basic hospital functions specified in 42 CFR 482.21 through 482.27, 482.30, and 482.42 through the use of employees or under contract or agreements with entities other than the host hospital or any third entity that controls both hospitals;

  - The cost of services obtained by the hospital under contracts or other agreements with the host facility or any third party that controls both hospitals does not exceed 15 percent of its total inpatient operating costs during the six-month qualifying period; or

  - For the initial six-month qualifying period the hospital has an inpatient population of whom at least 75 percent were referred from a source other than the host hospital.

The SA notifies the CMS RO as soon as it becomes aware of any long-term hospital planning to operate as a hospital-within-a-hospital and notifies the facility immediately that it must demonstrate compliance with the special hospital-within-a-hospital criteria. The SA will review documentation for hospitals that intend to operate as hospitals-within-hospitals to make an initial recommendation to the ROs regarding a hospital's compliance or

noncompliance with the above criteria (see §3104.D). *For example, State licensure and special State Life Safety Code requirements must be met. After initial State review*, final determinations will be made on a case-by-case basis by the RO using whatever procedure it deems appropriate. In some instances, it may be necessary to authorize SA onsite inspection of the hospital to collect additional information. The hospital must submit a completed Form CMS-855 to notify the FI of its intent to be a hospital-within-a-hospital.

3106 - *Common Requirements* for Rehabilitation Units

An IPPS-excluded rehabilitation unit must meet the *following requirements* for units and the *additional requirements* for rehabilitation units below.

3106A - *Common Requirements* for Units

- The unit is a part of an institution that:
  - Has in effect a provider agreement to participate as a hospital;
  - Is not excluded in its entirety from IPPS; and
  - Has enough beds that are not excluded from IPPS to permit the provision of adequate cost information.
- The unit has written admission criteria applied uniformly to both Medicare and non-Medicare patients;
- The unit has admission and discharge records that are identified separately from those of the hospital in which it is located and are readily retrievable. The medical records of the unit's patients need not be physically separate from the records of patients in the acute care portion of the hospital. It is not necessary to create a second medical record when a patient is moved from the acute care portion of the hospital to the IPPS-excluded unit or vice versa. The record, however, must indicate, for Medicare purposes, the dates of admission and discharge from the IPPS-excluded unit. The unit's policies provide that necessary clinical information will accompany a patient upon transfer from the hospital to the unit;
- If State law provides special licensing requirements for psychiatric or rehabilitation units, the unit is licensed in accordance with the applicable requirements;
- The hospital's utilization review (UR) plan includes specific standards for the type of care offered by the unit;
- The beds assigned to the unit are physically separate from (not commingled with) beds not included in the unit;

The unit must also meet certain accounting requirements. *The FI will verify the accounting requirements.* These include requirements that:

- The unit is treated as a separate cost center for cost finding and apportionment purposes;
- *The unit must be served by the same FI as the hospital;*
- The hospital's accounting system properly allocates costs;
- *The unit maintains adequate statistical data to support the basis of allocation;*
- The cost report for the hospital includes the costs of the unit in the same fiscal period and uses a single method of cost apportionment;
- As of the first day of the first reporting period for which all other exclusion requirements are met, the unit is fully equipped, staffed, and capable of providing inpatient psychiatric or rehabilitation care, regardless of whether there are any inpatients in the unit on that date; and
- Each hospital may have only one unit of each type (psychiatric or rehabilitation) excluded from IPPS. *There is no size limit for an acute care hospital rehabilitation unit.*

3106C - *Additional Requirements* for Rehabilitation Units

An SA onsite verification or re-verification survey for IPPS exclusion for a rehabilitation unit is to be performed for a hospital's first-time request for IPPS exclusion for its rehabilitation unit, a rehabilitation unit that is selected as part of a sample for an annual validation compliance survey, and/or a complaint against a rehabilitation unit. For cost reporting periods following the first cost reporting period, the hospital will self-attest that its rehabilitation unit is in compliance with the requirements in 42 CFR 412.29.

The unit *must* meet the requirement in §3104.B, except as provided below, with respect to patients treated in the unit during the hospital's most recent 12-month cost reporting period (i.e., the period immediately preceding the period for which the exclusion would be effective). This finding is based on the medical conditions of all (i.e., Medicare and non-Medicare) patients who occupy the beds assigned to the physically separate unit. The medical condition of all patients treated in the unit is considered.

If a hospital has not previously sought exclusion for any rehabilitation unit and has increased its bed capacity under *both* State licensure and Medicare certification to greater than 50% of the *original* number of beds in the unit, it may identify the new beds as a new rehabilitation unit for the first full 12-month cost reporting period during which the unit is in service. For purposes of these provisions, "new beds" are defined as ones for which the hospital has obtained approval by increasing its bed capacity under both State licensure and Medicare

certification. Note that there is no net increase if the hospital adds 20 new beds and deletes 20 beds previously licensed and certified for conversion. A unit that is comprised of some beds that were previously licensed and certified and some new beds will be recognized as a new rehabilitation unit only if over half of the beds are new. Beds are considered "new" only for the first full 12-month cost reporting period in which a hospital seeks IPPS exclusion of a new rehabilitation unit. The hospital may provide written certification that the inpatient population it intends the unit to serve meets the current compliance percentage threshold instead of showing that it has treated such a population during its most recent 12-month cost reporting period.

A hospital that has an IPPS-excluded rehabilitation unit must obtain approval for added bed capacity under State licensure requirements. If the hospital seeks to add the new beds to its existing excluded unit for the first full 12-month cost reporting period during which the new beds are used to furnish inpatient care, it must provide written certification that the new beds are intended to meet the current compliance percentage threshold (see §3104.B) instead of showing that those beds were used to treat such a population during the unit's most recent 12-month cost reporting period.

The written certification described above is effective for any cost reporting period of not less than one month and not more than 11 months occurring between the dates the hospital began participating in Medicare and the start of the hospital's regular 12-month cost reporting period. For purposes of this exclusion, a hospital that has undergone a change of ownership (see §3210) is not considered to have participated previously in the Medicare program. *A rehabilitation hospital or rehabilitation unit of an acute care hospital* can therefore use the attestation process for the first cost reporting year.

If a hospital has a new rehabilitation unit excluded from the IPPS for a cost reporting period or expands an existing IPPS-excluded rehabilitation unit through the addition of new beds as defined above, but the inpatient population treated in the new unit of added beds during the period does not actually meet the current compliance percentage threshold, a retroactive adjustment of payments to the hospital for the period is needed. Where this occurs, the FI advises the RO of the identity of the hospital and the dates of the cost reporting period involved.

If a hospital that has not previously participated in the Medicare program seeks *IPPS* exclusion *for* a rehabilitation unit, it may designate certain beds as a new rehabilitation unit for the first full 12-month cost reporting period that occurs after it becomes a Medicare participating hospital. The written certification described above is *also* effective for any cost reporting period of not less than one month and not more than 11 months occurring between the dates the hospital began participating in Medicare and the start of the hospital's regular 12-month cost reporting period. For purposes of this exclusion, a hospital that has undergone a change of ownership or leasing (see §3210) is not considered to have participated previously in the Medicare program. *The unit must:*

- *Meet* the requirements for a rehabilitation hospital in §3104.B. The intermediary verifies current compliance percentage threshold ***(also known as the 75 percent rule)***.

- *Have* a director of rehabilitation who:
    - Is a Doctor of Medicine or Osteopathy licensed under State law to practice medicine or surgery;
    - Has had, after completing a one-year hospital internship, at least two years of training or experience in the medical management of inpatients requiring intensive rehabilitation services; and
    - Provides services to the unit and its inpatients for at least 20 hours per week. These services maybe any combination of administrative/direct patient care services.

If the rehabilitation unit serves both inpatients and outpatients through a single, integrated unit, the time spent by the director in performing administrative duties for the entire unit counts toward the time requirement. The SA does not prorate this administrative time between inpatients and outpatients. However, time devoted to performing direct patient care can count toward the time requirement only if furnished to inpatients of the unit. **A physician assistant's time cannot count toward the director of rehabilitation's 20-hour requirement.**

3108 - SA First-Time Verification Procedures for Hospitals and Rehabilitation Units of Acute Care Hospitals

For first-time verification of IPPS exclusion for a rehabilitation hospital or a rehabilitation unit of an acute care hospital, the SA completes the appropriate part of the criteria worksheet, Form CMS-437A or CMS-437B (refer to Exhibit 73). The SA verifies that the criteria specified below are met for IPPS exclusions of hospitals and units of hospitals. In addition, the RO may instruct the SA to verify some or all of the general criteria for units given in §3106.A.

3108A - Rehabilitation Hospitals and Rehabilitation Units of Hospitals

1. **Rehabilitation Hospitals -** The SA verifies that the criteria in §3104.B are met. (The FI verifies the current compliance percentage threshold.)

2. **Rehabilitation Units -** The SA verifies that the criteria in §3106.C are met. (The FI verifies the current compliance percentage threshold.)

3. **Criteria Presumed Met by Accredited Rehabilitation Hospitals and Units -** A rehabilitation hospital or unit may be presumed to meet the criteria in §3104.B or §3106.C (excluding the current compliance percentage threshold and the director of rehabilitation requirement) if it is accredited by the:

- Commission on Accreditation of Rehabilitation Facilities (CARF), surveyed under the Comprehensive Inpatient Rehabilitation Program (CIRP); or

- Joint Commission on Accreditation of Healthcare Organizations (JCAHO), *surveyed under the Joint Commission's Comprehensive Manual for Hospitals.*

Nevertheless, in either case *involving accreditation* the SA verifies that the criterion for full-time director of rehabilitation for rehabilitation hospitals or the 20-hour per week criterion for the rehabilitation unit is met. The SA reviews appropriate documentation submitted by the facility (e.g., payroll records, duty rosters or staff appointment notices specifying hours: either full-time or part-time of at least 20 hours per week).

3110 - SA Re-verification of IPPS-Excluded Hospitals and Units

3110A - Annual Re-verification Process for IPPS-Excluded Rehabilitation Hospitals and Units

- 120 days before the beginning of a cost reporting period, the SA notifies the excluded hospital or unit (refer to Exhibit 126) that it must self-attest to compliance with the appropriate requirements in 42 CFR 412.23(b)(2), 412.25, and/or 412.29. However, the FI must verify the criteria at §412.23(b)(2) annually.

- The SA includes a copy of the attestation statement (Exhibit 127) and the appropriate rehabilitation hospital or rehabilitation unit criteria worksheet (Form CMS-437A or Form CMS-437B, Exhibit 73).

- The hospital or unit is to return the completed, signed worksheet and signed attestation statement to the SA office no later than 90 days before the beginning of the next cost reporting period.

- The SA transmits the completed attestation statement and worksheet, along with its recommendation for re-verification, to the RO at least 60 days prior to the end of the hospital's cost reporting period for inclusion with other information necessary for determining exclusion from IPPS. ***As an example of other information needed, the SA is to allow time for a Plan of Correction, if recommended. A Plan of Correction may be required for continuation of the IPPS exclusion when the SA receives a Form CMS-437A or Form CMS-437B that shows a hospital or unit doesn't meet all the criteria. In this case a Plan of Correction may result in continuation of the IPPS exclusion if deficiencies are corrected and the corrections are verified prior to the start of the next cost reporting period.***

3112 - RO Procedures for Exclusion from IPPS for Hospitals and Units

For initial exclusion from IPPS, hospitals and hospital units are to notify the RO of their eligibility for exclusion. They are to refer to *Chapter 3,* Section 140 *(Medicare IRF Classification Requirement)*of the *Medicare Claims Processing Manual* to notify the RO of their eligibility for exclusion. Notification should be in writing and include the following: name of hospital, type of hospital/units, address, current provider identification number, name of contact person and FI, and a statement that the hospital/units(s) meets the criteria for exclusion. Notification should be made, where possible, no later than five months before the date the hospital would become subject to IPPS.

Hospitals and units that have already been excluded from IPPS need not reapply for exclusion. These facilities will be reevaluated based on the criteria described in §3112.2 to determine whether they still meet the IPPS-exclusion criteria.

If the RO does not receive notification *that* a hospital or unit meets the *IPPS-exclusion* criteria of this section, but has knowledge that it should be excluded, the RO *is to* identify the hospital or unit for exclusion. For example, the SA should annually contact all IPPS-excluded units for re-verification per *SOM* §3110.A, but if the SA doesn't receive timely notification, the RO may follow up with the facility.

Except for currently certified psychiatric hospitals, the RO notifies the hospital and the FI, in writing, 45 days prior to the start of the next cost reporting period, of the excluded status of the hospital or unit(s) and of any new provider number(s). The RO coordinates these activities very closely with the servicing intermediary of the hospital. Prior to making a decision on hospital *or* unit exclusion, the RO determines whether the hospital *or* unit meets all exclusion criteria including those criteria that are the responsibility of the servicing intermediary.

IPPS-excluded or non-excluded status for a hospital or hospital unit remains in effect for the entire cost reporting period for which the determination is made. If a change in meeting applicable criteria occurs during a cost reporting period or the hospital requests exclusion after the start of its cost reporting period, the status already determined for that period will remain for the duration of the period. However, any change in status resulting from the beginning or end of a hospital's participation in an approved demonstration project or State reimbursement control program will be effective on the date the change occurs, *regardless of* whether the date coincides with the start of a cost reporting period. A hospital may increase or decrease the space (square footage or number of beds) assigned to an excluded unit only at the start of the hospital's next cost reporting period.

3112.1 - RO Procedures for First-Time Exclusion of Hospitals and Units

When considering a hospital or hospital unit for exclusion for the first time, the RO has the SA and the FI verify the facility's compliance with exclusion criteria, as follows:

- **Rehabilitation Hospitals -** The RO has the SA verify that the exclusion criteria in §3104 are met. As noted in §3108, a rehabilitation hospital may be presumed to meet certain criteria based on accreditation by CARF or JCAHO; however, the SA must verify compliance with the medical director requirement, and the FI must verify compliance with the current compliance percentage threshold (75 percent rule) for hospitals other than new hospitals.

- **Rehabilitation Distinct Part Units -** The RO has the intermediary verify that the *common requirements* for units in §3106 are met. The RO has the SA verify that the exclusion criteria in §3104 are met. As noted in §3108, a rehabilitation hospital may be presumed to meet certain criteria based on accreditation by CARF or by JCAHO; however, the SA must verify compliance with the director of rehabilitation requirement, and the FI must verify compliance with the current compliance threshold requirement for rehabilitation distinct part hospital units other than new units.

3112.2 - RO Verifying Continued Compliance with Exclusion Criteria by Currently Excluded Hospitals or Units

3112.2A - Self-Attestation Procedures for IPPS-Excluded Hospitals and Units

1. **Rehabilitation Hospitals/Units -** Annual re-verification surveys for all previously excluded rehabilitation hospitals and units are ***not*** **required.** The new procedure is as follows:

    - At least 120 days prior to the beginning of the next cost reporting period, SAs provide (refer to Exhibit 126) excluded rehabilitation hospitals/units with the attestation statement (refer to Exhibit 127) for exclusion from IPPS and the appropriate criteria worksheet, Form CMS-437A or Form CMS-437B;

    - Rehabilitation hospital *or* unit officials complete and sign the attestation statement and the appropriate worksheet and return them to the SA no later than 90 days before the beginning of the next cost reporting period; and

    - After receiving the hospital *or* unit self-attestation materials from the SA and the FI verification report of the current compliance percentage threshold, the RO notifies the SA, FI, and the hospital/unit (refer to Exhibit 193) 45 *days* prior to the end of the current cost reporting period) that recertification has been approved or denied.

- Previously excluded hospitals *or* units are required to report any change in operations (e.g., expansion) to the appropriate CMS RO and to provide the SA with a copy of the report ***two months before the change occurs;***

- The SA conducts annual validation compliance surveys at excluded hospitals *and* units;

- SAs continue to conduct complaint surveys at excluded hospitals *and* units;

- SAs continue to conduct first-time verification surveys in connection with a hospital *or* unit's first exclusion from IPPS; and

- FIs continue to verify, on an annual basis, compliance with the current compliance percentage threshold (see 42 CFR 412.23 through 412.30) for rehabilitation hospitals and units.

3112.2B - RO Verifying Exclusion Eligibility of Other Facilities

1. The "hospital-within-hospital" *IPPS-exclusion* criteria described in §3112.1 apply to all long-term hospitals with cost reporting periods beginning on or after October 1, 1995. If the RO becomes aware of any long-term hospital operated in a building or campus occupied by another hospital, *it must ensure* the hospital is in compliance with the criteria.

3112.3 - Role of FIs in Re-verification of IPPS-Excluded Hospitals and Units

The FIs are to verify the following:

- **Rehabilitation Hospitals and Units -** *The hospital or unit meets the* current compliance percentage threshold applied to medical conditions.

- **All Distinct Part Units -** *The* unit is a separate cost center for cost finding and apportionment as verified by the FI.

3114 - Future Section for CAH DPUs

3116 - Future Section for the IRF-PAI

Verification Procedures for New Rehabilitation Hospitals or Rehabilitation Units in Acute Care Hospitals

An **Acute Care Hospital** notifies the **RO** and **FI** that it meets criteria for exclusion and applies for IPPS Exempt status no later than **5 months** before the date the hospital begins its next cost reporting period.

RO
Requests **FI** to verify information contained on Form CMS-855A and accounting requirements contained in §412.25.

After the information is verified, the **RO**:

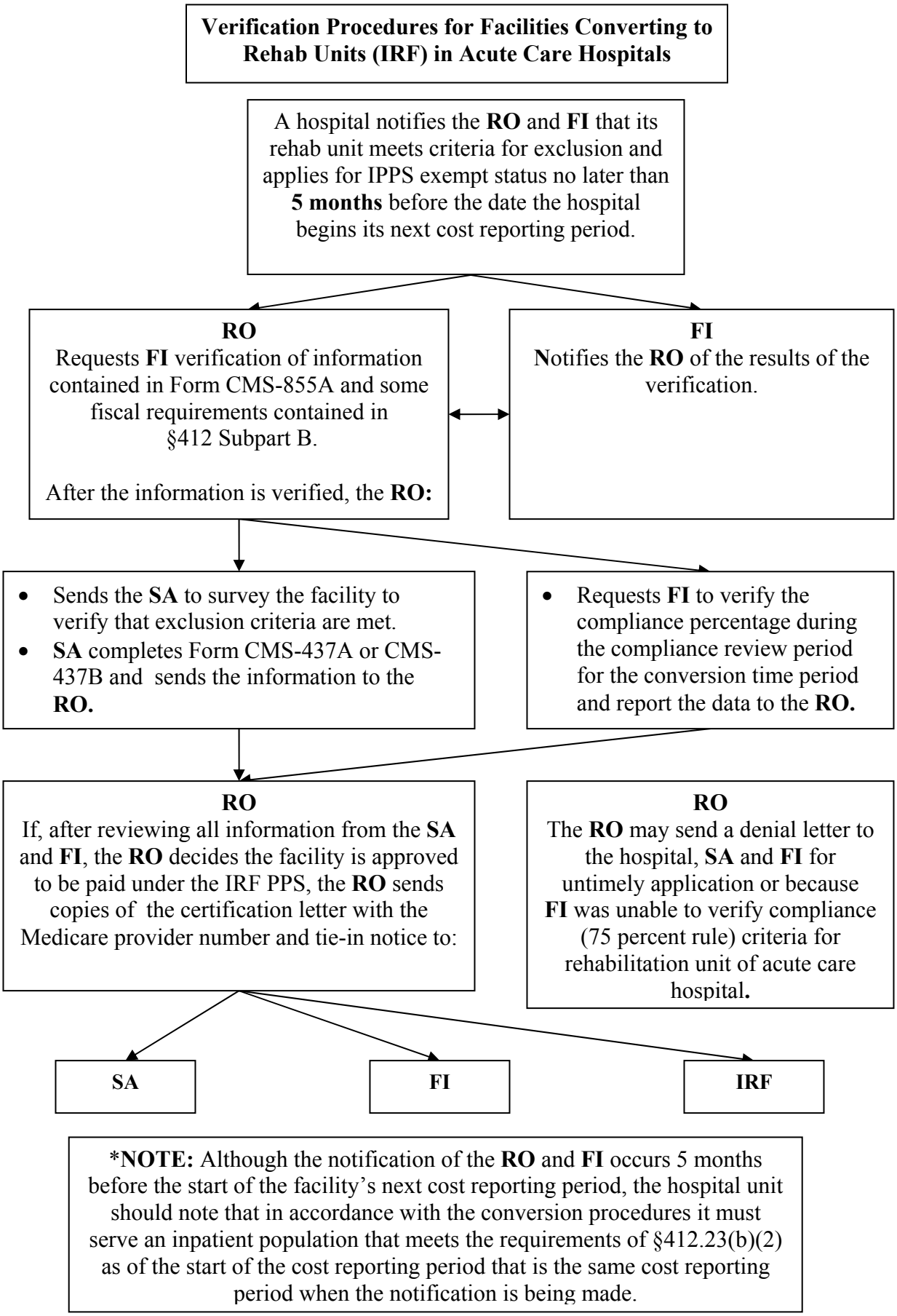
FI
Notifies the **RO** of the results of the verification.

- Sends **SA** to survey the facility to verify that criteria under Subpart B of Part 412 of the regulations are met.
- **SA** collects **IRF** attestation that it plans to meet the applicable compliance percentage threshold.
- **SA** completes 437A/B and sends to **RO**.

RO
If the facility is approved, the **RO** sends copies of the certification letter, with the Medicare provider number and tie-in notice, **45 days** prior to the start of the cost reporting period stating that the facility is classified as an **IRF** at the start of the facility's next cost reporting period.

RO
The **RO** sends copies of a denial letter to the **SA**, **FI** and facility if the facility fails to meet certification criteria.

SA | **FI** | **IRF**



***NOTE:** Although the notification of the **RO** and **FI** occurs 5 months before the start of the facility's next cost reporting period, the hospital unit should note that in accordance with the conversion procedures it must serve an inpatient population that meets the requirements of §412.23(b)(2) as of the start of the cost reporting period that is the same cost reporting period when the notification is being made.

SA/RO/FI Re-verification Procedures for Rehabilitation Hospitals and Rehabilitation Units in Acute Care Hospitals

SA

IRF

- **120** days before the beginning of the next cost reporting period, the SA sends a letter (**Exhibit 126**) notifying the IRF to complete the self-attestation statement (**Exhibit 127**) and Form CMS-437A or CMS-437B (**Exhibit 73**).

IRF

- The IRF returns the completed signed paperwork to the **SA** at least **90** days before the beginning of the next cost reporting period.

SA

- **SA** transmits the completed attestation statement and worksheet along with recommendations for re-verification to the **RO** at least **60** days prior to the end of the hospital's cost reporting period.
- **The Medical Director criterion cannot be self-attested to by the IRF. It must be re-verified by the SA. (The re-verification of the criteria doesn't necessarily require an onsite visit).**
- Note: The **IRF** may be selected for a sample validation survey.

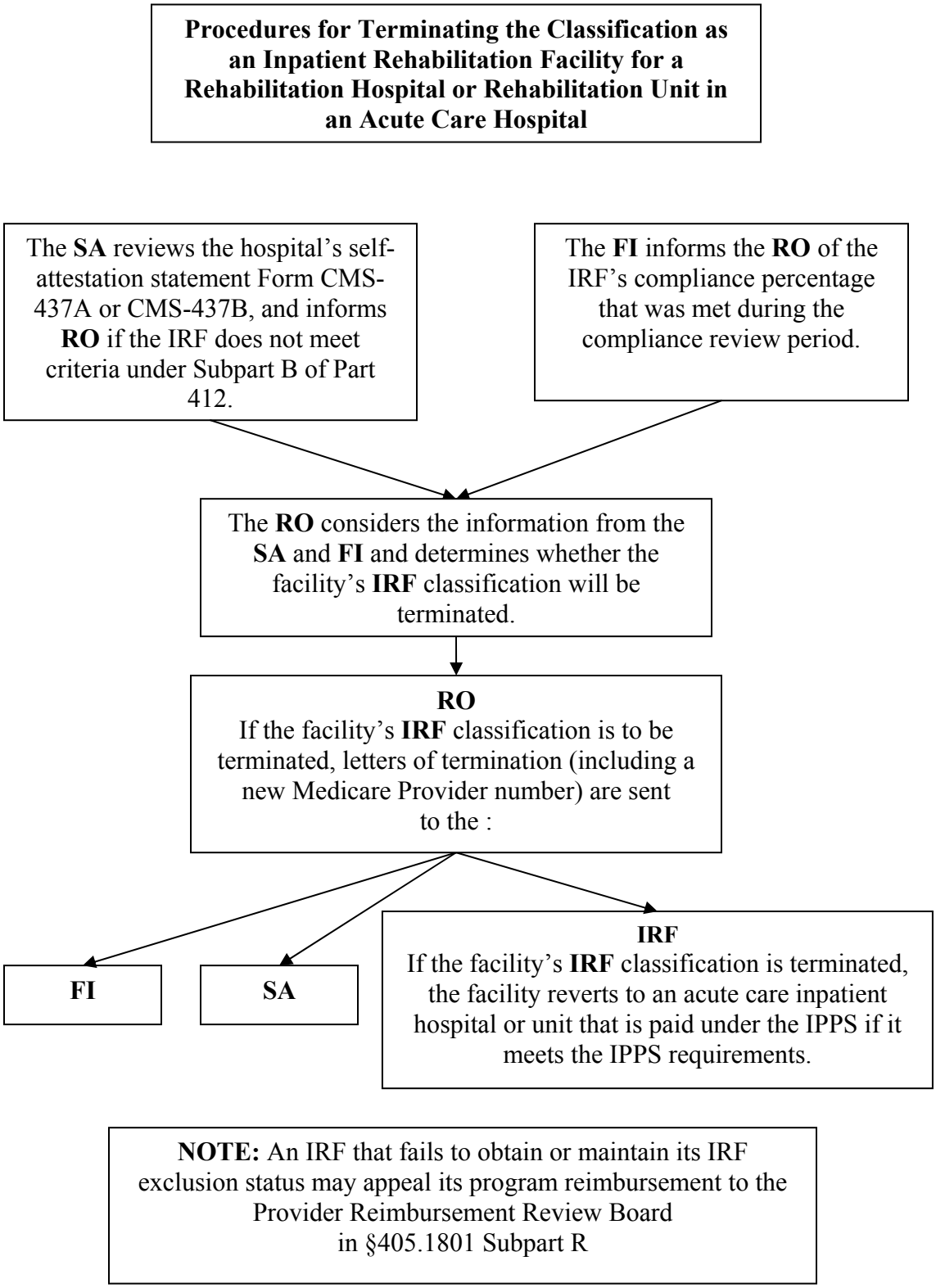
RO

- Requests **FI** to determine the compliance percentage during the compliance review period.
- **FI** must verify annually the current compliance percentage threshold. **FI** automatically initiates this verification process 4 months prior to the end of the provider's fiscal year. The **RO** notifies the provider of the compliance percentage no later than the end of the provider's fiscal year.

RO

Sends notification of recertification approval or sends notice of termination of the IRF classification status prior to the end of the provider's fiscal year to:

SA | **FI** | **IRF**


Procedures for Terminating the Classification as an Inpatient Rehabilitation Facility for a Rehabilitation Hospital or Rehabilitation Unit in an Acute Care Hospital
The SA reviews the hospital's self-attestation statement Form CMS-437A or CMS-437B, and informs RO if the IRF does not meet criteria under Subpart B of Part 412.
The FI informs the RO of the IRF's compliance percentage that was met during the compliance review period.
The RO considers the information from the SA and FI and determines whether the facility's IRF classification will be terminated.
RO
If the facility's IRF classification is to be terminated, letters of termination (including a new Medicare Provider number) are sent to the :
FI
SA
IRF
If the facility's IRF classification is terminated, the facility reverts to an acute care inpatient hospital or unit that is paid under the IPPS if it meets the IPPS requirements.
NOTE: An IRF that fails to obtain or maintain its IRF exclusion status may appeal its program reimbursement to the Provider Reimbursement Review Board in §405.1801 Subpart R

Rehabilitation Reference Manual

Tab 18:
IRF Survey Process

18.1 IRF Survey Process

18.2 Q&A

18.1 IRF Survey Process

18.1: IRF Survey Process

When conducting a full survey of an accredited or non accredited rehabilitation hospital, survey the hospital's compliance with exclusion criteria using the methods in this module.

Surveys of prospective payment system (PPS)-excluded rehabilitation hospitals utilizing these methods will count as annual validation compliance surveys of the hospital's self-attestation of compliance with the exclusion criteria.

Background
The term "exclusion" is a reimbursement term. Patient care in a PPS-excluded rehabilitation hospital is reimbursed at the IRF rate. In order for a hospital to receive the IRF PPS rate for rehabilitation care provided, the hospital must comply with the exclusion requirements found at 42 CFR 412.

A PPS-excluded rehabilitation hospital is regulated by the hospital Conditions of Participation (CoPs) at 42 CFR 482, also found in Appendix A of the *State Operations Manual (SOM*)*,* and by the PPS-excluded rehabilitation hospital requirements at 42 CFR 412.

Regulatory Authority and Requirements for PPS-Excluded Rehabilitation Hospitals
- 42 CFR 482 Conditions of Participation for hospitals.
- 42 CFR 412.22 Excluded hospitals and hospital units: General rules.
- 42 CFR 412.23 Excluded hospitals: Classifications.

Activities Conducted Prior to a Rehabilitation Hospital Survey
- Contact the CMS Regional Office (RO) to determine whether the hospital has approval as a PPS-excluded rehabilitation hospital.
- Contact the RO to determine the hospital's cost-reporting period.
- Do not conduct the survey of the PPS-excluded rehabilitation hospital requirements within 90 days of the end of the hospital's cost-reporting period.
- Identify any satellite locations of the hospital.
- Verify with the RO that the hospital is in compliance with the inpatient population percent rule and that each satellite, if any, is independently in compliance with the rule.
- Review the *Rehabilitation Hospital Criteria Work Sheet,* Form CMS-437B.

Survey Tool
Rehabilitation Hospital Criteria Work Sheet, Form CMS-437B.

Survey Procedures for Determining Compliance with the PPS-Excluded Rehabilitation Hospital Requirements
- Survey activities to determine hospital compliance with the PPS-excluded rehabilitation hospital requirements should be conducted concurrently with the full survey of the hospital's compliance with the hospital CoPs.
- Using the *Rehabilitation Hospital Criteria Work Sheet,* Form CMS-437B, verify whether the requirements have been met by checking the appropriate box marked "Yes" or "No." Under the column "Explanatory Statement," document specifics about the findings. Additional findings can be documented in a narrative note that should be attached to the worksheet.

- Select a minimum of two current inpatients for the patient sample.
- Select additional patients (open or closed records) as needed to determine compliance with the PPS-excluded rehabilitation hospital requirements.
- The selected patients should be included in the patient sample used for the full hospital survey.
- Identify whether the unit has a satellite or satellites that were unknown prior to the survey. Record the location, name, address and telephone number for every satellite on the Form CMS-437B, in the last "Explanatory Statement" block.

Exit Conference

- Inform the hospital of findings of non-compliance with the excluded rehabilitation hospital requirements.
- Inform the hospital that the SA will forward the completed Form CMS-437B to the hospital at the same time as the completed Form CMS-2567.

Post-Survey Activities

- Do not include the survey findings for the PPS-excluded rehabilitation hospital requirements on the Form CMS-2567.
- If there are PPS-excluded hospital requirements that have not been met, notify the RO. Document survey findings of the PPS-excluded rehabilitation hospital requirements on Form CMS-437B. Submit the completed Form CMS-437B to the RO within the same timeframe as the completion of the Form CMS-2567 and at least 60 days prior to the end of the hospital's cost-reporting period.
- Follow the requirements in the *SOM* for post-survey activities.

Inpatient Rehabilitation Unit Survey Model

When conducting a full survey of an accredited or non-accredited hospital that has a PPS-excluded rehabilitation unit, conduct a survey of the rehabilitation unit using the survey methods in this module to assess the hospital's compliance with the exclusion requirements.

Surveys of the PPS-excluded rehabilitation units using these methods will count as annual validation compliance surveys of the hospital's self-attestation of compliance with the exclusion requirements.

Background

The PPS-excluded rehabilitation unit is part of the hospital and is included as part of the overall hospital survey. The term "exclusion" is a reimbursement term. Patient care in a PPS-excluded rehabilitation unit is reimbursed at the PPS-excluded rehabilitation unit rate rather than the hospital PPS rate. In order for a hospital to receive the PPS-excluded rate for rehabilitation care provided in its excluded unit, the unit must comply with the excluded rehabilitation unit requirements found at 42 CFR 412.

A PPS-excluded rehabilitation unit is regulated by the hospital CoPs at 42 CFR 482, also found in Appendix A of the *State Operations Manual (SOM),* and the PPS-excluded rehabilitation unit requirements at 42 CFR 412.

Requirements for PPS-excluded Rehabilitation Units

- 42 CFR 482 Conditions of Participation for hospitals.
- 42 CFR 412.25 Excluded hospital units: Common requirements.
- 42 CFR 412.29 Excluded rehabilitation units: Additional requirements.
- *State Operations Manual (SOM),* Section 3100.

Activities Conducted Prior to Rehabilitation Unit Survey

- Contact the RO to determine whether the hospital has approval for a PPS-excluded rehabilitation unit.
- Contact the RO to determine the unit's cost-reporting period.
- Do not conduct the survey of the PPS-excluded rehabilitation unit requirements within 90 days of the end of the hospital's cost-reporting period.
- Verify with the RO that the hospital is in compliance with the inpatient population percent rule for the unit and that each rehabilitation unit satellite, if any, is independently in compliance with the rule.
- If possible, establish the location or locations of the rehabilitation unit. Determine if the unit has a satellite or satellites in other locations. Determination or verification of this information may have to wait until the survey team is onsite.
- Review the *Rehabilitation Unit Criteria Work Sheet,* Form CMS-437A.

Survey Tool

Use *Rehabilitation Unit Criteria Work Sheet,* Form CMS-437A.

Survey Procedures for Determining Compliance with the PPS-Excluded Rehabilitation Unit Requirements

- Survey activities to determine hospital compliance with the PPS-excluded rehabilitation unit requirements should be conducted concurrently with the full survey of the hospital's compliance with the hospital CoPs.
- Using the *Rehabilitation Unit Criteria Work Sheet,* Form CMS-437A, verify whether the requirements have been met by checking the appropriate box marked "Yes" or "No." Under the column "Explanatory Statement," document specifics about the findings. Additional findings can be documented in a narrative note that should be attached to the worksheet.
- Select 10% of the unit's average daily census or a minimum of two current patients for the patient sample.
- The selected patients should be included in the patient sample used for the full hospital survey.
- Select additional patients (open or closed records) as needed to determine compliance with the excluded rehabilitation unit requirements.
- If there are no patients on the unit at the time the survey is conducted, review closed patient records of unit patients treated within six months of the survey.
- Identify if the unit has a satellite or satellites that were unknown prior to the survey. Record the location, name, address and telephone number for every satellite on Form CMS-437A, in the last "Explanatory Statement" block.

Exit Conference

- Inform the hospital of findings of compliance or non-compliance with the PPS-excluded rehabilitation unit requirements.
- In the case of non-compliance inform the hospital that the SA will forward the completed Form CMS-437A to the hospital at the same time as the completed Form CMS-2567.

Post-Survey Activities

- Do not include the survey findings for the PPS-excluded rehabilitation unit requirements on Form CMS-2567.
- If there are PPS-excluded unit requirements that have not been met, notify the RO. Document survey finding of the PPS rehabilitation unit requirements on Form CMS-437A. Submit the completed Form CMS-437A to the RO within the same timeframe as the completion of Form CMS-2567 and at least 60 days prior to the end of the hospital's cost-reporting period.
- Follow the requirements in the *SOM* for post-survey activities.

18.2 Q&A

18.2: Q&A

Q: Can a physician assistant's hours substitute for some of the medical director's hours?

A: No, a physician assistant's hours cannot be substituted for any of the medical director's hours.

Q: What is the "three hour" rule?

A: Patients admitted to IRFs should be able to tolerate approximately three hours of rehabilitation services per day. This rule is guidance to aid IRFs in determining if the patient is appropriate for this level of rehabilitation services.

Q: How often should team conferences be held to determine the appropriateness of treatment?

A: Team conferences should be held at least every two weeks.

Q: How many hours per week is the director of rehabilitation expected to provide services to the rehabilitation unit?

A: The director of rehabilitation services is expected to provide 20 hours of service to the unit per week.

Q: How many hours per week is the director of rehabilitation expected to provide services to the rehabilitation hospital?

A: The director of rehabilitation in a rehabilitation hospital is expected to provide services full-time. The hospital is expected to determine what constitutes full time employment at its facility and apply the same standards to all of its employees.

Q: What experience is expected from a director of rehabilitation?

A: A director must be a doctor of medicine or osteopathy. After completing a year of internship, the medical director is expected to have at least two years of training or experience in the medical management of inpatients requiring rehabilitation services.

Q: What is the "75% rule?"

A: An IRF must show that during its most recent, consecutive and appropriate 12-month time period (defined by CMS or the FI), it served an inpatient population that meets the criteria under paragraph § 412.23(b)(2)(i) or § 412.23(b)(2)(ii).

Q: Is there a moratorium on the "75" rule?

A: For cost-reporting periods beginning on or after July 1, 2005 and before July 1, 2006 the hospital demonstrates it has served an inpatient population of whom at least 60 percent of the population meets the above referenced criteria. On or after July 1, 2006 and before July 1, 2007 the percentage changes to 65. Effective July 1, 2007 the percentage is 75.

Rehabilitation Reference Manual

Tab 19: *Basic Hospital Surveyor Training* Modules: IRFs

19.1 42 CFR 482.56, Rehabilitation Services

19.2 PPS Exclusions: Hospitals and Units

19.1 42 CFR 482.56, Rehabilitation Services

19.1: 42 CFR §482.56 Rehabilitation Services

CoP: Rehabilitation Services

- 42 CFR 482.56:
  - "If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients."

Standard (a): Organization and Staffing

- "The organization of the service must be appropriate to the scope of the services offered."
  - 482.56 (a)(1):
    - "The director of the services must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services."
  - 482.56 (a)(2):
    - "Physical therapy, occupational therapy, or speech therapy, or audiology services, if provided, must be provided by staff who meet the qualifications specified by the medical staff, consistent with State law."

Standard (b): Delivery of Services

- "Services must be furnished in accordance with a written plan of treatment. Services must be given in accordance with orders of practitioners who are authorized by the medical staff to order the services, and the orders must be incorporated into the patient's record."

Physical Environment

- Equipment
  - Adequate and appropriate?
  - Clean and maintained?
  - Remember to look at the training kitchen!

- Safety
  - Storage of chemicals and medications
  - Evacuation route and plan

Infection Control

- Universal precautions
  - Handwashing
  - Wound care supplies and equipment
- Cleaning of spills of body fluids

Patients' Rights

- Participation in development of their therapy treatment plan
- Privacy during therapy sessions
- Confidentiality of therapy records
- Freedom from restraint
  - Therapy evaluation should address restraint use, if applicable
  - Constraint-induced movement therapies

QAPI

- Service/department activities
- Integration into hospital-wide activities

Medical Records

- Receiving verbal orders
- Security of records
- Filing of entries

19.2 PPS Exclusions: Hospitals and Units

19.2: PPS Exclusions: Hospitals and Units

Prospective Payment System (PPS)

- Effective October 1, 1983
- Complex system for paying hospital using Diagnostic Related Groups (DRG)
- Hospital reimbursement is based on the patient's DRG
- Different providers and different locations receive different reimbursement amounts

PPS Exclusion

- Medicare hospital PPS-excluded status *is not* optional
- Rehabilitation hospitals and rehab units must comply with the requirements in 42 CFR Part 412 to be reimbursed under the new *inpatient rehabilitation facilities* (IRF) PPS

PPS Exclusion Process

- Exclusion applies to entire rehab hospital
- Hospital and hospital units notify CMS:
  - Information about hospital
  - Name of contact person
  - Fiscal intermediary (FI)
  - A statement that the hospital/unit meets the criteria for exclusion
  - Units identify the designated area and specify the number of beds and square footage
- Notification made no later than 5 months before the date the hospital would be subject to PPS
- SA verifies that exclusion criteria are met for:
  - Rehabilitation units of general hospitals (Form CMS-437A)
  - Rehabilitation hospitals (Form CMS-437B)

PPS-Excluded Hospitals

- Psychiatric hospitals
- Rehabilitation hospitals
- Children's hospitals
  - More than 50% of inpatients are under 18 years old
- Long-term care hospitals
  - ALS greater than 25 days
  - Agreement with QIO for admission and quality review
- Cancer hospitals
  - Primarily for treatment and research in cancer
- Hospitals outside the 50 States, the District of Columbia, or Puerto Rico

PPS-Excluded Units

- Distinct part of a hospital not otherwise excluded
- Separate cost center
- Written admission criteria uniformly applied
- Medical records identified separately from the hospital records and readily retrievable
- Meet State licensure requirements
- Physically separate and not commingled with other hospital beds
- Only one unit of each type per hospital

Rehab Unit Criteria: General

- Part of a hospital that:
  - Has a Medicare provider agreement
  - Is not excluded in its entirety from PPS
  - Has enough beds not excluded from PPS to permit the provision of adequate cost information
- Written admission criteria applied uniformly
- Admission and discharge records readily retrievable and separately identifiable from those of the hospital
- Beds assigned to the unit are physically separate
- Licensed in accordance with State law
- Unit is treated as separate cost center
- Hospital's accounting system properly allocates costs attributable to the unit
- Hospital cost report includes the costs of the unit in the same fiscal period
- Fully equipped and staffed as of the first day of the first reporting period

Rehabilitation Hospital

- 75% of inpatient population are treated with intensive rehabilitative services for:
  - Stroke
  - Spinal cord injury
  - Congenital deformity
  - Amputation
  - Major multiple trauma
  - Hip fracture
  - Brain injury
  - Polyarthritis, including rheumatoid arthritis
  - Neurological disorders including MS, muscular dystrophy and Parkinson's disease
  - Burns

Rehabilitation Hospital: PPS Exclusion Requirements

- Preadmission screening procedure
- Plan of treatment
- Treatment provision—medical, nursing, PT, OT, ST, social services, psychological services, orthotic and prosthetic services
- Coordinated multidisciplinary team approach
- Director of Rehabilitation (full-time services of MD, not PA)
- Meets the 75% rule (final rule in final clearance)

Rehabilitation Hospital: Deemed

- Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
- Commission on Accreditation of Rehabilitation Facilities (CARF)

Rehab Unit Criteria: Specific

- Meets the 75% rule (final rule in final clearance)
- Has a Director of Rehabilitation (20 hours weekly provided by a physician, not PA)
- Onsite verification or reverification survey for first time request
- Self-attestation of compliance
- Annual reverification survey by SA (5% random sample)

PPS-Excluded Hospitals and Units: Reverification

- 120 days before the start of the next cost-reporting period
- Attestation statement of compliance
- Form CMS-437A (rehab unit) or CMS-437B (rehab hospital)
- Signed attestation and forms returned to SA no later than 90 days before the start of cost-reporting period
- Transmits to RO 60 days before start of cost-reporting period

PPS Forms

- Rehab hospital and unit forms have been revised to include the interpretive guidelines
- ASPEN tags are being issued (for data purposes) and will be entered in the OSCAR system
- Letter of instruction to follow regarding inputting responses into the OSCAR system
- New forms may be used upon receipt for verification and annual reverification

PPS-Excluded Hospitals and Units: Role of the FIs

- Verify that the 75% rule applied to diagnoses at rehabilitation hospitals and units
- Verify that all distinct part units are separate cost center for cost finding and apportionment

Rehabilitation Reference Manual

Tab 20:
Forms for IRF Survey

20.1 Form CMS-437A

20.2 Form CMS-437B

20.3 Exhibit 126

20.4 Exhibit 127

20.1 Form CMS-437A

FORM APPROVED
OMB NO. 0938-0358

REHABILITATION UNIT CRITERIA WORK SHEET

RELATED MEDICARE PROVIDER NUMBER	ROOM NUMBERS IN THE UNIT	FACILITY NAME AND ADDRESS (City, State, Zip Code)
NUMBER OF BEDS IN THE UNIT	RELATED MEDICARE PROVIDER NUMBER	
REQUEST FOR EXCLUSION FOR COST REPORTING PERIOD: ___/___/_____ to ___/___/_____ (MM DD YYYY MM DD YYYY)		VERIFIED BY

ALL CRITERIA UNDER SUBPART B OF PART 412 OF THE REGULATIONS MUST BE MET FOR EXCLUSION FROM MEDICARE'S ACUTE CARE HOSPITAL PROSPECTIVE PAYMENT SYSTEM

TAG	REGULATION	GUIDANCE	YES	NO	EXPLANATORY STATEMENT
	§412.25 Excluded hospital units: Common requirements.				
	(a) Basis for exclusion. In order to be excluded from the Medicare's Acute Care Hospital Prospective Payment System (PPS) and to be paid under the Inpatient Rehabilitation Facility Prospective Payment System, a rehabilitation unit must meet the following requirements in addition to the all criteria under subpart B of part 412 of the regulations:				
M50	(1) Be part of an institution that — has in effect an agreement under part 489 to participate as a hospital and is not excluded in its entirety from the Acute Care Hospital PPS.	• Has the Fiscal Intermediary (FI) verified the rehab unit meets the 75% rule? • The surveyor should check State Agency (SA) records and/or verify with the Regional Office (RO) to ensure the hospital has an agreement to participate in the Medicare program and to ensure that the hospital is not already excluded in its entirety from PPS, such as a rehabilitation hospital. In other words, the unit seeking exclusion cannot comprise the entire hospital.			
M51	(2) Have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients.	Verify that the hospital has admission criteria and review same. Verify through open and closed record review that the approved admission criteria is being followed for all patients.			
M52	(3) Have admission & discharge records that are separately identified from those of the hospital in which it is located and are readily available.	Verify that medical records are separate and not commingled with other hospital records and are readily available for review.			

TAG	REGULATION	GUIDANCE	YES	NO	EXPLANATORY STATEMENT
M53	(4) Have policies specifying that necessary clinical information is transferred to the unit when a patient of the hospital is transferred to the unit.	Verify that the hospital has a policy detailing the *prompt* transfer of information and that it is being followed. Review records to ensure that the clinical information that should be transferred with the record is actually in the medical record.			
M54	(5) Meet applicable State licensure laws.	• Verify and document that all applicable State licensure laws are met. • Document all unmet State licensure requirements. • Verify the hospital has current licenses for its professional staff. • Are the licenses issued by the State in which the hospital is located? • Does the unit meet special licensing requirements issued by the State?			
M55	(6) Have utilization review standards applicable for the type of care offered in the unit.	Verify that the hospital has a utilization review plan that includes the review of rehab services (No utilization review (UR) standards are required if the QIO is conducting review activities.)			
M56	(7) Have beds physically separate from (that is, not commingled with) the hospital's other beds. **NOTE:** §412.25(a) (8)-(12) are verified by the FI.	Is the space containing the rehab beds separate from the beds in other units of the hospital?			
M57	(13) As part of the first day of the first cost reporting period for which all other exclusion requirements are met, the unit is fully equipped and staffed and is capable of providing hospital inpatient rehabilitation care regardless of whether there are any inpatients in the unit on that date.	Prior to scheduling the survey, verify with the FI that the unit is operational: fully staffed and equipped. (It is not required that the unit has inpatients on the day of the survey, but must demonstrate capability of caring for patients.)			

TAG	REGULATION	GUIDANCE	YES	NO	EXPLANATORY STATEMENT
	§412.29 Excluded rehabilitation units. Additional requirements. In order to be excluded from the Acute Care Hospital PPS, a rehabilitation unit must meet the following requirements:				
M58	(a) Have met either the requirements for: (1) New units under §412.30(b); or (2) Converted units under §412.30(c); or (3) Is excluded for the current cost-reporting period.	The SA will check these provisions with the RO prior to the survey.			
M59	(b) Have in effect a pre-admission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient program or assessment.	Review the pre-admission screening protocol.			
M60	(c) Ensure that the patients receive close medical supervision and furnish, through the use of qualified personnel, rehabilitation nursing, physical therapy, and occupational therapy, plus, as needed, speech therapy, social services or psychological services, and orthotic and prosthetic services.	• Verify that every patient is under the care of a physician and has authenticated orders in the chart. • If the State issues licenses, verify that all licenses are current & are issued by the State in which qualified personnel are providing services. • Determine that the hospital has a means of ensuring that its personnel remain qualified/competent. • Refer to State laws and hospital policies to determine the qualifications of personnel providing rehabilitation services. • Review medical charts if patients have been admitted.			
M61	(d) Have a plan of treatment (POT) for each inpatient that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient.	Ensure that all patients have a POT in their medical record. Verify the physician and other professional personnel participate in the establishment, review, and revision of the POT. (This could be a signature, a record of a conference, or record of consultation.)			

TAG	REGULATION	GUIDANCE	YES	NO	EXPLANATORY STATEMENT
M62	(e) Use a coordinated multidisciplinary team approach in the rehabilitation of each inpatient, as documented by periodic clinical entries made in the patient's medical record to note the patient's status in relationship to goal attainment, and that team conferences are held at least every 2 weeks to determine the appropriateness of treatment.	Review hospital policy regarding multidisciplinary team meetings, frequency, and medical record documentation.			
M63	(f) Have a director of rehabilitation who —	Verify the rehab unit has a director of rehab.			
M64	(1) Provides services to the unit and to its inpatients for at least 20 hours per week;	The 20 hours may be any combination of patient services and administration. Hours cannot be substituted by a Physician Assistant or by any other qualified professional. Verify the 20 hours through review of personnel time cards/logs, etc.			
M65	(2) Is a doctor of medicine or osteopathy;	Ensure license is current and issued by the State in which the service is being provided.			
M66	(3) Is licensed under State law to practice medicine or surgery; and	Ensure license is current and issued by the State in which the service is being provided.			
M67	(4) Has had, after completing a 1 year hospital internship, at least 2 years of training or experience in the medical management of inpatients requiring rehabilitation services.	Review personnel files.			

TAG	REGULATION	GUIDANCE	YES	NO	EXPLANATORY STATEMENT
	§412.30 Exclusion of new distinct part rehabilitation units and expansion of units already excluded.				
M68	(a) **Bed capacity in units.** A decrease in bed capacity must remain in effect for at least a full 12-month cost reporting period before an equal or lesser number of beds can be added to the hospital's licensure and certification and considered "new" under §412.30(b) below.	The SA must verify a previous decrease in State licensed hospital beds. The RO will verify any corresponding reduction in the number of beds for Medicare certification purposes.			
M69	(b) **New units.** A hospital unit is considered a new unit if the hospital has not previously sought exclusion for any rehabilitation unit; and has obtained approval under State licensure and Medicare certification, for an increase in its hospital bed capacity that is greater than 50 percent of the number of beds in the unit. For a hospital seeking exclusion of a new rehabilitation unit, the hospital may provide a written certification that at least 75 percent of the inpatient population it intends the unit to serve will require intensive rehabilitation services for treatment of one or more of the following conditions instead of showing that it has treated such a population during its most recent 12-month cost reporting period: (i) Stroke. (ii) Spinal cord injury (iii) Congenital deformity (iv) Amputation (v) Major multiple trauma. (vi) Fracture of femur (hip fracture). (vii) Brain injury. (viii) Polyarthritis, including rheumatoid arthritis. (ix) Neurological disorders, including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular distrophy, and Parkinson's disease. (x) Burns.	• SA/RO to verify that the hospital has not previously sought exclusion. • SA to verify that hospital received approval for unit under State licensure. • SA to verify that the hospital has provided written certification to the RO/FI. • The regulations at §412.30 state that a hospital unit is considered a converted unit if it doesn't qualify as a new unit. Therefore, existing excluded units are treated as converted units for purposes of reverification of the 75% rule.			

TAG	REGULATION	GUIDANCE	YES	NO	EXPLANATORY STATEMENT
M70	(c) **Converted units** A hospital unit is considered a converted unit if it does not qualify as a new unit and it must have treated, for the hospital's most recent 12-month cost reporting period, an inpatient population of which at least 75 percent required intensive rehabilitation services for the treatment of one or more conditions listed under §412.23(b)(2).	Verify through the RO that the hospital unit provided intensive rehab services to 75% of the unit's population for the most recent 12-month cost reporting period. (The FI is responsible for verifying this criteria.)			
M71	(d) **Expansion of Excluded Rehabilitation Units** (1) The beds that a hospital seeks to add to its excluded rehabilitation unit are considered new only if the State-licensed & Medicare certified bed capacity increases at the start of the cost reporting period (for which the hospital seeks to increase the size of its excluded rehabilitation unit) or at any time after the start of the preceding cost report period; and the hospital has obtained approval, under State licensure and Medicare certification, for an increase in its hospital bed capacity that is greater than 50 percent of the number of beds it seeks to add to the unit. (2) A hospital may increase the size of its excluded rehabilitation unit through conversion of existing bed capacity only if it shows that, for all of the hospital's most recent cost reporting period of at least 12 months, the beds have been used to treat an inpatient population meeting the requirements of §412.23(b)(2).	• Verify the hospital obtained State approval for an increase in its bed capacity. • FI to verify hospital has met the 75% rule for all of the most recent cost reporting period.			

According to the Paperwork Reduction of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0358. The time required to complete this information collection is estimated to average 15 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

20.2 Form CMS-437B

FORM APPROVED
OMB NO. 0938-0358

REHABILITATION HOSPITAL CRITERIA WORK SHEET

RELATED MEDICARE PROVIDER NUMBER	ROOM NUMBERS IN THE UNIT	FACILITY NAME AND ADDRESS (City, State, Zip Code)
NUMBER OF BEDS IN THE UNIT	SURVEY DATE	
REQUEST FOR EXCLUSION FOR COST REPORTING PERIOD: ___/___/_____ to ___/___/_____ (MM DD YYYY MM DD YYYY)		VERIFIED BY

ALL CRITERIA UNDER SUBPART B OF PART 412 OF THE REGULATIONS MUST BE MET FOR EXCLUSION FROM MEDICARE'S ACUTE CARE HOSPITAL PROSPECTIVE PAYMENT SYSTEM

TAG	REGULATION **§412.23 Excluded hospitals:**	GUIDANCE TO SURVEYORS	YES	NO	EXPLANATORY STATEMENT
	(b) Rehabilitation hospitals. In order to be excluded from the Medicare's Acute Care Hospital Prospective Payment System (PPS) and to be paid under the Inpatient Rehabilitation Facility Prospective Payment System, a rehabilitation hospital must meet the following requirements in addition to all the criteria under subpart B of part 412 of the regulations:				
M75	(1) Have a provider agreement under part 489 to participate as a hospital.	• The surveyor should check State Agency (SA) records and/or verify with the Regional Office (RO) to ensure the hospital has an agreement to participate in the Medicare program.			
M76	(2) Except in the case of a newly participating hospital seeking exclusion for its first 12-month cost reporting period, as described in paragraph (b)(8) of this section, show that during its most recent 12-month cost reporting period, it served an inpatient population of whom at least 75 percent required intensive rehabilitative services for the treatment of one or more of the following conditions: (i) Stroke (ii) Spinal cord injury (iii) Congenital deformity (iv) Amputation (v) Major multiple trauma (vi) Fracture of femur (hip fracture) (vii) Brain injury (viii) Polyarthritis, including rheumatoid arthritis (ix) Neurological disorders, including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular distrophy, and Parkinson's disease (x) Burns	• Has the Fiscal Intermediary verified the rehab hospital meets the 75% rule?			

TAG	REGULATION	GUIDANCE TO SURVEYORS	YES	NO	EXPLANATORY STATEMENT
M77	(3) Have in effect a pre-admission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient program or assessment.	• Review the pre-admission screening protocol and verify the protocol is applied to each potential admission (through record review, etc).			
M78	(4) Ensure that the patients receive close medical supervision and furnish, through the use of qualified personnel, rehabilitation, nursing, physical therapy, and occupational therapy, plus, as needed, speech therapy, social services or psychological services, and orthotic and prosthetic services.	• Verify that every patient is under the care of a physician and has signed orders in the chart. • If the State issues licenses, verify that all licenses are current and are issued by the State in which qualified personnel are providing services. • Determine that the hospital has a means of ensuring that its personnel remain qualified/ competent? • Refer to State laws and hospital policies to determine the qualifications of personnel providing rehabilitation services. • Review medical charts if patients have been admitted.			
M79	(5) Have a director of rehabilitation who —	Verify the rehab unit has a director of rehab.			
M80	(i) Provides services to the hospital and its inpatients on a full time basis;	The full time hours may be any combination of patient services and administration. A director of rehabilitation hours cannot be substituted by a Physician Assistant. Verify the full time hours through review of personnel time cards/logs, etc.			
M81	(ii) Is a doctor of medicine or osteopathy;	Ensure license is current and issued by the State in which the service is being provided.			
M82	(iii) Is licensed under State law to practice medicine or surgery; and	Ensure license is current and issued by the State in which the service is being provided.			
M83	(iv) Has had, after completing a 1-year hospital internship, at least 2 years of training or experience in the medical management of inpatients requiring rehabilitation services.	Review personnel files.			
M84	(6) Have a plan of treatment (POT) for each inpatient that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient.	Ensure that all patients have a POT in their medical record. Verify the physician and other professional personnel participate in the establishment, review, and revision of the POT. (This could be a signature, a record of a conference, or record of consultation.)			

TAG	REGULATION	GUIDANCE TO SURVEYORS	YES	NO	EXPLANATORY STATEMENT
M85	(7) Use a coordinated multidisciplinary team approach in the rehabilitation of each inpatient, as documented by periodic clinical entries made in the patient's medical record to note the patient's status in relationship to goal attainment, and that team conferences are held at every 2 weeks to determine the appropriateness of treatment.	Review hospital policy regarding multidisciplinary team meetings, frequency, and medical record documentation.			
M86	(8) A hospital that seeks exclusion as a rehabilitation hospital for the first full 12-month cost reporting period that occurs after it becomes a Medicare participating hospital may provide a written certification that the inpatient population it intends to serve meets the requirements of paragraph (a)(2) of this section, instead of showing that it has treated such a population during its most recent 12-month cost reporting period.				

According to the Paperwork Reduction of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0358. The time required to complete this information collection is estimated to average 15 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, Attn: PRA Reports Clearance Officer, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

20.3 Exhibit 126: Model Letter Accompanying Self-Attestation Work Sheets

Exhibit 126

Model Letter Accompanying Self-Attestation Work Sheets (Form CMS 437A and 437B)

Name of IPPS-Excluded Hospital or Hospital Unit
Address
City, State, Zip

Dear Name of Hospital/Unit :

If this facility or unit continues to be eligible for exemption from the Medicare Inpatient Prospective Payment System (IPPS) for the fiscal year beginning _____, the Administrator or Chief Executive Officer of the hospital (i.e., the individual principally responsible for the operation of the hospital) must complete and return the attached attestation statement and work sheet. Hospitals and units may be excluded from IPPS if they meet certain requirements of 42 CFR Parts 412.23 through 412.30. Excluded units are paid under cost reimbursement rules at 42 CFR Part 412. If a hospital/unit does not in fact meet the exclusion criteria, Medicare payment will be made under the IPPS.

According to our records (name of IPPS-excluded hospital or unit) will need to be re-verified by (date). In order to continue to receive payment under Medicare and Medicaid as a (type of IPPS-excluded hospital or unit), an officer of the hospital/unit must certify, at least 90 days prior to the beginning of the next cost reporting period, that the hospital or unit currently meets and will continue to meet all of the IPPS-exclusion criteria.

In order to receive the certification in a timely manner, the Administrator or Chief Executive Officer, as appropriate, of the hospital must:

- Respond to every item on the attached worksheet;

- Sign and date the front page of the attached worksheet (Form CMS-437, 437A or 437B, as appropriate) in the space marked, "Verified By:"; and

- Return both the signed attestation statement and the signed completed work sheet to (State agency address) by (date that is 90 days prior to the beginning of the cost reporting period).

Please note that the hospital/unit should notify the Regional Office (RO address) immediately if it does not wish to continue as a PPS-excluded hospital/unit. In addition, if hospitals/units are not interested or otherwise unable to use the self-attestation process to apply for continued exclusion from IPPS, a survey process may be used to determine if the hospital/unit should continue to be excluded from IPPS.

Please note that hospitals/units are under a continuing obligation to notify the State agency if the hospital or unit fails to meet one of the applicable requirements in the period between the attestation and the start of the fiscal year. CMS will continue to verify separately, through the appropriate fiscal intermediary, compliance with certain criteria (e.g., the 75% requirement for rehabilitation hospitals and units) currently verified by the fiscal intermediary. Please be advised that CMS may validate the compliance of any requirement without prior notice.

If there are any questions about the requirements or completion of the worksheet or the attestation, please contact (name, address and telephone number of contact person).

State Agency Director
Signature

20.4 Exhibit 127: Attestation Statement For Exclusion From PPS For Fiscal Year Beginning: (Date)

Exhibit 127

Attestation Statement for Exclusion from IPPS
for Fiscal Year Beginning: _____

Name of State Agency Director
Name of State Agency
Address
City, State, Zip

Dear (State Agency Director):

This attestation must be signed by the Administrator/Chief Executive Officer of the hospital (including hospitals with excluded units).

ATTENTION: Read the following carefully before signing.

STATEMENTS OR ENTRIES GENERALLY: Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme or device a material fact, or makes any false, fictitious or fraudulent statement or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be fined not more than $10,000 or imprisoned not more than five years, or both. (18 U.S.C., Sec.1001)

Based upon my personal knowledge and belief, I attest that the responses on the attached inpatient prospective payment system (IPPS) exclusion work sheet are true and correct, and that (name of IPPS-Excluded Hospital or Unit) currently meets and will continue to meet the applicable requirements for exclusion from IPPS for the period beginning (first day of hospital's fiscal year), as set out in Subpart B of 42 CFR Part 412. I agree that if the (hospital or unit) fails to meet any of these requirements between the date of attestation and the first day of the hospital's fiscal year, I will notify the Regional Office (name and address of RO) of the change immediately in order to permit a valid determination of distinct part status prior to the beginning of the fiscal year. (Include the next sentence for units only): The unit is located in (enter building name, room numbers and address), and consists of ___square feet.

I understand that the Centers for Medicare and Medicaid Services (CMS) or its representative has the right to conduct an on-site survey at any time to validate whether the statements made on the attached work sheet are true.

Signature_____
(Administrator/Chief Executive Officer of the hospital)
Title_____
Date_____

Fill in blanks before sending the form to the facility.

Rehabilitation Reference Manual

Tab 21: References for IRF Survey

21.1 *Code of Federal Regulations*

21.2 *Federal Register*

21.3 Survey & Certification Memoranda

21.4 Social Security Act, Section 1886(j)

21.5 Setting the ODIE System Switch to Receive Data for IRFS

21.6 *Inpatient Rehabilitation Facility – Patient Assessment Instrument*

21.7 Chronic Care Policy Group Memoranda

21.8 Other Print and Online References

21.1 *Code of Federal Regulations*

42 CFR 412.20–30
42 CFR 412.600–632
42 CFR 482, Subparts A–D

FEDERAL REGISTER notice at least annually. Except as specified in paragraphs (c) and (d) of this section, the DRG changes are effective prospectively with discharges occurring on or after the same date the payment rates are effective.

(b) *Basis for changes in the DRG classification system.* All changes in the DRG classification system are made using the principles established for the DRG system. This means that cases are classified so each DRG is—

(1) Clinically coherent; and

(2) Embraces an acceptable range of resource consumption.

(c) *Interim coverage changes*—(1) *Criteria.* CMS makes interim changes to the DRG classification system during the Federal fiscal year to incorporate items and services newly covered under Medicare.

(2) *Implementation and effective date.* CMS issues interim coverage changes through its administrative issuance system and makes the change effective as soon as is administratively feasible.

(3) *Publication for comment.* CMS publishes any change made under paragraph (c)(1) of this section in the next annual notice of changes to the DRG classification system published in accordance with paragraph (a) of this section.

(d) *Interim changes to correct omissions and inequities*—(1) *Criteria.* CMS makes interim changes to the DRG classification system to correct a serious omission or inequity in the system only if failure to make the changes would have—

(i) A potentially substantial adverse impact on the health and safety of beneficiaries; or

(ii) A significant and unwarranted fiscal impact on hospitals or the Medicare program.

(2) *Publication and effective date.* CMS publishes these changes in the FEDERAL REGISTER in a final notice with comment period with a prospective effective date. The change is also published for public information in the next annual notice of changes to the DRG classification system published in accordance with paragraph (a) of this section.

(e) *Review by ProPAC.* Changes published annually in accordance with paragraph (a) of this section are subject to review and comment by ProPAC upon publication. Interim changes to the DRG classification system that are made in accordance with paragraphs (c) and (d) of this section are subject to review by ProPAC before implementation.

[50 FR 35688, Sept. 3, 1985, as amended at 51 FR 31496, Sept. 3, 1986; 57 FR 39820, Sept. 1, 1992]

Subpart B—Hospital Services Subject to and Excluded From the Prospective Payment Systems for Inpatient Operating Costs and Inpatient Capital-Related Costs

§ 412.20 Hospital services subject to the prospective payment systems.

(a) Except for services described in paragraphs (b), (c), and (d) of this section, all covered inpatient hospital services furnished to beneficiaries during subject cost reporting periods are paid under the prospective payment systems specified in § 412.1(a)(1).

(b)(1) Effective for cost reporting periods beginning on or after January 1, 2002, covered inpatient hospital services furnished to Medicare beneficiaries by a rehabilitation hospital or rehabilitation unit that meet the conditions of § 412.604 are paid under the prospective payment system described in subpart P of this part.

(2) CMS will not pay for services under Subpart P of this part if the services are paid for by a health maintenance organization (HMO) or competitive medical plan (CMP) that elects not to have CMS make payments to an inpatient rehabilitation facility for services, which are inpatient hospital services, furnished to the HMO's or CMP's Medicare enrollees, as provided under part 417 of this chapter.

(c) Effective for cost reporting periods beginning on or after October 1, 2002, covered inpatient hospital services furnished to Medicare beneficiaries by a long-term care hospital that meets the conditions for payment of §§ 412.505 through 412.511 are paid under the prospective payment system described in subpart O of this part.

(d) Inpatient hospital services will not be paid under the prospective payment systems specified in § 412.1(a)(1) under any of the following circumstances:

(1) The services are furnished by a hospital (or hospital unit) explicitly excluded from the prospective payment systems under §§ 412.23, 412.25, 412.27, and 412.29.

(2) The services are emergency services furnished by a nonparticipating hospital in accordance with § 424.103 of this chapter.

(3) The services are paid for by an HMO or competitive medical plan (CMP) that elects not to have CMS make payments directly to a hospital for inpatient hospital services furnished to the HMO's or CMP's Medicare enrollees, as provided in § 417.240(d) and § 417.586 of this chapter.

[50 FR 12741, Mar. 29, 1985, as amended at 53 FR 6648, Mar. 2, 1988; 57 FR 39820, Sept. 1, 1992; 59 FR 45400, Sept. 1, 1994; 66 FR 41386, Aug. 7, 2001; 67 FR 56048, Aug. 30, 2002; 68 FR 45698, Aug. 1, 2003]

§ 412.22 Excluded hospitals and hospital units: General rules.

(a) *Criteria.* Subject to the criteria set forth in paragraph (e) of this section, a hospital is excluded from the prospective payment systems specified in § 412.1(a)(1) of this part if it meets the criteria for one or more of the excluded classifications described in § 412.23. For purposes of this subpart, the term "hospital" includes a critical access hospital (CAH).

(b) *Cost reimbursement.* Except for those hospitals specified in paragraph (c) of this section and §§ 412.20(b) and (c), all excluded hospitals (and excluded hospital units, as described in §§ 412.23 through 412.29) are reimbursed under the cost reimbursement rules set forth in part 413 of this subchapter, and are subject to the ceiling on the rate of hospital cost increases described in § 413.40 of this subchapter.

(c) *Special payment provisions.* The following classifications of hospitals are paid under special provisions and therefore are not generally subject to the cost reimbursement or prospective payment rules of this chapter.

(1) Veterans Administration hospitals.

(2) Hospitals reimbursed under State cost control systems approved under part 403 of this chapter.

(3) Hospitals reimbursed in accordance with demonstration projects authorized under section 402(a) of Public Law 90–248 (42 U.S.C. 1395b–1) or section 222(a) of Public Law 92–603 (42 U.S.C. 1395b–1 (note)).

(4) Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

(d) *Changes in hospitals' status.* For purposes of exclusion from the prospective payment systems under this subpart, the status of each currently participating hospital (excluded or not excluded) is determined at the beginning of each cost reporting period and is effective for the entire cost reporting period. Any changes in the status of the hospital are made only at the start of a cost reporting period.

(e) *Hospitals-within-hospitals.* Except as provided in paragraph (f) of this section, a hospital that occupies space in a building also used by another hospital, or in one or more separate buildings located on the same campus as buildings used by another hospital, must meet the following criteria in order to be excluded from the prospective payment systems specified in § 412.1(a)(1):

(1) Except as specified in paragraph (f) of this section, for cost reporting periods beginning on or after October 1, 1997—

(i) *Separate governing body.* The hospital has a governing body that is separate from the governing body of the hospital occupying space in the same building or on the same campus. The hospital's governing body is not under the control of the hospital occupying space in the same building or on the same campus, or of any third entity that controls both hospitals.

(ii) *Separate chief medical officer.* The hospital has a single chief medical officer who reports directly to the governing body and who is responsible for all medical staff activities of the hospital. The chief medical officer of the hospital is not employed by or under contract with either the hospital occupying space in the same building or on the same campus or any third entity that controls both hospitals.

(iii) *Separate medical staff.* The hospital has a medical staff that is separate from the medical staff of the hospital occupying space in the same building or on the same campus. The hospital's medical staff is directly accountable to the governing body for the quality of medical care provided in the hospital, and adopts and enforces by-laws governing medical staff activities, including criteria and procedures for recommending to the governing body the privileges to be granted to individual practitioners.

(iv) *Chief executive officer.* The hospital has a single chief executive officer through whom all administration authority flows, and who exercises control and surveillance over all administrative activities of the hospital. The chief executive officer is not employed by, or under contract with, either the hospital occupying space in the same building or on the same campus or any third entity that controls both hospitals.

(v) *Performance of basic hospital functions.* The hospital meets one of the following criteria:

(A) The hospital performs the basic functions specified in §§482.21 through 482.27, 482.30, 482.42, 482.43, and 482.45 of this chapter through the use of employees or under contracts or other agreements with entities other than the hospital occupying space in the same building or on the same campus, or a third entity that controls both hospitals. Food and dietetic services and housekeeping, maintenance, and other services necessary to maintain a clean and safe physical environment could be obtained under contracts or other agreements with the hospital occupying space in the same building or on the same campus, or with a third entity that controls both hospitals.

(B) For the same period of at least 6 months used to determine compliance with the criterion regarding the age of patients in §412.23(d)(2) or the length-of-stay criterion in §412.23(e)(2), or for hospitals other than children's or long-term care hospitals, for a period of at least 6 months immediately preceding the first cost reporting period for which exclusion is sought, the cost of the services that the hospital obtains under contracts or other agreements with the hospital occupying space in the same building or on the same campus, or with a third entity that controls both hospitals, is no more than 15 percent of the hospital's total inpatient operating costs, as defined in §412.2(c). For purposes of this paragraph (e)(1)(v)(B), however, the costs of preadmission services are those specified under §413.40(c)(2) rather than those specified under §412.2(c)(5).

(C) For the same period of at least 6 months used to determine compliance with the criterion regarding the age of inpatients in §412.23(d)(2) or the length-of-stay criterion in §412.23(e)(2), or for hospitals other than children's or long-term care hospitals, for the period of at least 6 months immediately preceding the first cost reporting period for which exclusion is sought, the hospital has an inpatient population of whom at least 75 percent were referred to the hospital from a source other than another hospital occupying space in the same building or on the same campus.

(2) Effective for long-term care hospitals-within-hospitals for cost reporting periods beginning on or after October 1, 2004, the hospital must meet the governance and control requirements at paragraphs (e)(1)(i) through (e)(1)(iv) of this section.

(3) *Notification of co-located status.* A long-term care hospital that occupies space in a building used by another hospital, or in one or more separate buildings located on the same campus as buildings used by another hospital that meets the criteria of (e)(1) or (e)(2) of this section must notify its fiscal intermediary and CMS in writing of its co-location within 60 days of its first cost reporting period that begins on or after October 1, 2002.

(f) *Application for certain hospitals.* If a hospital was excluded from the prospective payment systems under the provisions of this section on or before September 30, 1995, and at that time occupied space in a building also used by another hospital, or in one or more buildings located on the same campus as buildings used by another hospital, the criteria in paragraph (e) of this section do not apply to the hospital as long as the hospital either—

(1) Continues to operate under the same terms and conditions, including

the number of beds and square footage considered to be part of the hospital for purposes of Medicare participation and payment in effect on September 30, 1995; or

(2) In the case of a hospital that changes the terms and conditions under which it operates after September 30, 1995, but before October 1, 2003, continues to operate under the same terms and conditions, including the number of beds and square footage considered to be part of the hospital for purposes of Medicare participation and payment in effect on September 30, 2003.

(g) *Definition of control.* For purposes of this section, control exists if an individual or an organization has the power, directly or indirectly, significantly to influence or direct the actions or policies of an organization or institution.

(h) *Satellite facilities.* (1) For purposes of paragraphs (h)(2) through (h)(4) of this section, a satellite facility is a part of a hospital that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital.

(2) Except as provided in paragraphs (h)(3), (h)(6), and (h)(7) of this section, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period:

(i) In the case of a hospital (other than a children's hospital) that was excluded from the prospective payment systems for the most recent cost reporting period beginning before October 1, 1997, the hospital's number of State-licensed and Medicare-certified beds, including those at the satellite facilities, does not exceed the hospital's number of State-licensed and Medicare-certified beds on the last day of the hospital's last cost reporting period beginning before October 1, 1997.

(ii) The satellite facility independently complies with—

(A) For psychiatric hospitals, the requirements under § 412.23(a);

(B) For rehabilitation hospitals, the requirements under § 412.23(b)(2);

(C) For the children's hospitals, the requirements under § 412.23(d)(2); or

(D) For long–term care hospitals, the requirements under §§ 412.23(e)(1) through (e)(3)(i).

(iii) The satellite facility meets all of the following requirements:

(A) Effective for cost reporting periods beginning on or after October 1, 2002, it is not under the control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the control of the medical staff or chief medical officer of the hospital in which it is located.

(B) It maintains admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.

(C) It has beds that are physically separate from (that is, not commingled with) the beds of the hospital in which it is located.

(D) It is serviced by the same fiscal intermediary as the hospital of which it is a part.

(E) It is treated as a separate cost center of the hospital of which it is a part.

(F) For cost reporting and apportionment purposes, it uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of allocation.

(G) It reports its costs on the cost report of the hospital of which it is a part, covering the same fiscal period and using the same method of apportionment as the hospital of which it is a part.

(3) Except as provided in paragraph (h)(4) of this section, the provisions of paragraph (h)(2) of this section do not apply to—

(i) Any hospital structured as a satellite facility on September 30, 1999, and excluded from the prospective payment systems on that date, to the extent the hospital continues operating under the same terms and conditions, including the number of beds and square footage considered, for purposes

of Medicare participation and payment, to be part of the hospital, in effect on September 30, 1999; or

(ii) Any hospital excluded from the prospective payment systems under §412.23(e)(2)(ii).

(4) In applying the provisions of paragraph (h)(3) of this section, any hospital structured as a satellite facility on September 30, 1999, may increase or decrease the square footage of the satellite facility or may decrease the number of beds in the satellite facility if these changes are made necessary by relocation of a facility—

(i) To permit construction or renovation necessary for compliance with changes in Federal, State, or local law; or

(ii) Because of catastrophic events such as fires, floods, earthquakes, or tornadoes.

(5) *Notification of co-located status.* A satellite of a long-term care hospital that occupies space in a building used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital and that meets the criteria of paragraphs (h)(1) through (h)(4) of this section must notify its fiscal intermediary and CMS in writing of its co-location within 60 days of its first cost reporting period beginning on or after October 1, 2002.

(6) The provisions of paragraph (h)(2)(i) of this section do not apply to any long-term care hospital that is subject to the long-term care hospital prospective payment system under Subpart O of this subpart, effective for cost reporting periods occurring on or after October 1, 2002, and that elects to be paid based on 100 percent of the Federal prospective payment rate as specified in §412.533(c), beginning with the first cost reporting period following that election, or when the LTCH is fully transitioned to 100 percent of the Federal prospective rate, or to a new long-term care hospital, as defined in §412.23(e)(4).

(7) The provisions of paragraph (h)(2)(i) of this section do not apply to any inpatient rehabilitation facility that is subject to the inpatient rehabilitation facility prospective payment system under subpart P of this part, effective for cost reporting periods beginning on or after October 1, 2003.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 34793, Sept. 30, 1986; 57 FR 39820, Sept. 1, 1994; 62 FR 46026, Aug. 29, 1997; 63 FR 26357, May 12, 1998; 64 FR 41540, July 30, 1999; 66 FR 41386, Aug. 7, 2001; 67 FR 50111, Aug. 1, 2002; 67 FR 56048, Aug. 30, 2002; 68 FR 10988, Mar. 7, 2003; 68 FR 34162, June 6, 2003; 68 FR 45469, Aug. 1, 2003; 69 FR 49240, Aug. 11, 2004; 69 FR 60252, Oct. 7, 2004]

§412.23 Excluded hospitals: Classifications.

Hospitals that meet the requirements for the classifications set forth in this section are not reimbursed under the prospective payment systems specified in §412.1(a)(1):

(a) *Psychiatric hospitals.* A psychiatric hospital must—

(1) Be primarily engaged in providing, by or under the supervision of a psychiatrist, psychiatric services for the diagnosis and treatment of mentally ill persons; and

(2) Meet the conditions of participation for hospitals and special conditions of participation for psychiatric hospitals set forth in part 482 of this chapter.

(b) *Rehabilitation hospitals.* A rehabilitation hospital must meet the following requirements to be excluded from the prospective payment systems specified in §412.1(a)(1) and to be paid under the prospective payment system specified in §412.1(a)(2) and in Subpart P of this part:

(1) Have a provider agreement under part 489 of this chapter to participate as a hospital.

(2) Except in the case of a newly participating hospital seeking classification under this paragraph as a rehabilitation hospital for its first 12-month cost reporting period, as described in paragraph (b)(8) of this section, a hospital must show that during its most recent, consecutive, and appropriate 12-month time period (as defined by CMS or the fiscal intermediary), it served an inpatient population that meets the criteria under paragraph (b)(2)(i) or (b)(2)(ii) of this section.

(i) For cost reporting periods beginning on or after July 1, 2004 and before July 1, 2005, the hospital has served an inpatient population of whom at least

50 percent, and for cost reporting periods beginning on or after July 1, 2005 and before July 1, 2006, the hospital has served an inpatient population of whom at least 60 percent, and for cost reporting periods beginning on or after July 1, 2006 and before July 1, 2007, the hospital has served an inpatient population of whom at least 65 percent, required intensive rehabilitative services for treatment of one or more of the conditions specified at paragraph (b)(2)(iii) of this section. A patient with a comorbidity, as defined at § 412.602, may be included in the inpatient population that counts towards the required applicable percentage if—

(A) The patient is admitted for inpatient rehabilitation for a condition that is not one of the conditions specified in paragraph (b)(2)(iii) of this section;

(B) The patient has a comorbidity that falls in one of the conditions specified in paragraph (b)(2)(iii) of this section; and

(C) The comorbidity has caused significant decline in functional ability in the individual such that, even in the absence of the admitting condition, the individual would require the intensive rehabilitation treatment that is unique to inpatient rehabilitation facilities paid under subpart P of this part and that cannot be appropriately performed in another care setting covered under this title.

(ii) For cost reporting periods beginning on or after July 1, 2007, the hospital has served an inpatient population of whom at least 75 percent required intensive rehabilitative services for treatment of one or more of the conditions specified in paragraph (b)(2)(iii) of this section. A patient with comorbidity as described in paragraph (b)(2)(i) is not included in the inpatient population that counts towards the required 75 percent.

(iii) *List of conditions.*

(A) Stroke.

(B) Spinal cord injury.

(C) Congenital deformity.

(D) Amputation.

(E) Major multiple trauma.

(F) Fracture of femur (hip fracture).

(G) Brain injury.

(H) Neurological disorders, including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson's disease.

(I) Burns.

(J) Active, polyarticular rheumatoid arthritis, psoriatic arthritis, and seronegative arthropathies resulting in significant functional impairment of ambulation and other activities of daily living that have not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission or that result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.

(K) Systemic vasculidities with joint inflammation, resulting in significant functional impairment of ambulation and other activities of daily living that have not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission or that result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.

(L) Severe or advanced osteoarthritis (osteoarthrosis or degenerative joint disease) involving two or more major weight bearing joints (elbow, shoulders, hips, or knees, but not counting a joint with a prosthesis) with joint deformity and substantial loss of range of motion, atrophy of muscles surrounding the joint, significant functional impairment of ambulation and other activities of daily living that have not improved after the patient has participated in an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission but have the potential to improve with more intensive rehabilitation. (A joint replaced by a prosthesis no longer is considered to have osteoarthritis, or other arthritis, even though this condition was the reason for the joint replacement.)

(M) Knee or hip joint replacement, or both, during an acute hospitalization immediately preceding the inpatient rehabilitation stay and also meet one or more of the following specific criteria:

(*1*) The patient underwent bilateral knee or bilateral hip joint replacement surgery during the acute hospital admission immediately preceding the IRF admission.

(*2*) The patient is extremely obese with a Body Mass Index of at least 50 at the time of admission to the IRF.

(*3*) The patient is age 85 or older at the time of admission to the IRF.

(3) Have in effect a preadmission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient hospital program or assessment.

(4) Ensure that the patients receive close medical supervision and furnish, through the use of qualified personnel, rehabilitation nursing, physical therapy, and occupational therapy, plus, as needed, speech therapy, social or psychological services, and orthotic and prosthetic services.

(5) Have a director of rehabilitation who—

(i) Provides services to the hospital and its inpatients on a full-time basis;

(ii) Is a doctor of medicine or osteopathy;

(iii) Is licensed under State law to practice medicine or surgery; and

(iv) Has had, after completing a one-year hospital internship, at least two years of training or experience in the medical-management of inpatients requiring rehabilitation services.

(6) Have a plan of treatment for each inpatient that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient.

(7) Use a coordinated multidisciplinary team approach in the rehabilitation of each inpatient, as documented by periodic clinical entries made in the patient's medical record to note the patient's status in relationship to goal attainment, and that team conferences are held at least every two weeks to determine the appropriateness of treatment.

(8) A hospital that seeks classification under this paragraph as a rehabilitation hospital for the first full 12-month cost reporting period that occurs after it becomes a Medicare-participating hospital may provide a written certification that the inpatient population it intends to serve meets the requirements of paragraph (b)(2) of this section, instead of showing that it has treated that population during its most recent 12-month cost reporting period. The written certification is also effective for any cost reporting period of not less than one month and not more than 11 months occurring between the date the hospital began participating in Medicare and the start of the hospital's regular 12-month cost reporting period.

(9) For cost reporting periods beginning on or after October 1, 1991, if a hospital is excluded from the prospective payment systems specified in §412.1(a)(1) or is paid under the prospective payment system specified in §412.1(a)(2) for a cost reporting period under paragraph (b)(8) of this section, but the inpatient population it actually treated during that period does not meet the requirements of paragraph (b)(2) of this section, we adjust payments to the hospital retroactively in accordance with the provisions in §412.130.

(c) [Reserved]

(d) *Children's hospitals.* A children's hospital must—

(1) Have a provider agreement under part 489 of this chapter to participate as a hospital; and

(2) Be engaged in furnishing services to inpatients who are predominantly individuals under the age of 18.

(e) *Long-term care hospitals.* A long-term care hospital must meet the requirements of paragraph (e)(1) and (e)(2) of this section and, where applicable, the additional requirements of §412.22(e), to be excluded from the prospective payment systems specified in §412.1(a)(1) and to be paid under the prospective payment system specified in §412.1(a)(3) and in Subpart O of this part.

(1) *Provider agreements.* The hospital must have a provider agreement under

Part 489 of this chapter to participate as a hospital; and

(2) *Average length of stay.* (i) The hospital must have an average Medicare inpatient length of stay of greater than 25 days (which includes all covered and noncovered days of stay of Medicare patients) as calculated under paragraph (e)(3) of this section; or

(ii) For cost reporting periods beginning on or after August 5, 1997, a hospital that was first excluded from the prospective payment system under this section in 1986 meets the length of stay criterion if it has an average inpatient length of stay for all patients, including both Medicare and non-Medicare inpatients, of greater than 20 days and demonstrates that at least 80 percent of its annual Medicare inpatient discharges in the 12-month cost reporting period ending in fiscal year 1997 have a principal diagnosis that reflects a finding of neoplastic disease as defined in paragraph (f)(1)(iv) of this section.

(3) *Calculation of average length of stay.* (i) Subject to the provisions of paragraphs (e)(3)(ii) through (e)(3)(iv) of this section, the average Medicare inpatient length of stay specified under paragraph (e)(2)(i) of this section is calculated by dividing the total number of covered and noncovered days of stay of Medicare inpatients (less leave or pass days) by the number of total Medicare discharges for the hospital's most recent complete cost reporting period. Subject to the provisions of paragraphs (e)(3)(ii) through (e)(3)(iv) of this section, the average inpatient length of stay specified under paragraph (e)(2)(ii) of this section is calculated by dividing the total number of days for all patients, including both Medicare and non-Medicare inpatients (less leave or pass days) by the number of total discharges for the hospital's most recent complete cost reporting period.

(ii) Effective for cost reporting periods beginning on or after July 1, 2004, in calculating the hospital's average length of stay, if the days of a stay of an inpatient involves days of care furnished during two or more separate consecutive cost reporting periods, that is, an admission during one cost reporting period and a discharge during a future consecutive cost reporting period, the total number of days of the stay are considered to have occurred in the cost reporting period during which the inpatient was discharged. However, if after application of this provision, a hospital fails to meet the average length of stay specified under paragraphs (e)(2)(i) and (ii) of this section, Medicare will determine the hospital's average inpatient length of stay for cost reporting periods beginning on or after July 1, 2004, but before July 1, 2005, by dividing the applicable total days for Medicare inpatients under paragraph (e)(2)(i) of this section or the total days for all inpatients under paragraph (e)(2)(ii) of this section, during the cost reporting period when they occur, by the number of discharges occurring during the same cost reporting period.

(iii) If a change in a hospital's average length of stay specified under paragraph (e)(2)(i) or paragraph (e)(2)(ii) of this section is indicated, the calculation is made by the same method for the period of at least 5 months of the immediately preceding 6-month period.

(iv) If a hospital has undergone a change of ownership (as described in § 489.18 of this chapter) at the start of a cost reporting period or at any time within the period of at least 5 months of the preceding 6-month period, the hospital may be excluded from the prospective payment system as a long-term care hospital for a cost reporting period if, for the period of at least 5 months of the 6 months immediately preceding the start of the period (including time before the change of ownership), the hospital has the required average length of stay, continuously operated as a hospital, and continuously participated as a hospital in Medicare.

(4) *Rules applicable to new long-term care hospitals*—(i) *Definition.* For purposes of payment under the long-term care hospital prospective payment system under subpart O of this part, a new long-term care hospital is a provider of inpatient hospital services that meets the qualifying criteria in paragraphs (e)(1) and (e)(2) of this section and, under present or previous ownership (or both), its first cost reporting period as a LTCH begins on or after October 1, 2002.

(ii) *Satellite facilities and remote locations of hospitals seeking to become new long-term care hospitals.* Except as specified in paragraph (e)(4)(iii) of this section, a satellite facility (as defined in §412.22(h)) or a remote location of a hospital (as defined in §413.65(a)(2) of this chapter) that voluntarily reorganizes as a separate Medicare participating hospital, with or without a concurrent change in ownership, and that seeks to qualify as a new long-term care hospital for Medicare payment purposes must demonstrate through documentation that it meets the average length of stay requirement as specified under paragraphs (e)(2)(i) or (e)(2)(ii) of this section based on discharges that occur on or after the effective date of its participation under Medicare as a separate hospital.

(iii) *Provider-based facility or organization identified as a satellite facility and remote location of a hospital prior to July 1, 2003.* Satellite facilities and remote locations of hospitals that became subject to the provider-based status rules under §413.65 as of July 1, 2003, that become separately participating hospitals, and that seek to qualify as long-term care hospitals for Medicare payment purposes may submit to the fiscal intermediary discharge data gathered during 5 months of the immediate 6 months preceding the facility's separation from the main hospital for calculation of the average length of stay specified under paragraph (e)(2)(i) or paragraph (e)(2)(ii) of this section.

(f) *Cancer hospitals*—(1) *General rule.* Except as provided in paragraph (f)(2) of this section, if a hospital meets the following criteria, it is classified as a cancer hospital and is excluded from the prospective payment systems beginning with its first cost reporting period beginning on or after October 1, 1989. A hospital classified after December 19, 1989, is excluded beginning with its first cost reporting period beginning after the date of its classification.

(i) It was recognized as a comprehensive cancer center or clinical cancer research center by the National Cancer Institute of the National Institutes of Health as of April 20, 1983.

(ii) It is classified on or before December 31, 1990, or, if on December 19, 1989, the hospital was located in a State operating a demonstration project under section 1814(b) of the Act, the classification is made on or before December 31, 1991.

(iii) It demonstrates that the entire facility is organized primarily for treatment of and research on cancer (that is, the facility is not a subunit of an acute general hospital or university-based medical center).

(iv) It shows that at least 50 percent of its total discharges have a principal diagnosis that reflects a finding of neoplastic disease. (The principal diagnosis for this purpose is defined as the condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital. For the purposes of meeting this definition, only discharges with ICD–9–CM principal diagnosis codes of 140 through 239, V58.0, V58.1, V66.1, V66.2, or 990 will be considered to reflect neoplastic disease.)

(2) *Alternative.* A hospital that applied for and was denied, on or before December 31, 1990, classification as a cancer hospital under the criteria set forth in paragraph (f)(1) of this section is classified as a cancer hospital and is excluded from the prospective payment systems beginning with its first cost reporting period beginning on or after January 1, 1991, if it meets the criterion set forth in paragraph (f)(1)(i) of this section and the hospital is—

(i) Licensed for fewer than 50 acute care beds as of August 5, 1997;

(ii) Is located in a State that as of December 19, 1989, was not operating a demonstration project under section 1814(b) of the Act; and

(iii) Demonstrates that, for the 4-year period ending on December 31, 1996, at least 50 percent of its total discharges have a principal diagnosis that reflects a finding of neoplastic disease as defined in paragraph (f)(1)(iv) of this section.

(g) *Hospitals outside the 50 States, the District of Columbia, or Puerto Rico.* A hospital is excluded from the prospective payment systems if it is not located in one of the fifty States, the District of Columbia, or Puerto Rico.

(h) *Hospitals reimbursed under special arrangements.* A hospital must be excluded from prospective payment for

inpatient hospital services if it is reimbursed under special arrangement as provided in § 412.22(c).

(i) *Changes in classification of hospitals.* For purposes of exclusions from the prospective payment system, the classification of a hospital is effective for the hospital's entire cost reporting period. Any changes in the classification of a hospital are made only at the start of a cost reporting period.

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 35688, Sept. 3, 1985; 51 FR 22041, June 17, 1986; 51 FR 31496, Sept. 3, 1986; 52 FR 33057, Sept. 1, 1987; 55 FR 36068, Sept. 4, 1990; 55 FR 46887, Nov. 7, 1990; 56 FR 43240, Aug. 30, 1991; 57 FR 39820, Sept. 1, 1992; 59 FR 45396, Sept. 1, 1994; 60 FR 45846, Sept. 1, 1995; 62 FR 46026, Aug. 29, 1997; 66 FR 39933, Aug. 1, 2001; 66 FR 41386, Aug. 7, 2001; 67 FR 56048, Aug. 30, 2002; 68 FR 45469, Aug. 1, 2003; 69 FR 25720, May 7, 2004; 69 FR 25775, May 7, 2004]

§ 412.25 Excluded hospital units: Common requirements.

(a) *Basis for exclusion.* In order to be excluded from the prospective payment systems specified in § 412.1(a)(1), a psychiatric or rehabilitation unit must meet the following requirements.

(1) Be part of an institution that—

(i) Has in effect an agreement under part 489 of this chapter to participate as a hospital;

(ii) Is not excluded in its entirety from the prospective payment systems; and

(iii) Has enough beds that are not excluded from the prospective payment systems to permit the provision of adequate cost information, as required by § 413.24(c) of this chapter.

(2) Have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients.

(3) Have admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.

(4) Have policies specifying that necessary clinical information is transferred to the unit when a patient of the hospital is transferred to the unit.

(5) Meet applicable State licensure laws.

(6) Have utilization review standards applicable for the type of care offered in the unit.

(7) Have beds physically separate from (that is, not commingled with) the hospital's other beds.

(8) Be serviced by the same fiscal intermediary as the hospital.

(9) Be treated as a separate cost center for cost finding and apportionment purposes.

(10) Use an accounting system that properly allocates costs.

(11) Maintain adequate statistical data to support the basis of allocation.

(12) Report its costs in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital.

(13) As of the first day of the first cost reporting period for which all other exclusion requirements are met, the unit is fully equipped and staffed and is capable of providing hospital inpatient psychiatric or rehabilitation care regardless of whether there are any inpatients in the unit on that date.

(b) *Changes in the size of excluded units.* For purposes of exclusions from the prospective payment systems under this section, changes in the number of beds and square footage considered to be part of each excluded unit are allowed as specified in paragraphs (b)(1) through (b)(3) of this section.

(1) *Increase in size.* Except as described in paragraph (b)(3) of this section, the number of beds and square footage of an excluded unit may be increased only at the start of a cost reporting period.

(2) *Decrease in size.* Except as described in paragraph (b)(3) of this section, the number of beds and square footage of an excluded unit may be decreased at any time during a cost reporting period if the hospital notifies its fiscal intermediary and the CMS Regional Office in writing of the planned decrease at least 30 days before the date of the decrease, and maintains the information needed to accurately determine costs that are attributable to the excluded unit. Any decrease in the number of beds or square footage considered to be part of an excluded unit made during a cost reporting period must remain in effect for the rest of that cost reporting period.

(3) *Exception to changes in square footage and bed size.* The number of beds in an excluded unit may be decreased, and

the square footage considered to be part of the unit may be either increased or decreased, at any time, if these changes are made necessary by relocation of a unit—

(i) To permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility; or

(ii) Because of catastrophic events such as fires, floods, earthquakes, or tornadoes.

(c) *Changes in the status of hospital units.* For purposes of exclusions from the prospective payment systems under this section, the status of each hospital unit (excluded or not excluded) is determined as specified in paragraphs (c)(1) and (c)(2) of this section.

(1) The status of a hospital unit may be changed from not excluded to excluded only at the start of the cost reporting period. If a unit is added to a hospital after the start of a cost reporting period, it cannot be excluded from the prospective payment systems before the start of a hospital's next cost reporting period.

(2) The status of a hospital unit may be changed from excluded to not excluded at any time during a cost reporting period, but only if the hospital notifies the fiscal intermediary and the CMS Regional Office in writing of the change at least 30 days before the date of the change, and maintains the information needed to accurately determine costs that are or are not attributable to the excluded unit. A change in the status of a unit from excluded to not excluded that is made during a cost reporting period must remain in effect for the rest of that cost reporting period.

(d) *Number of excluded units.* Each hospital may have only one unit of each type (psychiatric or rehabilitation) excluded from the prospective payment systems.

(e) *Satellite facilities.* (1) For purposes of paragraphs (e)(2) through (e)(4) of this section, a satellite facility is a part of a hospital unit that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital.

(2) Except as provided in paragraphs (e)(3) and (e)(5) of this section, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period:

(i) In the case of a unit excluded from the prospective payment systems for the most recent cost reporting period beginning before October 1, 1997, the unit's number of State-licensed and Medicare-certified beds, including those at the satellite facility, does not exceed the unit's number of State-licensed and Medicare-certified beds on the last day of the unit's last cost reporting period beginning before October 1, 1997.

(ii) The satellite facility independently complies with—

(A) For a rehabilitation unit, the requirements under §412.23(b)(2); or

(B) For a psychiatric unit, the requirements under §412.27(a).

(iii) The satellite facility meets all of the following requirements:

(A) Effective for cost reporting periods beginning on or after October 1, 2002, it is not under the control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the control of the medical staff or chief medical officer of the hospital in which it is located.

(B) It maintains admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.

(C) It has beds that are physically separate from (that is, not commingled with) the beds of the hospital in which it is located.

(D) It is serviced by the same fiscal intermediary as the hospital unit of which it is a part.

(E) It is treated as a separate cost center of the hospital unit of which it is a part.

(F) For cost reporting and apportionment purposes, it uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of allocation.

(G) It reports its costs on the cost report of the hospital of which it is a part, covering the same fiscal period and using the same method of apportionment as the hospital of which it is a part.

(3) Except as specified in paragraph (e)(4) of this section, the provisions of paragraph (e)(2) of this section do not apply to any unit structured as a satellite facility on September 30, 1999, and excluded from the prospective payment systems on that date, to the extent the unit continues operating under the same terms and conditions, including the number of beds and square footage considered to be part of the unit, in effect on September 30, 1999.

(4) In applying the provisions of paragraph (e)(3) of this section, any unit structured as a satellite facility as of September 30, 1999, may increase or decrease the square footage of the satellite facility or may decrease the number of beds in the satellite facility at any time, if these changes are made necessary by relocation of the facility—

(i) To permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility; or

(ii) Because of catastrophic events such as fires, floods, earthquakes, or tornadoes.

(5) The provisions of paragraph (e)(2)(i) of this section do not apply to any inpatient rehabilitation facility that is subject to the inpatient rehabilitation facility prospective payment system under subpart P of this part, effective for cost reporting periods beginning on or after October 1, 2003.

(f) *Changes in classification of hospital units.* For purposes of exclusions from the prospective payment system under this section, the classification of a hospital unit is effective for the unit's entire cost reporting period. Any changes in the classification of a hospital unit is made only at the start of a cost reporting period.

(g) *CAH units not meeting applicable requirements.* If a psychiatric or rehabilitation unit of a CAH does not meet the requirements of § 485.647 with respect to a cost reporting period, no payment may be made to the CAH for services furnished in that unit for that period. Payment to the CAH for services in the unit may resume only after the start of the first cost reporting period beginning after the unit has demonstrated to CMS that the unit meets the requirements of § 485.647.

[50 FR 12741, Mar. 29, 1985, as amended at 57 FR 39820, Sept. 1, 1992; 58 FR 46337, Sept. 1, 1993; 59 FR 45400, Sept. 1, 1994; 64 FR 41540, July 30, 1999; 66 FR 39933, Aug. 1, 2001; 66 FR 41387, Aug. 7, 2001; 67 FR 50111, Aug. 1, 2002; 68 FR 45469 and 45698, Aug. 1, 2003; 69 FR 49241, Aug. 11, 2004]

§ 412.27 Excluded psychiatric units: Additional requirements.

In order to be excluded from the prospective payment systems, a psychiatric unit must meet the following requirements:

(a) Admit only patients whose admission to the unit is required for active treatment, of an intensity that can be provided appropriately only in an inpatient hospital setting, of a psychiatric principal diagnosis that is listed in the Third Edition of the American Psychiatric Association's Diagnostic and Statistical Manual, or in Chapter Five ("Mental Disorders") of the International Classification of Diseases, Ninth Revision, Clinical Modification.

(b) Furnish, through the use of qualified personnel, psychological services, social work services, psychiatric nursing, occupational therapy, and recreational therapy.

(c) Maintain medical records that permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the unit, and that meet the following requirements:

(1) *Development of assessment/diagnostic data.* Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit.

(i) The identification data must include the inpatient's legal status.

(ii) A provisional or admitting diagnosis must be made on every inpatient at the time of admission, and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.

(iii) The reasons for admission must be clearly documented as stated by the inpatient or others significantly involved, or both.

(iv) The social service records, including reports of interviews with inpatients, family members, and others must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.

(v) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.

(2) *Psychiatric evaluation.* Each inpatient must receive a psychiatric evaluation that must—

(i) Be completed within 60 hours of admission;

(ii) Include a medical history;

(iii) Contain a record of mental status;

(iv) Note the onset of illness and the circumstances leading to admission;

(v) Describe attitudes and behavior;

(vi) Estimate intellectual functioning, memory functioning, and orientation; and

(vii) Include an inventory of the inpatient's assets in descriptive, not interpretative fashion.

(3) *Treatment plan.*

(i) Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include a substantiated diagnosis; short-term and long-term goals; the specific treatment modalities utilized; the responsibilities of each member of the treatment team; and adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out; and

(ii) The treatment received by the inpatient must be documented in such a way as to assure that all active therapeutic efforts are included.

(4) *Recording progress.* Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the inpatient, a nurse, social worker and, when appropriate, others significantly involved in active treatment modalities. The frequency of progress notes is determined by the condition of the inpatient but must be recorded at least weekly for the first two months and at least once a month thereafter and must contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the inpatient's progress in accordance with the original or revised treatment plan.

(5) *Discharge planning and discharge summary.* The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the inpatient's hospitalization in the unit and recommendations from appropriate services concerning follow-up or aftercare as well as a brief summary of the patient's condition on discharge.

(d) Meet special staff requirements in that the unit must have adequate numbers of qualified professional and supportive staff to evaluate inpatients, formulate written, individualized, comprehensive treatment plans, provide active treatment measures and engage in discharge planning, as follows:

(1) *Personnel.* The unit must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to—

(i) Evaluate inpatients;

(ii) Formulate written, individualized, comprehensive treatment plans;

(iii) Provide active treatment measures; and

(iv) Engage in discharge planning.

(2) *Director of inpatient psychiatric services: Medical staff.* Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program. The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services.

(i) The clinical director, service chief, or equivalent must meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.

(ii) The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.

(3) *Nursing services.* The unit must have a qualified director of psychiatric nursing services. In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each inpatient's active treatment program and to maintain progress notes on each inpatient.

(i) The director of psychiatric nursing services must be a registered nurse who has a master's degree in psychiatric or mental health nursing, or its equivalent, from a school of nursing accredited by the National League for Nursing, or be qualified by education and experience in the care of the mentally ill. The director must demonstrate competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished.

(ii) The staffing pattern must ensure the availability of a registered nurse 24 hours each day. There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each inpatient's active treatment program.

(4) *Psychological services.* The unit must provide or have available psychological services to meet the needs of the inpatients. The services must be furnished in accordance with acceptable standards of practice, service objectives, and established policies and procedures.

(5) *Social services.* There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished. The services must be furnished in accordance with accepted standards of practice and established policies and procedures. Social service staff responsibilities must include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate information with sources outside the hospital.

(6) *Therapeutic activities.* The unit must provide a therapeutic activities program.

(i) The program must be appropriate to the needs and interests of inpatients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.

(ii) The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each inpatient's active treatment program.

[50 FR 12741, Mar. 29, 1985, as amended at 57 FR 39820, Sept. 1, 1992; 59 FR 45397, 45400, Sept. 1, 1994]

§ 412.29 Excluded rehabilitation units: Additional requirements.

In order to be excluded from the prospective payment systems described in § 412.1(a)(1) and to be paid under the prospective payment system specified in § 412.1(a)(2), a rehabilitation unit must meet the following requirements:

(a) Have met either the requirements for—

(1) New units under § 412.30(a); or

(2) Converted units under § 412.30(c).

(b) Have in effect a preadmission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient program or assessment.

(c) Ensure that the patients receive close medical supervision and furnish, through the use of qualified personnel, rehabilitation nursing, physical therapy, and occupational therapy, plus, as needed, speech therapy, social services or psychological services, and orthotic and prosthetic services.

(d) Have a plan of treatment for each inpatient that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient.

(e) Use a coordinated multidisciplinary team approach in the rehabilitation of each inpatient, as documented by periodic clinical entries made in the patient's medical record to note the patient's status in relationship to goal attainment, and that team conferences are held at least every two weeks to determine the appropriateness of treatment.

(f) Have a director of rehabilitation who—

(1) Provides services to the unit and to its inpatients for at least 20 hours per week;

(2) Is a doctor of medicine or osteopathy;

(3) Is licensed under State law to practice medicine or surgery; and

(4) Has had, after completing a one-year hospital internship, at least two years of training or experience in the medical management of inpatients requiring rehabilitation services.

[50 FR 12741, Mar. 29, 1985, as amended at 57 FR 39821, Sept. 1, 1992; 59 FR 45397, 45400, Sept. 1, 1994; 60 FR 45847, Sept. 1, 1995; 66 FR 41387, Aug. 7, 2001; 68 FR 45699, Aug. 1, 2003]

§ 412.30 Exclusion of new rehabilitation units and expansion of units already excluded.

(a) *Bed capacity in units.* A decrease in bed capacity must remain in effect for at least a full 12-month cost reporting period before an equal or lesser number of beds can be added to the hospital's licensure and certification and considered "new" under paragraph (b) of this section. Thus, when a hospital seeks to establish a new unit under the criteria under paragraph (b) of this section, or to enlarge an existing unit under the criteria under paragraph (d) of this section, the regional office will review its records on the facility to determine whether any beds have been delicensed and decertified during the 12-month cost reporting period before the period for which the hospital seeks to add the beds. To the extent bed capacity was removed from the hospital's licensure and certification during that period, that amount of bed capacity may not be considered "new" under paragraph (b) of this section.

(b) *New units.* (1) A hospital unit is considered a new unit if the hospital—

(i) Has not previously sought exclusion for any rehabilitation unit; and

(ii) Has obtained approval, under State licensure and Medicare certification, for an increase in its hospital bed capacity that is greater than 50 percent of the number of beds in the unit.

(2) A hospital that seeks exclusion of a new rehabilitation unit may provide a written certification that the inpatient population the hospital intends the unit to serve meets the requirements of § 412.23(b)(2) instead of showing that the unit has treated such a population during the hospital's most recent cost reporting period.

(3) The written certification described in paragraph (b)(2) of this section is effective for the first full cost reporting period during which the unit is used to provide hospital inpatient care.

(4) If a hospital that has not previously participated in the Medicare program seeks exclusion of a rehabilitation unit, it may designate certain beds as a new rehabilitation unit for the first full 12-month cost reporting period that occurs after it becomes a Medicare-participating hospital. The written certification described in paragraph (b)(2) of this section also is effective for any cost reporting period of not less than 1 month and not more than 11 months occurring between the date the hospital began participating in Medicare and the start of the hospital's regular 12-month cost reporting period.

(5) A hospital that has undergone a change of ownership or leasing as defined in § 489.18 of this chapter is not considered to have participated previously in the Medicare program.

(c) *Converted units.* A hospital unit is considered a converted unit if it does not qualify as a new unit under paragraph (a) of this section. A converted unit must have treated, for the hospital's most recent, consecutive, and appropriate 12-month time period (as defined by CMS or the fiscal intermediary), an inpatient population meeting the requirements of § 412.23(b)(2).

(d) *Expansion of excluded rehabilitation units.*—(1) *New bed capacity.* The beds that a hospital seeks to add to its excluded rehabilitation unit are considered new beds only if—

(i) The hospital's State-licensed and Medicare-certified bed capacity increases at the start of the cost reporting period for which the hospital seeks to increase the size of its excluded rehabilitation unit, or at any time after the start of the preceding cost reporting period; and

(ii) The hospital has obtained approval, under State licensure and Medicare certification, for an increase in its hospital bed capacity that is greater than 50 percent of the number of beds it seeks to add to the unit.

(2) *Conversion of existing bed capacity.* (i) Bed capacity is considered to be existing bed capacity if it does not meet the definition of new bed capacity under paragraph (d)(1) of this section.

(ii) A hospital may increase the size of its excluded rehabilitation unit through the conversion of existing bed capacity only if it shows that, for the hospital's most recent, consecutive, and appropriate 12-month time period (as defined by CMS or the fiscal intermediary), the beds have been used to treat an inpatient population meeting the requirements of § 412.23(b)(2).

(e) *Retroactive adjustments for certain units.* For cost reporting periods beginning on or after October 1, 1991, if a hospital has a new rehabilitation unit excluded from the prospective payment systems for a cost reporting period under paragraph (a) of this section or expands an existing rehabilitation unit under paragraph (c) of this section, but the inpatient population actually treated in the new unit or the beds added to the existing unit during that cost reporting period does not meet the requirements in § 412.23(b)(2), CMS adjusts payments to the hospital retroactively in accordance with the provisions in § 412.130 of this part.

[50 FR 12741, Mar. 29, 1985, as amended at 56 FR 43420, Aug. 30, 1991; 57 FR 39821, Sept. 1, 1992; 59 FR 45400, Sept. 1, 1994; 60 FR 45847, Sept. 1, 1995; 62 FR 46027, Aug. 29, 1997; 68 FR 45699, Aug. 1, 2003; 69 FR 25776, May 7, 2004]

Subpart C—Conditions for Payment Under the Prospective Payment Systems for Inpatient Operating Costs and Inpatient Capital-Related Costs

§ 412.40 General requirements.

(a) A hospital must meet the conditions of this subpart to receive payment under the prospective payment systems for inpatient hospital services furnished to Medicare beneficiaries.

(b) If a hospital fails to comply fully with these conditions with respect to inpatient hospital services furnished to one or more Medicare beneficiaries, CMS may, as appropriate—

(1) Withhold Medicare payment (in full or in part) to the hospital until the hospital provides adequate assurances of compliance; or

(2) Terminate the hospital's provider agreement.

[50 FR 12741, Mar. 29, 1985, as amended at 57 FR 39821, Sept. 1, 1992]

§ 412.42 Limitations on charges to beneficiaries.

(a) *Prohibited charges.* A hospital may not charge a beneficiary for any services for which payment is made by Medicare, even if the hospital's costs of furnishing services to that beneficiary are greater than the amount the hospital is paid under the prospective payment systems.

(b) *Permitted charges—Stay covered.* A hospital receiving payment under the prospective payment systems for a covered hospital stay (that is, a stay that includes at least one covered day) may charge the Medicare beneficiary or other person only for the following:

(1) The applicable deductible and coinsurance amounts under §§ 409.82, 409.83, and 409.87 of this chapter.

(2) Noncovered items and services, furnished at any time during a covered stay, unless they are excluded from coverage only on the basis of the following:

(i) The exclusion of custodial care under § 405.310(g) of this chapter (see paragraph (c) of this section for when charges may be made for custodial care).

(ii) The exclusion of medically unnecessary items and services under § 405.310(k) of this chapter (see paragraphs (c) and (d) of this section for when charges may be made for medically unnecessary items and services).

(iii) The exclusion under § 405.310(m) of this chapter of nonphysician services furnished to hospital inpatients by other than the hospital or a provider or supplier under arrangements made by the hospital.

(iv) The exclusion of items and services furnished when the patient is not entitled to Medicare Part A benefits under subpart A of part 406 of this

weeks after the end of the biweekly period of service as described in §413.64(h)(6) of this subchapter. The interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if a long-term care hospital receives interim payments for less than a full reporting period. These payments are subject to final cost settlement.

(d) *Special interim payment for unusually long lengths of stay.*

(1) *First interim payment.* A hospital that is not receiving periodic interim payments under paragraph (b) of this section may request an interim payment 60 days after a Medicare beneficiary has been admitted to the hospital. Payment for the interim bill is determined as if the bill were a final discharge bill and includes any outlier payment determined as of the last day for which services have been billed.

(2) *Additional interim payments.* A hospital may request additional interim payments at intervals of at least 60 days after the date of the first interim bill submitted under paragraph (d)(1) of this section. Payment for these additional interim bills, as well as the final bill, is determined as if the bill were the final bill with appropriate adjustments made to the payment amount to reflect any previous interim payment made under the provisions of this paragraph.

(e) *Outlier payments.* Additional payments for outliers are not made on an interim basis. The outlier payments are made based on the submission of a discharge bill and represent final payment.

(f) *Accelerated payments.* (1) *General rule.* Upon request, an accelerated payment may be made to a long-term care hospital that is receiving payment under this subpart and is not receiving PIP under paragraph (b) of this section if the hospital is experiencing financial difficulties because of the following:

(i) There is a delay by the intermediary in making payment to the long-term care hospital.

(ii) Due to an exceptional situation, there is a temporary delay in the hospital's preparation and submittal of bills to the intermediary beyond its normal billing cycle.

(2) *Approval of payment.* A request by a long-term care hospital for an accelerated payment must be approved by the intermediary and by CMS.

(3) *Amount of payment.* The amount of the accelerated payment is computed as a percentage of the net payment for unbilled or unpaid covered services.

(4) *Recovery of payment.* Recovery of the accelerated payment is made by recoupment as long-term care hospital bills are processed or by direct payment by the long-term care hospital.

[67 FR 56049, Aug. 30, 2002, as amended at 68 FR 10988, Mar. 7, 2003]

Subpart P—Prospective Payment for Inpatient Rehabilitation Hospitals and Rehabilitation Units

SOURCE: 66 FR 41388, Aug. 7, 2001, unless otherwise noted.

§412.600 Basis and scope of subpart.

(a) *Basis.* This subpart implements section 1886(j) of the Act, which provides for the implementation of a prospective payment system for inpatient rehabilitation hospitals and rehabilitation units (in this subpart referred to as "inpatient rehabilitation facilities").

(b) *Scope.* This subpart sets forth the framework for the prospective payment system for inpatient rehabilitation facilities, including the methodology used for the development of payment rates and associated adjustments, the application of a transition phase, and related rules. Under this system, for cost reporting periods beginning on or after January 1, 2002, payment for the operating and capital costs of inpatient hospital services furnished by inpatient rehabilitation facilities to Medicare Part A fee-for-service beneficiaries is made on the basis of prospectively determined rates and applied on a per discharge basis.

§412.602 Definitions.

As used in this subpart—

Assessment reference date means the specific calendar day in the patient assessment process that sets the designated endpoint of the common patient observation period, with most patient assessment items usually referring back in time from this endpoint.

CMS stands for the Centers for Medicare & Medicaid Services.

Comorbidity means a specific patient condition that is secondary to the patient's principal diagnosis that is the primary reason for the inpatient rehabilitation stay.

Discharge. A Medicare patient in an inpatient rehabilitation facility is considered discharged when—

(1) The patient is formally released from the inpatient rehabilitation facility; or

(2) The patient dies in the inpatient rehabilitation facility.

Encode means entering data items into the fields of the computerized patient assessment software program.

Functional-related groups refers to the distinct groups under which inpatients are classified using proxy measurements of inpatient rehabilitation relative resource usage.

Interrupted stay means a stay at an inpatient rehabilitation facility during which a Medicare inpatient is discharged from the inpatient rehabilitation facility and returns to the same inpatient rehabilitation facility within 3 consecutive calendar days. The duration of the interruption of the stay of 3 consecutive calendar days begins with the day of discharge from the inpatient rehabilitation facility and ends on midnight of the third day.

Outlier payment means an additional payment beyond the standard Federal prospective payment for cases with unusually high costs.

Patient assessment instrument refers to a document that contains clinical, demographic, and other information on a patient.

Rural area means an area as defined in § 412.62(f)(1)(iii).

Transfer means the release of a Medicare inpatient from an inpatient rehabilitation facility to another inpatient rehabilitation facility, a short-term, acute-care prospective payment hospital, a long-term care hospital as described in § 412.23(e), or a nursing home that qualifies to receive Medicare or Medicaid payments.

Urban area means an area as defined in § 412.62(f)(1)(ii).

[66 FR 41388, Aug. 7, 2001, as amended at 67 FR 44077, July 1, 2002; 68 FR 45699, Aug. 1, 2003]

§ 412.604 Conditions for payment under the prospective payment system for inpatient rehabilitation facilities.

(a) *General requirements.* (1) Effective for cost reporting periods beginning on or after January 1, 2002, an inpatient rehabilitation facility must meet the conditions of this section to receive payment under the prospective payment system described in this subpart for inpatient hospital services furnished to Medicare Part A fee-for-service beneficiaries.

(2) If an inpatient rehabilitation facility fails to comply fully with these conditions with respect to inpatient hospital services furnished to one or more Medicare Part A fee-for-service beneficiaries, CMS or its Medicare fiscal intermediary may, as appropriate—

(i) Withhold (in full or in part) or reduce Medicare payment to the inpatient rehabilitation facility until the facility provides adequate assurances of compliance; or

(ii) Classify the inpatient rehabilitation facility as an inpatient hospital that is subject to the conditions of subpart C of this part and is paid under the prospective payment systems specified in § 412.1(a)(1).

(b) *Inpatient rehabilitation facilities subject to the prospective payment system.* Subject to the special payment provisions of § 412.22(c), an inpatient rehabilitation facility must meet the general criteria set forth in § 412.22 and the criteria to be classified as a rehabilitation hospital or rehabilitation unit set forth in §§ 412.23(b), 412.25, and 412.29 for exclusion from the inpatient hospital prospective payment systems specified in § 412.1(a)(1).

(c) *Completion of patient assessment instrument.* For each Medicare Part A fee-for-service patient admitted to or discharged from an IRF on or after January 1, 2002, the inpatient rehabilitation

facility must complete a patient assessment instrument in accordance with §412.606.

(d) *Limitation on charges to beneficiaries*—(1) *Prohibited charges.* Except as provided in paragraph (d)(2) of this section, an inpatient rehabilitation facility may not charge a beneficiary for any services for which payment is made by Medicare, even if the facility's costs of furnishing services to that beneficiary are greater than the amount the facility is paid under the prospective payment system.

(2) *Permitted charges.* An inpatient rehabilitation facility receiving payment under this subpart for a covered hospital stay (that is, a stay that includes at least one covered day) may charge the Medicare beneficiary or other person only for the applicable deductible and coinsurance amounts under §§409.82, 409.83, and 409.87 of this subchapter and for items or services as specified under §489.20(a) of this chapter.

(e) *Furnishing of inpatient hospital services directly or under arrangement.* (1) Subject to the provisions of §412.622(b), the applicable payments made under this subpart are payment in full for all inpatient hospital services, as defined in §409.10 of this subchapter. Inpatient hospital services do not include the following:

(i) Physicians' services that meet the requirements of §415.102(a) of this subchapter for payment on a fee schedule basis.

(ii) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(iii) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(iv) Certified nurse midwife services, as defined in section 1861(gg) of the Act.

(v) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(vi) Services of an anesthetist, as defined in §410.69 of this chapter.

(2) Medicare does not pay any provider or supplier other than the inpatient rehabilitation facility for services furnished to a Medicare beneficiary who is an inpatient of the inpatient rehabilitation facility, except for services described in paragraphs (e)(1)(i) through (e)(1)(vi) of this section.

(3) The inpatient rehabilitation facility must furnish all necessary covered services to the Medicare beneficiary either directly or under arrangements (as defined in §409.3 of this subchapter).

(f) *Reporting and recordkeeping requirements.* All inpatient rehabilitation facilities participating in the prospective payment system under this subpart must meet the recordkeeping and cost reporting requirements of §§413.20 and 413.24 of this subchapter.

[66 FR 41388, Aug. 7, 2001, as amended at 67 FR 44077, July 1, 2002; 68 FR 45699, Aug. 1, 2003]

§412.606 Patient assessments.

(a) *Admission orders.* At the time that each Medicare Part A fee-for-service patient is admitted, the inpatient rehabilitation facility must have physician orders for the patient's care during the time the patient is hospitalized.

(b) *Patient assessment instrument.* An inpatient rehabilitation facility must use the CMS inpatient rehabilitation facility patient assessment instrument to assess Medicare Part A fee-for-service inpatients who—

(1) Are admitted on or after January 1, 2002; or

(2) Were admitted before January 1, 2002, and are still inpatients as of January 1, 2002.

(c) *Comprehensive assessments.* (1) A clinician of the inpatient rehabilitation facility must perform a comprehensive, accurate, standardized, and reproducible assessment of each Medicare Part A fee-for-service inpatient using the inpatient rehabilitation facility patient assessment instrument specified in paragraph (b) of this section as part of his or her patient assessment in accordance with the schedule described in §412.610.

(2) A clinician employed or contracted by an inpatient rehabilitation facility who is trained on how to perform a patient assessment using the inpatient rehabilitation facility patient assessment instrument specified in paragraph (b) of the section must record appropriate and applicable data accurately and completely for each item on the patient assessment instrument.

(3) The assessment process must include—

(i) Direct patient observation and communication with the patient; and

(ii) When appropriate and to the extent feasible, patient data from the patient's physician(s), family, someone personally knowledgeable about the patient's clinical condition or capabilities, the patient's clinical record, and other sources.

§ 412.608 Patients' rights regarding the collection of patient assessment data.

(a) Before performing an assessment using the inpatient rehabilitation facility patient assessment instrument, a clinician of the inpatient rehabilitation facility must give a Medicare inpatient—

(1) The form entitled "Privacy Act Statement—Health Care Records"; and

(2) The simplified plain language description of the Privacy Act Statement—Health Care Records which is a form entitled "Data Collection Information Summary for Patients in Inpatient Rehabilitation Facilities."

(b) The inpatient rehabilitation facility must document in the Medicare inpatient's clinical record that the Medicare inpatient has been given the documents specified in paragraph (a) of this section.

(c) By giving the Medicare inpatient the forms specified in paragraph (a) of this section the inpatient rehabilitation facility will inform the Medicare patient of—

(1) Their privacy rights under the Privacy Act of 1974 and 45 CFR 5b.4(a)(3); and

(2) The following rights:

(i) The right to be informed of the purpose of the collection of the patient assessment data;

(ii) The right to have the patient assessment information collected be kept confidential and secure;

(iii) The right to be informed that the patient assessment information will not be disclosed to others, except for legitimate purposes allowed by the Federal Privacy Act and Federal and State regulations;

(iv) The right to refuse to answer patient assessment questions; and

(v) The right to see, review, and request changes on his or her patient assessment.

(d) The patient rights specified in this section are in addition to the patient rights specified in § 82.13 of this chapter.

[68 FR 45699, Aug. 1, 2003]

§ 412.610 Assessment schedule.

(a) *General.* For each Medicare Part A fee-for-service inpatient, an inpatient rehabilitation facility must complete a patient assessment instrument as specified in § 412.606 that covers a time period that is in accordance with the assessment schedule specified in paragraph (c) of this section.

(b) *Starting the assessment schedule day count.* The first day that the Medicare Part A fee-for-service inpatient is furnished Medicare-covered services during his or her current inpatient rehabilitation facility hospital stay is counted as day one of the patient assessment schedule.

(c) *Assessment schedules and reference dates.* The inpatient rehabilitation facility must complete a patient assessment instrument upon the Medicare Part A fee-for-service patient's admission and discharge as specified in paragraphs (c)(1) and (c)(2) of this section.

(1) *Admission assessment.*

(i) *General rule.* The admission assessment—

(A) Time period is a span of time that covers calendar days 1 through 3 of the patient's current Medicare Part A fee-for-service hospitalization;

(B) Has an admission assessment reference date that is the third calendar day of the span of time specified in paragraph (c)(1)(i)(A) of this section; and

(C) Must be completed by the calendar day that follows the admission assessment reference day.

(ii) *Exception to the general rule.* We may specify in the patient assessment instrument item-by-item guide and in other issued instructions, items that have a different admission assessment time period to most appropriately capture patient information for payment and quality of care monitoring objectives.

(2) *Discharge assessment.*

(i) *General rule.* The discharge assessment—

(A) Time period is a span of time that covers 3 calendar days, and is the discharge assessment reference date itself specified in paragraph (c)(2)(ii) of this section and the 2 calendar days prior to the discharge assessment reference date; and

(B) Must be completed on the 5th calendar day that follows the discharge assessment reference date specified in paragraph (c)(2)(ii) of this section with the discharge assessment reference date itself being counted as the first day of the 5 calendar day time span.

(ii) *Discharge assessment reference date.* The discharge assessment reference date is the actual day that the first of either of the following two events occurs:

(A) The patient is discharged from the inpatient rehabilitation facility; or

(B) The patient stops being furnished Medicare Part A fee-for-service inpatient rehabilitation services.

(iii) *Exception to the general rule.* We may specify in the patient assessment instrument item-by-item guide and in other issued instructions, items that have a different discharge assessment time period to most appropriately capture patient information for payment and quality of care monitoring objectives.

(d) *Encoding dates.* The admission and discharge patient assessments must be encoded by the 7th calendar day from the completion dates specified in paragraph (c) of this section.

(e) *Accuracy of the patient assessment data.* The encoded patient assessment data must accurately reflect the patient's clinical status at the time of the patient assessment.

(f) *Patient assessment instrument record retention.* An inpatient rehabilitation facility must maintain all patient assessment data sets completed on Medicare Part A fee-for-service patients within the previous 5 years either in a paper format in the patient's clinical record or in an electronic computer file format that the inpatient rehabilitation facility can easily obtain.

[66 FR 41388, Aug. 7, 2001, as amended at 67 FR 44077, July 1, 2002; 68 FR 45699, Aug. 1, 2003]

§412.612 Coordination of the collection of patient assessment data.

(a) *Responsibilities of the clinician.* A clinician of an inpatient rehabilitation facility who has participated in performing the patient assessment must have responsibility for—

(1) The accuracy and thoroughness of the specific data recorded by that clinician on the patient's assessment instrument; and

(2) The accuracy of the assessment reference date inserted on the patient assessment instrument completed under §412.610(c).

(b) *Penalty for falsification.*

(1) Under Medicare, an individual who knowingly and willfully—

(i) Completes a material and false statement in a patient assessment is subject to a civil money penalty of not more than $1,000 for each assessment; or

(ii) Causes another individual to complete a material and false statement in a patient assessment is subject to a civil money penalty of not more than $5,000 for each assessment.

(2) Clinical disagreement does not constitute a material and false statement.

§412.614 Transmission of patient assessment data.

(a) *Data format. General rule.* The inpatient rehabilitation facility must encode and transmit data for each Medicare Part A fee-for-service inpatient—

(1) Using the computerized version of the patient assessment instrument available from us; or

(2) Using a computer program(s) that conforms to our standard electronic record layout, data specifications, and data dictionary, includes the required patient assessment instrument data set, and meets our other specifications.

(3) *Exception to the general rule.* When the inpatient rehabilitation facility does not submit claim data to Medicare in order to be paid for any of the services it furnished to a Medicare Part A fee-for-service inpatient, the inpatient rehabilitation facility is not required to, but may, transmit to Medicare the inpatient rehabilitation facility patient assessment data associated with the services furnished to that

same Medicare Part A fee-for-service inpatient.

(b) *How to transmit data.* The inpatient rehabilitation facility must—

(1) Electronically transmit complete, accurate, and encoded data from the patient assessment instrument for each Medicare Part A fee-for-service inpatient to our patient data system in accordance with the data format specified in paragraph (a) of this section; and

(2) Transmit data using electronic communications software that provides a direct telephone connection from the inpatient rehabilitation facility to the our patient data system.

(c) *Transmission dates.* The inpatient rehabilitation facility must transmit both the admission patient assessment and the discharge patient assessments at the same time to the our patient data system by the 7th calendar day in the period beginning with the applicable patient assessment instrument encoding date specified in § 412.610(d).

(d) *Late transmission penalty.* (1) We assess a penalty when an inpatient rehabilitation facility does not transmit the required data from the patient assessment instrument to the our patient data system in accordance with the transmission timeframe in paragraph (c) of this section.

(2) If the actual patient assessment data transmission date is later than 10 calendar days from the transmission date specified in paragraph (c) of this section, the patient assessment data is considered late and the inpatient rehabilitation facility receives a payment rate that is 25 percent less than the payment rate associated with a case-mix group.

(e) *Exemption to being assessed a penalty for transmitting the IRF–PAI data late.* CMS may waive the penalty specified in paragraph (d) of this section when, due to an extraordinary situation that is beyond the control of an inpatient rehabilitation facility, the inpatient rehabilitation facility is unable to transmit the patient assessment data in accordance with paragraph (c) of this section. Only CMS can determine if a situation encountered by an inpatient rehabilitation facility is extraordinary and qualifies as a situation for waiver of the penalty specified in paragraph (d)(2) of this section. An extraordinary situation may be due to, but is not limited to, fires, floods, earthquakes, or similar unusual events that inflict extensive damage to an inpatient rehabilitation facility. An extraordinary situation may be one that produces a data transmission problem that is beyond the control of the inpatient rehabilitation facility, as well as other situations determined by CMS to be beyond the control of the inpatient rehabilitation facility. An extraordinary situation must be fully documented by the inpatient rehabilitation facility.

[66 FR 41388, Aug. 7, 2001, as amended at 68 FR 45699, Aug. 1, 2003]

§ 412.616 Release of information collected using the patient assessment instrument.

(a) *General.* An inpatient rehabilitation facility may release information from the patient assessment instrument only as specified in § 482.24(b)(3) of this chapter.

(b) *Release to the inpatient rehabilitation facility's agent.* An inpatient rehabilitation facility may release information that is patient-identifiable to an agent only in accordance with a written contract under which the agent agrees not to use or disclose the information except for the purposes specified in the contract and only to the extent the facility itself is permitted to do so under paragraph (a) of this section.

§ 412.618 Assessment process for interrupted stays.

For purposes of the patient assessment process, if a Medicare Part A fee-for-service patient has an interrupted stay, as defined under § 412.602, the following applies:

(a) *Assessment requirements.* (1) The initial case-mix group classification from the admission assessment remains in effect (that is, no new admission assessment is performed).

(2) When the patient has completed his or her entire rehabilitation episode stay, a discharge assessment must be performed.

(b) *Recording and encoding of data.* The clinician must record the interruption of the stay on the patient assessment instrument.

(c) If the interruption in the stay occurs during the admission assessment time period, the assessment reference date, completion date, and encoding date for the admission assessment are advanced by the same number of calendar days as the length of the patient's interruption in the stay.

[66 FR 41388, Aug. 7, 2001, as amended at 67 FR 44077, July 1, 2002]

§412.620 Patient classification system.

(a) *Classification methodology.*

(1) A patient classification system is used to classify patients in inpatient rehabilitation facilities into mutually exclusive case-mix groups.

(2) For purposes of this subpart, case-mix groups are classes of Medicare patient discharges by functional-related groups that are based on a patient's impairment, age, comorbidities, functional capabilities, and other factors that may improve the ability of the functional-related groups to estimate variations in resource use.

(3) Data from admission assessments under §412.610(c)(1) are used to classify a Medicare patient into an appropriate case-mix group.

(4) Data from the discharge assessment under §412.610(c)(2) are used to determine the weighting factors under paragraph (b)(4) of this section.

(b) *Weighting factors.*

(1) *General.* An appropriate weight is assigned to each case-mix group that measures the relative difference in facility resource intensity among the various case-mix groups.

(2) *Short-stay outliers.* We will determine a weighting factor or factors for patients that are discharged and not transferred (as defined in §412.602) within a number of days from admission as specified by us.

(3) *Patients who expire.* We will determine a weighting factor or factors for patients who expire within a number of days from admission as specified by us.

(4) *Comorbidities.* We will determine a weighting factor or factors to account for the presence of a comorbidity, as defined in §412.602, that is relevant to resource use in the classification system.

(c) *Revision of case-mix group classifications and weighting factors.* We may periodically adjust the case-mix groups and weighting factors to reflect changes in—

(1) Treatment patterns;

(2) Technology;

(3) Number of discharges; and

(4) Other factors affecting the relative use of resources.

§412.622 Basis of payment.

(a) *Method of payment.*

(1) Under the prospective payment system, inpatient rehabilitation facilities receive a predetermined amount per discharge for inpatient services furnished to Medicare Part A fee-for-service beneficiaries.

(2) The amount of payment under the prospective payment system is based on the Federal payment rate, including adjustments described in §412.624 and, if applicable, during a transition period, on a blend of the Federal payment rate and the facility-specific payment rate described in §412.626.

(b) *Payment in full.* (1) The payment made under this subpart represents payment in full (subject to applicable deductibles and coinsurance as described in subpart G of part 409 of this subchapter) for inpatient operating and capital-related costs associated with furnishing Medicare covered services in an inpatient rehabilitation facility, but not for the cost of an approved medical education program described in §§413.85 and 413.86 of this chapter.

(2) In addition to payments based on prospective payment rates, inpatient rehabilitation facilities receive payments for the following:

(i) Bad debts of Medicare beneficiaries, as provided in §413.80 of this chapter; and

(ii) A payment amount per unit for blood clotting factor provided to Medicare inpatients who have hemophilia.

§412.624 Methodology for calculating the Federal prospective payment rates.

(a) *Data used.* To calculate the prospective payment rates for inpatient hospital services furnished by inpatient rehabilitation facilities, we use—

(1) The most recent Medicare data available, as of the date of establishing the inpatient rehabilitation facility prospective payment system, to estimate payments for inpatient operating and capital-related costs made under part 413 of this subchapter;

(2) An appropriate wage index to adjust for area wage differences;

(3) An increase factor to adjust for the most recent estimate of increases in the prices of an appropriate market basket of goods and services included in covered inpatient rehabilitation services; and

(4) Patient assessment data described in § 412.606 and other data that account for the relative resource utilization of different patient types.

(b) *Determining the average costs per discharge for fiscal year 2001.* We determine the average inpatient operating and capital costs per discharge for which payment is made to each inpatient rehabilitation facility using the available data specified under paragraph (a)(1) of this section. The cost per discharge is adjusted to fiscal year 2001 by an increase factor, described in paragraph (a)(3) of this section, under the update methodology described in section 1886(b)(3)(B)(ii) of the Act for each year through the midpoint of fiscal year 2001.

(c) *Determining the Federal prospective payment rates*—(1) *General.* The Federal prospective payment rates will be established using a standard payment amount referred to as the standard payment conversion factor. The standard payment conversion factor is a standardized payment amount based on average costs from a base year that reflects the combined aggregate effects of the weighting factors, various facility and case level adjustments, and other adjustments.

(2) *Update the cost per discharge.* CMS applies the increase factor described in paragraph (a)(3) of this section to the facility's cost per discharge determined under paragraph (b) of this section to compute the cost per discharge for fiscal year 2002. Based on the updated cost per discharge, CMS estimates the payments that would have been made to the facility for fiscal year 2002 under part 413 of this chapter without regard to the prospective payment system implemented under this subpart.

(3) *Computation of the standard payment conversion factor.* The standard payment conversion factor is computed as follows:

(i) *For fiscal year 2002.* Based on the updated costs per discharge and estimated payments for fiscal year 2002 determined in paragraph (c)(2) of this section, CMS computes a standard payment conversion factor for fiscal year 2002, as specified by CMS, that reflects, as appropriate, the adjustments described in paragraph (d) of this section.

(ii) *For fiscal years after 2002.* The standard payment conversion factor for fiscal years after 2002 will be the standardized payments for the previous fiscal year updated by the increase factor described in paragraph (a)(3) of this section, including adjustments described in paragraph (d) of this section as appropriate.

(4) *Determining the Federal prospective payment rate for each case-mix group.* The Federal prospective payment rates for each case-mix group is the product of the weighting factors described in § 412.620(b) and the standard payment conversion factor described in paragraph (c)(3) of this section.

(d) *Adjustments to the standard payment conversion factor.* The standard payment conversion factor described in paragraph (c)(3) of this section will be adjusted for the following:

(1) *Outlier payments.* CMS determines a reduction factor equal to the estimated proportion of additional outlier payments described in paragraph (e)(4) of this section.

(2) *Budget neutrality.* CMS adjusts the Federal prospective payment rates for fiscal year 2002 so that aggregate payments under the prospective payment system, excluding any additional payments associated with elections not to be paid under the transition period methodology under § 412.626(b), are estimated to equal the amount that would have been made to inpatient rehabilitation facilities under part 413 of this chapter without regard to the prospective payment system implemented under this subpart.

(3) *Coding and classification changes.* CMS adjusts the standard payment conversion factor for a given year if

CMS determines that revisions in case-mix classifications or weighting factors for a previous fiscal year (or estimates that those revisions for a future fiscal year) did result in (or would otherwise result in) a change in aggregate payments that are a result of changes in the coding or classification of patients that do not reflect real changes in case-mix.

(e) *Calculation of the adjusted Federal prospective payment.* For each discharge, an inpatient rehabilitation facility's Federal prospective payment is computed on the basis of the Federal prospective payment rate that is in effect for its cost reporting period that begins in a Federal fiscal year specified under paragraph (c) of this section. A facility's Federal prospective payment rate will be adjusted, as appropriate, to account for area wage levels, payments for outliers and transfers, and for other factors as follows:

(1) *Adjustment for area wage levels.* The labor portion of a facility's Federal prospective payment is adjusted to account for geographical differences in the area wage levels using an appropriate wage index. The application of the wage index is made on the basis of the location of the facility in an urban or rural area as defined in §412.602. Adjustments or updates to the wage data used to adjust a facility's Federal prospective payment rate under paragraph (e)(1) of this section will be made in a budget neutral manner. CMS determines a budget neutral wage adjustment factor, based on any adjustment or update to the wage data, to apply to the standard payment conversion factor.

(2) *Adjustments for low-income patients.* We adjust the Federal prospective payment, on a facility basis, for the proportion of low-income patients that receive inpatient rehabilitation services as determined by us.

(3) *Adjustments for rural areas.* We adjust the Federal prospective payment by a factor, as specified by us for facilities located in rural areas, as defined in §412.602.

(4) *Adjustment for high-cost outliers.* CMS provides for an additional payment to an inpatient rehabilitation facility if its estimated costs for a patient exceeds a fixed dollar amount (adjusted for area wage levels and factors to account for treating low-income patients and for rural locations) as specified by CMS. The additional payment equals 80 percent of the difference between the estimated cost of the patient and the sum of the adjusted Federal prospective payment computed under this section and the adjusted fixed dollar amount. Effective for discharges occurring on or after October 1, 2003, additional payments made under this section will be subject to the adjustments at §412.84(i), except that national averages will be used instead of statewide averages. Effective for discharges occurring on or after October 1, 2003, additional payments made under this section will also be subject to adjustments at §412.84(m).

(5) *Adjustments related to the patient assessment instrument.* An adjustment to a facility's Federal prospective payment amount for a given discharge will be made, as specified under §412.614(d), if the transmission of data from a patient assessment instrument is late.

(f) *Special payment provision for patients that are transferred.*

(1) A facility's Federal prospective payment will be adjusted to account for a discharge of a patient who—

(i) Is transferred from the inpatient rehabilitation facility to another site of care, as defined in §412.602; and

(ii) Stays in the facility for a number of days that is less than the average length of stay for nontransfer cases in the case-mix group to which the patient is classified.

(2) We calculate the adjusted Federal prospective payment for patients who are transferred in the following manner:

(i) By dividing the Federal prospective payment by the average length of stay for nontransfer cases in the case-mix group to which the patient is classified to equal the payment per day.

(ii) By multiplying the payment per day under paragraph (f)(2)(i) of this section by the number of days the patient stayed in the facility prior to being discharged to equal the per day payment amount.

(iii) By multiplying the payment per day under paragraph (f)(2)(i) by 0.5 to

equal an additional one half day payment for the first day of the stay before the discharge.

(iv) By adding the per day payment amount under paragraph (f)(2)(ii) and the additional one-half day payment under paragraph (f)(2)(iii) to equal the unadjusted payment amount.

(v) By applying the adjustments described in paragraphs (e)(1), (e)(2), and (e)(3) of this section to the unadjusted payment amount determined in paragraph (f)(2)(iv) of this section to equal the adjusted transfer payment amount.

(g) *Special payment provision for interrupted stays.* When a patient in an inpatient rehabilitation facility has one or more interruptions in the stay, as defined in § 412.602 and as indicated on the patient assessment instrument in accordance with § 412.618(b), we will make payments in the following manner:

(1) *Patient is discharged and returns on the same day.* Payment for a patient who is discharged and returns to the same inpatient rehabilitation facility on the same day will be the adjusted Federal prospective payment under paragraph (e) of this section that is based on the patient assessment data specified in § 412.618(a)(1). Payment for a patient who is discharged and returns to the same inpatient rehabilitation facility on the same day will only be made to the inpatient rehabilitation facility.

(2) *Patient is discharged and does not return by the end of the same day.* Payment for a patient who is discharged and does not return on the same day but does return to the same inpatient rehabilitation facility by or on midnight of the third day, defined as an interrupted stay under § 412.602, will be—

(i) The adjusted Federal prospective payment under paragraph (e) of this section that is based on the patient assessment data specified in § 412.618(a)(1) made to the inpatient rehabilitation facility; and

(ii) If the reason for the interrupted patient stay is to receive inpatient acute care hospital services, an amount based on the prospective payment systems described in § 412.1(a)(1) made to the acute care hospital.

[66 FR 41388, Aug. 7, 2001, as amended at 67 FR 44077, July 1, 2002; 68 45700, Aug. 1, 2003]

§ 412.626 Transition period.

(a) *Duration of transition period and proportion of the blended transition rate.* (1) Except for a facility that makes an election under paragraph (b) of this section, for cost reporting periods beginning on or after January 1, 2002 and before October 1, 2002, an inpatient rehabilitation facility receives a payment comprised of a blend of the adjusted Federal prospective payment, as determined under § 412.624(e) or § 412.624(f) and a facility-specific payment as determined under paragraph (a)(2) of this section.

(i) For cost reporting periods beginning on or after January 1, 2002 and before October 1, 2002, payment is based on 33⅓ percent of the facility-specific payment and 66⅔ percent of the adjusted FY 2002 Federal prospective payment.

(ii) For cost reporting periods beginning on or after October 1, 2002, payment is based entirely on the adjusted Federal prospective payment.

(2) *Calculation of the facility-specific payment.* The facility-specific payment is equal to the payment for each cost reporting period in the transition period that would have been made without regard to this subpart. The facility's Medicare fiscal intermediary calculates the facility-specific payment for inpatient operating costs and capital-related costs in accordance with part 413 of this chapter.

(b) *Election not to be paid under the transition period methodology.* An inpatient rehabilitation facility may elect a payment that is based entirely on the adjusted Federal prospective payment for cost reporting periods beginning before fiscal year 2003 without regard to the transition period percentages specified in paragraph (a)(1)(i) of this section.

(1) *General requirement.* An inpatient rehabilitation facility will be required to request the election under this paragraph (b) within 30 days of its first cost reporting period for which payment is based on the inpatient rehabilitation facility prospective payment system for cost reporting periods beginning on or after January 1, 2002 and before October 1, 2002.

(2) *Notification requirement to make election.* The request by the inpatient

rehabilitation facility to make the election under this paragraph (b) must be made in writing to the Medicare fiscal intermediary. The intermediary must receive the request on or before the 30th day before the applicable cost reporting period begins, regardless of any postmarks or anticipated delivery dates. Requests received, postmarked, or delivered by other means after the 30th day before the cost reporting period begins will not be approved. If the 30th day before the cost reporting period begins falls on a day that the postal service or other delivery sources are not open for business, the inpatient rehabilitation facility is responsible for allowing sufficient time for the delivery of the request before the deadline. If an inpatient rehabilitation facility's request is not received timely or is otherwise not approved, payment will be based on the transition period rate specified in paragraph (a)(1)(i) of this section.

[66 FR 41388, Aug. 7, 2001, as amended at 67 FR 44077, July 1, 2002]

§412.628 Publication of the Federal prospective payment rates.

We publish information pertaining to the inpatient rehabilitation facility prospective payment system effective for each fiscal year in the FEDERAL REGISTER. This information includes the unadjusted Federal payment rates, the patient classification system and associated weighting factors, and a description of the methodology and data used to calculate the payment rates. This information is published on or before August 1 prior to the beginning of each fiscal year.

§412.630 Limitation on review.

Administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, is prohibited with regard to the establishment of the methodology to classify a patient into the case-mix groups and the associated weighting factors, the unadjusted Federal per discharge payment rates, additional payments for outliers and special payments, and the area wage index.

§412.632 Method of payment under the inpatient rehabilitation facility prospective payment system.

(a) *General rule.* Subject to the exceptions in paragraphs (b) and (c) of this section, an inpatient rehabilitation facility receives payment under this subpart for inpatient operating costs and capital-related costs for each discharge only following submission of a discharge bill.

(b) *Periodic interim payments.*

(1) *Criteria for receiving periodic interim payments.*

(i) An inpatient rehabilitation facility receiving payment under this subpart may receive periodic interim payments (PIP) for Part A services under the PIP method subject to the provisions of §413.64(h) of this subchapter.

(ii) To be approved for PIP, the inpatient rehabilitation facility must meet the qualifying requirements in §413.64(h)(3) of this subchapter.

(iii) Payments to a rehabilitation unit are made under the same method of payment as the hospital of which it is a part as described in §412.116.

(iv) As provided in §413.64(h)(5) of this chapter, intermediary approval is conditioned upon the intermediary's best judgment as to whether payment can be made under the PIP method without undue risk of its resulting in an overpayment to the provider.

(2) *Frequency of payment.* For facilities approved for PIP, the intermediary estimates the inpatient rehabilitation facility's Federal prospective payments net of estimated beneficiary deductibles and coinsurance and makes biweekly payments equal to 1/26 of the total estimated amount of payment for the year. If the inpatient rehabilitation facility has payment experience under the prospective payment system, the intermediary estimates PIP based on that payment experience, adjusted for projected changes supported by substantiated information for the current year. Each payment is made 2 weeks after the end of a biweekly period of service as described in §413.64(h)(6) of this subchapter. The interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if an inpatient rehabilitation facility receives interim payments for

less than a full reporting period. These payments are subject to final settlement.

(3) *Termination of PIP.* (i) *Request by the inpatient rehabilitation facility.* Subject to the provisions of paragraph (b)(1)(iii) of this section, an inpatient rehabilitation facility receiving PIP may convert to receiving prospective payments on a non-PIP basis at any time.

(ii) *Removal by the intermediary.* An intermediary terminates PIP if the inpatient rehabilitation facility no longer meets the requirements of §413.64(h) of this chapter.

(c) *Interim payments for Medicare bad debts and for Part A costs not paid under the prospective payment system.* For Medicare bad debts and for costs of an approved education program and other costs paid outside the prospective payment system, the intermediary determines the interim payments by estimating the reimbursable amount for the year based on the previous year's experience, adjusted for projected changes supported by substantiated information for the current year, and makes biweekly payments equal to 1/26 of the total estimated amount. Each payment is made 2 weeks after the end of a biweekly period of service as described in §413.64(h)(6) of this chapter. The interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if an inpatient rehabilitation facility receives interim payments for less than a full reporting period. These payments are subject to final cost settlement.

(d) *Outlier payments.* Additional payments for outliers are not made on an interim basis. The outlier payments are made based on the submission of a discharge bill and represent final payment.

(e) *Accelerated payments.* (1) *General rule.* Upon request, an accelerated payment may be made to an inpatient rehabilitation facility that is receiving payment under this subpart and is not receiving PIP under paragraph (b) of this section if the inpatient rehabilitation facility is experiencing financial difficulties because of the following:

(i) There is a delay by the intermediary in making payment to the inpatient rehabilitation facility.

(ii) Due to an exceptional situation, there is a temporary delay in the inpatient rehabilitation facility's preparation and submittal of bills to the intermediary beyond its normal billing cycle.

(2) *Approval of payment.* An inpatient rehabilitation facility's request for an accelerated payment must be approved by the intermediary and us.

(3) *Amount of payment.* The amount of the accelerated payment is computed as a percentage of the net payment for unbilled or unpaid covered services.

(4) *Recovery of payment.* Recovery of the accelerated payment is made by recoupment as inpatient rehabilitation facility bills are processed or by direct payment by the inpatient rehabilitation facility.

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

Subpart A—Introduction and General Rules

Sec.
413.1 Introduction.
413.5 Cost reimbursement: General.
413.9 Cost related to patient care.
413.13 Amount of payment if customary charges for services furnished are less than reasonable costs.
413.17 Cost to related organizations.

Subpart B—Accounting Records and Reports

413.20 Financial data and reports.
413.24 Adequate cost data and cost finding.

Subpart C—Limits on Cost Reimbursement

413.30 Limitations on payable costs.
413.35 Limitations on coverage of costs: Charges to beneficiaries if cost limits are applied to services.
413.40 Ceiling on the rate of increase in hospital inpatient costs.

Subpart D—Apportionment

413.50 Apportionment of allowable costs.
413.53 Determination of cost of services to beneficiaries.

SUBCHAPTER G—STANDARDS AND CERTIFICATION

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

Subpart A—General Provisions

Sec.
482.1 Basis and scope.
482.2 Provision of emergency services by nonparticipating hospitals.

Subpart B—Administration

482.11 Condition of participation: Compliance with Federal, State and local laws.
482.12 Condition of participation: Governing body.
482.13 Condition of participation: Patients' rights.

Subpart C—Basic Hospital Functions

482.21 Condition of participation: Quality assessment and performance improvement program.
482.22 Condition of participation: Medical staff.
482.23 Condition of participation: Nursing services.
482.24 Condition of participation: Medical record services.
482.25 Condition of participation: Pharmaceutical services.
482.26 Condition of participation: Radiologic services.
482.27 Condition of participation: Laboratory services.
482.28 Condition of participation: Food and dietetic services.
482.30 Condition of participation: Utilization review.
482.41 Condition of participation: Physical environment.
482.42 Condition of participation: Infection control.
482.43 Condition of participation: Discharge planning.
482.45 Condition of participation: Organ, tissue, and eye procurement.

Subpart D—Optional Hospital Services

482.51 Condition of participation: Surgical services.
482.52 Condition of participation: Anesthesia services.
482.53 Condition of participation: Nuclear medicine services.
482.54 Condition of participation: Outpatient services.
482.55 Condition of participation: Emergency services.
482.56 Condition of participation: Rehabilitation services.
482.57 Condition of participation: Respiratory care services.

Subpart E—Requirements for Specialty Hospitals

482.60 Special provisions applying to psychiatric hospitals.
482.61 Condition of participation: Special medical record requirements for psychiatric hospitals.
482.62 Condition of participation: Special staff requirements for psychiatric hospitals.
482.66 Special requirements for hospital providers of long-term care services ("swing-beds").

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 51 FR 22042, June 17, 1986, unless otherwise noted.

Subpart A—General Provisions

§ 482.1 Basis and scope.

(a) *Statutory basis.* (1) Section 1861(e) of the Act provides that—

(i) Hospitals participating in Medicare must meet certain specified requirements; and

(ii) The Secretary may impose additional requirements if they are found necessary in the interest of the health and safety of the individuals who are furnished services in hospitals.

(2) Section 1861(f) of the Act provides that an institution participating in Medicare as a psychiatric hospital must meet certain specified requirements imposed on hospitals under section 1861(e), must be primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons, must maintain clinical records and other records that the Secretary finds necessary, and must meet staffing requirements that the Secretary finds necessary to carry out an active program of treatment for individuals who are furnished services in the hospital. A distinct part of an institution can participate as a psychiatric hospital if the institution meets the specified 1861(e) requirements and is primarily engaged in providing psychiatric services, and if the

distinct part meets the records and staffing requirements that the Secretary finds necessary.

(3) Sections 1861(k) and 1902(a)(30) of the Act provide that hospitals participating in Medicare and Medicaid must have a utilization review plan that meets specified requirements.

(4) Section 1883 of the Act sets forth the requirements for hospitals that provide long term care under an agreement with the Secretary.

(5) Section 1905(a) of the Act provides that "medical assistance" (Medicaid) payments may be applied to various hospital services. Regulations interpreting those provisions specify that hospitals receiving payment under Medicaid must meet the requirements for participation in Medicare (except in the case of medical supervision of nurse-midwife services. See §§440.10 and 440.165 of this chapter.).

(b) *Scope.* Except as provided in subpart A of part 488 of this chapter, the provisions of this part serve as the basis of survey activities for the purpose of determining whether a hospital qualifies for a provider agreement under Medicare and Medicaid.

[51 FR 22042, June 17, 1986, as amended at 60 FR 50442, Sept. 29, 1995]

§ 482.2 Provision of emergency services by nonparticipating hospitals.

(a) The services of an institution that does not have an agreement to participate in the Medicare program may, nevertheless, be reimbursed under the program if—

(1) The services are emergency services; and

(2) The institution meets the requirements of section 1861(e) (1) through (5) and (7) of the Act. Rules applicable to emergency services furnished by nonparticipating hospitals are set forth in subpart G of part 424 of this chapter.

(b) Secton 440.170(e) of this chapter defines emergency hospital services for purposes of Medicaid reimbursement.

[51 FR 22042, June 17, 1986, as amended at 53 FR 6648, Mar. 2, 1988]

Subpart B—Administration

§ 482.11 Condition of participation: Compliance with Federal, State and local laws.

(a) The hospital must be in compliance with applicable Federal laws related to the health and safety of patients.

(b) The hospital must be—

(1) Licensed; or

(2) Approved as meeting standards for licensing established by the agency of the State or locality responsible for licensing hospitals.

(c) The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.

§ 482.12 Condition of participation: Governing body.

The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.

(a) *Standard: Medical staff.* The governing body must:

(1) Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff;

(2) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff;

(3) Assure that the medical staff has bylaws;

(4) Approve medical staff bylaws and other medical staff rules and regulations;

(5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients;

(6) Ensure the criteria for selection are individual character, competence, training, experience, and judgment; and

(7) Ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon

certification, fellowship, or membership in a specialty body or society.

(b) *Standard: Chief executive officer.* The governing body must appoint a chief executive officer who is responsible for managing the hospital.

(c) *Standard: Care of patients.* In accordance with hospital policy, the governing body must ensure that the following requirements are met:

(1) Every Medicare patient is under the care of:

(i) A doctor of medicine or osteopathy (This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or a State's regulatory mechanism.);

(ii) A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State and who is acting within the scope of his or her license;

(iii) A doctor of podiatric medicine, but only with respect to functions which he or she is legally authorized by the State to perform;

(iv) A doctor of optometry who is legally authorized to practice optometry by the State in which he or she practices;

(v) A chiropractor who is licensed by the State or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist; and

(vi) A clinical psychologist as defined in § 410.71 of this chapter, but only with respect to clinical psychologist services as defined in § 410.71 of this chapter and only to the extent permitted by State law.

(2) Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital. If a Medicare patient is admitted by a practitioner not specified in paragraph (c)(1) of this section, that patient is under the care of a doctor of medicine or osteopathy.

(3) A doctor of medicine or osteopathy is on duty or on call at all times.

(4) A doctor of medicine or osteopathy is responsible for the care of each Medicare patient with respect to any medical or psychiatric problem that—

(i) is present on admission or develops during hospitalization; and

(ii) Is not specifically within the scope of practice of a doctor of dental surgery, dental medicine, podiatric medicine, or optometry; a chiropractor; or clinical psychologist, as that scope is—

(A) Defined by the medical staff;

(B) Permitted by State law; and

(C) Limited, under paragraph (c)(1)(v) of this section, with respect to chiropractors.

(d) *Standard: Institutional plan and budget.* The institution must have an overall institutional plan that meets the following conditions:

(1) The plan must include an annual operating budget that is prepared according to generally accepted accounting principles.

(2) The budget must include all anticipated income and expenses. This provision does not require that the budget identify item by item the components of each anticipated income or expense.

(3) The plan must provide for capital expenditures for at least a 3-year period, including the year in which the operating budget specified in paragraph (d)(2) of this section is applicable.

(4) The plan must include and identify in detail the objective of, and the anticipated sources of financing for, each anticipated capital expenditure in excess of $600,000 (or a lesser amount that is established, in accordance with section 1122(g)(1) of the Act, by the State in which the hospital is located) that relates to any of the following:

(i) Acquisition of land;

(ii) Improvement of land, buildings, and equipment; or

(iii) The replacement, modernization, and expansion of buildings and equipment.

(5) The plan must be submitted for review to the planning agency designated in accordance with section 1122(b) of the Act, or if an agency is not designated, to the appropriate health planning agency in the State. (See part 100 of this title.) A capital expenditure is not subject to section 1122 review if 75 percent of the health care facility's

patients who are expected to use the service for which the capital expenditure is made are individuals enrolled in a health maintenance organization (HMO) or competitive medical plan (CMP) that meets the requirements of section 1876(b) of the Act, and if the Department determines that the capital expenditure is for services and facilities that are needed by the HMO or CMP in order to operate efficiently and economically and that are not otherwise readily accessible to the HMO or CMP because—

(i) The facilities do not provide common services at the same site;

(ii) The facilities are not available under a contract of reasonable duration;

(iii) Full and equal medical staff privileges in the facilities are not available;

(iv) Arrangements with these facilities are not administratively feasible; or

(v) The purchase of these services is more costly than if the HMO or CMP provided the services directly.

(6) The plan must be reviewed and updated annually.

(7) The plan must be prepared—

(i) Under the direction of the governing body; and

(ii) By a committee consisting of representatives of the governing body, the administrative staff, and the medical staff of the institution.

(e) *Standard: Contracted services.* The governing body must be responsible for services furnished in the hospital whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services.

(1) The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.

(2) The hospital must maintain a list of all contracted services, including the scope and nature of the services provided.

(f) *Standard: Emergency services.* (1) If emergency services are provided at the hospital, the hospital must comply with the requirements of § 482.55.

(2) If emergency services are not provided at the hospital, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

(3) If emergency services are provided at the hospital but are not provided at one or more off-campus departments of the hospital, the governing body of the hospital must assure that the medical staff has written policies and procedures in effect with respect to the off-campus department(s) for appraisal of emergencies and referral when appropriate.

[51 FR 22042, June 17, 1986; 51 FR 27847, Aug. 4, 1986, as amended at 53 FR 6549, Mar. 1, 1988; 53 FR 18987, May 26, 1988; 56 FR 8852, Mar. 1, 1991; 56 FR 23022, May 20, 1991; 59 FR 46514, Sept. 8, 1994; 63 FR 20130, Apr. 23, 1998; 63 FR 33874, June 22, 1998; 68 FR 53262, Sept. 9, 2003]

§ 482.13 Condition of participation: Patients' rights.

A hospital must protect and promote each patient's rights.

(a) *Standard: Notice of rights.* (1) A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

(2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The hospital's governing body must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization. At a minimum:

(i) The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.

(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.

(iii) In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

(b) *Standard: Exercise of rights.* (1) The patient has the right to participate in the development and implementation of his or her plan of care.

(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

(3) The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with § 489.100 of this part (Definition), § 489.102 of this part (Requirements for providers), and § 489.104 of this part (Effective dates).

(4) The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.

(c) *Standard: Privacy and safety.* (1) The patient has the right to personal privacy.

(2) The patient has the right to receive care in a safe setting.

(3) The patient has the right to be free from all forms of abuse or harassment.

(d) *Standard: Confidentiality of patient records.* (1) The patient has the right to the confidentiality of his or her clinical records.

(2) The patient has the right to access information contained in his or her clinical records within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its recordkeeping system permits.

(e) *Standard: Restraint for acute medical and surgical care.* (1) The patient has the right to be free from restraints of any form that are not medically necessary or are used as a means of coercion, discipline, convenience, or retaliation by staff. The term "restraint" includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body. A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for the patient's medical or psychiatric condition.

(2) A restraint can only be used if needed to improve the patient's well-being and less restrictive interventions have been determined to be ineffective.

(3) The use of a restraint must be—

(i) Selected only when other less restrictive measures have been found to be ineffective to protect the patient or others from harm;

(ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital to order a restraint. This order must—

(A) Never be written as a standing or on an as needed basis (that is, PRN); and

(B) Be followed by consultation with the patient's treating physician, as soon as possible, if the restraint is not ordered by the patient's treating physician;

(iii) In accordance with a written modification to the patient's plan of care;

(iv) Implemented in the least restrictive manner possible;

(v) In accordance with safe and appropriate restraining techniques; and

(vi) Ended at the earliest possible time.

(4) The condition of the restrained patient must be continually assessed, monitored, and reevaluated.

(5) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of restraints.

(f) *Standard: Seclusion and restraint for behavior management.* (1) The patient has the right to be free from seclusion and restraints, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. The term "restraint" includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body. A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for the patient's medical or psychiatric condition. Seclusion is the involuntary confinement of a person in a room or an area where the person is physically prevented from leaving.

(2) Seclusion or a restraint can only be used in emergency situations if needed to ensure the patient's physical safety and less restrictive interventions have been determined to be ineffective.

(3) The use of a restraint or seclusion must be—

(i) Selected only when less restrictive measures have been found to be ineffective to protect the patient or others from harm;

(ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital to order seclusion or restraint. The following requirements will be superseded by existing State laws that are more restrictive:

(A) Orders for the use of seclusion or a restraint must never be written as a standing order or on an as needed basis (that is, PRN).

(B) The treating physician must be consulted as soon as possible, if the restraint or seclusion is not ordered by the patient's treating physician.

(C) A physician or other licensed independent practitioner must see and evaluate the need for restraint or seclusion within 1 hour after the initiation of this intervention.

(D) Each written order for a physical restraint or seclusion is limited to 4 hours for adults; 2 hours for children and adolescents ages 9 to 17; or 1 hour for patients under 9. The original order may only be renewed in accordance with these limits for up to a total of 24 hours. After the original order expires, a physician or licensed independent practitioner (if allowed under State law) must see and assess the patient before issuing a new order.

(iii) In accordance with a written modification to the patient's plan of care;

(iv) Implemented in the least restrictive manner possible;

(v) In accordance with safe appropriate restraining techniques; and

(vi) Ended at the earliest possible time.

(4) A restraint and seclusion may not be used simultaneously unless the patient is—

(i) Continually monitored face-to-face by an assigned staff member; or

(ii) Continually monitored by staff using both video and audio equipment. This monitoring must be in close proximity the patient.

(5) The condition of the patient who is in a restraint or in seclusion must continually be assessed, monitored, and reevaluated.

(6) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of seclusion and restraint application and techniques and alternative methods for handling behavior, symptoms, and situations that traditionally have been treated through the use of restraints or seclusion.

(7) The hospital must report to CMS any death that occurs while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion.

[64 FR 36088, July 2, 1999]

Subpart C—Basic Hospital Functions

§ 482.21 Condition of participation: Quality assessment and performance improvement program.

The hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.

(a) *Standard: Program scope.* (1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors.

(2) The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations.

(b) *Standard: Program data.* (1) The program must incorporate quality indicator data including patient care data, and other relevant data, for example, information submitted to, or received from, the hospital's Quality Improvement Organization.

(2) The hospital must use the data collected to—

(i) Monitor the effectiveness and safety of services and quality of care; and

(ii) Identify opportunities for improvement and changes that will lead to improvement.

(3) The frequency and detail of data collection must be specified by the hospital's governing body.

(c) *Standard: Program activities.* (1) The hospital must set priorities for its performance improvement activities that—

(i) Focus on high-risk, high-volume, or problem-prone areas;

(ii) Consider the incidence, prevalence, and severity of problems in those areas; and

(iii) Affect health outcomes, patient safety, and quality of care.

(2) Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital.

(3) The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained.

(d) *Standard: Performance improvement projects.* As part of its quality assessment and performance improvement program, the hospital must conduct performance improvement projects.

(1) The number and scope of distinct improvement projects conducted annually must be proportional to the scope and complexity of the hospital's services and operations.

(2) A hospital may, as one of its projects, develop and implement an information technology system explicitly designed to improve patient safety and quality of care. This project, in its initial stage of development, does not need to demonstrate measurable improvement in indicators related to health outcomes.

(3) The hospital must document what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

(4) A hospital is not required to participate in a QIO cooperative project, but its own projects are required to be of comparable effort.

(e) *Standard: Executive responsibilities.* The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:

(1) That an ongoing program for quality improvement and patient safety,

including the reduction of medical errors, is defined, implemented, and maintained.

(2) That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety; and that all improvement actions are evaluated.

(3) That clear expectations for safety are established.

(4) That adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients.

(5) That the determination of the number of distinct improvement projects is conducted annually.

[68 FR 3454, Jan. 24, 2003]

§ 482.22 Condition of participation: Medical staff.

The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital.

(a) *Standard: Composition of the medical staff.* The medical staff must be composed of doctors of medicine or osteopathy and, in accordance with State law, may also be composed of other practitioners appointed by the governing body.

(1) The medical staff must periodically conduct appraisals of its members.

(2) The medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates.

(b) *Standard: Medical staff organization and accountability.* The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to patients.

(1) The medical staff must be organized in a manner approved by the governing body.

(2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.

(3) The responsibility for organization and conduct of the medical staff must be assigned only to an individual doctor of medicine or osteopathy or, when permitted by State law of the State in which the hospital is located, a doctor of dental surgery or dental medicine.

(c) *Standard: Medical staff bylaws.* The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:

(1) Be approved by the governing body.

(2) Include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, etc.)

(3) Describe the organization of the medical staff.

(4) Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.

(5) Include a requirement that a physical examination and medical history be done no more than 7 days before or 48 hours after an admission for each patient by a doctor of medicine or osteopathy, or, for patients admitted only for oromaxillofacial surgery, by an oromaxillofacial surgeon who has been granted such privileges by the medical staff in accordance with State law.

(6) Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.

(d) *Standard: Autopsies.* The medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. The mechanism for documenting permission to perform an autopsy must be defined. There must be a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed.

[51 FR 22042, June 17, 1986, as amended at 59 FR 64152, Dec. 13, 1994]

§ 482.23 Condition of participation: Nursing services.

The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.

(a) *Standard: Organization.* The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

(b) *Standard: Staffing and delivery of care.* The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.

(1) The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times, except for rural hospitals that have in effect a 24-hour nursing waiver granted under § 405.1910(c) of this chapter.

(2) The nursing service must have a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licensure.

(3) A registered nurse must supervise and evaluate the nursing care for each patient.

(4) The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient.

(5) A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.

(6) Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing service.

(c) *Standard: Preparation and administration of drugs.* Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under § 482.12(c), and accepted standards of practice.

(1) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

(2) All orders for drugs and biologicals must be in writing and signed by the practitioner or practitioners responsible for the care of the patient as specified under § 482.12(c) with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment for contraindications. When telephone or oral orders must be used, they must be—

(i) Accepted only by personnel that are authorized to do so by the medical staff policies and procedures, consistent with Federal and State law;

(ii) Signed or initialed by the prescribing practitioner as soon as possible; and

(iii) Used infrequently.

(3) Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures. If blood transfusions and intravenous medications are administered by personnel other than doctors of medicine or osteopathy, the personnel must have special training for this duty.

(4) There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

[51 FR 22042, June 17, 1986, as amended at 67 FR 61814, Oct. 2, 2002]

§ 482.24 Condition of participation: Medical record services.

The hospital must have a medical record service that has administrative responsibility for medical records. A

medical record must be maintained for every individual evaluated or treated in the hospital.

(a) *Standard: Organization and staffing.* The organization of the medical record service must be appropriate to the scope and complexity of the services performed. The hospital must employ adequate personnel to ensure prompt completion, filing, and retrieval of records.

(b) *Standard: Form and retention of record.* The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentification and protects the security of all record entries.

(1) Medical records must be retained in their original or legally reproduced form for a period of at least 5 years.

(2) The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.

(3) The hospital must have a procedure for ensuring the confidentiality of patient records. In-formation from or copies of records may be released only to authorized individuals, and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released by the hospital only in accordance with Federal or State laws, court orders, or subpoenas.

(c) *Standard: Content of record.* The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.

(1) All entries must be legible and complete, and must be authenticated and dated promptly by the person (identified by name and discipline) who is responsible for ordering, providing, or evaluating the service furnished.

(i) The author of each entry must be identifed and must authenticate his or her entry.

(ii) Authentication may include signatures, written initials or computer entry.

(2) All records must document the following, as appropriate:

(i) Evidence of a physical examination, including a health history, performed no more than 7 days prior to admission or within 48 hours after admission.

(ii) Admitting diagnosis.

(iii) Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.

(iv) Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia.

(v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.

(vi) All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.

(vii) Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow-up care.

(viii) Final diagnosis with completion of medical records within 30 days following discharge.

§ 482.25 Condition of participation: Pharmaceutical services.

The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

(a) *Standard: Pharmacy management and administration.* The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

(1) A full-time, part-time, or consulting pharmacist must be responsible

for developing, supervising, and coordinating all the activities of the pharmacy services.

(2) The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.

(3) Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.

(b) *Standard: Delivery of services.* In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

(1) All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.

(2) Drugs and biologicals must be kept in a locked storage area.

(3) Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.

(4) When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law.

(5) Drugs and biologicals not specifically prescribed as to time or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.

(6) Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital-wide quality assurance program.

(7) Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

(8) Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff.

(9) A formulary system must be established by the medical staff to assure quality pharmaceuticals at reasonable costs.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

§ 482.26 Condition of participation: Radiologic services.

The hospital must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.

(a) *Standard: Radiologic services.* The hospital must maintain, or have available, radiologic services according to needs of the patients.

(b) *Standard: Safety for patients and personnel.* The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

(1) Proper safety precutions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.

(2) Periodic inspection of equipment must be made and hazards identified must be promptly corrected.

(3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

(4) Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.

(c) *Standard: Personnel.* (1) A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

(2) Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.

(d) *Standard: Records.* Records of radiologic services must be maintained.

(1) The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.

(2) The hospital must maintain the following for at least 5 years:

(i) Copies of reports and printouts.

(ii) Films, scans, and other image records, as appropriate.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

§ 482.27 Condition of participation: Laboratory services.

(a) The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with part 493 of this chapter.

(b) *Standard: Adequacy of laboratory services.* The hospital must have laboratory services available, either directly or through a contractual agreement with a certified laboratory that meets requirements of part 493 of this chapter.

(1) Emergency laboratory services must be available 24 hours a day.

(2) A written description of services provided must be available to the medical staff.

(3) The laboratory must make provision for proper receipt and reporting of tissue specimens.

(4) The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.

(c) *Standard: Potentially infectious blood and blood products*—(1) *Potentially HIV infectious blood and blood products* are prior collections from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to the human immunodeficiency virus (HIV) on a later donation, and the FDA-licensed, more specific test or other followup testing recommended or required by FDA is positive and the timing of seroconversion cannot be precisely estimated.

(2) *Services furnished by an outside blood bank.* If a hospital regularly uses the services of an outside blood bank, it must have an agreement with the blood bank that governs the procurement, transfer, and availability of blood and blood products. The agreement must require that the blood bank promptly notify the hospital of the following:

(i) If it supplied blood and blood products collected from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to HIV on a later donation; and

(ii) The results of the FDA-licensed, more specific test or other followup testing recommended or required by FDA completed within 30 calendar days after the donor's repeatedly reactive screening test. (FDA regulations concerning HIV testing and lookback procedures are set forth at 21 CFR 610.45-et seq.)

(3) *Quarantine of blood and blood products pending completion of testing.* If the blood bank notifies the hospital of the repeatedly reactive HIV screening test results as required by paragraph (c)(2)(i) of this section, the hospital must determine the disposition of the blood or blood product and quarantine all blood and blood products from previous donations in inventory.

(i) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other followup testing recommended or required by FDA is negative, absent other informative test results, the hospital may release the blood and blood products from quarantine.

(ii) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other followup testing recommended or required by FDA is positive, the hospital must dispose of the blood and blood products in accordance with 21 CFR 606.40 and notify patients in accordance with paragraph (c)(4) of this section.

(4) *Patient notification.* If the hospital has administered potentially HIV infectious blood or blood products (either directly through its own blood bank or under an agreement described in paragraph (c)(2) of this section) or released such blood or blood products to another entity or appropriate individual,

the hospital must take the following actions:

(i) Promptly make at least three attempts to notify the patient's attending physician (that is, the physician of record) or the physician who ordered the blood or blood product that potentially HIV infectious blood or blood products were transfused to the patient.

(ii) Ask the physician to immediately notify the patient, or other individual as permitted under paragraph (c)(8) of this section, of the need for HIV testing and counseling.

(iii) If the physician is unavailable, declines to make the notification, or later informs the hospital that he or she was unable to notify the patient, promptly make at least three attempts to notify the patient, or other individual as permitted under paragraph (c)(8) of this section, of the need for HIV testing and counseling.

(iv) Document in the patient's medical record the notification or attempts to give the required notification.

(5) *Timeframe for notification.* The notification effort begins when the blood bank notifies the hospital that it received potentially HIV infectious blood and blood products and continues for 8 weeks unless—

(i) The patient is located and notified; or

(ii) The hospital is unable to locate the patient and documents in the patient's medical record the extenuating circumstances beyond the hospital's control that caused the notification timeframe to exceed 8 weeks.

(6) *Content of notification.* The notification given under paragraphs (c)(4) (ii) and (iii) of this section must include the following information:

(i) A basic explanation of the need for HIV testing and counseling.

(ii) Enough oral or written information so that the transfused patient can make an informed decision about whether to obtain HIV testing and counseling.

(iii) A list of programs or places where the patient can obtain HIV testing and counseling, including any requirements or restrictions the program may impose.

(7) *Policies and procedures.* The hospital must establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for confidentiality and medical records.

(8) *Notification to legal representative or relative.* If the patient has been adjudged incompetent by a State court, the physician or hospital must notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or hospital must notify the patient or his or her legal representative or relative. If the patient is deceased, the physician or hospital must continue the notification process and inform the deceased patient's legal representative or relative.

[57 FR 7136, Feb. 28, 1992, as amended at 61 FR 47433, Sept. 9, 1996]

§ 482.28 Condition of participation: Food and dietetic services.

The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel. However, a hospital that has a contract with an outside food management company may be found to meet this Condition of participation if the company has a dietitian who serves the hospital on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.

(a) *Standard: Organization.* (1) The hospital must have a full-time employee who—

(i) Serves as director of the food and dietetic service;

(ii) Is responsible for the daily management of the dietary services; and

(iii) Is qualified by experience or training.

(2) There must be a qualified dietitian, full-time, part-time, or on a consultant basis.

(3) There must be administrative and technical personnel competent in their respective duties.

(b) *Standard: Diets.* Menus must meet the needs of the patients.

(1) Therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the patients.

(2) Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the patients.

(3) A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.

§ 482.30 Condition of participation: Utilization review.

The hospital must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs.

(a) *Applicability*. The provisions of this section apply except in either of the following circumstances:

(1) A Utilization and Quality Control Quality Improvement Organization (QIO) has assumed binding review for the hospital.

(2) CMS has determined that the UR procedures established by the State under title XIX of the Act are superior to the procedures required in this section, and has required hospitals in that State to meet the UR plan requirements under §§ 456.50 through 456.245 of this chapter.

(b) *Standard: Composition of utilization review committee.* A UR committee consisting of two or more practitioners must carry out the UR function. At least two of the members of the committee must be doctors of medicine or osteopathy. The other members may be any of the other types of practitioners specified in § 482.12(c)(1).

(1) Except as specified in paragraphs (b) (2) and (3) of this section, the UR committee must be one of the following:

(i) A staff committee of the institution;

(ii) A group outside the institution—

(A) Established by the local medical society and some or all of the hospitals in the locality; or

(B) Established in a manner approved by CMS.

(2) If, because of the small size of the institution, it is impracticable to have a properly functioning staff committee, the UR committee must be established as specified in paragraph (b)(1)(ii) of this section.

(3) The committee's or group's reviews may not be conducted by any individual who—

(i) Has a direct financial interest (for example, an ownership interest) in that hospital; or

(ii) Was professionally involved in the care of the patient whose case is being reviewed.

(c) *Standard: Scope and frequency of review*. (1) The UR plan must provide for review for Medicare and Medicaid patients with respect to the medical necessity of—

(i) Admissions to the institution;

(ii) The duration of stays; and

(iii) Professional services furnished, including drugs and biologicals.

(2) Review of admissions may be performed before, at, or after hospital admission.

(3) Except as specified in paragraph (e) of this section, reviews may be conducted on a sample basis.

(4) Hospitals that are paid for inpatient hospital services under the prospective payment system set forth in Part 412 of this chapter must conduct review of duration of stays and review of professional services as follows:

(i) For duration of stays, these hospitals need review only cases that they reasonably assume to be outlier cases based on extended length of stay, as described in § 412.80(a)(1)(i) of this chapter; and

(ii) For professional services, these hospitals need review only cases that they reasonably assume to be outlier cases based on extraordinarily high costs, as described in § 412.80(a)(1)(ii) of this chapter.

(d) *Standard: Determination regarding admissions or continued stays.* (1) The determination that an admission or continued stay is not medically necessary—

(i) May be made by one member of the UR committee if the practitioner or practitioners responsible for the care of the patient, as specified of

§ 482.12(c), concur with the determination or fail to present their views when afforded the opportunity; and

(ii) Must be made by at least two members of the UR committee in all other cases.

(2) Before making a determination that an admission or continued stay is not medically necessary, the UR committee must consult the practitioner or practitioners responsible for the care of the patient, as specified in § 482.12(c), and afford the practitioner or practitioners the opportunity to present their views.

(3) If the committee decides that admission to or continued stay in the hospital is not medically necessary, written notification must be given, no later than 2 days after the determination, to the hospital, the patient, and the practitioner or practitioners responsible for the care of the patient, as specified in § 482.12(c);

(e) *Standard: Extended stay review.* (1) In hospitals that are not paid under the prospective payment system, the UR committee must make a periodic review, as specified in the UR plan, of each current inpatient receiving hospital services during a continuous period of extended duration. The scheduling of the periodic reviews may—

(i) Be the same for all cases; or

(ii) Differ for different classes of cases.

(2) In hospitals paid under the prospective payment system, the UR committee must review all cases reasonably assumed by the hospital to be outlier cases because the extended length of stay exceeds the threshold criteria for the diagnosis, as described in § 412.80(a)(1)(i). The hospital is not required to review an extended stay that does not exceed the outlier threshold for the diagnosis.

(3) The UR committee must make the periodic review no later than 7 days after the day required in the UR plan.

(f) *Standard: Review of professional services.* The committee must review professional services provided, to determine medical necessity and to promote the most efficient use of available health facilities and services.

§ 482.41 Condition of participation: Physical environment.

The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.

(a) *Standard: Buildings.* The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.

(1) There must be emergency power and lighting in at least the operating, recovery, intensive care, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available.

(2) There must be facilities for emergency gas and water supply.

(b) *Standard: Life safety from fire.* (1) Except as otherwise provided in this section—

(i) The hospital must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to hospitals.

(2) After consideration of State survey agency findings, CMS may waive

specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protects patients in hospitals.

(4) Beginning March 13, 2006, a hospital must be in compliance with Chapter 19.2.9, Emergency Lighting.

(5) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to hospitals.

(6) The hospital must have procedures for the proper routine storage and prompt disposal of trash.

(7) The hospital must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities.

(8) The hospital must maintain written evidence of regular inspection and approval by State or local fire control agencies.

(c) *Standard: Facilities.* The hospital must maintain adequate facilities for its services.

(1) Diagnostic and therapeutic facilities must be located for the safety of patients.

(2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

(3) The extent and complexity of facilities must be determined by the services offered.

(4) There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

[51 FR 22042, June 17, 1986, as amended at 53 FR 11509, Apr. 7, 1988; 68 FR 1386, Jan. 10, 2003; 69 FR 49267, Aug. 11, 2004]

§ 482.42 Condition of participation: Infection control.

The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

(a) *Standard: Organization and policies.* A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases.

(1) The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

(2) The infection control officer or officers must maintain a log of incidents related to infections and communicable diseases.

(b) *Standard: Responsibilities of chief executive officer, medical staff, and director of nursing services.* The chief executive officer, the medical staff, and the director of nursing services must—

(1) Ensure that the hospital-wide quality assurance program and training programs address problems identified by the infection control officer or officers; and

(2) Be responsible for the implementation of successful corrective action plans in affected problem areas.

§ 482.43 Condition of participation: Discharge planning.

The hospital must have in effect a discharge planning process that applies to all patients. The hospital's policies and procedures must be specified in writing.

(a) *Standard: Identification of patients in need of discharge planning.* The hospital must identify at an early stage of hospitalization all patients who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning.

(b) *Standard: Discharge planning evaluation.* (1) The hospital must provide a discharge planning evaluation to the patients identified in paragraph (a) of this section, and to other patients upon the patient's request, the request of a person acting on the patient's behalf, or the request of the physician.

(2) A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, the evaluation.

(3) The discharge planning evaluation must include an evaluation of the likelihood of a patient needing post- hospital services and of the availability of the services.

(4) The discharge planning evaluation must include an evaluation of the likelihood of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the hospital.

(5) The hospital personnel must complete the evaluation on a timely basis so that appropriate arrangements for post-hospital care are made before discharge, and to avoid unnecessary delays in discharge.

(6) The hospital must include the discharge planning evaluation in the patient's medical record for use in establishing an appropriate discharge plan and must discuss the results of the evaluation with the patient or individual acting on his or her behalf.

(c) *Standard: Discharge plan.* (1) A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, a discharge plan if the discharge planning evaluation indicates a need for a discharge plan.

(2) In the absence of a finding by the hospital that a patient needs a discharge plan, the patient's physician may request a discharge plan. In such a case, the hospital must develop a discharge plan for the patient.

(3) The hospital must arrange for the initial implementation of the patient's discharge plan.

(4) The hospital must reassess the patient's discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan.

(5) As needed, the patient and family members or interested persons must be counseled to prepare them for post-hospital care.

(6) The hospital must include in the discharge plan a list of HHAs or SNFs that are available to the patient, that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, in the geographic area requested by the patient. HHAs must request to be listed by the hospital as available.

(i) This list must only be presented to patients for whom home health care or post-hospital extended care services are indicated and appropriate as determined by the discharge planning evaluation.

(ii) For patients enrolled in managed care organizations, the hospital must indicate the availability of home health and posthospital extended care services through individuals and entities that have a contract with the managed care organizations.

(iii) The hospital must document in the patient's medical record that the list was presented to the patient or to the individual acting on the patient's behalf.

(7) The hospital, as part of the discharge planning process, must inform the patient or the patient's family of their freedom to choose among participating Medicare providers of posthospital care services and must, when possible, respect patient and family preferences when they are expressed. The hospital must not specify or otherwise limit the qualified providers that are available to the patient.

(8) The discharge plan must identify any HHA or SNF to which the patient is referred in which the hospital has a disclosable financial interest, as specified by the Secretary, and any HHA or SNF that has a disclosable financial interest in a hospital under Medicare. Financial interests that are disclosable under Medicare are determined in accordance with the provisions of Part 420, Subpart C, of this chapter.

(d) *Standard: Transfer or referral.* The hospital must transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for followup or ancillary care.

(e) *Standard: Reassessment.* The hospital must reassess its discharge planning process on an on-going basis. The reassessment must include a review of discharge plans to ensure that they are responsive to discharge needs.

[59 FR 64152, Dec. 13, 1994, as amended at 69 FR 49268, Aug. 11, 2004]

§ 482.45 Condition of participation: Organ, tissue, and eye procurement.

(a) *Standard: Organ procurement responsibilities.* The hospital must have and implement written protocols that:

(1) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose;

(2) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

(3) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its options to donate organs, tissues, or eyes or to decline to donate. The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

(4) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

(5) Ensure that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.

(b) *Standard: Organ transplantation responsibilities.* (1) A hospital in which organ transplants are performed must be a member of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274) and abide by its rules. The term "rules of the OPTN" means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS Act which are enforceable under 42 CFR 121.10. No hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act, or with the requirements of this paragraph, unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing.

(2) For purposes of these standards, the term "organ" means a human kidney, liver, heart, lung, or pancreas.

(3) If a hospital performs any type of transplants, it must provide organ-transplant-related data, as requested by the OPTN, the Scientific Registry, and the OPOs. The hospital must also provide such data directly to the Department when requested by the Secretary.

[63 FR 33875, June 22, 1998]

Subpart D—Optional Hospital Services

§ 482.51 Condition of participation: Surgical services.

If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

(a) *Standard: Organization and staffing.* The organization of the surgical services must be appropriate to the scope of the services offered.

(1) The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.

(2) Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as "scrub nurses" under the supervision of a registered nurse.

(3) Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the surpervision of a qualified registered nurse who is immediately available to respond to emergencies.

(4) Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.

(b) *Standard: Delivery of service.* Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

(1) There must be a complete history and physical work-up in the chart of every patient prior to surgery, except in emergencies. If this has been dictated, but not yet recorded in the patient's chart, there must be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient.

(2) A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies.

(3) The following equipment must be available to the operating room suites: call-in-system, cardiac monitor, resuscitator, defibrillator, aspirator, and tracheotomy set.

(4) There must be adequate provisions for immediate post-operative care.

(5) The operating room register must be complete and up-to-date.

(6) An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.

§ 482.52 Condition of participation: Anesthesia services.

If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.

(a) *Standard: Organization and staffing.* The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered only by—

(1) A qualified anesthesiologist;

(2) A doctor of medicine or osteopathy (other than an anesthesiologist);

(3) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;

(4) A certified registered nurse anesthetist (CRNA), as defined in § 410.69(b) of this chapter, who, unless exempted in accordance with paragraph (c)of this section, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or

(5) An anesthesiologist's assistant, as defined in § 410.69(b) of this chapter, who is under the supervision of an anesthesiologist who is immediately available if needed.

(b) *Standard: Delivery of services.* Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of preanesthesia and post anesthesia responsibilities. The policies must ensure that the following are provided for each patient:

(1) A preanesthesia evaluation by an individual qualified to administer anesthesia under paragraph (a) of this section performed within 48 hours prior to surgery.

(2) An intraoperative anesthesia record.

(3) With respect to inpatients, a postanesthesia followup report by the individual who administers the anesthesia that is written within 48 hours after surgery.

(4) With respect to outpatients, a postanesthesia evaluation for proper anesthesia recovery performed in accordance with policies and procedures approved by the medical staff.

(c) *Standard: State exemption.* (1) A hospital may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (a)(4) of this section, if the State in which the hospital is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.

[51 FR 22042, June 17, 1986 as amended at 57 FR 33900, July 31, 1992; 66 FR 56769, Nov. 13, 2001]

§ 482.53 Condition of participation: Nuclear medicine services.

If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.

(a) *Standard: Organization and staffing.* The organization of the nuclear medicine service must be appropriate to the scope and complexity of the services offered.

(1) There must be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.

(2) The qualifications, training, functions, and responsibilities of nuclear medicine personnel must be specified by the service director and approved by the medical staff.

(b) *Standard: Delivery of service.* Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.

(1) In-house preparation of radiopharmaceuticals is by, or under, the direct supervision of an appropriately trained registered pharmacist or a doctor of medicine or osteopathy.

(2) There is proper storage and disposal of radioactive material.

(3) If laboratory tests are performed in the nuclear medicine service, the service must meet the applicable requirement for laboratory services specified in § 482.27.

(c) *Standard: Facilities.* Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance. The equipment must be—

(1) Maintained in safe operating condition; and

(2) Inspected, tested, and calibrated at least annually by qualified personnel.

(d) *Standard: Records.* The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.

(1) The hospital must maintain copies of nuclear medicine reports for at least 5 years.

(2) The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretation of these tests.

(3) The hospital must maintain records of the receipt and disposition of radiopharmaceuticals.

(4) Nuclear medicine services must be ordered only by practitioner whose scope of Federal or State licensure and whose defined staff privileges allow such referrals.

[51 FR 22042, June 17, 1986, as amended at 57 FR 7136, Feb. 28, 1992]

§ 482.54 Condition of participation: Outpatient services.

If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.

(a) *Standard: Organization.* Outpatient services must be appropriately organized and integrated with inpatient services.

(b) *Standard: Personnel.* The hospitals must—

(1) Assign an individual to be responsible for outpatient services; and

(2) Have appropriate professional and nonprofessional personnel available.

§ 482.55 Condition of participation: Emergency services.

The hospital must meet the emergency needs of patients in accordance with acceptable standards of practice.

(a) *Standard: Organization and direction.* If emergency services are provided at the hospital—

(1) The services must be organized under the direction of a qualified member of the medical staff;

(2) The services must be integrated with other departments of the hospital;

(3) The policies and procedures governing medical care provided in the emergency service or department are established by and are a continuing responsibility of the medical staff.

(b) *Standard: Personnel.* (1) The emergency services must be supervised by a qualified member of the medical staff.

(2) There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.

§ 482.56 Condition of participation: Rehabilitation services.

If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients.

(a) *Standard: Organization and staffing.* The organization of the service must be appropriate to the scope of the services offered.

(1) The director of the services must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

(2) Physical therapy, occupational therapy, or speech therapy, or audiology services, if provided, must be provided by staff who meet the qualifications specified by the medical staff, consistent with State law.

(b) *Standard: Delivery of services.* Services must be furnished in accordance with a written plan of treatment. Services must be given in accordance with orders of practitioners who are authorized by the medical staff to order the services, and the orders must be incorporated in the patient's record.

§ 482.57 Condition of participation: Respiratory care services.

The hospital must meet the needs of the patients in accordance with acceptable standards of practice. The following requirements apply if the hospital provides respiratory care service.

(a) *Standard: Organization and Staffing.* The organization of the respiratory care services must be appropriate to the scope and complexity of the services offered.

(1) There must be a director of respiratory care services who is a doctor of medicine or osteopathy with the knowledge experience, and capabilities to supervise and administer the service properly. The director may serve on either a full-time or part-time basis.

(2) There must be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with State law.

(b) *Standard: Delivery of Services.* Services must be delivered in accordance with medical staff directives.

(1) Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures must be designated in writing.

(2) If blood gases or other laboratory tests are performed in the respiratory care unit, the unit must meet the applicable requirements for laboratory services specified in § 482.27.

(3) Services must be provided only on, and in accordance with, the orders of a doctor of medicine or osteopathy.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986, as amended at 57 FR 7136, Feb. 28, 1992]

Subpart E—Requirements for Specialty Hospitals

§ 482.60 Special provisions applying to psychiatric hospitals.

Psychiatric hospital must—

(a) Be primarily engaged in providing, by or under the supervision of a doctor of medicine or osteopathy, psychiatric services for the diagnosis and treatment of mentally ill persons;

21.2 *Federal Register*

66 Fed. Reg. 56681–7

conditions of participation in the Medicaid program. This means that a state may not include costs or revenues in the DSH calculation which are attributable to services rendered in a separately licensed/certified entity, even if that entity is owned by the same institution. Such health services are not ''hospital services.''

Louisiana SPA 01–03 is not consistent with either section 1923(g)(1) of the Act or 42 CFR 440.20, because it would include as hospital services (for purposes of the DSH calculations) health services that were not within the regulatory definition of hospital services or otherwise characterized as hospital services. Therefore, the CMS Administrator, after consulting with the Secretary as required by 42 CFR 430.15, informed Louisiana that Louisiana SPA 01–03 was disapproved.

The notice to Louisiana announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Mr. David W. Hood,

Secretary, Louisiana Department of Health and Hospitals, 1201 Capitol Access Road, P.O. Box 91030, Baton Rouge, LA 70821–9030

Dear Mr. Hood: I am responding to your request for reconsideration of the decision to disapprove Louisiana State Plan Amendment (SPA) 01–03.

At issue is whether Louisiana may include in the calculation of disproportionate share hospital (DSH) payments the uncompensated costs of providing certain health care services that were not within the regulatory definition of hospital services and are not treated as hospital services for any other purpose. This amendment proposed including rural health clinic uncompensated care costs in a hospital's DSH payment calculation.

Section 1923(g)(1) of the Social Security Act (the Act) sets forth a hospital-specific limit on DSH payments and permits only the costs of ''hospital services'' furnished by a hospital to be included in calculating this limit. Medicaid outpatient hospital services are defined in Federal regulations at 42 CFR 440.20(a). This regulation requires the services to be provided by an institution that is licensed or formally approved as a hospital by an officially designated authority for state standard setting. The institution also must meet the conditions of participation in the Medicaid program. This means that a state may not include costs or revenues in the DSH calculation which are attributable to services rendered in a separately licensed/certified entity, even if that entity is owned by the same institution. Such health services are not ''hospital services.''

Louisiana SPA 01–03 is not consistent with either section 1923(g)(1) of the Act or 42 CFR 440.20 because it would include as hospital services (for purposes of the disproportionate share calculations) health services that were not within the regulatory definition of hospital services or otherwise characterized as hospital services. Therefore, the Centers for Medicare & Medicaid Services' Administrator, after consulting with the Secretary as required by 42 CFR 430.15, informed Louisiana that Louisiana SPA 01–03 was disapproved.

I am scheduling a hearing on your request for reconsideration to be held on December 19, 2001, at 10 a.m.; 1301 Young Street; Conference Room 1113; Dallas, Texas 75202.

If this date is not acceptable, we would be glad to set another date that is mutually agreeable to the parties. The hearing will be governed by the procedures prescribed at 42 CFR, part 430.

I am designating Ms. Kathleen Scully-Hayes as the presiding officer. If these arrangements present any problems, please contact the presiding officer. In order to facilitate any communication which may be necessary between the parties to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the State at the hearing. The presiding officer may be reached at (410) 786–2055.

Sincerely,

Thomas A. Scully,

Administrator.

(Sec. 1116 of the Social Security Act (42 U.S.C. 1316); 42 CFR 430.18)

(Catalog of Federal Domestic Assistance Program No. 13.714, Medicaid Assistance Program)

Dated: November 5, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 01–28220 Filed 11–8–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Report of New System

AGENCY: Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) (formerly the Health Care Financing Administration).

ACTION: Notice of New System of Records (SOR).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new system of records. The proposed system is titled ''Inpatient Rehabilitation Facilities Patient Assessment Instrument (IRF-PAI), HHS/CMS/CMSO, 09–70–1518.'' CMS proposes to establish a new system of records containing data on the physical, cognitive, functional, and psychosocial status of all patients receiving the services of Inpatient Rehabilitation Facilities (IRF) that are approved to participate in the Medicare program. Information will not be retained in this system for those individuals who have non-Medicare payment sources.

The primary purpose of the IRF system of records is to support the IRF prospective payment system (PPS) for payment of the IRF Medicare Part A fee-for-services furnished by the IRF to Medicare beneficiaries. Other purposes for the system of records are to: (1) Help validate and refine the Medicare IRF-PPS; (2) study and help ensure the quality of care provided by IRFs; (3) enable CMS and its agents to provide IRFs with data for their own quality assurance and, (4) ultimately, quality improvement activities; (5) support agencies of the State government, deeming organizations or accrediting agencies to determine, evaluate and assess overall effectiveness and quality of IRF services provided in the State; (6) provide information to consumers to allow them to make better informed selections of providers; (7) support regulatory and policy functions performed within the IRF or by a contractor or consultant; (8) support constituent requests made to a Congressional representative; (9) support litigation involving the facility; and (10) support research on the utilization and quality of inpatient rehabilitation services; as well as, evaluation, or epidemiological projects related to the prevention of disease or disability, or the restoration or maintenance of health for understanding and improving payment systems. We have provided background information about the proposed system in the ''Supplementary Information'' section below. Although the Privacy Act requires only that the ''routine use'' portion of the system be published for comment, CMS invites comments on all portions of this notice. See ''Effective Dates section for comment period.

EFFECTIVE DATES: CMS filed a new system report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on November 2, 2001. In any event, we will not disclose any information under a routine use until 40 days after publication. We may defer implementation of this system of records or one or more of the routine use statements listed below if we receive comments that persuade us to defer implementation.

ADDRESSES: The public should address comments to: Director, Division of Data Liaison and Distribution (DDLD), CMS, Room N2–04–27, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.–3 p.m., eastern time zone.

FOR FURTHER INFORMATION CONTACT: Centers for Medicare & Medicaid Services (CMS), Director, Survey and Certification Group, 7500 Security Boulevard, S2–12–25, Baltimore, Maryland 21244–1850.

SUPPLEMENTARY INFORMATION:

I. Description of The New System of Records

A.Glossary of IRF–PAI Terms

1. IRF–PAI Data Set—The IRF–PAI data set is the patient assessment instrument that contains the sum of the identifiers and information.

2. Identifiers—Identifiers are the data elements that can be used to determine a patient's identity. These are: patient's name, social security number, Medicaid number, Medicare number, and patient identification number.

3. IRF–PAI Information IRF–PAI information includes the clinical items listed below and case mix adjusters.

Patient History
Social Cognition
Functional Status
Bowel/Bladder Management
Diagnoses
Medical Complexities
Pain Status
Oral/Nutrition Status
Functional Prognosis
Safety
Resources for Discharge

B. Statutory and Regulatory Basis For System of Records

Section 1886 (j) (2) (D) of the Social Security Act authorizes the Secretary to collect the data necessary to establish and administer the payment system.

C. Data/Information

The IRF–PAI information may contribute to development of the patient care plan by identifying patients at risk for adverse outcomes, such as weight loss, aspiration, or pressure ulcers, and ensure that these patients are monitored to prevent such outcomes which might negatively impact patients' likelihood of optimal rehabilitation. The data collected will generate quality indicators that would allow providers to assess their performance, and to compare it against benchmarks derived from standards of care or the performance of peers. The detection of quality of care problems will guide CMS, the State survey agencies and accrediting agencies in surveying IRFs. This information will be valuable to CMS in fulfilling its responsibility for validating surveys conducted by accrediting agencies. Also, IRF-PAI items may be useful in developing core measures that provide meaningful information on patient characteristics and outcomes across post-acute care settings. We will monitor the data obtained from the IRF-PAI to assess the effects of implementing the changes in the payment system on the quality of care provided in post-acute care settings.

The system of records will contain clinical assessment information (IRF-PAI records) for all Medicare Part A fee-for-service patients receiving the services of a Medicare approved IRF.

II. Collection and Maintenance of Data in the System

A. Scope of the Data Collected

The IRF–PAI will be completed on all Medicare Part A fee-for-service patients who receive services under Part A from an IRF. The IRF–PAI may be completed on Medicare+Choice enrollees, but it is not a requirement. The IRF–PAI data set includes identifiers and information (the specific areas have already been identified in the **SUPPLEMENTARY INFORMATION** section IA).

B. Agency Policies, Procedures, and Restrictions on the Routine Use

The Privacy Act permits us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such disclosure of data is known as a ''routine use.'' The government will only release IRF–PAI information that can be associated with an individual patient as provided for under ''Section III. Entities Who May Receive Disclosures Under Routine Use.'' Both identifiable and non-identifiable data may be disclosed under a routine use. Identifiable data includes individual records with IRF–PAI information and identifiers. Non-identifiable data includes individual records with IRF–PAI information and masked identifiers or IRF–PAI information with identifiers stripped out of the file.

We will only disclose the minimum personal data necessary to achieve the purpose of the IRF–PAI. CMS has the following policies and procedures concerning disclosures of information that will be maintained in the system. In general, disclosure of information from the SOR will be approved only for the minimum information necessary to accomplish the purpose of the disclosure after CMS:

1. Determines that the use or disclosure is consistent with the reason that the data is being collected; e.g., developing and refining payment systems and monitoring the quality of care provided to patients.

2. Determines that:

a. The purpose for which the disclosure is to be made can only be accomplished if the record is provided in individually identifiable form;

b. The purpose for which the disclosure is to be made is of sufficient importance to warrant the effect and/or risk on the privacy of the individual that additional exposure of the record might bring; and

c. There is a strong probability that the proposed use of the data would in fact accomplish the stated purpose(s).

3. Requires the information recipient to:

a. Establish administrative, technical, and physical safeguards to prevent

b. Unauthorized use of disclosure of the record;

c. Remove or destroy at the earliest time all patient-identifiable information; and

d. Agree to not use or disclose the information for any purpose other than the stated purpose under which the information was disclosed.

4. Determines that the data are valid and reliable.

III. Proposed Routine Use Disclosures of Data in the System

A. Entities Who May Receive Disclosures Under Routine Use

These routine uses specify circumstances, in addition to those provided by statute in the Privacy Act of 1974, under which CMS may release information from the IRF–PAI without the consent of the individual to whom such information pertains. Each proposed disclosure of information under these routine uses will be evaluated to ensure that the disclosure is legally permissible, including but not limited to ensuring that the purpose of the disclosure is compatible with the purpose for which the information was collected. We are proposing to establish the following routine use disclosures of information maintained in the system:

1. To agency contractors, or consultants who have been contracted by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contractual or similar agreement with a third party to assist in accomplishing agency business functions relating to purposes for this system of records.

CMS occasionally contracts out certain of its functions when doing so would contribute to effective and efficient operations. CMS must be able to give a contractor whatever information is necessary for the contractor to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor from using or disclosing the information for any purpose other than that described in the contract and requires the contractor to return or destroy all information at the completion of the contract.

2. To a Peer Review Organization (PRO) in order to assist the PRO to perform Title XI and Title XVIII functions relating to assessing and improving IRF quality of care. PROs will work with IRFs to implement quality improvement programs, provide consultation to CMS, its contractors, and to State agencies.

The PROs may use these data to support quality improvement activities and other PRO responsibilities as detailed in Title XI, Sections 1151–1164.

3. To another Federal or State agency:

a. To contribute to the accuracy of CMS's proper payment of Medicare benefits,

b. To enable such agency to administer a Federal health benefits program, or as necessary to enable such agency to fulfill a requirement of a Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds, or

c. To improve the state survey process for investigation of complaints related to health and safety or quality of care and to implement a more outcome oriented survey and certification program.

Other Federal or State agencies in their administration of a Federal health program may require IRF–PAI information in order to support evaluations and monitoring of quality of care for special populations or special care areas, including proper payment for services provided. Releases of information would be allowed if the proposed use(s) for the information proved compatible with the purpose for which CMS collects the information.

4. To an individual or organization for research on the utilization of inpatient rehabilitation services as well as evaluation or epidemiological projects related to the prevention of disease or disability, the restoration or maintenance of health, or for understanding and improving payment projects.

The IRF–PAI data will provide an opportunity for comprehensive research, evaluation and epidemiological projects regarding IRF patients. CMS anticipates that many researchers will have legitimate requests to use these data in projects that could ultimately improve the care provided to IRF patients and the policy that governs the care.

5. To a Member of Congress or to a congressional staff member in response to an inquiry of the Congressional Office made at the written request of the constituent about whom the record is maintained.

Beneficiaries sometimes request the help of a Member of Congress in resolving some issue relating to a matter before CMS. The Member of Congress then writes CMS, and CMS must be able to give sufficient information to be responsive to the inquiry.

6. To the Department of Justice (DOJ), court or adjudicatory body when:

a. The agency or any component thereof, or

b. Any employee of the agency in his or her official capacity; or

c. Any employee of the agency in his or her individual capacity where the DOJ has agreed to represent the employee, or

d. The United States Government;

Is a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are both relevant and necessary to the litigation.

Whenever CMS is involved in litigation, or occasionally when another party is involved in litigation and CMS's policies or operations could be affected by the outcome of the litigation, CMS would be able to disclose information to the DOJ, court or adjudicatory body involved. A determination would be made in each instance that, under the circumstances involved, the purposes served by the use of the information in the particular litigation is compatible with a purpose for which CMS collects the information.

7. To a CMS contractor (including, but not necessarily limited to fiscal intermediaries and carriers) that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud or abuse in such program.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contractual relationship or grant with a third party to assist in accomplishing CMS functions relating to the purpose of combating fraud and abuse.

CMS occasionally contracts out certain of its functions and makes grants when doing so would contribute to effective and efficient operations. CMS must be able to give a contractor or grantee whatever information is necessary for the contractor or grantee to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor or grantee from using or disclosing the information for any purpose other than that described in the contract and requiring the contractor or grantee to return or destroy all information.

8. To another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any State or local governmental agency), that administers, or that has the authority to investigate potential fraud or abuse in, a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud or abuse in such programs.

Other agencies may require IRF–PAI information for the purpose of combating fraud and abuse in such Federally funded programs. Releases of information would be allowed if the proposed use(s) for the information proved compatible with the purposes of collecting the information.

9. To a national accrediting organization whose accredited facilities are presumed to meet certain Medicare requirements for inpatient hospital rehabilitation services (e.g., the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO), the American Osteopathic Association (AOA) or the Commission on Accreditation of Rehabilitation Facilities (CARF)). Information will be released to these organizations only for those facilities that they accredit and that participate in Medicare.

At this time, CMS anticipates providing accrediting organizations with IRF–PAI information to enable them to target potential or identified problems during the organization's

accreditation review process of the facility.

10. To insurance companies, third party administrators (TPA), employers, self-insurers, managed care organizations, other supplemental insurers, non-coordinating insurers, multiple employer trusts, group health plans (i.e., health maintenance organizations (HMO) or a competitive medical plan (CMP)) with a Medicare contract, or a Medicare-approved health care prepayment plan (HCPP), directly or through a contractor, and other groups providing protection for their enrollees. Information to be disclosed shall be limited to Medicare entitlement data. In order to receive the information, they must agree to:

a. Certify that the individual about whom the information is being provided is one of its insured or employees, or is insured and/or employed by another entity for whom they serve as a third party administrator;utilize the information solely for the purpose of processing the individual's insurance claims; and

b. Safeguard the confidentiality of the data and prevent unauthorized access. Other insurers, CMP, HMO, and HCPP may require IRF–PAI information in order to support evaluations and monitoring of Medicare claims information of beneficiaries, including proper payment for services provided.

B. Additional Provisions Affecting Routine Use Disclosures

In addition, our policy will be to prohibit release even of non-identifiable data, except pursuant to one of the routine uses, if there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that individuals who are familiar with the enrollees could, because of the small size, use this information to deduce the identity of the beneficiary).

This System of Records contains Protected Health Information as defined by the Department of Health and Human Services' regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR parts 160 and 164, 65 FR 82462 as amended by 66 FR 12434). Disclosures of Protected Health Information authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information.''

IV. Safeguards

The HHS IRF–PAI system will conform to applicable law and policy governing the privacy and security of Federal automated information systems. These include but are not limited to: the Privacy Act of 1984, Computer Security Act of 1987, the Paperwork Reduction Act of 1995, the Clinger-Cohen Act of 1996, and OMB Circular A–130, Appendix III, ''Security of Federal Automated Information Resources.'' HCFA has prepared a comprehensive system security plan as required by OMB Circular A–130, Appendix III. This plan conforms fully to guidance issued by the National Institute for Standards and Technology (NIST) in NIST Special Publication 800–18, ''Guide for Developing Security Plans for Information Technology Systems.'' Paragraphs A–C of this section highlight some of the specific methods that HCFA is using to ensure the security of this system and the information within it.

A. Authorized Users

Personnel having access to the system have been trained in Privacy Act requirements. Employees who maintain records in the system are instructed not to release any data until the intended recipient agrees to implement appropriate administrative, technical, procedural, and physical safeguards sufficient to protect the confidentiality of the data and to prevent unauthorized access to the data. Records are used in a designated work area and system location is attended at all times during working hours.

To ensure security of the data, the proper level of class user is assigned for each individual user level. This prevents unauthorized users from accessing and modifying critical data. The system database configuration includes five classes of database users:

- Database Administrator class owns the database objects (e.g., tables, triggers, indexes, stored procedures, packages) and has database administration privileges to these objects.
- Quality Control Administrator class has read and write access to key fields in the database;
- Quality Index Report Generator class has read-only access to all fields and tables;
- Policy Research class has query access to tables, but are not allowed to access confidential patient identification information; and
- Submitter class has read and write access to database objects, but no database administration privileges.

B. Physical Safeguards

All server sites will implement the following minimum requirements to assist in reducing the exposure of computer equipment and thus achieve an optimum level of protection and security for the CMS system:

Access to all servers is to be controlled, with access limited to only those support personnel with a demonstrated need for access. Servers are to be kept in a locked room accessible only by specified management and system support personnel. Each server is to require a specific log-on process. All entrance doors are identified and marked. A log is kept of all personnel who were issued a security card, key and/or combination, which grants access to the room housing the server, and all visitors are escorted while in this room. All servers are housed in an area where appropriate environmental security controls are implemented, which include measures implemented to mitigate damage to Automated Information Systems (AIS) resources caused by fire, electricity, water and inadequate climate controls.

Protection applied to the workstations, servers and databases include:

- User Log-on—Authentication is to be performed by the Primary Domain Controller/Backup Domain Controller of the log-on domain.
- Workstation Names—Workstation naming conventions may be defined and implemented at the agency level.
- Hours of Operation—May be restricted by Windows NT. When activated all applicable processes will automatically shut down at a specific time and not be permitted to resume until the predetermined time. The appropriate hours of operation are to be determined and implemented at the agency level.
- Inactivity Lockout—Access to the NT workstation is to be automatically locked after a specified period of inactivity.
- Warnings—Legal notices and security warnings are to be displayed on all servers and workstations.
- Remote Access Security—Windows NT Remote Access Service (RAS) security handles resource access control. Access to NT resources is to be controlled for remote users in the same manner as local users, by utilizing Windows NT file and sharing permissions. Dial-in access can be granted or restricted on a user-by-user basis through the Windows NT RAS administration tool.

C. Procedural Safeguards

All automated systems must comply with Federal laws, guidance, and policies for information systems security. These include, but are not limited to: the Privacy Act of 1974; the Computer Security Act of 1987; OMB

Circular A–130, revised; Information Resource Management (IRM) Circular #10; HHS Automated Information Systems Security Program; the CMS Information Systems Security Policy, Standards, and Guidelines Handbook; and other CMS systems security policies. Each automated information system should ensure a level of security commensurate with the level of sensitivity of the data, risk, and magnitude of the harm that may result from the loss, misuse, disclosure, or modification of the information contained in the system.

V. Effects of the New System on Individual Rights

CMS proposes to establish this system in accordance with the principles and requirements of the Privacy Act and will collect, use, and disseminate information only as prescribed therein. Data in this system will be subject to the authorized releases in accordance with the routine uses identified in this system of records.

CMS will monitor the collection and reporting of IRF–PAI data. IRF–PAI information on patients is completed by the IRF and submitted to CMS through standard systems. Accuracy of the data is important since incorrect information could result in the wrong payment for services and a less effective process for assuring quality of services. CMS will utilize a variety of onsite and offsite edits and audits to increase the accuracy of IRF–PAI data.

CMS will take precautionary measures (see item IV. above) to minimize the risks of unauthorized access to the records and the potential harm to individual privacy or other personal or property rights of patients whose data is maintained in the system. CMS will collect only that information necessary to perform the system's functions. In addition, CMS will make disclosure from the proposed system only with consent of the subject individual, or his/her legal representative, or in accordance with an applicable exception provision of the Privacy Act.

CMS, therefore, does not anticipate an unfavorable effect on individual privacy as a result of maintaining this system of records.

Dated: November 2, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

09–70–1518.

SYSTEM NAME:

Inpatient Rehabilitation Facilities Patient Assessment Instrument (IRF PAI), HHS/CMS/CMSO.

SECURITY CLASSIFICATION:

Level 3, Privacy Act Sensitive.

SYSTEM LOCATION:

CMS Data Center, 7500 Security Boulevard, North Building, First Floor, Baltimore, Maryland 21244–1850 and CMS contractors and agents at various locations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The system of records will contain clinical assessment information (IRF-PAI records) for all Medicare Part A fee-for-service patients receiving the services of a Medicare approved Inpatient Rehabilitation Facility (IRF). Information will be retained in the system of records only for those individuals whose payments come from Medicare.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system of records will contain individual-level demographic and identifying data, as well as clinical status data for patients with the payment source of traditional Medicare Part A fee-for-service and Medicare+Choice Enrollees.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 1886 (j) (2) (D) of the Social Security Act authorizes the Secretary to collect the data necessary to establish and administer the payments system

PURPOSE(S) OF THE SYSTEM:

The primary purpose of the IRF system of records is to support the IRF prospective payment system (PPS) for payment of the IRF Medicare Part A fee-for-services furnished by the IRF to Medicare beneficiaries. Other purposes for the system of records are to: (1) Help validate and refine the Medicare IRF-PPS; (2) study and help ensure the quality of care provided by IRFs; (3) enable CMS and its agents to provide IRFs with data for their own quality assurance and, (4) ultimately, quality improvement activities; (5) support agencies of the State government, deeming organizations or accrediting agencies to determine, evaluate and assess overall effectiveness and quality of IRF services provided in the State; (6) provide information to consumers to allow them to make better informed selections of providers; (7) support regulatory and policy functions performed within the IRF or by a contractor or consultant; (8) support constituent requests made to a Congressional representative; (9) support litigation involving the facility; and (10) support research on the utilization and quality of inpatient rehabilitation services; as well as, evaluation, or epidemiological projects related to the prevention of disease or disability, or the restoration or maintenance of health for understanding and improving payment systems.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OR USERS AND THE PURPOSES OF SUCH USES:

These routine uses specify circumstances, in addition to those provided by statute in the Privacy Act of 1974, under which CMS may release information from the IRF-PAI without the consent of the individual to whom such information pertains. Each proposed disclosure of information under these routine uses will be evaluated to ensure that the disclosure is legally permissible, including but not limited to ensuring that the purpose of the disclosure is compatible with the purpose for which the information was collected. In addition, our policy will be to prohibit release even of non-identifiable data, except pursuant to one of the routine uses, if there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that individuals who are familiar with the enrollees could, because of the small size, use this information to deduce the identity of the beneficiary). Be advised, this System of Records contains Protected Health Information as defined by the Department of Health and Human Services' regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR parts 160 and 164, 65 FR 8462 as amended by 66 FR 12434). Disclosures of Protected Health Information authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information.''

1. To agency contractors or consultants who have been contracted by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity.

2. To a Peer Review Organization (PRO) in order to assist the PRO to

perform Title XI and Title XVIII functions relating to assessing and improving IRF quality of care. PROs will work with IRFs to implement quality improvement programs, provide consultation to CMS, its contractors, and to State agencies.

3. To another Federal or State agency:

a. To contribute to the accuracy of CMS's proper payment of Medicare benefits,

b. To enable such agency to administer a Federal health benefits program, or as necessary to enable such agency to fulfill a requirement of a Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds, or

c. To improve the state survey process for investigation of complaints related to health and safety or quality of care and to implement a more outcome oriented survey and certification program.

4. To an individual or organization for research on the utilization of inpatient rehabilitation services as well as evaluation or epidemiological projects related to the prevention of disease or disability, or the restoration or maintenance of health epidemiological, or for understanding and improving payment projects.

5. To a member of Congress or to a congressional staff member in response to an inquiry of the Congressional Office made at the written request of the constituent about whom the record is maintained.

6. To the Department of Justice (DOJ), court or adjudicatory body when:

a. The agency or any component thereof; or

b. Any employee of the agency in his or her official capacity; or

c. Any employee of the agency in his or her individual capacity where the DOJ has agreed to represent the employee; or

d. The United States Government; is a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are both relevant and necessary to the litigation and the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

7. To a CMS contractor (including, but not necessarily limited to fiscal intermediaries and carriers) that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud or abuse in such program.

8. To another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any State or local governmental agency), that administers, or that has the authority to investigate potential fraud or abuse in, a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud or abuse in such programs.

9. To a national accrediting organization that has been approved for deeming authority for Medicare requirements for inpatient rehabilitation services (i.e., the Joint Commission for the Accreditation of Healthcare Organizations, the American Osteopathic Association and the Commission on Accreditation of Rehabilitation Facilities). Data will be released to these organizations only for those facilities that participate in Medicare by virtue of their accreditation status.

10. To insurance companies, third party administrators (TPA), employers, self-insurers, managed care organizations, other supplemental insurers, non-coordinating insurers, multiple employer trusts, group health plans (i.e., health maintenance organizations (HMO) or a competitive medical plan (CMP)) with a Medicare contract, or a Medicare-approved health care prepayment plan (HCPP), directly or through a contractor, and other groups providing protection for their enrollees. Information to be disclosed shall be limited to Medicare entitlement data. In order to receive the information, they must agree to:

a. Certify that the individual about whom the information is being provided is one of its insured or employees, or is insured and/or employed by another entity for whom they serve as a third party administrator;

b. Utilize the information solely for the purpose of processing the individual's insurance claims; and

c. Safeguard the confidentiality of the data and prevent unauthorized access

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

All records are stored on magnetic media.

RETRIEVABILITY:

The Medicare records are retrieved by health insurance claim (HIC) number, social security number.

SAFEGUARDS:

CMS has safeguards for authorized users and monitors such users to ensure against excessive or unauthorized use. Personnel having access to the system have been trained in the Privacy Act and systems security requirements. Employees who maintain records in the system are instructed not to release any data until the intended recipient agrees to implement appropriate administrative, technical, procedural, and physical safeguards sufficient to protect the confidentiality of the data and to prevent unauthorized access to the data.

In addition, CMS has physical safeguards in place to reduce the exposure of computer equipment and thus achieve an optimum level of protection and security for the CMS system. For computerized records, safeguards have been established in accordance with HHS standards and National Institute of Standards and Technology guidelines; e.g., security codes will be used, limiting access to authorized personnel. System securities are established in accordance with HHS, Information Resource Management (IRM) Circular #10, Automated Information Systems Security Program; CMS Information Systems Security, Standards Guidelines Handbook and OMB Circular No. A–130 (revised) Appendix III.

RETENTION AND DISPOSAL:

CMS will retain identifiable IRF–PAI data for a total period of 15 years.

SYSTEM MANAGER AND ADDRESSES:

Health Care Financing Administration, Center for Medicaid and State Operations, Director, Survey and Certification Group, 7500 Security Boulevard, S2–12–25, Baltimore, Maryland 2124–1850.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager who will require the system name, health insurance claim number, and for verification purposes, the subject individual's name (woman's maiden name, if applicable), address, age, and sex, and social security number (SSN) (furnishing the SSN is voluntary, but it may make searching for a record easier and prevent delay).

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification

Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5(a)(2).)

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7.)

RECORD SOURCE CATEGORIES:

Inpatient Rehabilitation Facilities—Patient Assessment Instrument.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 01–28219 Filed 11–8–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0335]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Food Labeling: Nutrition Labeling of Dietary Supplements on a ''Per Day'' Basis

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by December 10, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food Labeling: Nutrition Labeling of Dietary Supplements on a ''Per Day''' Basis

Section 403(q)(5)(F) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(F)) provides that dietary supplements must bear nutrition labeling in a manner that is appropriate for the product and that is specified in regulations issued by FDA. FDA issued regulations establishing the requirements for dietary supplements in nutrition labeling in 21 CFR 101.36 in the September 23, 1997, final rule (62 FR 49826). FDA published a proposed rule in the **Federal Register** of January 12, 1999 (64 FR 1765), to amend its nutrition labeling regulations for dietary supplements. This amendment would provide that the quantitative amount and the percentage of the daily value of a dietary ingredient may be voluntarily presented on a ''per day'' basis in addition to the required ''per serving'' basis. The proposed rule stated that this voluntary information may be provided if a dietary supplement label recommends that the dietary supplement be consumed more than once per day. These proposed provisions are in response to a citizen petition submitted by a manufacturer and marketer of dietary supplements. This proposed action would provide suppliers of dietary supplements flexibility to present additional label information voluntarily to consumers.

In the **Federal Register** of August 14, 2001 (66 FR 42663), the agency requested comments on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Operating & Maintenance Costs	Total Hours
101.36(d)	85	10	850	0.25	$83,000	213

[1] There are no capital costs associated with this collection of information.

These estimates are based on agency communications with industry and FDA's knowledge of, and experience with, food labeling. FDA estimated in the September 23, 1997, final rule (62 FR 49826 at 49846) that there was a maximum of 850 suppliers of dietary supplements and that, on average, each supplier had 40 products whose labels required revision. FDA estimates that only 10 percent, or 85 of the dietary supplement suppliers, would revise the labels of their products to incorporate nutrition levels for the daily use of their products. FDA also estimates that daily use levels for nutrition information would generally be placed on at most 25 percent, or at most 10 of a firm's estimated 40 products, although this number would vary by firm based on the types of products that it produces. FDA also believes that the burden associated with the proposed disclosure of nutrition information on a daily use basis for dietary supplements would be a one-time burden for the small number of firms that would decide voluntarily to add this additional information to the labels for their products. FDA estimates that at least 90 percent of firms would coordinate the addition of daily use nutrition information with other changes in their labels, in which case the voluntary cost of transmitting the information to consumers in labeling would be subsumed almost entirely in the cost of these other voluntary or required labeling changes. The incremental cost for these 76 firms would be approximately $50 per label for 760 labels, or $38,000 total. For the remaining 9 firms that would not coordinate changes with other labeling changes, FDA estimates that the cost would be approximately $500 per label (64 FR 1765 at 1769) for 90 labels, or $45,000 total. The estimated total operating costs in table 1 of this

21.3 Survey & Certification Memoranda

There are no Survey & Certification letters specific to IRFs as of the date of this reference manual.

21.4 Social Security Act, Section 1886(j): Inpatient Rehabilitation Facilities

Social Security Act, Section 1886(j): Inpatient Rehabilitation Facilities

(j) PROSPECTIVE PAYMENT FOR INPATIENT REHABILITATION SERVICES.—

(1) PAYMENT DURING TRANSITION PERIOD.—

(A) IN GENERAL.—Notwithstanding section 1814(b), but subject to the provisions of section 1813, the amount of the payment with respect to the operating and capital costs of inpatient hospital services of a rehabilitation hospital or a rehabilitation unit (in this subsection referred to as a "rehabilitation facility"), other than a facility making an election under subparagraph (F) in a cost reporting period beginning on or after October 1, 2000, and before October 1, 2002, is equal to the sum of—

(i) the TEFRA percentage (as defined in subparagraph (C)) of the amount that would have been paid under part A with respect to such costs if this subsection did not apply, and

(ii) prospective payment percentage (as defined in subparagraph (C)) of the product of (I) the per unit payment rate established under this subsection for the fiscal year in which the payment unit of service occurs, and (II) the number of such payment units occurring in the cost reporting period.

(B) FULLY IMPLEMENTED SYSTEM.—Notwithstanding section 1814(b), but subject to the provisions of section 1813, the amount of the payment with respect to the operating and capital costs of inpatient hospital services of a rehabilitation facility for a payment unit in a cost reporting period beginning on or after October 1, 2002, or, in the case of a facility making an election under subparagraph (F), for any cost reporting period described in such subparagraph, is equal to the per unit payment rate established under this subsection for the fiscal year in which the payment unit of service occurs.

(C) TEFRA AND PROSPECTIVE PAYMENT PERCENTAGES SPECIFIED.—For purposes of subparagraph (A), for a cost reporting period beginning—

(i) on or after October 1, 2000, and before October 1, 2001, the "TEFRA percentage" is 66 2/3 percent and the "prospective payment percentage" is 33 1/3 percent; and

(ii) on or after October 1, 2001, and before October 1, 2002, the "TEFRA percentage" is 33 1/3 percent and the "prospective payment percentage" is 66 2/3 percent.

(D) PAYMENT UNIT.—For purposes of this subsection, the term "payment unit" means a discharge.

(E) CONSTRUCTION RELATING TO TRANSFER AUTHORITY.—Nothing in this subsection shall be construed as preventing the Secretary from providing for an adjustment to payments to take into account the early transfer of a patient from a rehabilitation facility to another site of care.

(F) ELECTION TO APPLY FULL PROSPECTIVE PAYMENT SYSTEM.—A rehabilitation facility may elect, not later than 30 days before its first cost

reporting period for which the payment methodology under this subsection applies to the facility, to have payment made to the facility under this subsection under the provisions of subparagraph (B) (rather than subparagraph (A)) for each cost reporting period to which such payment methodology applies.

(2) PATIENT CASE MIX GROUPS.—

(A) ESTABLISHMENT.—The Secretary shall establish—

(i) classes of patient discharges of rehabilitation facilities by functional-related groups (each in this subsection referred to as a "case mix group"), based on impairment, age, comorbidities, and functional capability of the patient and such other factors as the Secretary deems appropriate to improve the explanatory power of functional independence measure-function related groups; and

(ii) a method of classifying specific patients in rehabilitation facilities within these groups.

(B) WEIGHTING FACTORS.—For each case mix group the Secretary shall assign an appropriate weighting which reflects the relative facility resources used with respect to patients classified within that group compared to patients classified within other groups.

(C) ADJUSTMENTS FOR CASE MIX.—

(i) IN GENERAL.—The Secretary shall from time to time adjust the classifications and weighting factors established under this paragraph as appropriate to reflect changes in treatment patterns, technology, case mix, number of payment units for which payment is made under this title, and other factors which may affect the relative use of resources. Such adjustments shall be made in a manner so that changes in aggregate payments under the classification system are a result of real changes and are not a result of changes in coding that are unrelated to real changes in case mix.

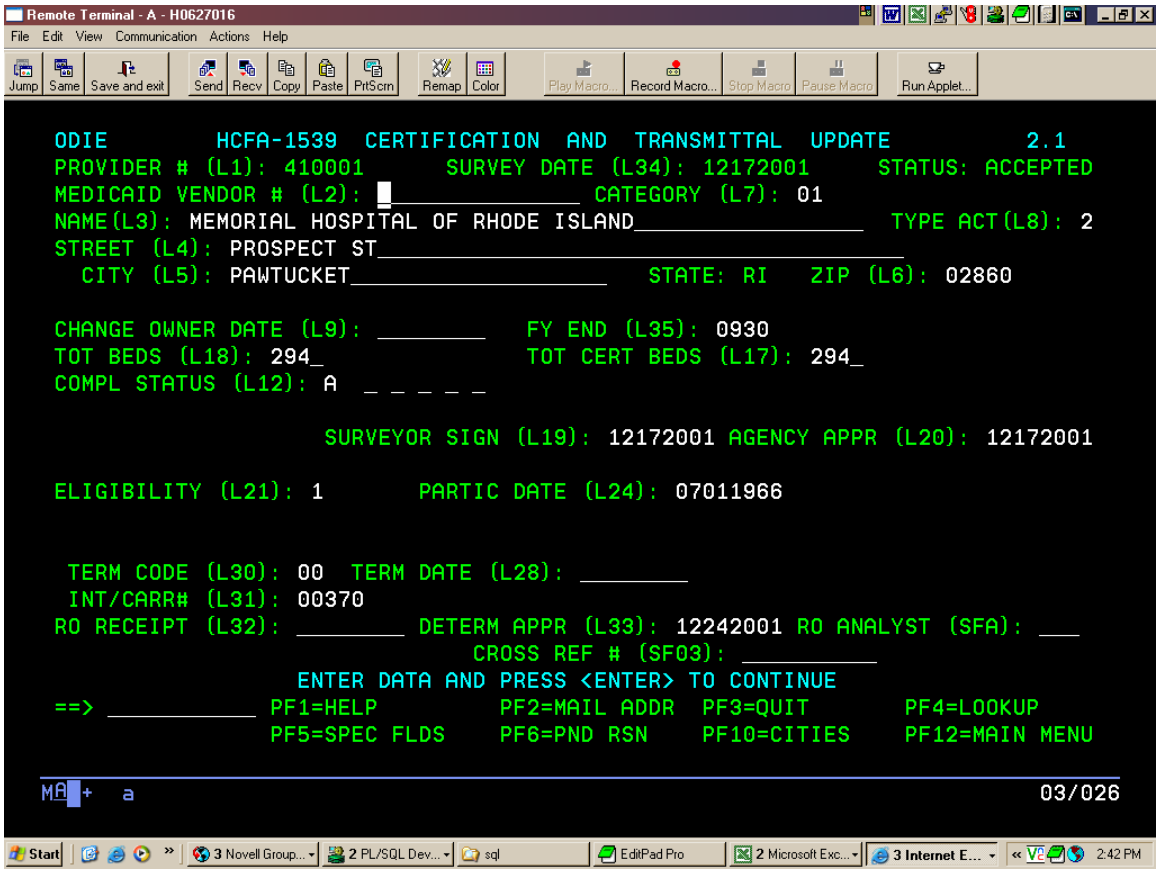
(ii) ADJUSTMENT.—Insofar as the Secretary determines that such adjustments for a previous fiscal year (or estimates that such adjustments for a future fiscal year) did (or are likely to) result in a change in aggregate payments under the classification system during the fiscal year that are a result of changes in the coding or classification of patients that do not reflect real changes in case mix, the Secretary shall adjust the per payment unit payment rate for subsequent years so as to eliminate the effect of such coding or classification changes.

(D) DATA COLLECTION.—The Secretary is authorized to require rehabilitation facilities that provide inpatient hospital services to submit such data as the Secretary deems necessary to establish and administer the prospective payment system under this subsection.

21.5 Setting the ODIE System Switch to Receive Data for IRFs

Setting The ODIE System Switch to Receive Data for Inpatient Rehabilitation

The regional office must set a switch in the Online Data Input and Edit (ODIE) system, which is a subsystem of the Online Survey Certification and Reporting (OSCAR) system, a database and retrieval program, in order to receive data about inpatient rehabilitation.



On the first page of the Update option for the current survey in ODIE, press PF5.

```
ODIE              S P E C I A L   F I E L D S   U P D A T E            2.1A

PROVIDER # (L1): 410001                    STATUS: ACCEPTED
PRIOR INTER # (SF01):                      FLAG INDICATOR (SF08): 2
BEDS OVERRIDE (SF11): _   STAFF OVERRIDE (SF12): _   NURSE OVERRIDE (SF13): _

SAMPLE REVIEW (SF26): _
RO DATE: _________     RO TEXT: ______________________________
SA DATE: _________     SA TEXT: ______________________________
                  UNIT IND  BED SIZE   EFF DATE        TERM CD  TERM DATE
PSYCHIATRIC       SF45: _   SF46: ___  SF49: ________  SF51: _  SF52: ________
REHABILITATION    SF47: Y   SF48: 16_  SF50: 10011984  SF53: 0  SF54: ________
ALCOHOL/DRUG      SF56:     SF57:      SF58:            SF59:    SF60:
DATE VALIDATION SURVEY (SF32): 01182000
      CHANGE OWNER COUNT:   0                        RESURVEY COUNT: 19
  MASTER SURVEY ADD DATE: 12242001          PENDING SURVEY ADD DATE: 12242001
        LAST UPDATE DATE: 04082003     DATE APPROVAL ENTERED (SF24): 12242001
   CURRENT SURVEY ADD LOCATION: SA      INITIAL SURVEY ADD LOCATION: MMAC
    670 TOTALS BY SURVEY (1-4):            304.75

                ENTER DATA AND PRESS <ENTER> TO CONTINUE
==> ___________ PF1=HELP      PF2=ASPEN STATS   PF3=QUIT         PF4=LOOKUP
                PF6=PND RSN   PF11=PROV SCRN    PF12=MAIN MENU

MA  +   a                                                          07/024
```

Enter a Y in the SF47 field.

21.6 *Inpatient Rehabilitation Facility – Patient Assessment Instrument*

INPATIENT REHABILITATION FACILITY - PATIENT ASSESSMENT INSTRUMENT

Identification Information*

1. Facility Information
   A. Facility Name
   _____
   _____
   _____
   B. Facility Medicare Provider Number _____

2. Patient Medicare Number _____

3. Patient Medicaid Number _____

4. Patient First Name _____

5A. Patient Last Name _____

5B. Patient Identification Number _____

6. Birth Date _____/_____/_____ (MM / DD / YYYY)

7. Social Security Number _____

8. Gender (*1 - Male; 2 - Female*) _____

9. Race/Ethnicity *(Check all that apply)*
   - *American Indian or Alaska Native* A. _____
   - *Asian* B. _____
   - *Black or African American* C. _____
   - *Hispanic or Latino* D. _____
   - *Native Hawaiian or Other Pacific Islander* E. _____
   - *White* F. _____

10. Marital Status _____
    (*1 - Never Married; 2 - Married; 3 - Widowed; 4 - Separated; 5 - Divorced*)

11. Zip Code of Patient's Pre-Hospital Residence _____

Admission Information*

12. Admission Date _____/_____/_____ (MM / DD / YYYY)

13. Assessment Reference Date _____/_____/_____ (MM / DD / YYYY)

14. Admission Class _____
    (*1 - Initial Rehab; 2 - Evaluation; 3 - Readmission; 4 - Unplanned Discharge; 5 - Continuing Rehabilitation)*

15. Admit From _____
    (*01 - Home; 02 - Board & Care; 03 - Transitional Living; 04 - Intermediate Care; 05 - Skilled Nursing Facility; 06 - Acute Unit of Own Facility; 07 - Acute Unit of Another Facility; 08 - Chronic Hospital; 09 - Rehabilitation Facility; 10 - Other; 12 - Alternate Level of Care Unit; 13 – Subacute Setting; 14 - Assisted Living Residence*)

16. Pre-Hospital Living Setting _____
    (*Use codes from item 15 above*)

17. Pre-Hospital Living With _____
    (*Code only if item 16 is 01 - Home; Code using 1 - Alone; 2 - Family/Relatives; 3 - Friends; 4 - Attendant; 5 - Other*)

18. Pre-Hospital Vocational Category _____
    (*1 - Employed; 2 - Sheltered; 3 - Student; 4 - Homemaker; 5 - Not Working; 6 - Retired for Age; 7 - Retired for Disability*)

19. Pre-Hospital Vocational Effort _____
    (*Code only if item 18 is coded 1 - 4; Code using 1 - Full-time; 2 - Part-time; 3 - Adjusted Workload*)

Payer Information*

20. Payment Source
    A. Primary Source _____
    B. Secondary Source _____

    (*01 - Blue Cross; 02 - Medicare non-MCO; 03 - Medicaid non-MCO; 04 - Commercial Insurance; 05 - MCO HMO; 06 - Workers' Compensation; 07 - Crippled Children's Services; 08 – Developmental Disabilities Services; 09 - State Vocational Rehabilitation; 10 - Private Pay; 11 - Employee Courtesy; 12 - Unreimbursed; 13 - CHAMPUS; 14 - Other; 15 - None; 16 – No-Fault Auto Insurance; 51 – Medicare MCO; 52 - Medicaid MCO)*

Medical Information*

21. Impairment Group _____ Admission _____ Discharge
    Condition requiring admission to rehabilitation; code according to Appendix A, attached.

22. Etiologic Diagnosis _____
    (*Use an ICD-9-CM code to indicate the etiologic problem that led to the condition for which the patient is receiving rehabilitation*)

23. Date of Onset of Impairment _____/_____/_____ (MM / DD / YYYY)

24. Comorbid Conditions; Use ICD-9-CM codes to enter up to ten medical conditions

    A. _____ B. _____
    C. _____ D. _____
    E. _____ F. _____
    G. _____ H. _____
    I. _____ J. _____

Medical Needs

25. Is patient comatose at admission? _____ (0 - No, 1 - Yes)

26. Is patient delirious at admission? _____ (0 - No, 1 - Yes)

27. Swallowing Status _____ Admission _____ Discharge

    3 - Regular Food: solids and liquids swallowed safely without supervision or modified food consistency
    2 - Modified Food Consistency/ Supervision: subject requires modified food consistency and/or needs supervision for safety
    1 - Tube /Parenteral Feeding: tube / parenteral feeding used wholly or partially as a means of sustenance

28. Clinical signs of dehydration _____ Admission _____ Discharge

    (Code 0 – No; 1 – Yes) e.g., e*vidence of oliguria, dry skin, orthostatic hypotension, somnolence, agitation*

*The FIM data set, measurement scale and impairment codes incorporated or referenced herein are the property of U B Foundation Activities, Inc. ©1993, 2001 U B Foundation Activities, Inc. The FIM mark is owned by UBFA, Inc.

OMB-0938-0842 (expires: 07-31-2005)

INPATIENT REHABILITATION FACILITY - PATIENT ASSESSMENT INSTRUMENT

Function Modifiers*

Complete the following specific functional items prior to scoring the FIM™ Instrument:

	ADMISSION	DISCHARGE
29. Bladder Level of Assistance (Score using FIM Levels 1 - 7)		
30. Bladder Frequency of Accidents (Score as below)		

7 - No accidents
6 - No accidents; uses device such as a catheter
5 - One accident in the past 7 days
4 - Two accidents in the past 7 days
3 - Three accidents in the past 7 days
2 - Four accidents in the past 7 days
1 - Five or more accidents in the past 7 days

Enter in Item 39G (Bladder) the lower (more dependent) score from Items 29 and 30 above.

	ADMISSION	DISCHARGE
31. Bowel Level of Assistance (Score using FIM Levels 1 - 7)		
32. Bowel Frequency of Accidents (Score as below)		

7 - No accidents
6 - No accidents; uses device such as an ostomy
5 - One accident in the past 7 days
4 - Two accidents in the past 7 days
3 - Three accidents in the past 7 days
2 - Four accidents in the past 7 days
1 - Five or more accidents in the past 7 days

Enter in Item 39H (Bowel) the lower (more dependent) score of Items 31 and 32 above.

	ADMISSION	DISCHARGE
33. Tub Transfer		
34. Shower Transfer		

(Score Items 33 and 34 using FIM Levels 1 - 7; use 0 if activity does not occur) *See training manual for scoring of Item 39K (Tub/Shower Transfer)*

	ADMISSION	DISCHARGE
35. Distance Walked		
36. Distance Traveled in Wheelchair		

(Code items 35 and 36 using: 3 - 150 feet; 2 - 50 to 149 feet; 1 - Less than 50 feet; 0 – activity does not occur)

	ADMISSION	DISCHARGE
37. Walk		
38. Wheelchair		

(*Score Items 37 and 38 using FIM Levels 1 - 7; 0 if activity does not occur) See training manual for scoring of Item 39L (Walk/ Wheelchair)*

*The FIM data set, measurement scale and impairment codes incorporated or referenced herein are the property of U B Foundation Activities, Inc. ©1993, 2001 U B Foundation Activities, Inc. The FIM mark is owned by UBFA, Inc.

39. FIM™ Instrument*

	ADMISSION	DISCHARGE	GOAL
SELF-CARE			
A. Eating			
B. Grooming			
C. Bathing			
D. Dressing - Upper			
E. Dressing - Lower			
F. Toileting			
SPHINCTER CONTROL			
G. Bladder			
H. Bowel			
TRANSFERS			
I. Bed, Chair, Whlchair			
J. Toilet			
K. Tub, Shower			
LOCOMOTION (W - Walk; C - wheelChair; B - Both)			
L. Walk/Wheelchair			
M. Stairs			
COMMUNICATION (A - Auditory; V - Visual; B - Both)			
N. Comprehension			
O. Expression (V - Vocal; N - Nonvocal; B - Both)			
SOCIAL COGNITION			
P. Social Interaction			
Q. Problem Solving			
R. Memory			

FIM LEVELS

No Helper

7 Complete Independence (Timely, Safely)

6 Modified Independence (Device)

Helper - Modified Dependence

5 Supervision (Subject = 100%)

4 Minimal Assistance (Subject = 75% or more)

3 Moderate Assistance (Subject = 50% or more)

Helper - Complete Dependence

2 Maximal Assistance (Subject = 25% or more)

1 Total Assistance (Subject less than 25%)

0 Activity does not occur; Use this code only at admission

OMB-0938-0842 (expires: 07-31-2005)

Discharge Information*

40. Discharge Date _____/_____/_____
MM / DD / YYYY

41. Patient discharged against medical advice? _____
(*0 - No, 1 - Yes*)

42. Program Interruption(s) _____
(*0 - No; 1 - Yes*)

43. Program Interruption Dates
(Code only if Item 42 is 1 - Yes)

A. 1st Interruption Date _____ MM / DD / YYYY

B. 1st Return Date _____ MM / DD / YYYY

C. 2nd Interruption Date _____ MM / DD / YYYY

D. 2nd Return Date _____ MM / DD / YYYY

E. 3rd Interruption Date _____ MM / DD / YYYY

F. 3rd Return Date _____ MM / DD / YYYY

44A. Discharge to Living Setting _____
(*01 - Home; 02 - Board and Care; 03 - Transitional Living; 04 - Intermediate Care; 05 - Skilled Nursing Facility; 06 - Acute Unit of Own Facility; 07 - Acute Unit of Another Facility; 08 - Chronic Hospital; 09 - Rehabilitation Facility; 10 - Other; 11 - Died; 12 - Alternate Level of Care Unit; 13 - Subacute Setting; 14 - Assisted Living Residence)*

44B. Was patient discharged with Home Health Services? _____
(*0 - No; 1 - Yes*)
(Code only if Item 44A is 01 - Home, 02 - Board and Care, 03 - Transitional Living, or 14 - Assisted Living Residence)

45. Discharge to Living With _____
(*Code only if Item 44A is 01 - Home; Code using 1 - Alone; 2 - Family / Relatives; 3 - Friends; 4 - Attendant; 5 - Other*

46. Diagnosis for Interruption or Death _____
(Code using ICD-9-CM code)

47. Complications during rehabilitation stay
(*Use ICD-9-CM codes to specify up to six conditions that began with this rehabilitation stay*)

A. _____ B. _____

C. _____ D. _____

E. _____ F. _____

Quality Indicators

RESPIRATORY STATUS
(*Score items 48 to 50 as 0 - No; 1 - Yes*)

	Admission	Discharge
48. Shortness of breath with exertion	_____	_____
49. Shortness of breath at rest	_____	_____
50. Weak cough and difficulty clearing airway secretions	_____	_____

Quality Indicators

PAIN
51. Rate the highest level of pain reported by the patient within the assessment period:
Admission: _____ Discharge: _____

(*Score using the scale below; report whole numbers only)*

0 1 2 3 4 5 6 7 8 9 10
No Pain — Moderate Pain — Worst Possible Pain

Pressure Ulcers

52A. Highest current pressure ulcer stage
Admission _____ Discharge _____

(*0 - No pressure ulcer; 1 - Any area of persistent skin redness (Stage 1); 2 - Partial loss of skin layers (Stage 2); 3 - Deep craters in the skin (Stage 3); 4 - Breaks in skin exposing muscle or bone (Stage 4); 5 - Not stageable (necrotic eschar predominant; no prior staging available*)

52B. Number of current pressure ulcers
Admission _____ Discharge _____

PUSH Tool v. 3.0 ã

SELECT THE CURRENT LARGEST PRESSURE ULCER TO CODE THE FOLLOWING. Calculate three components (C through E) and code total score in F.

52C. Length multiplied by width (open wound surface area)
Admission _____ Discharge _____

(*Score as 0 - 0 cm^2; 1 - < 0.3 cm^2; 2 - 0.3 to 0.6 cm^2; 3 - 0.7 to 1.0 cm^2; 4 - 1.1 to 2.0 cm^2; 5 - 2.1 to 3.0 cm^2; 6 - 3.1 to 4.0 cm^2; 7 - 4.1 to 8.0 cm^2; 8 - 8.1 to 12.0 cm^2; 9 - 12.1 to 24.0 cm^2; 10 - > 24 cm^2)*

52D. Exudate amount
Admission _____ Discharge _____
0 - None; 1 - Light; 2 - Moderate; 3 - Heavy

52E. Tissue type
Admission _____ Discharge _____
0 - Closed/resurfaced: The wound is completely covered with epithelium (new skin); 1 - Epithelial tissue: For superficial ulcers, new pink or shiny tissue (skin) that grows in from the edges or as islands on the ulcer surface. 2 - Granulation tissue: Pink or beefy red tissue with a shiny, moist, granular appearance. 3- Slough: Yellow or white tissue that adheres to the ulcer bed in strings or thick clumps or is mucinous. 4 - Necrotic tissue (eschar): Black, brown, or tan tissue that adheres firmly to the wound bed or ulcer edges.

52F. TOTAL PUSH SCORE (Sum of above three items – C, D and E)
Admission _____ Discharge _____

SAFETY	Admission	Discharge
53. Balance problem (*0 - No; 1 - Yes*) *e.g., dizziness, vertigo, or light-headedness*	_____	_____
		Discharge
54. Total number of falls during the rehabilitation stay		_____

* The FIM data set, measurement scale and impairment codes incorporated or referenced herein are the property of U B Foundation Activities, Inc. ©1993, 2001 U B Foundation Activities, Inc. The FIM mark is owned by UBFA, Inc.

21.7 Chronic Care Policy Group Memoranda

June 21, 2005: Enforcement of the Inpatient Rehabilitation Facility (IRF) Classification Criteria – ACTION

August 4, 2005: Collection of Data Associated with the Classification of an Inpatient Rehabilitation Facility (IRF) – ACTION

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-15
Baltimore, Maryland 21244-1850

JSM-05382, 06-15-05

MEMORANDUM

DATE: June 21, 2005

FROM: Director, Chronic Care Policy Group
Center for Medicare Management

Director, Medicare Contractor Management Group
Center for Medicare Management

SUBJECT: Enforcement of the Inpatient Rehabilitation Facility (IRF) Classification Criteria -- ACTION

TO: All Regional Administrators
All Fiscal Intermediaries (FI)

On May 7, 2004, the Centers for Medicare & Medicaid Services (CMS) published a final rule (69 FR 25752) revising the IRF regulatory requirements specified in §412.23(b)(2) that are commonly referred to as the "75 percent rule". The revised regulatory requirements were effective for IRF cost reporting periods starting on or after July 1, 2004. On January 25, 2005, the Center for Medicare Management (CMM) issued a joint signature memorandum to the Regional Offices (ROs) and FIs suspending enforcement of the regulatory requirements specified under §412.23(b)(2). The CMM is now directing that effective immediately enforcement of the regulatory requirements specified under §412.23(b)(2) is to resume.

Background

In order to receive payment under the IRF prospective payment system (PPS), a hospital or unit of a hospital must first be excluded from the acute care hospital PPS in accordance with the requirements specified in subpart B of Part 412 of the regulations, which includes §412.23(b)(2). In addition, under subpart P of Part 412 of the regulations the requirements at §412.23(b)(2) must be met to in order for an IRF to be paid under the IRF PPS. Section 412.23(b)(2) specifies the compliance percentage threshold that a facility must meet in order to be classified as an IRF. The FI is responsible for determining the compliance percentage threshold a facility met and reporting that result to the RO. A facility that failed to meet any of the requirements to be classified as an IRF may be reclassified as an acute care hospital and paid under the inpatient PPS, or, if applicable, may be classified as a portion of a critical access hospital.

The January 25, 2005, joint signature memorandum stated that in accordance with the Consolidated Appropriations Act, 2005 (Pub. Law 108-447 enacted on December 8, 2004), CMS could not use the revised §412.23(b)(2) requirements to change the classification of facilities that were classified as IRFs as of June 30, 2004, until CMS either: (1) Determined that our regulations at §412.23(b)(2) were not inconsistent with the recommendations of a soon-to-be-released Government Accountability

Office (GAO) IRF report; or (2) In accordance with the recommendations of the soon-to-be-released GAO IRF report issued an interim final rule revising the criteria at §412.23(b)(2) used to classify a facility as an IRF. The GAO issued the final IRF report in late April 2005. In addition, to comply with the Consolidated Appropriations Act, 2005 the joint signature memorandum instructed FIs to perform the compliance review on all IRFs in accordance with Change Requests (CRs) 3334, 3503, and any subsequent CRs regarding compliance with §412.23(b)(2). However, CMM instructed the ROs to not make any changes to the status of a hospital or a unit of a hospital that was classified as an IRF on or before June 30, 2004, and failed to meet the requirements specified in §412.23(b)(2).

CMS' Action

On June 21, 2005, we issued a Federal Register notice stating that the Secretary has determined that the recommendations in the GAO's IRF report are not inconsistent with our regulations as revised in the May 7, 2004, final rule. Therefore, effective immediately ROs and FIs are to take appropriate enforcement action if a facility does not meet any of the criteria used to classify a facility as an IRF, including the regulatory requirements specified under revised §412.23(b)(2). A facility will not be classified as an IRF at the start of its next cost reporting period if it does not meet the regulatory requirements specified under §412.23(b)(2) or any of the other requirements a facility must meet to be classified as an IRF.

If you have any questions, please contact Pete Diaz at (410) 786-1235.

/s/	/s/
Laurence Wilson	Karen Jackson

cc:
All Consortium Contractor Management Officers (CCMOs)
Jeff Hinson, CMM/MCMG

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-15
Baltimore, Maryland 21244-1850

JSM-05452, 08-03-05

MEMORANDUM

DATE: August 4, 2005

FROM: Director, Chronic Care Policy Group
Center for Medicare Management

Director, Medicare Contractor Management Group
Center for Medicare Management

SUBJECT: Collection of Data Associated with the Classification of an Inpatient Rehabilitation Facility (IRF) -- ACTION

TO: All Regional Administrators
All Fiscal Intermediaries (FI)

Background

On May 7, 2004, the Centers for Medicare & Medicaid Services (CMS) published a final rule (69 FR 25752) revising the IRF regulatory requirement specified in §412.23(b)(2) that is commonly referred to as the "75 percent rule". On June 21, 2005, the Center for Medicare Management (CMM) issued a joint signature memorandum to the Regional Offices (ROs) and FIs stating that effective immediately ROs and FIs are to take appropriate enforcement action if a facility does not meet any of the criteria used to classify a facility as an IRF, including the regulatory requirements specified under revised §412.23(b)(2). A facility will not be classified as an IRF at the start of its next cost reporting period if it does not meet the regulatory requirements specified under §412.23(b)(2) or any of the other requirements a facility must meet to be classified as an IRF. Please refer to the regulatory requirements in 42 Code of Federal Regulations Part 412 and the instructions in program transmittals for more information regarding IRF classification requirements.

This memorandum is a request for monitoring data related to the 75 percent rule classification determinations. The specific requested data and timeframes are listed below.

Data Requested

As stipulated in previous program transmittals, the cost reporting period of an IRF, or a provider that wants to be classified as an IRF, has an associated compliance review period. The data from the compliance review period is used to determine the compliance percentage. By using data from the appropriate compliance review period, as well as other data, CMM must ascertain how many providers *will or will not* maintain their IRF classification status due to an IRF compliance determination applicable to cost reporting periods starting on or after July 1, 2005. Therefore, by August 19, 2005, and, then, thereafter monthly by the 15th day of the month, the FI responsible

for determining whether a provider with a cost reporting period that started, or will start, on or after July 1, 2005, met the compliance requirements necessary to be classified as an IRF, will e-mail the following data to Robert Kuhl (Robert.Kuhl@cms.hhs.gov), Pedro Diaz (Pedro.Diaz@cms.hhs.gov), and to the RO liaison:

(PROVIDE ITEMS 1-4 FOR ALL IRFs UNDER FI's JURISTICTION)

1. Provider's name.
2. Provider's address.
3. Provider's Medicare provider number.
4. The exact month and day of the month when the provider's cost reporting period starts.

(PROVIDE ITEMS 5-9 FOR IRFs WITH COMPLETED COMPLIANCE REVIEWS)

5. The compliance review period "from and to" dates.
6. The percentage of Medicare inpatients that was part of the total inpatient population during the compliance review period.
7. The compliance percentage that the provider achieved under the presumptive method during the compliance review period.
8. If applicable, the compliance percentage a provider achieved when reading a sample of medical records -- for a particular provider this data request is only required if the compliance percentage was determined by the FI reading a sample of medical records instead of using the presumptive method.
9. If applicable, identification of any of the non-75 percent rule requirements that the provider failed to meet. For example, §412.25(a) references non-75 percent rule requirements than must be met by a hospital unit in order for it to be excluded from being paid under the inpatient prospective payment system.

We will be sending out a formal change request soon regarding the monthly reporting requirement.

The table below provides a format for reporting the data.

(NAME OF FI FURNISHING THE DATA)
IRF DATA AS OF: (supply date)

Provider's Name	Provider's Address	Medicare Provider Number	Exact Date that Provider's Cost Reporting Period Starts	Compliance Review Period "From and To" Dates	Percentage of Medicare Inpatients that was Part of the Total Inpatient Population	Compliance Percentage Achieved Under the Presumptive Method	If Applicable, Compliance Percentage Achieved by Provider When FI Read Sample of Medical Records	If Applicable, Which Non-75 Percent Rule Requirement Provider Did Not Meet

Please report the data for providers that both met and did not meet the 75 percent rule criteria. In addition, report any additional data relating to classifying a provider as an IRF.

If you have any questions, please contact Pete Diaz at (410) 786-1235.

/s/	/s/
Laurence Wilson	Karen Jackson

cc:
All Consortium Contractor Management Officers (CCMOs)
Jeff Hinson, CMM/MCMG

21.8 Other Print and Online References

75 percent rule: Changes to the Criteria for Being Classified as an IRF; Final Rule (69 FR 25752):
http://new.cms.hhs.gov/InpatientRehabFacPPS/LIRFF/list.asp#TopOfPage

75 percent rule: Changes to the Criteria for Being Classified as an IRF; Notice (70 FR 36640):
http://new.cms.hhs.gov/InpatientRehabFacPPS/LIRFF/list.asp#TopOfPage

Clarification of the Verification Process to be Used to Determine if the Inpatient Rehabilitation Facility (IRF) Meets The IRF Classification Criteria:
http://new.cms.hhs.gov/MedlearnMattersArticles/2005MMA/List.asp#TopOfPage
Note: This is in the Medlearn 2005 list.This list has 676 items. To go to the article, enter "r347cp" in the "Show only articles containing keywords" box.

CMS forms:
http://www.cms.hhs.gov/forms/

Code of Federal Regulations search page:
http://www.gpoaccess.gov/cfr/index.html

Federal Register search page:
http://www.gpoaccess.gov/fr/index.html

Inpatient Rehabilitation Facility Prospective Payment System page:
http://new.cms.hhs.gov/InpatientRehabFacPPS/

IRF Classification Requirements (Medlearn 2004):
http://new.cms.hhs.gov/MedlearnMattersArticles/2004MMA/List.asp#TopOfPage
Note: This is in the Medlearn 2004 list.This list has 646 items. To go to the article, enter "r347cp" in the "Show only articles containing keywords" box.

Overview of PPS for Inpatient Rehabilitation Facilities:
http://www.cms.hhs.gov/InpatientRehabFacPPS/01_overview.asp

Social Security Act index page:
http://www.ssa.gov/OP_Home/ssact/comp-ssa.htm

State Operations Manual Appendix index:
http://new.cms.hhs.gov/manuals/downloads/som107c09_appendixtoc.pdf

Survey & Certification letters:
http://www.cms.hhs.gov/SurveyCertificationGenInfo/01_Overview.asp#TopOfPage

Rehabilitation Reference Manual

Tab 22: IRF Survey Documentation

22.1 Examples

22.2 Survey Tool: IRFs

22.1 Examples

Sample Deficiencies for IRFs

At present, we have no sample Statements of Deficiency. Please forward any samples you have for inclusion in the manual.

22.2 Survey Tool: IRFs

Inpatient Rehabilitation Facility A Tags and A-Tag Identifiers

Tag	*Identifier*
A0001	Provision of emergency services
A0002	***Compliance w/Fed., State & Local Laws***
A0003	Compliance w/ fed. health & safety laws
A0004	Hospital licensed/approv. by licensing agency
A0005	Hospital personnel licens./meet State, local laws
A0006	***Governing Body***
A0007	Standard: Medical Staff
A0008	Eligibility of practitioners for medical staff
A0009	Appoint members w/med. staff recommendations
A0010	Assure that medical staff has bylaws
A0011	Approve med. staff bylaws, rules & regulations
A0012	Med. staff accountable to gov. body for patient QoC
A0013	Selec. criteria: char., competence, train., exp., judg.
A0014	Prvlg. not solely for cert., fellowship/society member
A0015	Standard: Chief Executive Officer
A0016	Standard: Care of Patients
A0017	Medicare pt.med./osteo, dent., pod., opt., chiro., psyc.
A0018	Pts. admitted by State approved licensed practitioner
A0019	Pt. admitted by med./osteo. if not by licensed pract.
A0020	Dr. of medicine or osteo. on duty/on call at all times
A0021	Med/osteo responsible pt. prob. before/during stay
A0022	Standard: Institutional Plan & Budget
A0023	Plan submitted to designated agency for review
A0024	Capital expenditure not subject to 1122 review
A0025	Plan must be reviewed & updated annually
A0026	Gov. body & committee prepare plan
A0027	Standard: Contracted Services
A0028	Contracted services performed safely & effectively
A0029	List/scope/nature of services maintained by hospital
A0030	Standard: Emergency Services
A0031	Compliance w/§482.55 emergency services provided
A0032	Med. staff has policies if no emergency services
A0033	Med. staff policies off-campus w/out emergency srvs.
A0038	***Patients' Rights***
A0039	Standard: Notice of Rights
A0040	Pt. informed of rights before care/discontinuing care
A0041	Prompt resol. pt. griev./pt. informed w/whom to file
A0042	Gov. body responsible for effective grievance process
A0043	Griev. proc. timely referral QoC/premature discharge
A0044	Clearly explained procedure for writ/verbal grievance
A0045	Griev. process specify review/response timeframe
A0046	Grievance resolution in writing w/contact info. to pt.
A0047	Standard: Excersis of Rights
A0048	Right of pt. participate in development of plan of care
A0049	Pt. has right to make informed decisions for care
A0050	Pt. rights include being informed of health status
A0051	Pt. involved in care planning/treatment
A0052	Pt. able to request/refuse treatment med. appropriate
A0053	Pt. right to form advanced directives w/ compliance
A0054	Pt. right to family/doctor notified hospital admission
A0055	Standard: Privacy & Safety
A0056	Pt. right to personal privacy
A0057	Pt. right to care in safe setting
A0058	Pt. right to be free of abuse/harassment
A0059	Standard: Confidentiality of Patient Records
A0060	Pt. right to confidentiality of clinical records

Tag	*Identifier*
A0061	Pt. right to information in clinical records
A0062	Standard: Restraint Acute Medical & Surgical Care
A0063	Pt. right to free from unnecessary restraints
A0064	Restraint used only to improve pt. well being
A0065	Restraint if other means ineffective/harm self & others
A0066	Physician/licensed indp. practitioner restraint order
A0067	Never written as a standing or on an as needed basis
A0068	Consultation w/treating physician if they didn't order
A0069	In accordance w/written modification to pt. PoC
A0070	Implemented in least restrictive manner possible
A0071	Accordance w/safe/appropriate restraining techniques
A0072	Ended at earliest possible time
A0073	Condition of restrained pt. continually assessed
A0074	Staff direct contact w/pt. trained in safe restraint use
A0075	Standard: Seclusion & Restraint for Behavior Mgmt.
A0076	Pt. free from seclusion/restraints: discipline/retaliation
A0077	Seclusion/restraint only used for emergency/pt. safety
A0078	Use of restraint/seclusion less restrictive ineffective
A0079	Physician/licensed practitioner orders restraints
A0080	Restraints never written as standing order/as needed
A0081	If not ordered by treating physician, contacted ASAP
A0082	Need for restraint evaluated within 1 hr. by physician
A0083	Restraint limited: 4 hrs. 18+yrs/2 hrs. -18yrs/1 hr -9yrs
A0084	Original order renewed up to total 24 hours
A0085	Assessed by physician/licensed prt. before new order
A0086	In accordance with a written modification to pt. PoC
A0087	Implemented in least restrictive manner possible
A0088	In accordance w/safe/appropriate techniques
A0089	Ended at earliest possible time
A0090	Restraint & seclusion not used simultaneously
A0091	Continually monitored w/video/audio close to patient
A0092	Condition continually monitored/assessed/reevaluated
A0093	Ongoing restraint training of staff direct contact w/pt.
A0094	Ongoing alt. methods training staff direct contact w/pt.
A0095	Report death of restrained/secluded pt. to CMS
A0141	***Quality Assessment & Performance Improvement***
A0142	Standard: Program Scope
A0143	Ongoing prog. showing improvement health outcomes
A0144	Ongoing prog. showing improv. reduce medical errors
A0145	Must measure, analyze & track quality indicators
A0146	Standard: Program Data
A0147	Prg. quality ind. pt. care date, & other relevant data
A0148	Use data collected to monitor effectiveness, QoC
A0149	Use data collected to identify opt. improvement
A0150	Freq./detail of data collection specified by gov. body
A0151	Standard: Program Activities
A0152	High risk/high volume, incidence, severity, QoC
A0153	High risk/high volume, incidence, severity, pt. safety
A0154	Impv. actv. track medical errors/adverse pt. evts.
A0155	Impv. actv. track medical errors/adverse evts./causes
A0156	Perf. Imp. implement actions that include feedback
A0157	Must take actions aimed at performance improvement
A0158	After implementing actions, must measure success
A0159	Track performance ensure improvements sustained
A0160	Standard: Performance Improvement Projects
A0161	No./scope distinct imp. proj. annually propor. services

Tag	*Identifier*
A0162	May implement info. tech syst. to improve pt. safety
A0163	Must doc. what quality imprvt. proj. being conducted
A0164	Must document reasons for conducting these projects
A0165	Must doc. measurable progress achieved on these projs
A0166	Not req. to partic. in a QIO coop. proj.
A0167	Standard: Executive Responsibilities
A0168	Ongoing proj quality improve. def./impld/maintained
A0169	Ongoing prg. pt. safety/red. med. errors maintained
A0170	Hospital-wide QA address priorities for imprv. pt QoC
A0171	Hospital-wide QA address priorities for imprv. pt safety
A0172	That clear expectations for safety are established
A0173	Adequate resources allocated: asses, imprv. perfor.
A0174	Determ. # of distinct imprv. projs. conducted annually
A0181	***Medical Staff***
A0182	Standard: Composition of the Medical Staff
A0183	Med. staff periodically conduct appraisal of members
A0184	Staff examine candidate credentials med.membership
A0185	Standard: Medical Staff Organization & Accountability
A0186	Standard: Medical Staff Bylaws
A0187	Be approved by the governing body
A0188	Include statement of duties/privileges of med. staff
A0189	Describe the organization of the medical staff
A0190	Qualif. to be met by candidate for med. staff recomd.
A0191	Req. phys. exam, med hist. for each pt. dr. med./osteo
A0192	Criteria for privg. to ind. pract. & procedure for request
A0193	Standard: Autopsies
A0199	***Nursing Services***
A0200	Standard: Organization
A0201	Standard: Staffing & Delivery of Care
A0202	Provide 24 hr. on duty RN/LPN, services./sup RN
A0203	Nurse service ensure nurse personnel valid licensure
A0204	RN must supervise/evaluate care for each patient
A0205	Hosp. ensure nurse staff develop/keep plan each patient
A0206	RN must assign care to nurses according to pt. need
A0207	Non-employee LN adhere to hospital policies
A0208	Standard: Preparation& Administration of Drugs
A0209	Drugs/biolog. admin. by/supv. nuring/personnel by law
A0210	Orders drugs/biolog. in writing & signed by practitioner
A0211	Accepted only authorized personnel by Fed/State law
A0212	Signed or initialed by prescribing practitioner ASAP
A0213	Used frequently
A0214	Blood tranf./IV meds. admin accordance w/ State law
A0215	Hospital procedure reporting transf., reactions, errors
A0221	***Medical Record Services***
A0222	Standard: Organization & Staffing
A0223	Standard: Form & Retention of Record
A0224	Med. records retained original/legal copy min. 5 yrs.
A0225	System of coding/indexing medical records
A0226	Procedure for confidentiality of records
A0227	Unauthorized indv. can't gain access to pt. records
A0228	Org. med. records released in accord. Fed/ State laws
A0229	Standard: Content of Record
A0230	All entries legible/complete authenticated/dated
A0231	Author of each entry identified entry authenticated
A0232	Authentication : signatures, written initials, pc entry
A0233	All record must document following as appropriate

Tag	Identifier
A0234	Evid. physical examination &health history
A0235	Admitting diagnosis
A0236	Results of consul. evaluations of pt. & findings
A0237	Doc. of complic., hospital acq. infections, reactions
A0238	Properly executed consent forms for procedures
A0239	All pract. ords., nurse notes, med. recs. to monitor pt.
A0240	Discharge summary w/outcome of hospitalization
A0241	Final diagnosis w/complt. of med. rec. within 30 days
A0247	***Pharmaceutical Services***
A0248	Standard: Pharmacy Management @ Administration
A0249	All pharmacists respons. develp./sup./coord services
A0250	Pharm. service adequate personnel quality services
A0251	Current/accurate records receipt/disposition drugs
A0252	Standard: Delivery of Services
A0253	Pkg., disp., drugs/biolog. under pharmacist superv.
A0254	Drugs and biologicals kept in locked storage area
A0255	Outdated/mislabeled/unlabeled not for pt. use
A0256	Drugs/biolog. removed only by design. personnel
A0257	Drugs/biolog not specf. presc. to time/# auto. stopped
A0258	Drug admin errors, reactions, incomp. report immd.
A0259	Abuse/loss of controlled substances report by law
A0260	Info. relating drug interact./therapy/effects aval. staff
A0261	Formulary system established by med. staff
A0267	***Radiological Services***
A0268	Standard: Radiology Services
A0269	Standard: Safety for Patients & Personnel
A0270	Proper Safety Precautions maintained agst. radiation
A0271	Periodic inspection of equip. hazards identified
A0272	Radiation workers checked periodically
A0273	Radiology services only by order of practitioners
A0274	Standard: Personnel
A0275	Radiologist supervise services interp. tests detr. staff
A0276	Med. staff designated personnel radiological equip.
A0277	Standard: Records
A0278	Services by Radiologist/practitioner sign reports
A0279	Copies reports, printouts, films, scans, images 5 yrs.
A0284	***Laboratory Services***
A0285	Standard: Adequacy of Laboratory Services
A0286	Emergency lab services available 24 hrs a day
A0287	Written description of services available med. staff
A0288	Lab. must make provisions receipt/report tissue spec.
A0289	Med. staff/pathol. determine spec. macro/micro exam
A0290	Standard: Potentially Infectious Blood & Blood Prod.
A0295	***Food & Dietetic Services***
A0296	Standard: Organization
A0297	Dir. food/dietetic serv., mgmt. dietary svc. full time
A0298	Qualified dietitian full/part time or consultant basis
A0299	Admin/tech personnel competent in respective duties
A0300	Standard: Diets
A0301	Therapeutic diets prescribed by practitioner
A0302	Nutr. needs met accord. recog. practices/prac orders
A0304	Current therapeutic diet manual apprv. dietician/staff
A0308	***Utilization Review***
A0309	Standard: Applicability
A0310	Standard: Composition Utilization Rev. Committee
A0311	Standard: Scope & Frequency Review
A0312	Standard: Determ. Regarding Admis. or Cont. Stays
A0313	Standard: Extended Stay Review
A0314	Standard: Review of Professional Services
A0317	***Physical Environment***
A0318	Standard: Buildings
A0319	Emergency Power: operating, recovery, IC, ER, stairs
A0320	There must be facilities emergency gas/water supply
A0321	Standard: Life Safety From Fire
A0322	Meet applicable provisions 2000 ed. LSC NFPA
A0323	CMS waive specific provisions LSC hardship facility
A0324	CMS may allow State's fire safety code instead LSC
A0325	March 13, 2006 in comp. w/19.3.3.3.2 & 19.2.9
A0326	Procedures proper routine storage & trash disposal
A0327	Fire control plans prompt reporting fires, pt protection
A0328	Maintain written evidence regular inspection
A0329	Standard: Facilities
A0330	Diagnostic/therapeutic facilities located pt. safety
A0331	Facilities, supplies, equip. maintained
A0332	Extent/complexity of facilities deter. services offered
A0333	Proper vent., light, temp. controls in pharm, food prep
A0338	***Infection Control***
A0339	Standard: Organization & Policies
A0340	IC officer system identify, report, investigate, control
A0341	IC officer maintain log incidents infect./com. diseases
A0342	Std.: Resp. Chief Exec. Off., Med Staff, Dir. Nursing
A0349	***Discharge Planning***
A0350	Standard: Identification of Pts. Need of Discharge
A0351	Standard: Discharge Planning Evaluation
A0352	Nurse/social work. develop/supervise devp. evaluation
A0353	Discharge planning evaluation, post hospital services
A0354	Pt. self-care/cared in env. from which entered hospital
A0355	Personnel cmpt. eval. tmely for post-hospital arrang.
A0356	Discharge planning included in pts. med. record
A0357	Standard: Discharge Plan
A0358	RN/social worker develop discharge plan when indic.
A0359	Pt. physician may req. discharge plan
A0360	Must arrange initial implementation pt. discharge plan
A0361	Reassess pt. discharge plan if factors cont. care needs
A0362	Pt/fam/interested persons must be counseled post-hosp
A0363	Standard: Transfer or Referral
A0364	Standard: Reassessment
A0369	Organ, Tissue & Eye Procurement
A0371	OPO medical suitability tissue, eye
A0372	Agrmt. at least 1 tissue bank: retrieval, proces, storage
A0373	Family informed options to donate or decline
A0374	Designated requestor for family
A0375	Discretion/sensitivity w/respect circumstances/beliefs
A0376	Hospital works w/ designated OPP educating staff
A0377	Reviewing death records improve id. potential donors
A0378	Maintain potential donors testing/placement organs
A0379	Standard: Organ Transplantation Responsibilities
A0384	***Surgical Services***
A0385	Standard: Organization & Staffing
A0386	ORs supervised by exp. RN or dr. med./osteopathy
A0387	LPNs/surg. tech. serve "scrub nurses" under RN sup.
A0388	RN circulating duties in OR accord. State law
A0389	Surg. priv. delineate. all practit. performing surgery
A0390	Standard: Delivery of Service
A0391	Complete history /phys work-up in chart pt prior surg.
A0392	Informed consent form operation in pt chart prior surg.
A0393	OR: call-in sys., cardi. mon., resus., defib., asp., trach.
A0394	Adequate provisions for post-OP care
A0395	OR register complete/ up to date
A0396	OR report: techn., findings, tissues remov./alter.
A0416	***Anesthesia Services***
A0417	Standard: Organization & Staffing
A0418	Standard: Delivery of Systems
A0419	Pre-anesthesia eval. qualified indiv. to admin anes.
A0420	An intraoperative anesthesia record
A0421	Inpatients post-anesthesia follow-up report
A0422	Outpatients post-anesthesia evaluation for proper recov.
A0428	***Nuclear Medicine Services***
A0429	Standard: Organization & Staffing
A0430	Dir. who is dr. medicine/osteo. qualified nuclear med.
A0431	Qualif./train./funct./resp. nuclear med. staff spec. by dir
A0432	Standard: Delivery of Service
A0433	In-house prep. radio pharma. trained, regis. pharm./doc
A0434	There is proper storage & disposal of radioactive mater.
A0435	Lab tests in nuc. med. srv. meet requirement lab srvs.
A0436	Standard: Facilities
A0437	Equip. safe oper. cond./insp, tested, calibrated annually
A0438	Standard: Records
A0439	Hosp. maintain copies nuc med. reports at least 5yrs.
A0440	Pract. approv. med, staff interpret diag. proc. sign, date
A0441	Hospital maintain records receipt distr. radio pharma.
A0442	Nuc. ordered practitioners Fed/State licensure referrals
A0446	***Outpatient Services***
A0447	Standard: Organization
A0448	Standard: Personnel
A0452	***Emergency Services***
A0453	Standard: Organization & Direction
A0454	Service organized dir. qualified member med. staff
A0455	Services integrated w/other depts. of hospital
A0456	Polic. med care prov. in emer. serv. dept. est. med. staff
A0457	Standard: Personnel
A0458	Emer services. supervised qualified member med. staff
A0459	Adeq. med./nursing personnel qual. in emr. care facility
A0463	***Rehabilitation Services***
A0464	Standard: Organization & Staffing
A0465	Dir. of serv. knwlg., exp., capab. administer services
A0466	Phys/occup/speech/audio therapy staff State law
A0467	Standard: Delivery of Services
A0471	***Respiratory Services***
A0472	Standard: Organization & Staffing
A0473	Dir of resp. is dr. med./osteo w/knwlg admin. service
A0474	Adeq. # resp. therapists/technicians consist. w/law
A0475	Standard: Delivery of Services
A0476	Personnel qualif. perform spec. procedures/sup. req.
A0477	Blood gases/clinical lab tests, unit meet lab services
A0478	Services provided accord w/orders dr. med or osteo

Rehabilitation Reference Manual

Tab 23: Introduction to Critical Access Hospital Rehabilitation Distinct Part Units

23.1 Introductory Comments

23.2 Skills Checklist: CAH DPUs

23.1 Introductory Comments

23.1: Introductory Comments

Effective October 1, 2004, section 405(g)(1) of the Medicare Medication Act (MMA) amended section 1820(c)(2)(E) of the Social Security Act to permit critical access hospitals (CAHs) to have rehabilitation distinct part units (DPUs).

The CAH rehabilitation DPU functions in much the same way that an inpatient rehabilitation facility (IRF) unit does. The DPU must comply with the following:

- Conditions of Participation for hospitals specified in 42 CFR 482 subparts A, B, C and D.
- Requirements of the Prospective Payment System (42 CFR 412):
  - The common requirements for hospital units excluded from the prospective payment systems of 42 CFR 412.25(a)(2) through (g) of Part 412.
  - The additional requirements of 42 CFR 412.29 for rehabilitation units, 412.30 for new or converted rehabilitation units and 42 CFR 412, subpart P, for inpatient rehabilitation hospitals and rehabilitation units (412.600 through 412.632).

If the CAH fails to operate its rehabilitation DPU in compliance with applicable requirements (noted above), at any time during the cost report period, the CAH DPU will not be reimbursed for the entire cost report period. Payment may resume only after the cost report period ends, assuming the CAH DPU is found in compliance with the CoPs and the requirements of the Prospective Payment System (42 CFR Part 412). Note: This is different from an acute care hospital that would be reimbursed under the IPPS for a cost report period in which they failed to meet the applicable requirements specified in 42 CFR Part 412.

Information from Proposed and Final Rules affecting CAHs can be found in this section of the Desk Reference.

A CAH DPU must complete the inpatient rehabilitation facility patient assessment instrument (IRF-PAI) for each Medicare Part A fee-for-service patient in order to receive the inpatient rehabilitation facility prospective payment system (IRF-PPS) reimbursement rate.

A CAH DPU is limited to 10 beds, which are excluded from the 25 bed inpatient bed-count limit. Lengths-of-stay in rehabilitation DPUs are not subject to the 96-hour average length of inpatient stay limitation for CAHs; a patient's stay in the CAH DPU may be longer.

Form CMS-437A will be used when surveying CAH DPUs.

23.2 Skills Checklist: CAH DPUs

23.2: Skills Checklist: CAH DPUs

The following list enumerates skills and knowledge necessary to conduct a successful survey of the CAH rehabilitation DPU. The surveyor should be able to:

- ☐ Identify and be familiar with the sections of the *State Operations Manual* that refer to the IPPS excluded rehabilitation units during survey.
- ☐ Identify the sections of Title 42 of the *Code of Federal Regulations* pertaining to IRF units during survey.
- ☐ Identify the Conditions of Participation relevant to rehabilitation services in Medicare hospitals.
- ☐ Use Form CMS-437A when surveying a rehabilitation distinct part unit in a critical access hospital.
- ☐ Verify the hours per week worked by the director of rehabilitation in a rehabilitation unit.
- ☐ Identify the requirements expected of the director of rehabilitation.
- ☐ Identify the specific patient assessment instrument used to gather data on patients admitted to the rehabilitation distinct part unit.
- ☐ Specify the number of rehabilitation distinct part units that a critical access hospital may have.

CMS Rehabilitation Desk Reference

Tab 24:
State Operations Manual Excerpts Pertaining to CAH Rehabilitation DPUs

24.1 Appendix W

24.1 Appendix W

State Operations Manual

Appendix W - Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs - (Rev. 05-21-04)

INDEX

Survey Protocol

Introduction
Regulatory and Policy Reference
Tasks in the Survey Protocol
Survey Team
Task 1 - Off-Site Survey Preparation
Task 2 - Entrance Activities
Task 3 - Information Gathering/Investigation
Task 4 - Preliminary Decision Making and Analysis of Findings
Task 5 - Exit Conference
Task 6 - Post-Survey Activities

Regulations and Interpretive Guidelines for CAHs

§485.608 Condition of Participation: Compliance With Federal, State, and Local Laws and Regulations
§485.608(a) Standard: Compliance With Federal Laws and Regulations
§485.608(b) Standard: Compliance With State and Local Laws and Regulations
§485.608(c) Standard: Licensure of CAH
§485.608(d) Standard: Licensure, Certification or Registration of Personnel
§485.610 Condition of Participation: Status and Location
§485.610(a) Standard: Status
§485.610(b) Standard: Location in a Rural Area or Treatment as Rural
§485.610(c) Standard: Location Relative to Other Facilities or Necessary Provider Certification
§485.612 Condition of Participation: Compliance With CAH Requirements at the Time of Application
§485.616 Condition of Participation: Agreements
§485.616(a) Standard: Agreements With Network Hospitals
§485.616(b) Standard: Agreements for Credentialing and Quality Assurance
§485.618 Condition of Participation: Emergency Services

§485.618(a) Standard: Availability
§485.618(b) Standard: Equipment, Supplies, and Medication
§485.618(c) Standard: Blood and Blood Products
§485.618(d) Standard: Personnel
§485.618(e) Standard: Coordination With Emergency Response Systems
§485.620 Condition of Participation: Number of Beds and Length of Stay
§485.620(a) Standard: Number of Beds
§485.620(b) Standard: Length of Stay
§485.623 Condition of Participation: Physical Plant and Environment
§485.623(a) Standard: Construction
§485.623(b) Standard: Maintenance
§485.623(c) Standard: Emergency Procedures
§485.623(d) Standard: Life Safety From Fire
§485.627 Condition of Participation: Organizational Structure
§485.627(a) Standard: Governing Body or Responsible Individual
§485.627(b) Standard: Disclosure
§485.631 Condition of Participation: Staffing and Staff Responsibilities
§485.631(a) Standard: Staffing
§485.631(b) Standard: Responsibilities of the Doctor of Medicine or Osteopathy
§485.631(c) Standard: Physician Assistant, Nurse Practitioner, and Clinical Nurse Specialist Responsibilities
§485.635 Condition of Participation: Provision of Services
§485.635(a) Standard: Patient Care Policies
§485.635(b) Standard: Direct Services
§485.635(c) Standard: Services Provided Through Agreements or Arrangements
§485.635(d) Standard: Nursing Services
§485.638 Condition of Participation: Clinical Records
§485.638(a) Standard: Records System
§485.638(b) Standard: Protection of Record Information
§485.638(c) Standard: Retention of Records
§485.639 Condition of Participation: Surgical Services.
§485.639(a) Standard: Designation of Qualified Practitioners
§485.639(b) Standard: Anesthetic Risk and Evaluation
§485.639(c) Standard: Administration of Anesthesia
§485.639(d) Standard: Discharge
§485.639(e) Standard: State Exemption
§485.641 Condition of Participation: Periodic Evaluation and Quality Assurance Review
§485.641(a) Standard: Periodic Evaluation

§485.641(b) Standard: Quality Assurance

§485.643 Condition of Participation: Organ, Tissue, and Eye Procurement

§485.645 Special Requirements for CAH Providers of Long-Term Care Services ("Swing-Beds")

§485.645(a) Eligibility

§485.645(b) Facilities Participating as Rural Primary Care Hospitals (RPCHs) on September 30, 1997

§485.645(c) Payment

§485.645(d) SNF Services

§483.10 Resident Rights

§483.10(a) Exercise of Rights

§483.10(b) Notice of Rights and Services

§483.10(d) Free Choice

§483.10(e) Privacy and Confidentiality

§483.10(h) Work

§483.10(i) Mail

§483.10(j) Access and Visitation Rights

§483.10(l) Personal Property

§483.10(m) Married Couples

§483.12 Admission, Transfer and Discharge Rights

§483.12(a) Transfer and Discharge

§483.13 Resident Behavior and Facility Practices

§483.13(a) Restraints

§483.13(b) Abuse

§483.13(c) Staff Treatment of Residents

§483.15(f) Activities

§483.15(g) Social Services

§483.20 Resident Assessment

§483.20(k) Comprehensive Care Plans

§483.20(l) Discharge Summary

§483.25(i) Nutrition

§483.45 Specialized Rehabilitative Services

§483.45(a) Provision of Services

§483.55 Dental Services

Survey Protocol

Introduction

Critical Access Hospitals (CAHs) are required to be in compliance with the Federal requirements set forth in the Medicare Conditions of Participation (CoP) in order to receive Medicare/Medicaid payment. The goal of a CAH survey is to determine if the CAH is in compliance with the CoP set forth at 42 CFR Part 485 Subpart F.

Certification of CAH compliance with the CoP is accomplished through observations, interviews, and document/record reviews. The survey process focuses on a CAH's performance of organizational and patient-focused functions and processes. The CAH survey is the means used to assess compliance with Federal health, safety, and quality standards that will assure that the beneficiary receives safe, quality care and services.

Regulatory and Policy Reference

- The Medicare Conditions of Participation for CAHs are found at 42 CFR Part 485 Subpart F.
- Survey authority and compliance regulations can be found at 42 CFR Part 488 Subpart A.
- If an individual or entity (CAH) refuses to allow immediate access to either a State Agency or CMS surveyor, the Office of Inspector General (OIG) may terminate the CAH from participation in the Medicare/Medicaid programs in accordance with 42 CFR 1001.1301.
- The regulatory authority for the photocopying of records and information during the survey is found at 42 CFR 489.53.
- The CMS State Operations Manual (SOM) provides CMS policy regarding survey and certification activities.

Surveyors assess the CAH's compliance with the CoP for all services, areas and locations in which the provider receives reimbursement for patient care services billed under its provider number.

Although the survey generally occurs during daytime working hours (Monday through Friday), surveyors may conduct the survey at other times. These survey hours may include weekends and times outside of daytime (Monday through Friday) working hours. When the survey begins at times outside of normal work times, the survey team modifies the survey, if needed, in recognition of patients' activities and the staff available.

All routine CAH surveys are unannounced. Do not provide CAHs with advance notice of the survey.

Tasks in the Survey Protocol

Listed below, and discussed in this document, are the tasks that comprise the survey protocol for CAHs.

Task 1 Off-Site Survey Preparation
Task 2 Entrance Activities
Task 3 Information Gathering/ Investigation
Task 4 Preliminary Decision Making and Analysis of Findings
Task 5 Exit Conference
Task 6 Post-Survey Activities

Survey Modules for Specialized CAH services

The modules for CAH distinct part psychiatric units and rehabilitation units and CAH swing beds are attached to this document. The survey team is expected to use all the modules that apply to the CAH being surveyed. For example if the CAH has swing beds, a distinct part rehabilitation unit, and a distinct part psychiatric unit, the team will use all three modules to conduct the survey of those activities.

Survey Team

Size and Composition

The SA (or the RO for Federal teams) decides the composition and size of the team. In general, a suggested survey team for a full survey of a CAH would include 1-4 surveyors who will be at the facility for one or more days. Each survey team should include at least one RN with hospital/CAH survey experience, as well as other surveyors who have the expertise needed to determine whether the facility is in compliance. Survey team size and composition are normally based on the following factors:

- Size of the facility to be surveyed, based on average daily census;
- Complexity of services offered, including outpatient services;
- Type of survey to be conducted;
- Whether the facility has special care units or off-site clinics or locations;
- Whether the facility has a historical pattern of serious deficiencies or complaints; and
- Whether new surveyors are to accompany a team as part of their training.

Team Coordinator

Surveyors conduct the survey under the leadership of a team coordinator. The SA (or the RO for Federal teams) should designate this individual. The team coordinator is responsible for assuring that all survey preparation and survey activities are completed within the specified time frames and in a manner consistent with this protocol, SOM, and SA procedures.

Responsibilities of the team coordinator include:

- Scheduling the date and time of survey activities;
- Acting as the spokesperson for the team;
- Assigning staff to areas of the CAH or tasks for the survey;
- Facilitating time management;
- Encouraging on-going communication among team members;
- Evaluating team progress;
- Coordinating daily team meetings;
- Coordinating any ongoing conferences with CAH leadership (as determined appropriate by the circumstances and SA/RO policy) and providing on-going feedback, as appropriate, to CAH leadership on the status of the survey;
- Coordinating Task 2 Entrance Conference;
- Facilitating Task 4 Preliminary Decision Making;
- Coordinating Task 5 Exit Conference; and
- Coordinating the preparation of the Form CMS-2567.

Task 1 - Off-Site Survey Preparation

General Objective

The objective of this task is to analyze information about the provider in order to identify areas of potential concern to be investigated during the survey and to determine if those areas, or any special features of the provider (e.g., provider-based clinics, specialty units, services offered, etc.) require the addition of any specialty surveyors to the team. Information obtained about the provider will also allow the SA (or the RO for Federal

teams) to determine survey team size and composition, and to develop a preliminary survey plan. The type of provider information needed includes:

- Information from the provider file (to be updated on the survey using the Hospital/CAH Medicare Database Worksheet, Exhibit 286), such as the facility's ownership, the type(s) of services offered, whether the facility is a provider of swing-bed services, any distinct part units, the number, type and location of any off-site locations; and the number and categories of personnel.

- Previous Federal and state survey results for patterns, number, and nature of deficiencies, as well as the number, frequency, and types of complaint investigations and the findings;

- Information from CMS databases available to the SA and CMS. Note the exit date of the most recent survey;

- Waivers and variances, if they exist. Determine if there are any applicable survey directive(s) from the SA or the CMS Regional Office (RO); and

- Any additional information available about the facility (e.g. the CAH's Web site, any media reports about the CAH, etc.).

Off-Site Survey Preparation Team Meeting

The team should prepare for the survey off site so they are ready to begin the survey immediately upon entering the facility. The team coordinator should arrange an off-site preparation meeting with as many team members as possible, including specialty surveyors. This meeting may be a conference call if necessary.

During the meeting, discuss at least the following:

- Information gathered by the team coordinator;

- Significant information from the CMS databases that are reviewed;

- Update and clarify information from the provider file (a surveyor can update the Medicare data base on survey using the Hospital/CAH Medicare Database Worksheet, Exhibit 286);

- Layout of the facility (if available);

- Preliminary team member assignments;

- Date, location and time team members will meet to enter the facility;

- The time for the daily team meetings; and

- Potential date and time of the exit conference.

Gather copies of resources that may be needed. These may include:

- CAH Regulations and Interpretive Guidelines (Appendix W);
- Survey protocol and modules;
- Immediate Jeopardy (Appendix Q);
- Responsibilities of Medicare Participating Hospitals in Emergency Cases (Appendix V);
- Hospital/CAH Medicare Database Worksheet, Exhibit 286;
- Letter of authorization to obtain facilities most recent accreditation survey, Exhibit 287; and
- Worksheets for swing bed and CAH distinct part rehabilitation and psychiatric units, Exhibit 288.

Task 2 - Entrance Activities

General Objectives

The objectives of this task are to explain the survey process to the provider and obtain the information needed to conduct the survey.

General Procedures

Arrival

The entire survey team should enter the facility together. Upon arrival, surveyors should present their identification. The team coordinator should announce to the Administrator, or whoever is in charge, that a survey is being conducted. If the Administrator (or person in charge) is not on site or available (e.g., if the survey begins outside normal daytime, Monday – Friday working hours), ask that they be notified that a survey is being conducted. Do not delay the survey because the Administrator or other staff is/are not on site or available.

Entrance Conference

The entrance conference sets the tone for the entire survey. Be prepared and courteous, and make requests, not demands. The entrance conference should be informative, concise, and brief; it should not utilize a significant amount of time. Conduct the entrance conference with

administrative staff available at the time of entrance. During the entrance conference, the Team Coordinator should address the following:

- Explain the purpose and scope of the survey;
- Briefly explain the survey process;
- Introduce survey team members, including any additional surveyors who may join the team at a later time. Discuss the general area that each will be responsible for, and the various documents that they may request;
- Clarify that all CAH areas and locations, departments, and patient care settings under the CAH provider number may be surveyed, including any contracted patient care activities or patient services;
- Explain that all interviews will be conducted privately with patients, staff, and visitors, unless requested otherwise by the interviewee;
- Discuss and determine how the facility will ensure that surveyors are able to obtain the photocopies of material, records, and other information as they are needed;
- Obtain the names, locations, and telephone numbers of key staff to whom questions should be addressed;
- Discuss the approximate time, location, and possible attendees of any meetings to be held during the survey. The team coordinator should coordinate any meetings with facility leadership; and
- Propose a date and time for the exit conference.

During the entrance conference, the Team Coordinator will arrange with the CAH administrator, or available CAH administrative/supervisory staff if he/she is unavailable, to obtain the following:

- A location (e.g., conference room) where the team may meet privately during the survey;
- A telephone for team communications, preferably in the team meeting location;
- A list of inpatients**,** providing each patient's name, room number, diagnosis (es), admission date, age, attending physician, and other significant information as it applies to that patient. The team coordinator will explain to the CAH representative that in order to complete the survey within the allotted time it is important the survey team is given this information as soon as possible, and request that it be

no later than 3 hours after the request is made. SAs may develop a worksheet to give to the facility for obtaining this information;

- A list of department heads with their locations and telephone numbers;
- A copy of the facility's organizational chart;
- The names and addresses of all off-site locations operating under the same provider number;
- The CAH'S infection control plan;
- A list of employees;
- The medical staff bylaws and rules and regulations;
- A list of contracted services; and
- A copy of the facility's floor plan, indicating the location of patient care and treatment areas.

Arrange an interview with a member of the administrative staff to update and clarify information from the provider file.

Facility Tours

Guided tours of the facility are not encouraged and should be avoided. A tour of a facility could consume several man-hours of allocated survey time and resources that are needed to conduct the survey.

Initial On-Site Team Meeting

After the conclusion of the Entrance Conference, the team will meet in order to evaluate information gathered and modify surveyor assignments, as necessary. The team should not delay the continuation of the survey process waiting for information from the provider, and should adjust survey activities as necessary. During the on-site team meeting, team members should:

- Review the scope of services;
- Identify all locations to be surveyed, including all off-site locations;
- Adjust surveyor assignments, as necessary, based on new information;
- Discuss issues such as change of ownership, sentinel events, construction activities, and disasters, if they have been reported;

- Make an initial patient sample selection (the patient list may not be available immediately after the entrance conference, therefore the team may delay patients completing the initial patient sample selection a few hours as meets the needs of the survey team); and

- Set the next meeting time and date.

Sample Size and Selection

To select the patient sample, review the patient list provided by the facility and select patients who represent a cross section of the patient population and services provided. The sample should include inpatients, outpatients and closed records of discharged patients. Inpatients should have a length of stay sufficient to assure knowledge of the various services they received. Their open record should include information about care already provided by all services and departments. The anticipated discharge date should be used to assist in determining which patients will be in the CAH long enough for the surveyor to contact the patient during the course of the survey. Patient logs (ED, OB, OR, etc.) in conjunction with the patient list provided by the facility, provide a good source to use when selecting patients for the sample. If the team finds it necessary during the survey to remove a patient from the sample (e.g., the patient refused to participate in an interview), replace this patient with another who fits a similar profile. Make the substitution as early in the survey as possible.

Whenever possible and appropriate, surveyors should interview patients that are in the facility during the time of the survey to assess the facility's compliance with the CoP. Therefore, open patient records should be selected whenever possible. Open records allow the surveyor to conduct a patient-focused survey and allow the surveyor to compare the medical record with patient observations and interviews. There are situations where closed records will be needed to assess compliance and there may be other situations where there are not adequate numbers of open records to assess compliance. The selected patient records should reflect the scope of services provided by the facility. The sample needs to be no fewer than 20 inpatient records, provided that number is adequate to determine compliance. Additionally, select a sample of outpatients in order to determine compliance in outpatient and emergency services.

Give each patient in the sample a unique identifier. Appropriate identifiable information should be kept on a separate identifier list. Do not use medical record numbers, Social security numbers, care unit or billing record numbers to identify patients.

To conduct an initial survey of a CAH there must be enough inpatients currently in the CAH and patient records (open and closed) for surveyors to determine whether the CAH can demonstrate compliance with all the applicable CoPs. The number of current and discharged inpatients and outpatients in relation to the complexity of care provided to patients and the length of stay of those patients needs to be large enough for surveyors to evaluate the manner

and degree to which the CAH satisfies all the standards within each CoP. Utilize the same sample size and selection methods as previously discussed.

If a complaint is being investigated during the survey, patients who have been identified as part of a complaint should be added to the sample. Issues or concerns identified in complaints may be a focus of concern when selecting sample patients.

Task 3 - Information Gathering/Investigation

General Objective

The objective of this task is to determine the provider's compliance with the Medicare Conditions of Participation through observations, interviews, and documentation review.

Guiding Principles

- Focus attention on actual and potential patient outcomes, as well as required processes.
- Assess the care and services provided, including the appropriateness of the care and services within the context of the regulations.
- Visit patient care settings, including inpatient units, outpatient clinics, anesthetizing locations, emergency departments, imaging, rehabilitation, etc.
- Observe the actual provision of care and services to patients and the effects of that care, in order to assess whether the care provided meets the needs of the individual patient.
- Use the interpretive guidelines and other published CMS policy statements to guide the survey.
- Use Appendix Q for guidance if Immediate Jeopardy is suspected.

General Procedures

During the Survey

- Visit as many patient care settings as possible, including all on campus and off-campus patient care locations that bill for services under the CAH'S provider number and are considered a part of the CAH. Because the CAH'S compliance with the requirements is being assessed, all patient care locations should be part of the total CAH survey. A surveyor should observe what activities are taking place and assess the CoP that represent the scope and complexity of the patient care services located at each location, as well as, any other CoP that apply to those locations. The depth of

assessment of the CoP will be determined by what the surveyor observes at each location. The surveyor expands the survey activities as necessary.

- On any Medicare survey, contracted patient care activities or patient services (such as dietary services, treatment services, diagnostic services, etc.) located on the CAH campus or at CAH provider based locations should be included in the survey.

- The SA and surveyors have discretion whether to allow, or to refuse to allow, facility personnel to accompany the surveyors during a survey. Sometimes facility personnel may be helpful and may answer questions or point out concerns to the survey team. Conversely, facility personnel may sometimes hinder the surveyor, and argue about observed problems. Surveyors should make a decision whether to allow facility personnel to accompany them based on the circumstances at the time of the survey.

- The team should meet at least daily in order to assess the status of the survey, progress of completion of assigned tasks, areas of concern, and to identify areas for additional investigations. The team meetings should include an update by each surveyor that addresses findings and areas of concern that have been identified. If areas of concern are identified in the discussion, the team should coordinate efforts to obtain additional information. Additional team meetings can be called at any time during the survey to discuss crucial problems or issues.

- All significant issues or significant adverse events must be brought to the team coordinator's attention immediately.

- Maintain open and ongoing dialogue with the facility staff throughout the survey process. Conferences with facility staff may be held in order to inform them of survey findings. This affords facility staff the opportunity to present additional information or to offer explanations concerning identified issues. Survey information must not be discussed unless the investigation process and data collection for the specific concerns is completed.

- Surveyors should always maintain a professional working relationship with facility staff.

- Surveyors need to respect patient privacy and maintain patient confidentiality at all times during the survey.

- Surveyors should maintain their role as representatives of a regulatory agency. Although non-consultative information may be provided upon request, the surveyor is not a consultant.

Patient Review

A comprehensive review of care and services received by each patient in the sample should be part of the survey. A comprehensive review includes observations of care/services provided to the patient, patient and/or family interview(s), staff interview(s), and medical record review. After obtaining the patient's permission, observe each sample patient receiving treatments (e.g., intravenous therapy, tube feedings, wound dressing changes) and observe the care provided in a variety of treatment settings, as necessary, to determine if patient needs are met.

Observations

Observations provide first-hand knowledge of CAH practice. The regulations and interpretive guidelines offer guidance for conducting observations. Observation of the care environment provides valuable information about how the care delivery system works and how CAH departments work together to provide care. Surveyors are encouraged to make observations, complete interviews, and review records and policies/procedures by stationing themselves as physically close to patient care as possible. While completing a chart review, for instance, it may be possible to also observe the environment and the patients, staff interactions with patients, safety hazards, and infection control practices. When conducting observations, particular attention should be given to the following:

- Patient care, including treatments and therapies in all patient care settings;
- Staff member activities, equipment, documentation, building structure, sounds and smells;
- People, care, activities, processes, documentation, policies, equipment, etc., that are present that should not be present, as well as, those that are not present that should be present;
- Integration of all services, such that the facility is functioning as one integrated whole;
- Whether quality assurance (QA) is a facility-wide activity, incorporating every service and activity of the provider and whether every facility department and activity reports to, and receives reports from, the facility's central organized body managing the facility-wide QA program; and
- Storage, security, and confidentiality of medical records.

A surveyor should take complete notes of all observations and should document: the date and time of the observation(s); location; patient identifiers, individuals present during the observation, and the activity being observed (e.g., therapy, treatment modality, etc.).

A surveyor should have observations verified by the patient, family, facility staff, other survey team member(s), or by another mechanism. For example, when finding an out-dated medication in the pharmacy, ask the pharmacist to verify that the drug is out-dated. In addition, a surveyor should integrate the data from observations with data gathered through interviews and document reviews.

A surveyor must not examine patients by themselves, although in certain circumstances, in order to determine a patient's health status and whether safe and appropriate health care is being provided, especially to ensure a patient's welfare where he/she appears to be in immediate jeopardy, it is permissible and necessary to examine the patient. After obtaining permission from the patient, the surveyor should request that a staff member of the facility examine the patient in the surveyor's presence. The health and dignity of the patient is always of paramount concern. A surveyor must respect the patient's right to refuse to be examined.

Interviews

Interviews provide a method to collect information, and to verify and validate information obtained through observations. Informal interviews should be conducted throughout the duration of the survey. Use the information obtained from interviews to determine what additional observations, interviews, and record reviews are necessary. When conducting interviews, observe the following:

- Maintain detailed documentation of each interview conducted. Document the interview date, time, and location; the full name and title of the person interviewed; and key points made and/or topics discussed. To the extent possible, document quotes from the interviewee.

- Interviews with facility staff should be brief. Use a few well-phrased questions to elicit the desired information. For example, to determine if a staff member is aware of disaster procedures and his/her role in such events, simply ask, "If you smelled smoke, what would you do?"

- When interviewing staff, begin your interviews with staff that work most closely with the patient.

- Conduct patient interviews regarding their knowledge of their plan of care, the implementation of the plan, and the quality of the services received. Other topics for patient or family interview may include advanced directives and the facility's grievance/complaint procedure.

- Interviews with patients must be conducted in privacy and with the patient's prior permission.

- Use open-ended questions during your interview.

- Validate all information obtained.

- Telephone interviews may be conducted if necessary, but a preference should be made for in-person interviews.

- Integrate the data from interviews with data gathered through observations and document reviews.

Staff interviews should gather information about the staff's knowledge of the patient's needs, plan of care, and progress toward goals. Problems or concerns identified during a patient or family interview should be addressed in the staff interview in order to validate the patient's perception, or to gather additional information.

Patient interviews should include questions specific to the patient's condition, reason for admission, quality of care received, and the patient's knowledge of their plan of care. For instance, a surgical patient should be questioned about the process for preparation for surgery, the patient's knowledge of and consent for the procedure, pre-operative patient teaching, post-operative patient goals and discharge plan.

Document Review

Document review focuses on a facility's compliance with the CoP. When conducting a document review, document the source and date of the information obtained. When making document copies identify the original date of the document and indicate the date and time the copies were made. Once a document review is completed, integrate the data obtained with data gathered through observations and interviews to decide if the CAH is in compliance with the CoP. Documents reviewed may be both written and electronic and include the following:

- Patient's clinical records, to validate information gained during the interviews, as well as for evidence of advanced directives, discharge planning instructions, and patient teaching. This review will provide a broad picture of the patient's care. Plans of care and discharge plans should be initiated immediately upon admission, and be modified, as patient care needs change. The record review for that patient who has undergone surgery would include a review of the pre-surgical assessment, informed consent, operative report, and pre-, inter-, and post-operative anesthesia notes. Although team members may have a specific area assigned during the survey, the team should avoid duplication of efforts during review of medical records and each surveyor should review the record as a whole instead of targeting the assigned area of concern. Surveyors should use open patient records rather than closed records, whenever practical.

- Closed medical records may be used to determine past practice, and the scope or frequency of a deficient practice. Closed records should also be reviewed to provide information about services that are not being provided by the CAH at the time of the survey. For example, if there are no obstetrical patients in the facility at the time of

the survey, review closed OB records to determine care practices, or to evaluate past activities that cannot be evaluated using open records. In the review of closed clinical records, review all selected medical records for an integrated plan of care, timelines of implementation of the plan of care, and the patient responses to the interventions.

- Personnel files to determine if staff members have the appropriate educational requirements, have had the necessary training required, and are licensed, if it is required;

- Credential files to determine if the facility complies with CMS requirements and State law, as well as, follows its own written policies for medical staff privileges and credentialing;

- Maintenance records to determine if equipment is periodically examined and to determine if it is in good working order and if environmental requirements have been met;

- Staffing documents to determine if adequate numbers of staff are provided according to the number and acuity of patients;

- Policy and procedure manuals. When reviewing policy and procedure manuals, verify with the person in charge of an area that the policy and procedure manuals are current;

- Contracts, if applicable, to what requirements are provided under arrangements or agreements.

- Diet menus to ensure they meet the needs of the sample patients.

Photocopies

Surveyors should make photocopies of all documents needed to support survey findings. The surveyor needs access to a photocopier where he/she can make his/her own photocopies of needed documents. If requested by the hospital, the surveyor should make the hospital a copy of all items photocopied. All photocopies need to be dated and timed as to when photocopied, and identified such as "CAH IV management policy- 2/27/04 page 3" or "Patient # 6, progress note –2/17/04."

Completion of Hospital/CAH Medicare Database Worksheet

Interview a member of the administrative staff to update and clarify information from the provider file.

The Hospital/CAH Medicare Database worksheet will be used to collect information about the CAH services, locations, and staffing by the Medicare CAH surveyors during the CAH survey. The worksheet will be completed by the surveyors using observation, staff interviews, and document review. The worksheet will not be given to the CAH staff to complete. The worksheet is used to collect information that will later be entered into the Medicare Database.

Clarify any inconsistencies from prior information or information gathered during the survey.

Task 4 - Preliminary Decision Making and Analysis of Findings

General Objectives

The general objectives of this task are to integrate findings, review and analyze all information collected from observations, interviews, and record reviews, and to determine whether or not the CAH meets the Conditions of Participation found at 42 CFR Part 485. The team's preliminary decision-making and analysis of findings assist it in preparing the exit conference report. Based on the team's decisions, additional activities may need to be initiated.

General Procedures

Preparation

Prior to beginning this Task, each team member should review his/her notes, worksheets, records, observations, interviews, and document reviews to assure that all investigations are complete and organized for presentation to the team.

Discussion Meeting

At this meeting, the surveyors will share their findings with the team, evaluate the evidence, and make team decisions regarding compliance with each requirement. Proceed sequentially through the requirements for each condition appropriate to the facility as they appear in regulation. For any issues of noncompliance, the team needs to reach a consensus. Decisions about deficiencies are to be team decisions, with each member having input. The team should document their decisions, the substance of the evidence, and the numbers of patients impacted, in order to identify the extent of facility noncompliance. The team should document their decisions, the substance of the evidence, and the numbers of patients impacted, in order to identify the extent of facility noncompliance. The team must ensure that their findings are supported by adequate documentation of observations, interviews, and document reviews, and includes any needed evidence such as photocopies. Any additional documentation or evidence needed to support identified noncompliance should be gathered prior to the exit conference but at a minimum prior to exiting the hospital.

Determining the Severity of Deficiencies

The regulations at 42 CFR § 488.26 states, "The decision as to whether there is compliance with a particular requirement, condition of participation, or condition for coverage, depends upon the manner and degree to which the provider or supplier satisfies the various standards within each condition." When noncompliance with a condition of participation is noted, the determination of whether a lack of compliance is at the standard or condition level depends upon the nature (how severe, how dangerous, how critical, etc.) and extent (how prevalent, how many, how pervasive, how often, etc.) of the lack of compliance. The cited level of noncompliance is determined by the interrelationship between the nature and extent of the noncompliance.

A deficiency at the condition level may be due to noncompliance in a single standard or several standards, or parts of standards within the condition, or because of noncompliance with a single part (tag) representing a severe or critical health or safety breach. Even a seemingly small breach in critical actions or at critical times can kill or severely injure a patient, and represents a critical or severe health or safety threat.

A deficiency is at the standard level when there is noncompliance with any single requirement or several requirements within a particular standard that are not of such character as to substantially limit a facility's capacity to furnish adequate care, or which would not jeopardize or adversely affect the health or safety of patients if the deficient practice recurred.

On a complaint investigation where the CAH states that it has corrected the deficient practice/issue (noncompliance) that is the basis of the complaint, issues for the survey team to consider would include:

- Is the corrective action superficial or inadequate, or is the corrective action adequate and systemic?
- Has the CAH implemented the corrective intervention(s) or action(s)?
- Has the CAH taken a QA approach to the corrective action to ensure monitoring, tracking and sustainability?

The survey team uses their judgment to determine if any action(s) taken by the CAH prior to the survey is sufficient to correct the noncompliance and to prevent the deficient practice from continuing or recurring. If the deficient practice is corrected prior to the survey, do not cite noncompliance. However, if the noncompliance with any requirements is noted during the survey, even when the CAH corrects the noncompliance during the survey, cite noncompliance.

All noted noncompliance must be cited even when corrected on site during the survey. Citing noncompliance at the appropriate level is important to the integrity of the survey process. Citing too high a level is unfair to the CAH. Citing noncompliance at a level below

the noted degree and manner of the noncompliance does not ensure that the CAH will develop acceptable plans of correction and implement corrective actions, does not depict whether the care provided adversely affects the health and safety of patients, and whether continued deficient practices may lead to adverse patient outcomes such as injury or death.

Gathering Additional Information

If it is determined that the survey team needs additional information to determine facility compliance or noncompliance, the team coordinator should decide the best way to conduct the additional review.

Task 5 - Exit Conference

General Objective

The general objective of this task is to inform the facility staff of the team's preliminary findings.

Prior to the Exit Conference

- The team coordinator is responsible for organization of the presentation of the exit.
- The team determines who will present the findings.
- If the team feels it may encounter a problem during the exit, they should contact their immediate supervisor.

Discontinuation of an Exit Conference

It is CMS general policy to conduct an exit conference at the conclusion of each survey. However, there are some situations that justify refusal to continue or to conduct an exit conference. For example:

- If the provider is represented by counsel (all participants in the exit conference should identify themselves), surveyors may refuse to conduct the conference if the lawyer tries to turn it into an evidentiary hearing; or
- Any time the provider creates an environment that is hostile, intimidating, or inconsistent with the informal and preliminary nature of an exit conference, surveyors may refuse to conduct or continue the conference. Under such circumstances, it is suggested that the team coordinator stop the exit conference and call the State agency for further direction.

Recording the Exit Conference

If the facility wishes to audio tape the conference, it must provide two tapes and tape recorders, recording the meeting simultaneously. The surveyors should take one of the tapes at the conclusion of the conference. Videotaping is also permitted if it is not disruptive to the conference, and a copy is provided at the conclusion of the conference. It is at the sole discretion of the surveyor(s) to determine if videotaping is permitted.

General Principles

The following general principles apply when conducting an exit conference:

- The facility determines which CAH staff will attend the exit conference.
- The identity of an individual patient or staff member must not be revealed in discussing survey results. Identity includes not just the name of an individual patient or staff member, but also includes any references by which identity might be deduced.
- Because of the ongoing dialogue between surveyors and facility staff during the survey, there should be few instances in which the facility is unaware of surveyor concerns or has not had an opportunity to present additional information prior to the exit conference.

Exit Conference Sequence

The following discusses the sequence of events in conducting an exit conference.

A - Introductory Remarks:

- Thank everyone for cooperation during the survey.
- Introduce all team members, mentioning any that have concluded their portion of the survey and have left the facility.
- Briefly mention the reason for the survey.
- Explain that the exit conference is an informal meeting to discuss preliminary findings.
- Indicate that official findings are presented in writing on the Form CMS-2567.

B - Ground Rules

- Explain how the team will conduct the exit conference and any ground rules.

- Ground rules may include waiting until the surveyor finishes discussing each deficiency before accepting comments from facility staff.

- State that the provider will have an opportunity to present new information after the exit conference for consideration after the survey.

C - Presentation of Findings

- Avoid referring to data tag numbers.

- Present the findings of noncompliance, explaining why the findings are a violation. If the provider asks for the regulatory basis, provide it.

- Refrain from making any general comments (e.g., "Overall the facility is very good"). Stick to the facts. Do not rank findings. Treat requirements as equal as possible.

- Do not identify unmet requirements as condition or standard level. Avoid statements such as, "the condition was not met" or "the standard was not met." It is better to state, "the requirement is not met."

- If immediate jeopardy was identified, explain the significance and the need for immediate correction. Follow instructions in Appendix Q.

- Assure that all findings are discussed at the exit conference.

D - Closure

- Explain that a statement of deficiencies (Form CMS-2567) will be mailed within 10 working days to the CAH.

- Explain that the Form CMS-2567 is the document disclosed to the public about the facility's deficiencies and what is being done to remedy them. The Form CMS-2567 is made public no later than 90 calendar days following completion of the survey. It documents specific deficiencies cited, the facility's plans for correction and timeframes, and it provides an opportunity for the facility to refute survey findings and furnish documentation that requirements are met.

- Inform the facility that a written plan of correction must be submitted to the survey agency within 10 calendar days following receipt of the written statement of deficiencies.

- Explain the required characteristics of a plan of correction. The characteristics include:

    - Corrective action to be taken for each individual affected by the deficient practice, including any system changes that must be made;

  - The position of the person who will monitor the corrective action and the frequency of monitoring;
  - Dates each corrective action will be completed;
  - The administrator or appropriate individual must sign and date the Form CMS-2567 before returning it to the survey agency;
  - The submitted plan of correction must meet the approval of the State agency, or in some cases the CMS Regional Office for it to be acceptable.

- If the exit conference was audio or video taped, obtain a copy of the tape in its entirety before leaving the facility.

All team members should leave the facility together immediately following the exit conference. If the facility staff provides further information for review, the team coordinator should decide the best way to conduct the further review. It is usually prudent for at least two individuals to remain.

Task 6 - Post-Survey Activities

General Objective

The general objective of this task is to complete the survey and certification requirements, in accordance with the regulations found at 42 CFR Part 488.

General Procedures

Each State agency and CMS Regional Office should follow directives in the State Operations Manual. The procedures include:

- Timelines for completing each step of the process;
- Responsibilities of the team coordinator and other team members to complete the Form CMS-2567, Statement of Deficiencies, using the **Principles of Documentation** as reference;
- Notification to the facility staff regarding survey results;
- Additional survey activities based on the survey results (e.g., revisit, forwarding documents to the Regional Office for further action/direction);
- Compilation of documents for the provider file;

- Obtain signed Letter of Authorization to obtain facilities most recent accreditation survey and send to RO;

- Enter the information collected on the Hospital/CAH Medicare Database Worksheet into the Medicare database.

Plan of Correction

Regulations at 42 CFR 488.28(a) allow certification of providers with deficiencies at the Standard or Condition level "only if the facility has submitted an acceptable Plan of Correction (POC) for achieving compliance within a reasonable period of time acceptable to the Secretary." Failure to submit a POC may result in termination of the provider agreement as authorized by 42 CFR §§488.28(a) and 489.53(a)(1). After a POC is submitted, the surveying entity makes the determination of the appropriateness of the POC.

CAH Swing-Bed Survey Module

When conducting a full survey of an accredited or unaccredited CAH that has swing bed approval, conduct a survey of the CAH swing-bed requirements found at 42 CFR Part 485.645. These requirements, as well as interpretive guidelines, are found in Appendix W of the State Operations Manual (SOM). The optional survey worksheet may be used.

Background

Swing-bed patients are CAH patients who are situated in the CAH but for whom the CAH is receiving reimbursement for skilled nursing services, as opposed to acute-care reimbursement. The reference to swing-bed is a patient care and reimbursement status and has no relationship to geographic location in the facility. The patient may be in acute-care status one day and change to swing-bed status the next day. It is not necessary for the patient to change location in the hospital when the reimbursement status changes, but moving to a different location is allowed. A 3-day qualifying stay for the same spell of illness in any hospital or CAH is required prior to admission to swing-bed status. The 3-day qualifying stay does not need to be from the same facility as the swing-bed admission.

Regulatory Authority and Requirements for CAH Providers of Extended Care Services ("Swing Beds")

CAH swing-bed care is regulated by both the CAH requirements and the swing-bed requirements at 42 CFR Part 485. The actual swing-bed survey requirements are referenced in the Medicare Nursing Homes requirements at 42 CFR Part 483.

Section 18883 of the Act authorizes payment under Medicare for post-hospital SNF services provided by any CAH that meets certain requirements. By regulation, the Secretary has specified these requirements at 42 CFR § 485.645.

- **The CAH has a Medicare provider agreement;**
- **The total number of beds that may be used at any time for furnishing swing-bed services or acute inpatient services does not exceed 25 beds.**
- **The CAH has not had a swing-bed approval terminated within two years previous to application; and**
- **The CAH meets the swing-bed CoP on Resident Rights; Admission, Transfer, and Discharge Rights; Resident Behavior and Facility Practices; Patients Activities; Social Services; Discharge Planning; Specialized Rehabilitative Services; and Dental Services.**

Activities Conducted Prior to Swing-Bed Survey

Prior to conducting the swing-bed survey, verify the following:

- **The hospital's swing-bed approval is in effect and has not been terminated within the two previous years.**

Survey Procedures

In conducting the survey, verify that the CAH has fewer than 25 hospital-type beds. Count the hospital-type beds in each nursing unit. Count any hospital-type bed that is located in or adjoining any location where the bed could be used for inpatient care. Do not count beds in recovery rooms, labor and delivery rooms (do count birthing beds where patients remain after giving birth), operating rooms, newborn nurseries or stretchers in emergency departments. Do not count examination tables, procedure tables or stretchers. Do not count beds in Medicare certified rehabilitation or psychiatric distinct part units.

Swing bed certification is limited to the CAH itself and does not include any distinct part rehabilitation or psychiatric units. Swing bed services may not be provided in CAH distinct part units.

Assess the CAH's compliance with the swing-bed requirements at 42 CFR §485.645 found in appendix W of the SOM. Swing-bed requirements apply to any patient discharged from a hospital or CAH and admitted to a swing-bed for skilled nursing services. The requirements for acute-care CAHs also apply to swing-bed patients.

If swing bed patients are present during the on-site inspection, conduct an open record review and an environmental assessment. Include patient interviews and observations of care and services. However, if no swing-bed patients are present during the on-site inspection, review two closed records for compliance with swing-bed requirements. In all cases, review policies, procedures, and contracted services to assure that the CAH has the capability to provide the services needed.

It is important for surveyors to maintain on-going documentation of their findings during the course of the survey for later reference. Surveyors may use the optional swing-bed worksheet as note-taking tool to document and record their findings on the survey.

Exit Conference

Any findings of noncompliance may be discussed during the time of the CAH exit conference.

Post-Survey Activities

The findings for swing-bed deficiencies must be documented on a separate Form CMS-2567, even though the swing-bed survey is being conducted simultaneously with the CAH survey.

Regulations and Interpretive Guidelines for CAHs

C-0150

§485.608 Condition of Participation: Compliance With Federal, State, and Local Laws and Regulations

The CAH and its staff are in compliance with applicable Federal, State and local laws and regulations.

Interpretive Guidelines §485.608

Failure of the CAH to meet a Federal, State or local law may only be cited when the Federal, State or local authority having jurisdiction has made both a determination of noncompliance and has taken a final adverse action as a result.

Refer or report suspected violations to the appropriate Federal, State, or local agency.

C-0151

§485.608(a) Standard: Compliance With Federal Laws and Regulations

The CAH is in compliance with applicable Federal laws and regulations related to the health and safety of patients.

Survey Procedures §485.608(a)

Interview the CEO, or appropriate individual, to determine whether the CAH is in compliance with Federal laws related to patient health and safety. For example, if the CAH has been convicted of violating a Federal law such as denying people with disabilities access to care, verify that satisfactory corrections have been made to bring the CAH into compliance with that law.

Refer noted noncompliance with Federal laws and regulations to the appropriate agency having jurisdiction (e.g., accessibility issues, blood borne pathogens, universal precautions, TB control to OSHA, hazardous chemical and waste issues to EPA, etc.)

C-0152

§485.608(b) Standard: Compliance With State and Local Laws and Regulations

All patient care services are furnished in accordance with applicable State and local laws and regulations.

Interpretive Guidelines §485.608(b)

There are wide variations in the States' practice acts relative to the extent to which MD/DOs may delegate responsibilities to nurse practitioners, clinical nurse specialists, and physician assistants. Some states have updated their practice acts to include definitions and specific references to permitted/prohibited activities, supervision/guidance required by a MD/DO, and local situations in which nurse practitioners, clinical nurse specialists, and physician assistants may function.

Survey Procedures §485.608(b)

Prior to going on the survey, determine what professional specialists provide patient care services at the CAH and review State practice act requirements.

C-0153

§485.608(c) Standard: Licensure of CAH

The CAH is licensed in accordance with applicable Federal, State and local laws and regulations.

Survey Procedures §485.608(c)

Prior to the survey, determine whether the CAH is subject to licensure requirements and verify that the licensing agency has approved the CAH as meeting the standards for licensure as set forth by the agency of the State or locality responsible for licensing CAHs.

C-0154

§485.608(d) Standard: Licensure, Certification or Registration of Personnel

Staff of the CAH are licensed, certified, or registered in accordance with applicable Federal, State, and local laws and regulations.

Interpretive Guidelines §485.608(d)

All staff required by the State to be licensed must possess a current license. The CAH must ensure that these personnel are in compliance with the State's licensure laws. The laws requiring licensure vary from state to state. Examples of healthcare professionals that a state may require to be licensed could include: nurses, MD/DOs, physician assistants, dieticians, x-ray technologists, dentists, physical therapists, occupational therapists, respiratory technicians and facility administrators.

All CAH staff must meet all applicable standards required by State or local law for CAH personnel. This would include at a minimum:

- Certification requirements;
- Minimum qualifications; and
- Training/education requirements.

Survey Procedures §485.608(d)

- Verify for those personnel required to be licensed by the State, that the CAH has established, and follows, procedures for determining that personnel providing patient care services are properly licensed.
- Check a sample of personnel files to verify that licensure information is up to date. Verify that appropriate categories of staff and personnel are licensed in accordance with State requirements. Verify state licensure compliance of the direct care personnel, as well as administrators and supervisory personnel, and any contracted personnel.
- Verify that there are procedures in place to guarantee licensure of employees working at the CAH under contract or agreement.
- Review CAH policies regarding certification, licensure, and registration of personnel. Are the CAH policies compliant with State and local laws? Are the personnel in compliance with CAH policy?

C-0160

§485.610 Condition of Participation: Status and Location

Interpretive Guidelines §485.610

This COP only applies to initial surveys unless the facility relocates. If the CAH moves the location of the CAH to another location, the status and relocation must be reassessed.

C-0161

§485.610(a) Standard: Status

The facility is--

(1) A currently participating hospital that meets all conditions of participation set forth in this subpart;

(2) A recently closed facility, provided that the facility--

(i) Was a hospital that ceased operations on or after the date that is 10 years before November 29, 1999; and

(ii) Meets the criteria for designation under this subpart as of the effective date of its designation; or

(3) A health clinic or a health center (as defined by the State) that--

(i) Is licensed by the State as a health clinic or a health center;

(ii) Was a hospital that was downsized to a health clinic or a health center; and

(iii) As of the effective date of its designation, meets the criteria for designation set forth in this subpart.

Interpretive Guidelines §485.610(a)

Confirm that a CAH meets the basic status requirement prior to scheduling the survey. The appropriate RO will reverify the status requirement prior to approving a CAH for Medicare certification.

C-0162

§485.610(b) Standard: Location in a Rural Area or Treatment as Rural

The CAH meets the requirements of either paragraph (b)(1) or (b)(2) of this section.

(1) The CAH meets the following requirements:

(i) The CAH is located outside any area that is a Metropolitan Statistical Area, as defined by the Office of Management and Budget, or that has been recognized as urban under §412.62(f) of this chapter;

(ii) The CAH is not deemed to be located in an urban area under §412.63(b) of this chapter; and

(iii) The CAH has not been classified as an urban CAH for purposes of the standardized payment amount by CMS or the Medicare Geographic Classification Review Board under §412.230(e) of this chapter, and is not among a group of CAHs that have been redesignated to an adjacent urban area under §412.232 of this chapter.

(2) The CAH is located within a Metropolitan Statistical Area, as defined by the Office of Management and Budget, but is being treated as being located in a rural area in accordance with §412.103 of this chapter.

Interpretive Guidelines §485.610(b)

"**Urban**" as defined at 42 CFR §412.62(f), means a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Executive Office of Management and Budget, or the following New England Counties: Litchfield County, Connecticut; York County, Maine; Merrimack County, New Hampshire; Newport County, Rhode Island; and Fagadahoe County, Maine.

"**Urban area**," as defined at 42 CFR §412.62 (f) and referenced in 42 CFR § 412.63(b), applies to CAHs located within an MSA or NECMA that crosses census division boundaries. In such cases, the MSA or NECMA in which the CAH is located is deemed to belong to the census divisions in which most of the CAHs within the MSA or NECMA are located.

A "**Metropolitan CAH**" is a CAH that is located within a MSA but is being treated as being located in a rural area. A CAH that wishes to convert to a CAH, and is located in an urban area, must be reclassified as a rural CAH by submitting an application, prior to conversion, to the regional office of CMS. Prior to conversion, the CAH must meet one of the following criteria and explain how they meet the criteria for reclassification as rural, including data and documentation necessary to support the request, in the application for reclassification. Reference 42 CFR §412.103.

- The CAH is located in a rural census tract of an MSA as determined under the most recent version of the Goldsmith Modification; or
- The CAH is located in an area designated as a rural area by any law or regulation of the State in which it is located; or
- The CAH is designated as a rural CAH by State law or regulation; or
- The CAH would qualify as a rural referral center or as a sole community hospital.

Survey Procedures §485.610(b)

Determine that a CAH meets the basic location requirement prior to scheduling the survey. The appropriate RO will reverify the location requirement prior to approving a CAH for Medicare certification.

C-0165

§485.610(c) Standard: Location Relative to Other Facilities or Necessary Provider Certification

The CAH is located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH, or the CAH is certified by the State as being a necessary provider of health care services to residents in the area.

Interpretive Guidelines §485.610(c)

One may reasonably consider a road "**secondary**" if it is not an Interstate, U.S., or State highway.

After January 1, 2006, the "necessary provider" waiver will no longer be used to waive the mileage requirements. Those CAHs designated as necessary providers prior to January 1, 2006, will retain the necessary provider waiver issued by the State. [See MMA § 405(h)(2)]

C-0170

§485.612 Condition of Participation: Compliance With CAH Requirements at the Time of Application

Except for recently closed facilities as described in §485.610(a)(2), or health clinics or health centers as described in §485.610(a)(3), the facility is a hospital that has a provider agreement to participate in the Medicare program as a hospital at the time the hospital applies for designation as a CAH.

Interpretive Guidelines §485.612

This COP only applies to initial surveys. All facilities that apply to become a CAH are surveyed using the CAH CoP to determine compliance, whether they are:

- A currently operating CAH; or
- A re-opened CAH; or
- A CAH that down-sized to become a clinic.

If a facility has never been a Medicare participating hospital and wishes to be a CAH, the facility is a new provider to Medicare and must first meet the certification as a hospital and then put in a change of status request to be a CAH. In these cases, the facility must be surveyed twice. They must be initially surveyed using the hospital CoP and, when the change request is received, they must be surveyed again using the CAH CoP. In addition,

these facilities are to be treated as new providers to Medicare necessitating completion of an application package as a new Medicare provider.

C-0190

§485.616 Condition of Participation: Agreements

C-0191

§485.616(a) Standard: Agreements With Network Hospitals

In the case of a CAH that is a member of a rural health network as defined in §485.603 of this chapter, the CAH has in effect an agreement with at least one hospital that is a member of the network for:

Interpretive Guidelines §485.616(a)

Section 485.603 defines a rural health network as an organization that includes at least one hospital that the State has designated or plans to designate as a CAH, and at least one hospital that furnishes acute care (hospital) services.

Survey Procedures §485.616(a)

- If the CAH is a member of a rural health network having a communications system, ask to see the agreement.
- How does the CAH participate with other hospitals and facilities in the network communications system?
    - Is a communications log kept at the facility?
    - Ask staff if there have been difficulties in contacting network members. If so, ask how the CAH deals with communication delays.
- How does the network's communications system compare with any available communications equipment in the CAH?
- When the network communications system is not in operation, how does the CAH communicate and share patient data with other network members?
- Review any policies and procedures related to the operation of any communications system.
- How is the CAH staff educated on the use of any communication system utilized in the facility?

- Review any written agreements with the local EMS service.

C-0192

§485.616(a)(1) Patient referral and transfer;

C-0193

§485.616(a)(2) The development and use of communications systems of the network, including the network's system for the electronic sharing of patient data, and telemetry and medical records, if the network has in operation such a system; and

---

C-0194

§485.616(a)(3) The provision of emergency and non-emergency transportation between the facility and the hospital.

C-0195

§485.616(b) Standard: Agreements for Credentialing and Quality Assurance

Each CAH that is a member of a rural health network shall have an agreement with respect to credentialing and quality assurance with at least--

(1) One hospital that is a member of the network;

(2) One QIO or equivalent entity; or

(3) One other appropriate and qualified entity identified in the State rural health care plan.

Interpretive Guidelines §485.616(b)

Other qualified entities could include another CAH or any licensed firms, businesses, or agencies that provide credentialing and QA services. The location for these other qualified entities is not limited to local entities.

Agreements for QA need to include medical record review as part of the determination of the quality and medical necessity of medical care at the CAH.

Survey Procedures §485.616(b)

- Review any agreements related to credentialing or quality assurance to determine the level of assistance to be provided and the responsibilities of the CAH.

- Review policies and procedures to determine how information is to be obtained, utilized, and how confidentiality of information will be maintained.

C-0200

§485.618 Condition of Participation: Emergency Services

The CAH provides emergency care necessary to meet the needs of its inpatients and outpatients.

Interpretive Guidelines §485.618

All emergency services must be provided as a direct service in the CAH. The ED cannot be a provider-based off-site location. Emergency needs of patients must be met in accordance with acceptable standards of practice.

Acceptable standards of practice include maintaining compliance with applicable Federal and State laws, regulations, and guidelines governing all services provided in the CAH'S emergency department, as well as any standards and recommendations promoted by or established by nationally recognized professional organizations such as the American Medical Association, American Association for Respiratory Care, American Society of Emergency Medicine, American College of Surgeons, American Nursing Association, etc.

The CAH'S emergency services must be under the direction of a qualified member of the CAH'S medical staff. The CAH'S medical staff establishes criteria for the qualifications for the director of the CAH'S emergency services in accordance with State law and acceptable standards of practice.

The CAH'S medical staff must establish policies and procedures governing the medical care provided in the emergency services or emergency department. Emergency services or emergency department policies must be current and revised as necessary based on the ongoing monitoring conducted by the medical staff and the emergency service or department QA activities. The CAH'S emergency services must be integrated into the CAH-wide QA program.

The medical staff must establish criteria, in accordance with State law, regulations, and guidelines, delineating the qualifications a medical staff member must possess in order to be granted privileges for the provision of emergency care services. Qualifications include necessary education, experience and specialized training, consistent with State law and acceptable standards of practice.

The CAH must staff the emergency department with the appropriate numbers and types of professionals and other staff who possess the skills, education, certifications, specialized training and experience in emergency care to meet the written emergency procedures and needs anticipated by the facility. There must be sufficient medical and nursing personnel to respond to the emergency medical needs and care of the patient population being served.

The CAH must determine the categories and numbers of MD/DOs, specialists, RNs, EMTs, and emergency department support staff the CAH needed to met its anticipated emergency needs. The medical staff must establish criteria, in accordance with State law and regulations and acceptable standards of practice delineating the qualifications required for each category of emergency services staff (e.g., emergency physicians, specialist MD/DO, RNs, EMTs, mid-level practitioners, etc.).

The CAH must conduct ongoing assessments of its emergency needs in order to anticipate the policies, procedures, staffing, training, and other resources that may be needed to address likely demands.

Emergency care necessary to meet the needs of its inpatients and outpatients would include the provision of respiratory services as needed by the CAH'S emergency patients. When respiratory services are provided those services must be provided in accordance with acceptable standards of practice. The scope of diagnostic and/or therapeutic respiratory services offered by the CAH should be defined in writing, and approved by the medical staff.

The CAH must provide the appropriate equipment and qualified personnel necessary to furnish all services offered in a safe manner in accordance with acceptable standards of practice.

There should be written policies for the delivery of any services provided. The policies and procedures must be developed and approved by the medical staff and include the participation of any mid-level practitioners working in the ED. The written policies should address the following services, as appropriate:

- Each type of service provided by the CAH;
- The qualifications, including job title, licensure requirements, education, training and experience of personnel authorized to perform each type of respiratory care service and whether they may perform it without supervision;
- Equipment assembly and operation;
- Safety practices, including infection control measures;
- Handling, storage, and dispensing of therapeutic gases;
- Cardiopulmonary resuscitation;
- Procedures to follow in the advent of adverse reactions to treatments or interventions;
- Pulmonary function testing;
- Therapeutic percussion and vibration;

- Bronchopulmonary drainage;
- Mechanical ventilatory and oxygenation support;
- Aerosol, humidification, and therapeutic gas administration;
- Administration of medications; and
- Procedures for obtaining and analyzing blood samples (arterial blood gases).

Survey Procedures §485.618

- Verify that emergency services are organized under the direction of a qualified member of the medical staff.
- Verify that procedures and policies for emergency medical services (including triage of patients and any respiratory services provided) are established, evaluated, and updated on an ongoing basis.
- Verify that there are sufficient medical and nursing personnel qualified in the needs anticipated by the facility and that there are specific assigned duties for emergency care
- Review any policies and procedures for emergency services in the CAH. What evidence indicates that the CAH is capable of providing necessary emergency care for its inpatients and outpatients?
- Review a sample of patient records for patients treated in the emergency services department to see if the CAH followed its own policies and procedures.
- Verify that emergency services are provided in accordance with acceptable standards of practice.
- Interview staff to determine that they are knowledgeable, within their own level of participation in emergency care including:
    - Parenteral administration of electrolytes, fluids, blood and blood components;
    - Care and management of injuries to extremities and central nervous system;
    - Prevention of contamination and cross infection; and
    - Provision of emergency respiratory services.
- Determine if the CAH provides any degree of respiratory care services and that

the type and amount of respiratory care provided meets the needs of the patients and is delivered in accordance with acceptable standards of practice.

- Review the CAH policies and procedures to verify that the scope of the diagnostic and/or therapeutic respiratory care services provided is defined in writing and approved by the medical staff.
- Review staffing schedules to determine that the number and type of staff available is appropriate to the volume and types of treatments furnished.
- If blood gases or other laboratory tests are performed as part of the delivery of respiratory services, verify that there is a current CLIA certificate.

C-0201

§485.618(a) Standard: Availability

Emergency services are available on a 24-hours a day basis.

Interpretive Guidelines §485.618(a)

The CAH "makes available 24-hour emergency services." This does not mean that the CAH must remain open 24 hours a day when it does not have inpatients (including swing-bed patients). A CAH that does not have inpatients may close with no staff present, provided that it has an effective system in place to meet the requirement. The system must ensure that a practitioner with training and experience in emergency care is on call and immediately available by telephone or radio, and available on site within 30 minutes, (or 1 hour in certain frontier areas), 24 hours a day.

In addition to these items, the CAH must maintain the types, quality and numbers of supplies, drugs and biologicals, blood and blood products, and equipment required by state and local law and in accordance with accepted standards of practice.

Survey Procedures §485.618(a)

Ascertain by record review of patients admitted through the emergency department, interviews with staff, patients, and families, and/or observations that ED services were made available to patients presenting on a 24-hour a day basis. How does the CAH ensure that emergency services are made available on a 24-hour a day basis?

C-0202

§485.618(b) Standard: Equipment, Supplies, and Medication

Equipment, supplies, and medication used in treating emergency cases are kept at the CAH and are readily available for treating emergency cases. The items available must include the following:

Interpretive Guidance §485.618(b)

In addition to these items, the CAH must maintain the types, quality and numbers of supplies, drugs and biologicals, blood and blood products, and equipment required by State and local law and in accordance with accepted standards of practice.

Survey Procedures §485.618(b)

- How does the CAH ensure that the required equipment, supplies and medications are always readily available in the CAH?
- Interview staff and tour the ER to ascertain compliance and ability to provide emergency services.

C-0203

§485.618(b)(1) Drugs and biologicals commonly used in life-saving procedures, including analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarrythmics, cardiac glycosides, antihypertensives, diuretics, and electrolytes and replacement solutions.

Survey Procedures §485.618(b)(1)

- How does the CAH ensure that staff knows where drugs and biologicals are kept?
- How is the inventory maintained?
- Who is responsible for monitoring drugs and biologicals?
- How are drugs and biologicals replaced?

C-0204

§485.618(b)(2) Equipment and supplies commonly used in life-saving procedures, including airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, immobilization devices, nasogastric tubes, splints, IV therapy supplies, suction machine, defibrillator, cardiac monitor, chest tubes, and indwelling urinary catheters.

Survey Procedures §485.618(b)(2)

- How does the CAH ensure that required equipment and supplies are readily available to staff?
- How does the CAH ensure that staff knows where emergency equipment and supplies are kept?
- How is the supply inventory maintained?
- Who is responsible for monitoring supplies?
- How are supplies replaced?
- When was the last time emergency supplies were used?
- Is there an equipment maintenance schedule (e.g., for the defibrillator)?
- Ask staff if equipment has ever failed to work when needed.
- Examine sterilized equipment (e.g., tracheostomy sets) for expiration dates when applicable.
- Examine the oxygen supply system to determine functional capabilities.
- Check the force of the vacuum (suction) equipment to see that it is in operating condition.

C-0205

§485.618(c) Standard: Blood and Blood Products

The facility provides, either directly or under arrangements, the following--

(1) Services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hours a day basis.

Interpretive Guidelines §485.618(c)(1)

This requirement can be met at a CAH by providing blood or blood products on an emergency basis at the CAH, either directly or through arrangement, if that is what the patient's condition requires. There is no requirement in the regulation for a CAH to store blood on site, although it may choose to do so. In some cases, it may be more practical to transport a patient to the source of the blood supply than to bring blood to the patient at the CAH. A facility that has the capability of providing blood services on site would be in

compliance even if, in virtually all cases, the patients were actually taken to the blood rather than vice versa.

A CAH that performs CLIA tests on blood on-site must have a CLIA certificate and is subject to survey under CLIA. A CAH that is only storing blood for transfusion and refers all related testing out to another laboratory, is not performing testing as defined by CLIA. However, under this regulation, the CAH must ensure that blood is appropriately stored to prevent deterioration, including documenting refrigerator temperatures. The provision of blood services between the CAH and the testing laboratory should be reflected in the written agreement or arrangement between the two. Also, if the CAH is collecting blood, it must register with the Food and Drug Administration.

"**Availability**" in this context, means that the blood and blood products must be accessible to CAH staff in time to effectively treat emergency patients at the CAH. In order to comply with this requirement, a CAH must demonstrate that it has the capability (i.e., an effective system is in place regardless of whether, in actual practice, it has been utilized) of making blood products available to its emergency patients 24 hours a day.

If a CAH performs type and compatibility testing it must have the necessary equipment, (i.e., serofuge and heat block), as well as typing and cross matching reagents, some of which have a 30-day expiration date. Another way for a CAH to meet this requirement would be to properly store 4 units of O negative packed red blood cells (the universal donor type) for availability at all times for emergencies only. CAHs that choose to store O negative packed red blood cells for emergency release of uncross matched blood will require a release form to be signed by a doctor, prior to transfusion, acknowledging that the blood has not been cross matched for the patient. Facilities that elect to store units of O negative packed red blood cells should be able to demonstrate that they have an arrangement (e.g., with the Red Cross or other similar product provider) for the provision of fresh units of O negative packed red blood cells.

C-0206

§485.618(c)(2) Blood storage facilities that meet the requirements of 42 CFR part 493, subpart K, and are under the control and supervision of a pathologist or other qualified doctor of medicine or osteopathy. If blood banking services are provided under an arrangement, the arrangement is approved by the facility's medical staff and by the persons directly responsible for the operation of the facility.

Survey Procedures §485.618(c)(2)

- If blood banking services are provided on site, what evidence shows that the blood facility is under the control and supervision of a pathologist or other qualified MD/DO?

- For blood banking services provided under arrangement, what evidence shows that the CAH medical staff and the person responsible for CAH operations have approved the arrangement?

C-0207

§485.618(d) Standard: Personnel

(1) Except as specified in paragraph (d)(2) of this section, there must be a doctor of medicine or osteopathy, a physician assistant, or a nurse practitioner with training or experience in emergency care on call and immediately available by telephone or radio contact, and available on site within the following timeframes:

(i) Within 30 minutes, on a 24-hour a day basis, if the CAH is located in an area other than an area described in paragraph (d)(1)(ii) of this section; or

(ii) Within 60 minutes, on a 24-hour a day basis, if all of the following requirements are met:

(A) The CAH is located in an area designated as a frontier area (that is, an area with fewer than six residents per square mile based on the latest population data published by the Bureau of the Census) or in an area that meets criteria for a remote location adopted by the State in its rural health care plan, and approved by CMS, under section 1820(b) of the Act.

(B) The State has determined under criteria in its rural health care plan, that allowing an emergency response time longer than 30 minutes is the only feasible method of providing emergency care to residents of the area served by the CAH.

(C) The State maintains documentation showing that the response time of up to 60 minutes at a particular CAH it designates is justified because other available alternatives would increase the time needed to stabilize a patient in an emergency.

(2) A registered nurse satisfies the personnel requirement specified in paragraph (d)(1) of this section for a temporary period if--

(i) The CAH has no greater than 10 beds;

(ii) The CAH is located in an area designated as a frontier area or remote location as described in paragraph (d)(1)(ii)(A) of this section;

(iii) The State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation on the issue of using RNs on a temporary basis as part of their State rural health care plan with the State Boards of Medicine and Nursing, and in accordance with State law, requesting that a registered

nurse with training and experience in emergency care be included in the list of personnel specified in paragraph (d)(1) of this section. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of emergency services in the States. The letter from the Governor must also describe the circumstances and duration of the temporary request to include the registered nurses on the list of personnel specified in paragraph (d)(1) of this section;

(iv) Once a Governor submits a letter, as specified in paragraph (d)(2)(ii) of this section, a CAH must submit documentation to the State survey agency demonstrating that it has been unable, due to the shortage of such personnel in the area, to provide adequate coverage as specified in this paragraph (d).

(3) The request, as specified in paragraph (d)(2)(ii) of this section, and the withdrawal of the request, may be submitted to us at any time, and are effective upon submission.

Interpretive Guidance § 485.618(d)

When State laws are more stringent and require more stringent staffing or expanded operational hours, the CAH must staff its emergency department in accordance with state laws. For example, if State law requires the CAH emergency department be open and be staffed with a MD/DO 24/7 then the CAH must comply.

Survey Procedures §485.618(d)

- Review on-call schedules to determine how the CAH ensures that a qualified staff member is on call 24 hours a day and available on site at the CAH within 30 minutes, or 60 minutes in certain frontier areas.
- Interview staff to determine how the CAH staff knows who is on call.
- What documentation demonstrates that a MD/DO, nurse practitioner, physician assistant, or registered nurse (as allowed under (d)(2)) with emergency training or experience has been on call and available on site at the CAH within 30 or 60 minutes, as appropriate?

C-0209

§485.618(e) Standard: Coordination With Emergency Response Systems

The CAH must, in coordination with emergency response systems in the area, establish procedures under which a doctor of medicine or osteopathy is immediately available by telephone or radio contact on a 24-hours a day basis to receive emergency calls, provide information on treatment of emergency patients, and refer patients to the CAH or other appropriate locations for treatment.

Interpretive Guidelines §485.618(e)

The CAH, not the local ambulance service, is responsible for ensuring that an effective procedure is in place to meet this requirement.

Survey Procedures §485.618(e)

- Verify that the CAH has policies and procedures in place to ensure an MD/DO is available by telephone or radio, on a 24-hour a day basis to receive emergency calls and provide medical direction in emergency situations?
- What evidence demonstrates that the procedures are followed and evaluated for effectiveness?
- Interview staff to see how an MD/DO is contacted when emergency instructions are needed.

C-0210

§485.620 Condition of Participation: Number of Beds and Length of Stay

---

C-0211

§485.620(a) Standard: Number of Beds

Except as permitted for CAHs having swing-bed agreements under §485.645 of this chapter, the CAH maintains no more than 15 inpatient beds.

Interpretive Guidelines §485.620(a)

All hospital-type beds located in the CAH will be counted to establish the number of beds. The Medicare Modernization Act (MMA) has changed the total number of beds a CAH may maintain. The CAH may not have more than 25 beds that **could be** used for inpatient care. Any hospital-type bed located in or adjacent to any location where the bed could be used for inpatient care counts toward the 25 bed limit. Beds that do no count toward the 25 bed limit are:

- Examination or procedure tables;
- Stretchers;
- Operating room tables located in the operating room and used exclusively to conduct surgery on a patient;
- Beds in a surgical recovery room that are used exclusively for surgical patients during recovery from anesthesia;

- Beds in an obstetric delivery room that are used exclusively for observation of OB patients in active labor and delivery of newborn infants (do count beds in birthing rooms where the patient remains after giving birth);
- Newborn bassinets and isolettes used for well baby boarders; and
- Stretchers in emergency departments.
- Beds in Medicare certified distinct part rehabilitation or psychiatric units.

Observation Patient Services

Observation services are defined as services furnished by a CAH to evaluate an outpatient's condition to determine the need for discharge or possible admission as an inpatient.

The maximum stay in observation status is 48 hours. If the stay needs to be extended, the patient should be admitted or transferred, as appropriate.

The stays must always be medically necessary (not for MD/DO or patient convenience). An MD/DO order is required for observation status. An outpatient observation patient should not be commingled with inpatients.

Samples of appropriate use of observation status include:

- Following an ER visit to ensure the patient is stable;
- Following outpatient medical procedures;
- Following minor surgery; or
- Chest pain workup, asthma, or congestive heart failure treatments.

The beneficiary may not be aware that observation stays fall under Part B and require coinsurance. The CAH must give written notice of noncoverage to the beneficiary prior to the stay. Beds, used by patients on observation status, that conform to the hospital-type beds previously discussed in this requirement will be counted as part of the maximum bed count.

Counting Hospice Patients in a CAH

A CAH can dedicate beds to a hospice under arrangement but the beds must count as part of the maximum bed count. The computation contributing to the 96 hour annual average length of stay does not apply to hospice patients. The hospice patient can be admitted to the CAH for any care involved in their hospice treatment plan or for respite care.

Medicare does not reimburse the CAH for the hospice CAH benefit. Medicare reimburses the hospice. The CAH must negotiate payment for services from the hospice through an agreement.

Survey Procedures §485.620(a)

Count the hospital-type beds in each nursing unit. Count any hospital-type beds located in or adjoining any location where the bed could be used for inpatient care.

Do not count the following as a hospital-type bed:

- Examination or procedure tables;
- Stretchers;
- Operating room tables located in the operating room and used exclusively to conduct surgery on a patient;
- Beds in a surgical recovery room that are used exclusively for surgical patients during recovery from anesthesia;
- Beds in an obstetric delivery room that are used exclusively for observation of OB patients in active labor and delivery of newborn infants (do count beds in birthing rooms where the patient remains after giving birth);
- Newborn bassinets and isolettes used for well baby boarders; and
- Stretchers in emergency departments.

Exclude from the 25 bed count any beds in Medicare certified distinct part rehabilitation or psychiatric units.

C-0212

§485.620(b) Standard: Length of Stay

The CAH provides acute inpatient care for a period that does not exceed, on an annual average basis, 96 hours per patient.

Interpretive Guidelines §485.620(b)

The Fiscal Intermediary (FI) will determine compliance with this CoP. The FI will calculate the CAH'S length of stay based on patient census data. If a CAH exceeds the length of stay limit, the FI will send a report to the CMS-RO as well as a copy of the report to the SA. The

CAH will be required to develop and implement a plan of correction (POC) acceptable to the CMS Regional Office or provide adequate information to demonstrate compliance.

C-0220

§485.623 Condition of Participation: Physical Plant and Environment

Interpretive Guidelines §485.623

This CoP applies to all locations of the CAH, all campuses, all satellites, all provider-based activities, and all inpatient and outpatient locations.

The CAH'S departments or services responsible for the CAH'S building and equipment maintenance (both facility equipment and patient care equipment) must be incorporated into the CAH'S QA program and be in compliance with the QA requirements.

C-0221

§485.623(a) Standard: Construction

The CAH is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of direct services.

Interpretive Guidelines §485.623(a)

Physical facilities must be large enough, numerous enough, appropriately designed and equipped, and of appropriate complexity to provide the services offered in accordance with Federal and State laws, regulations and guidelines and accepted standards of practice for that location or service.

Survey Procedures §485.623(a)

Verify through observation that the physical facilities are large enough and properly equipped for the scope of services provided and the number of patients served.

C-0222

§485.623(b) Standard: Maintenance

The CAH has housekeeping and preventive maintenance programs to ensure that--

(1) All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition;

Interpretive Guidelines §485.623(b)(1)

The CAH must ensure that the condition of the physical plant and overall CAH environment is developed and maintained in a manner to ensure the safety and well being of patients. This includes ensuring that routine and preventive maintenance and testing activities are performed as necessary, in accordance with Federal and State laws, regulations, and guidelines and manufacturer's recommendations, by establishing maintenance schedules and conducting ongoing maintenance inspections to identify areas or equipment in need of repair. The routine and preventive maintenance and testing activities should be incorporated into the CAH'S QA plan.

Facilities must be maintained to ensure an acceptable level of safety and quality.

Supplies must be maintained to ensure an acceptable level of safety and quality.

Equipment must be maintained to ensure an acceptable level of safety and quality.

Equipment includes both facility equipment (e.g., elevators, generators, air handlers, medical gas systems, air compressors and vacuum systems, etc.) and medical equipment (e.g., biomedical equipment, radiological equipment, patient beds, stretchers, IV infusion equipment, ventilators, laboratory equipment, etc.).

There must be a regular periodical maintenance and testing program for medical devices and equipment. A qualified individual such as a clinical or biomedical engineer, or other qualified maintenance person, must monitor, test, calibrate and maintain the equipment periodically in accordance with the manufacturer's recommendations and Federal and State laws and regulations. Equipment maintenance may be conducted using CAH staff, contracts, or through a combination of CAH staff and contracted services.

Survey Procedures §485.623(b)(1)

- Verify that the condition of the CAH is maintained in a manner to ensure the safety and well being of patients (e.g., condition or ceilings, walls, and floors, presence of patient hazards, etc.).

- Review the CAH'S routine and preventive maintenance schedules to determine that ongoing maintenance inspections are performed and that necessary repairs are completed.

- Interview the person in charge of medical equipment and determine if there is an adequate periodical maintenance and repair program.

- Verify that all medical devices and equipments are routinely checked by a clinical or biomedical engineer.

- Review maintenance logs for significant medical equipment (e.g., cardiac monitors, IV infusion pumps, ventilators, etc.).

C-0223

§485.623(b)(2) There is proper routine storage and prompt disposal of trash;

Interpretive Guidelines §485.623(b)(2)

The term trash refers to common garbage as well as biohazardous waste. The storage and disposal of trash must be in accordance with Federal, State and local laws and regulations (i.e., EPA, OSHA, CDC, State environmental, health and safety regulations). The Radiology requirements address handling and storage of radioactive materials.

Survey Procedures §485.623(b)(2)

Verify that the CAH has developed and implemented policies for the proper storage and disposal of trash. Verify through observation that staff adhere to these policies and that the CAH has signage, as appropriate.

C-0224

§485.623(b)(3) Drugs and biologicals are appropriately stored;

Survey Procedures §485.623(b)(3)

What standards, guidelines, State and Federal law is the CAH following to ensure that drugs and biologicals are appropriately stored (e.g., properly locked) in all storage areas?

C-0225

§485.623(b)(4) The premises are clean and orderly; and

Interpretive Guidelines §485.623(b)(4)

"**Clean and orderly**" means an uncluttered physical environment where patients and staff can function safely. Equipment and supplies are stored in proper spaces, not in corridors. Spills are not left unattended. There are no floor obstructions. The area is neat and well kept. There is no evidence of peeling paint, visible water leaks, or plumbing problems.

C-0226

§485.623(b)(5) There is proper ventilation, lighting, and temperature control in all pharmaceutical, patient care, and food preparation areas.

Interpretive Guidelines §485.623(b)(5)

There must be proper ventilation in at least the following areas:

- Areas using ethylene oxide, nitrous oxide, guteraldehydes, xylene, pentamidine, or other potentially hazardous substances;
- Locations where oxygen is transferred from one container to another;
- Isolation rooms and reverse isolation rooms (both must be in compliance with Federal and State laws, regulations, and guidelines such as OSHA, CDC, NIH, etc.);
- Pharmaceutical preparation areas (hoods, cabinets, etc.); and
- Laboratory locations.

There must be adequate lighting in all the patient care, food and medication preparation areas.

Temperature, humidity and airflow in the operating rooms must be maintained within acceptable standards to inhibit bacterial growth and prevent infection, and promote patient comfort. Excessive humidity in the operating room is conducive to bacterial growth and compromises the integrity of wrapped sterile instruments and supplies. Each operating room should have separate temperature control. Acceptable standards such as from the Association of Operating Room Nurses (AORN) or the American Institute of Architects (AIA) should be incorporated into CAH policy.

The CAH must ensure that an appropriate number of refrigerators and/or heating devices are provided and ensure that food and pharmaceuticals are stored properly and in accordance with nationally accepted guidelines (food) and manufacturer's recommendations (pharmaceuticals).

Survey Procedures §485.623(b)(5)

- Verify that all food and medication preparation areas are well lit.
- Verify that the CAH is in compliance with ventilation requirements for patients with contagious airborne diseases, such as tuberculosis, patients receiving treatments with hazardous chemical, surgical areas, and other areas where hazardous materials are stored.
- Verify that food products are stored under appropriate conditions (e.g., time, temperature, packaging, location) based on nationally-accepted sources such as the United States Department of Agriculture, the Food and Drug Administration, or other nationally-recognized standard.

- Verify that pharmaceuticals are stored at temperatures recommended by the product manufacturer.
- Verify that each operating room has temperature and humidity control mechanisms.
- Review temperature and humidity tracking logs to ensure that appropriate temperature and humidity levels are maintained.

C-0227

§485.623(c) Standard: Emergency Procedures

The CAH assures the safety of patients in non-medical emergencies by--

(1) Training staff in handling emergencies, including prompt reporting of fires, extinguishing of fires, protection and, where necessary, evacuation of patients, personnel, and guests, and cooperation with fire fighting and disaster authorities;

Survey Procedures §485.623(c)(1)

- How does the CAH ensure that all personnel on its staff, including new additions to the staff, are trained to manage non-medical emergencies?
- Ask facility staff what they are supposed to do in case of an emergency such as a tornado or a blizzard.
- Review staff training documents and inservice records to validate training.
- Review the CAH'S written fire control plans to verify they contain the required provisions of the Life Safety Code or State law.
- Verify that CAH staff reported all fires as required to State officials.
- Interview staff throughout the facility to verify their knowledge of their responsibilities during a fire (this is usually done during the LSC survey, but health surveyors may also verify staff knowledge).

C-0228

§485.623(c)(2) Providing for emergency power and lighting in the emergency room and for battery lamps and flashlights in other areas;

Interpretive Guidelines §485.623(c)(2)

The CAH must comply with the applicable provisions of the Life Safety Code, National Fire Protection Amendments (NFPA) 101, 2000 Edition and applicable references such as NFPA-99: Health Care Facilities, for emergency lighting and emergency power.

Survey Procedures §485.623(c)(2)

Use the Life Safety Code Survey Report Form (CMS-2786) to evaluate compliance with this item.

C-0229

§485.623(c)(3) Providing for an emergency fuel and water supply; and

Interpretive Guidelines §485.623(c)(3)

The CAH must have a system to provide emergency gas and water as needed to provide care to inpatients and other persons who may come to the CAH in need of care. This includes making arrangements with local utility companies and others for the provision of emergency sources of water and gas. The CAH should consider nationally accepted references or calculations made by qualified staff when determining the need for at least water and gas. For example, one source for information on water is the Federal Emergency Management Agency (FEMA).

Emergency gases include fuels such as propane, natural gas, fuel oil, liquefied natural gas, as well as any gases the CAH uses in the care of patients such as oxygen, nitrogen, nitrous oxide, etc.

The CAH should have a plan to protect these limited emergency supplies, and have a plan for prioritizing their use until adequate supplies are available. The plan should also address the event of a disruption in supply (e.g., disruption to the entire surrounding community).

Survey Procedures §485.623(c)(3)

- Review the system used by CAH staff to determine the CAH'S emergency needs for gas and water. Verify that the system accounts for not only inpatients, but also staff and other persons who come to the CAH in need of care during emergencies.

- Determine the source of emergency gas and water, both the quantity of these supplies readily available at the CAH, and that are needed within a short time through additional deliveries.

- Verify that arrangements have been made with utility companies and others for the provision of emergency sources of critical utilities, such as water and gas.

C-0230

§485.623(c)(4) Taking other appropriate measures that are consistent with the particular conditions of the area in which the CAH is located.

Interpretive Guidelines §485.623(c)(4)

Assuring the safety and well being of patients would include developing and implementing appropriate **emergency preparedness** plans and capabilities. The CAH must develop and implement a comprehensive plan to ensure that the safety and well being of patients are assured during emergency situations. The CAH must coordinate with Federal, State, and local emergency preparedness and health authorities to identify likely risks for their area (e.g., natural disasters, bioterrorism threats, disruption of utilities such as water, sewer, electrical communications, fuel; nuclear accidents, industrial accidents, and other likely mass casualties, etc.) and to develop appropriate responses that will ensure the safety and well being of patients. The following issues should be considered when developing the comprehensive emergency plans(s):

- Differences needed for each location where the certified CAH operates;
- The special needs of patient populations treated at the CAH (e.g., patients with psychiatric diagnosis, patients on special diets, newborns, etc.);
- Security of patients and walk-in patients;
- Security of supplies from misappropriation;
- Pharmaceuticals, food, other supplies and equipment that may be needed during emergency/disaster situations;
- Communication to external entities if telephones and computers are not operating or become overloaded (e.g., ham radio operators, community officials, other healthcare facilities if transfer of patients is necessary, etc.);
- Communication among staff within the CAH itself;
- Qualifications and training needed by personnel, including healthcare staff, security staff, and maintenance staff, to implement and carry out emergency procedures;
- Identification, availability and notification of personnel that are needed to implement and carry out the CAH'S emergency plans;

- Identification of community resources, including lines of communication and names and contact information for community emergency preparedness coordinators and responders;
- Provisions for gas, water, electricity supply if access is shut off to the community;
- Transfer or discharge of patients to home or other healthcare settings
- Methods to evaluate repairs needed and to secure various likely materials and supplies to effectuate repairs.

Survey Procedures §485.623(c)(4)

Verify that the CAH has developed and implemented a comprehensive plan to ensure the safety and well being of patients during local emergency situations.

C-0231

§485.623(d) Standard: Life Safety From Fire

(1) Except as otherwise provided in this section, the CAH must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capital Street NW, Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes. Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the Life Safety Code does not apply to a CAH.

Interpretive Guidelines §485.623(d)(1)

Medicare-participating CAHs, regardless of size or number of beds, must comply with the Hospital/healthcare Life Safety Code requirements for all inpatient care locations. CAH departments and locations such as emergency departments, outpatient care locations, etc. must comply with Hospital/healthcare Life Safety Code Requirements. Additionally, the CAH must be in compliance with all applicable codes referenced in the Life Safety Code, such as NFPA-99: Health Care Facilities.

This revision adopts the 2000 edition of the LSC and deletes provisions for the use of roller latches in the facility.

Survey Procedures §482.41(b)(1)

- There is a separate survey form, (CMS-2786) used by the Fire Authority surveyor to evaluate compliance with the Life Safety Code and a separate 1985 Life Safety Code Addendum to be used when surveying for compliance with the 1985 Life Safety Code. (Life Safety Code Guidelines and a copy of the 1985 Life Safety Code Addendum are contained in SOM Appendix I.)

- Survey the entire building occupied by the CAH unless there is a 2-hour firewall separating the space designated as the CAH from the remainder of the building. A 2-hour floor slab does not count; it must be a vertical firewall to constitute a separate building or part of a building.

C-0232

§485.623(d)(2) If CMS finds that the State has a fire and safety code imposed by State law that adequately protects patients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the LSC.

Interpretive Guidelines §485.623(d)(2)

This revision deletes "grandfathering" of older editions of the LSC and allows the use of a State code if approved by CMS.

C-0233

§485.623(d)(3) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the CAH, but only if the waiver does not adversely affect the health and safety of patients.

Interpretive Guidelines §485.623(d)(3)

Life Safety Code waivers may be recommended by the State survey agency but only CMS (at the regional office level) may grant those waivers for Medicare or Medicaid-participating CAHs.

Survey Procedures §485.623(d)(3)

Consideration, assessment and recommendation for waivers of specific Life Safety Code provisions are handled by the Fire Authority surveyor as part of the Life Safety Code survey process.

C-0234

§485.623(d)(4) The CAH maintains written evidence of regular inspection and approval by State or local fire control agencies.

Survey Procedures §485.623(d)(4)

Examine copies of inspection and approval reports from State and local fire control agencies.

C-0235

§485.623(d)(5) A critical access CAH must be in compliance with the following provisions beginning on March 13, 2006:

(i) Chapter 19.3.6.3.2 exception number 2.

(ii) Chapter 19.2.9, Emergency Lighting.

Interpretive Guidelines §485.623(d)(5)

§ 485.623(d)(1) states, "Chapter 19.3.6.3.2 exception number 2 of the adopted edition of the Life Safety Code does not apply to CAH." The wording in § 485.623(d)(5) and § 485.623(d)(5)(i) when used together means that after March 13, 2006 a CAH may no longer continue to keep in service existing roller latches even when these roller latches have been demonstrating the ability to keep the door closed against 5lbf.

Medicare-participating CAHs must be in compliance with chapter 19.3.6.3.2 of the 2000 Edition of NFPA 101 beginning March 13, 2006. Exception number 2 of chapter 19.3.6.3.2 will not be allowed in Medicare-participating CAHs.

CAHs should develop plans for compliance with this requirement so that in all applicable locations roller latches have been replaced by positive latches prior to March 13, 2006.

Beginning March 13, 2006, Medicare-participating CAHs must be in compliance with Chapter 19.2.9 of the 2000 Edition of NFPA 101.

This section gives facilities until March 13, 2006, to replace roller latches and to replace 1 hour batteries with 1-1/2 hour batteries in emergency lighting systems that use batteries as power sources.

After March 13, 2006 a CAH with doors in service with roller latches or with emergency lighting systems with less than 1-1/2 hour batteries will not be in compliance and will be cited at 485.623(d)(1).

C-0240

§485.627 Condition of Participation: Organizational Structure

C-0241

§485.627(a) Standard: Governing Body or Responsible Individual

The CAH has a governing body or an individual that assumes full legal responsibility for determining, implementing and monitoring policies governing the CAH'S total operation and for ensuring that those policies are administered so as to provide quality health care in a safe environment.

Interpretive Guidelines §485.627(a)

The CAH must have only one governing body (or responsible individual) and this governing body (or responsible individual) is responsible for the conduct of the CAH as an institution. In the absence of an organized governing body, there must be written documentation that identifies the individual or individuals that are responsible for the conduct of the CAH operations.

The governing body (or responsible individual) must determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff.

It is the responsibility of the governing body (or responsible individual) to appoint, with the advice of the medical staff, the individual practitioners to the medical staff. After considering medical staff recommendations, and in accordance with established CAH medical staff criteria and State and Federal laws and regulations, the governing body (or responsible individual) decides whether or not to appoint new medical staff members or to continue current members of the medical staff.

The governing body (or responsible individual) must ensure that the medical staff has bylaws that comply with State and Federal law and the requirements of the CAH CoP.

The governing body (or responsible individual) decides whether or not to approve medical staff bylaws submitted by the medical staff. The medical staff bylaws and any revisions must be approved by the governing body (or responsible individual) before they are considered effective.

The governing body (or responsible individual) must ensure that the medical staff is accountable to the governing body (or responsible individual) for the quality of care provided to patients. The governing body (or responsible individual) is responsible for the conduct of the CAH and this conduct would include the quality of care provided to patients.

All CAH patients must be under the care of a member of the medical staff or under the care of a practitioner who is under the supervision of a member of the medical staff. All patient care is provided by or in accordance with the orders of a practitioner granted privileges to provide or order that care and is in accordance with State law.

Criteria for selection of both new medical staff members and selection of current medical staff members for continued membership must be based on:

- Individual character;
- Individual competence;
- Individual training;
- Individual experience; and
- Individual judgment

Survey Procedures §485.627(a)

- Verify that the CAH has an organized governing body or has written documentation that identifies the individual that is responsible for the conduct of the CAH operations.
- Review documentation and verify that the governing body (or responsible individual) has determined and stated the categories of practitioners that are eligible candidates for appointment to the medical staff.
- Have the facility's operating policies been updated to fully reflect its responsibilities as a CAH (e.g., PA responsibilities, provision of required CAH direct services)?
- What evidence (e.g., minutes of board meetings) demonstrates that the governing body or the individual who assumes responsibility for CAH operation is involved in the day-to-day operation of the CAH and is fully responsible for its operations?
- Evaluate records of medical staff appointments to substantiate the governing body's (or responsible individual's) involvement in appointments of medical staff members.
- Confirm that the governing body (or responsible individual) appoints all members to the medical staff in accordance with established policies based on the individual practitioner's scope of clinical expertise and in accordance with Federal and State law.
- Verify that the medical staff operates under current bylaws that are in accordance with Federal and State laws and regulations.

- Verify that the medical staff operates under current bylaws, rules and policies that have been approved by the governing body (or responsible individual).

- Verify that any revisions or modifications in the medical staff bylaws, rules, and policies, have been approved by the medical staff and the governing body (or responsible individual). For example, look at the bylaws and check for date of last review and initials by the person(s) responsible.

- Verify that the governing body (or responsible individual) is periodically apprised of the medical staff evaluation of patient care services provided in the CAH, at every patient care location of the CAH.

- Verify that any individual providing patient care services is a member of the medical staff or is accountable to a member of the medial staff qualified to evaluate the quality of services provided, and in turn, is responsible to the governing body (or responsible individual) for the quality of services provided.

- Verify that there are written criteria for staff appointments to the medical staff.

- Verify that selection of medical staff for membership, both new and renewal, is based upon an individual practitioner's compliance with the medical staff's membership criteria.

- Verify that at a minimum, criteria for selection to the medical staff are individual character, competence, training, experience, and judgment.

C-0242

§485.627(b) Standard: Disclosure

The CAH discloses the names and addresses of--

(1) Its owners, or those with a controlling interest in the CAH or in any subcontractor in which the CAH directly or indirectly has a 5 percent or more ownership interest, in accordance with subpart C of part 420 of this chapter;

Survey Procedures §485.627(b)(1)

- Review CAH policy for reporting changes of ownership.

- How does the CAH implement its policy or procedure for reporting changes in ownership to the State agency?

C-0243

§485.627(b)(2) The person principally responsible for the operation of the CAH; and

Survey Procedures §485.627(b)(2)

How does the CAH implement its policy or procedure for reporting changes in operating officials to the State agency?

C-0244

§485.627(b)(3) The person responsible for medical direction

Survey Procedures §485.627(b)(3)

How does the CAH implement its policy or procedure for reporting changes in medical director to the State agency?

C-0250

§485.631 Condition of Participation: Staffing and Staff Responsibilities

---

C-0251

§485.631(a) Standard: Staffing

(1) The CAH has a professional health care staff that includes one or more doctors of medicine or osteopathy, and may include one or more physician assistants, nurse practitioners, or clinical nurse specialists.

Interpretive Guidelines §485.631(a)(1)

A CAH may operate with a MD/DO on staff as well as with any combination of mid-level practitioners.

Survey Procedures §485.631(a)(1)

- Review listings or organizational charts showing the names of all staff MD/DOs, nurse practitioners, clinical nurse specialists and physician assistants on the CAH staff.

- Review work schedules showing normal CAH hours of operation and coverage by members of the CAH staff.

C-0252

§485.631(a)(2) Any ancillary personnel are supervised by the professional staff.

Survey Procedures §485.631(a)(2)

Use organizational charts and staff interviews to determine how the CAH ensures that the professional staff supervises all ancillary personnel.

C-0253

§485.631(a)(3) The staff is sufficient to provide the services essential to the operation of the CAH.

Survey Procedures §485.631(a)(3)

- How does the CAH ensure that staff coverage is sufficient to provide essential services at the facility (e.g., emergency services, direct services, and nursing services)?
- Review staffing schedules and daily census records.

C-0254

§485.631(a)(4) A doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant is available to furnish patient care services at all times the CAH operates.

Interpretive Guidelines §485.631(a)(4)

Section 485.635(b)(1) requires CAHs to provide "those diagnostic and therapeutic services and supplies that are commonly furnished in "a physicians office" such as low intensity outpatient services. In order to demonstrate compliance, a CAH must demonstrate that a practitioner is physically present and prepared to treat patients at the CAH when patients present at the CAH outpatient clinic during announced hours of outpatient clinic operation. This requirement does not mean the CAH must have a practitioner physically present in the facility 24 hours per day, nor does it require their presence 24 hours per day when the CAH has inpatients, including swing-bed patients.

Survey Procedures §485.631(a)(4)

- If the CAH does not have regular announced hours of operation, ask the individual who is principally responsible for the operation of the CAH, when is the CAH is open to the public to provide outpatient services.

- What kinds of arrangements have been made by the CAH to ensure that a practitioner is available on site at all times the CAH operates to furnish patient care services?

C-0255

§485.631(a)(5) A registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the CAH has one or more inpatients.

Survey Procedures §485.631(a)(5)

Review nursing staff schedules to ensure that a registered nurse, clinical nurse specialist or licensed practical nurse is on duty whenever the CAH has one or more inpatients.

C-0256

§485.631(b) Standard: Responsibilities of the Doctor of Medicine or Osteopathy

---

C-0257

485.631(b)(1) The doctor of medicine or osteopathy--

(i) Provides medical direction for the CAH'S health care activities and consultation for, and medical supervision of, the health care staff;

Interpretive Guidelines §485.631(b)(1)(i)

A CAH must have a MD/DO on its staff. That individual must perform all of the medical oversight functions.

Survey Procedures §485.631(b)(1)(i)

What evidence demonstrates that an MD/DO provides medical direction for the CAH'S health care activities and is available for consultation and supervision of the CAH health care staff?

C-0258

§485.631(b)(1)(ii) In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the CAH'S written policies governing the services it furnishes.

Survey Procedures §485.631(b)(1)(ii)

- What evidence demonstrates that an MD/DO has participated in the development of policies governing CAH services?
- How does the CAH ensure that an MD/DO periodically reviews these policies?

C-0259

§485.631(b)(1)(iii) In conjunction with the physician assistant and/or nurse practitioner members, periodically reviews the CAH'S patient records, provides medical orders, and provides medical care services to the patients of the CAH; and

Survey Procedures §485.631(b)(1)(iii)

- How does the CAH ensure that an MD/DO periodically reviews CAH patient records in conjunction with staff mid-level practitioners and provides medical care to CAH patients?
- What evidence demonstrates that there is a periodic review of patient records by the CAH MD/DO(s)?

C-0260

§485.631(b)(1)(iv) Periodically reviews and signs the records of patients cared for by nurse practitioners, clinical nurse specialists, or physician assistants.

Interpretive Guidelines §485.631(b)(1)(iv)

The CAH MD/DO(s) must review and sign all medical records for patients cared for by mid-level practitioners at the CAH.

Survey Procedures §485.631(b)(1)(iv)

Select a sample of inpatient and outpatient records, including both open and closed records, and verify that a **MD/DO has reviewed and signed all records for patients cared for by mid-level practitioners.**

C-0261

§485.631(b)(2) A doctor of medicine or osteopathy is present for sufficient periods of time, at least once in every 2 week period (except in extraordinary circumstances) to provide the medical direction, medical care services, consultation, and supervision described in this paragraph, and is available through direct radio or telephone communication for consultation, assistance with medical emergencies, or patient

referral. The extraordinary circumstances are documented in the records of the CAH. A site visit is not required if no patients have been treated since the latest site visit.

Interpretive Guidelines §485.631(b)(2)

An MD/DO must visit a CAH often enough to provide medical oversight for all patient services provided at the CAH in accordance with the scope of services provided.

Survey Procedures §485.631(b)(2)

- What documentation shows that an MD/DO visits the facility at least once every two weeks?
- How does the CAH ensure that an MD/DO is available by telephone or radio contact for consultation, assistance and/or patient referral?

C-0262

§485.631(c) Standard: Physician Assistant, Nurse Practitioner, and Clinical Nurse Specialist Responsibilities

---

C-0263

485.631(c)(1) The physician assistant, the nurse practitioner, or clinical nurse specialist members of the CAH'S staff--

(i) Participate in the development, execution and periodic review of the written policies governing the services the CAH furnishes; and

Survey Procedures §485.631(c)(1)(i)

- Interview any mid-level professional staff to ascertain their level of involvement in CAH policy development, execution, and periodic review.
- Does the CAH ensure that policies are updated to remain consistent with State standards of practice requirements for mid-level practitioners?

C-0264

485.631(c)(1)(ii) Participate with a doctor of medicine or osteopathy in a periodic review of the patients' health records.

Survey Procedures §485.631(c)(1)(ii)

How does the CAH ensure that mid-level practitioners at the CAH participate with an MD/DO in the review of their patients' health records?

C-0265

§485.631(c)(2) The physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathy:

(i) Provides services in accordance with the CAH'S policies.

Survey Procedures §485.631(c)(2)(i)

- Review policies and procedures.
- Interview mid-level practitioners to gauge their knowledge and application of CAH policies.

C-0267

§485.631(c)(2)(ii) Arranges for, or refers patients to, needed services that cannot be furnished at the CAH, and assures that adequate patient health records are maintained and transferred as required when patients are referred.

Survey Procedures §485.631(c)(2)(ii)

Verify that there are policies and procedures for transferring patients to other facilities.

C-0268

§485.631(c)(3) Whenever a patient is admitted to the CAH by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or osteopathy on the staff of the CAH is notified of the admission.

Interpretive Guidelines §485.631(c)(3)

The CAH regulations do permit licensed mid-level practitioners, as allowed by the State, to admit patients to a CAH. However, CMS regulations do require that Medicare and Medicaid patients be under the care of an MD/DO if admitted by a mid-level practitioner and the patient has any medical or psychiatric problem that is present on admission or develops during hospitalization that is outside the scope of practice of the admitting practitioner. Evidence of being under the care of an MD/DO must be in the patient's medical record. If a CAH allows a mid-level practitioner to admit and care for patients, as allowed by State law,

the governing body (or responsible individual) and medical staff would have to establish policies and bylaws to ensure patient safety. As applicable, the patient's medical record must demonstrate MD/DO responsibility/care.

Survey Procedures §485.631(c)(3)

- Verify that admitting privileges are limited to those categories of practitioners as allowed by State law.
- Verify that patients are admitted only by those practitioners who are currently licensed and have been granted admitting privileges by the governing body (or responsible individual) in accordance with State laws and medical staff bylaws.
- Verify that an MD/DO is responsible for and is monitoring the care of each Medicare or Medicaid patient for all medical problems during the hospitalization.
- If mid-level practitioners admit patients, verify that every Medicare/Medicaid patient is being monitored by an MD/DO who is responsible for any medical problem outside the scope of practice of the admitting practitioners.

C-0270

§485.635 Condition of Participation: Provision of Services

C-0271

§485.635(a) Standard: Patient Care Policies

(1) The CAH'S health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law.

Survey Procedures §485.635(a)(1)

- Review CAH health care services policies and sampled records.
- Observe staff delivering health care services to patients.
- What evidence indicates that patients are receiving care in accordance with written policies for health care services consistent with applicable State law?

C-0272

§485.635(a)(2) The policies are developed with the advice of a group of professional personnel that includes one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff

under the provisions of §485.631(a)(1); at least one member is not a member of the CAH staff.

Interpretive Guidelines §485.635(a)(2)

A CAH with a full time MD/DO is not required to have a mid-level practitioner on staff and would not have to obtain the services of a mid-level practitioner on a contractual or voluntary basis to participate in writing the facility's health care services policies.

Survey Procedures §485.635(a)(2)

- Review any meeting minutes to determine group composition and to ascertain the extent of the group's interactions with the CAH.
- Interview the Director of Nursing to determine the extent of his/her interactions with this group concerning policy development.

C-0273

§485.635(a)(3) The policies include the following:

(i) A description of the services the CAH furnishes directly and those furnished through agreement or arrangement.

Interpretive Guidelines §485.635(a)(3)(i)

Policies should clearly explain what types of health care services are available at the CAH and which services are furnished through agreements or arrangements. For example, statements like "taking complete medical histories, providing complete physical examinations, laboratory tests including" (with a list of tests provided) would satisfy this requirement.

Arrangement and agreements include services provided through formal contracts, joint ventures, informal agreements, or lease arrangements.

Additional services furnished through referral should be clearly described in statements such as: "arrangements have been made with Hospital X for CAH patients to receive the following services" (with a specific list of specialized diagnostic and laboratory testing, or specialized therapy).

C-0274

§485.635(a)(3)(ii) Policies and procedures for emergency medical services.

Interpretive Guidelines §485.635(a)(3)(ii)

Policies should show how the CAH would meet all of its emergency services requirements.

C-0275

§485.635(a)(3)(iii) Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the CAH.

Interpretive Guidelines §485.635(a)(3)(iii)

Guidelines for the medical management of health problems should include a description of the scope of medical acts that may be performed by the mid-level practitioners. Guidelines represent an agreement between the MD/DO providing the CAH'S medical direction and the CAH'S mid-level practitioners relative to the privileges and limits of those acts of medical diagnosis and treatment that may be undertaken with direct MD/DO supervision.

Guidelines should describe the regimens to follow and also stipulate the condition in the illness or health care management when consultation or referral is required.
Regardless of the format used by the CAH for its medical management guidelines, they should include the following essential elements:

- They should be comprehensive enough to cover most health problems that patients usually refer to a MD/DO;
- They should describe the medical procedures available to the PA, NP and/or CNS;
- They should describe the medical conditions, signs, or developments that require consultation or referral; and
- They should be compatible with State laws.

Survey Procedures §485.635(a)(3)(iii)

- What evidence demonstrates that the CAH'S guidelines for medical management of health problems accurately reflect the actual clinical capabilities of the facility?
- What evidence demonstrates that the guidelines are followed?

C-0276

§485.635(a)(3)(iv) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.

Interpretive Guidelines §485.635(a)(3)(iv)

Pharmaceutical services must be administered in accordance with accepted professional principles. Accepted professional principles include compliance with applicable Federal and State laws, regulations, and guidelines governing pharmaceutical services, as well as, standards or recommendations promoted by nationally recognized professional organizations such as the American Society of Health-System Pharmacists.

A fundamental purpose of pharmaceutical services is to ensure the safe and appropriate use of medications and medication-related devices. The pharmacy director, with input from appropriate CAH staff and committees, develops, implements and periodically reviews and revises policies and procedures governing provision of pharmaceutical services.

Methods a CAH uses to maintain professional principles include:

- Policies and procedures have been developed and are being followed;
- Drugs and biologicals are stored in accordance with manufacturer's directions and State and Federal requirements;
- Employees provide pharmaceutical services within their scope of license and education;
- Pharmacy records have sufficient detail to follow the flow of pharmaceuticals from their entry into the CAH through dispensation/administration;
- The pharmacy maintains controls over drugs and medications in all CAH locations, including floor stock;
- Maintaining pharmacy and accounting records pertaining to the requisitioning and dispensing of drugs and pharmaceutical supplies;
- Ensuring that drugs are being dispensed only by a licensed pharmacist; and
- Only pharmacists or pharmacy-supervised personnel compound, label and dispense drugs or biologicals.

Pharmaceutical services at a CAH can be provided either as direct services or through an agreement. The direction of pharmaceutical services may not require continuous on-premise supervision at the CAH'S pharmacy but may be accomplished through regularly scheduled visits, and/or telemedicine in accordance with Federal and State law and regulation and accepted professional principles.

A single pharmacist must be responsible for the overall administration of the pharmacy service whether employed by the CAH or obtained through agreement. The pharmacist must be responsible for developing, supervising, and coordinating all the activities of the CAH-wide pharmacy service and must be thoroughly knowledgeable about CAH pharmacy practice and management.

The job description or the written agreement for the responsibilities of the pharmacist should be clearly defined and include development, supervision and coordination of all the activities of pharmacy services.

Pharmacists and pharmacy technicians must perform their duties within the scope of their license and education. There must be sufficient personnel to respond to the pharmaceutical needs of the patient population being served. The pharmaceutical services staff must be sufficient in types, numbers, and training to provide quality services, including 24 hour, 7-day emergency coverage, or there may be an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff.

There must be sufficient numbers and types of personnel to provide accurate and timely medication delivery, ensure accurate and safe medication administration and to provide appropriate clinical services as well as the participation in continuous quality improvement programs that meet the needs of the patient population being served.

The CAH must have a system that ensures that medication orders get to the pharmacy and drugs get back to patients promptly.

Record System

Components of a record system to maintain current and accurate records of the receipt and disposition of scheduled drugs would include:

- Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs.
- Records of the receipt and disposition of all scheduled drugs must be current and must be accurate.
- Records trace the movement of scheduled drugs throughout the service.

The pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled.

The record system, delineated in policies and procedures, tracks movement of all scheduled drugs from the point of entry into the CAH to the point of departure either through administration to the patient, destruction of the drug, or return to the manufacturer. This system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

The CAH system should be capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual losses or diversion to the time of detection and determination of the extent of loss or diversion.

Facility policies and procedures should minimize scheduled drug diversion.

Receipt and Distribution of Drugs

Drugs and biologicals must be controlled and distributed in accordance with applicable Federal and State laws and regulations, and in accordance with applicable standards of practice. Applicable standards of practice include compliance with all Federal and State laws, regulations, and guidelines, as well as, standards and recommendations promoted by nationally recognized professional organizations, that apply to pharmaceutical safety and the control and distribution of drugs and biologicals.

The procedures established to prevent unauthorized usage and distribution must provide for an accounting of the receipt and disposition of drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970.

The pharmacist, in consultation with appropriate CAH staff and committees, is to develop and implement guidelines, protocols, policies and procedures for the provision of pharmaceutical services that ensure patient safety through the appropriate control and distribution of medications, medication-related devices, and biologicals.

All prescribers' medication orders (except in emergency situations) should be reviewed for appropriateness by a pharmacist before the first dose is dispensed.

Appropriate monitoring of medication therapy should be conducted. Medication-therapy monitoring includes an assessment of:

- Therapeutic appropriateness of a patient's medication regimen;
- Therapeutic duplication in the patient's medication regimen;
- Appropriateness of the route and method of administration;

- Medication-medication, medication-food, medication-laboratory test and medication-disease interactions;
- Clinical and laboratory data to evaluate the efficacy of medication therapy to anticipate or evaluate toxicity and adverse effects; and
- Physical signs and clinical symptoms relevant to the patient's medication therapy.

Sterile products should be prepared and labeled in a suitable environment by appropriately trained and qualified personnel.

The pharmacy should participate in CAH decisions about emergency medication kits. The supply and provision of emergency medications stored in the kits must be consistent with standards of practice and appropriate for a specified age group or disease treatment as well as consistent with applicable Federal and State laws.

The pharmacy should be involved in the evaluation, use and monitoring of drug delivery systems, administration devices and automated drug-dispensing machines. The evaluation and monitoring should include the potential for medication errors.

Dispensation of Drugs

Medications must be prepared safely. Safe preparation procedures could include:

- Only the pharmacy compounds or admixes all sterile medications, intravenous admixtures, or other drugs except in emergencies or when not feasible (for example, when the product's stability is short).
- Whenever medications are prepared, staff uses safety materials and equipment while preparing hazardous medications.
- Wherever medications are prepared, staff uses techniques to ensure accuracy in medication preparation.
- Whenever medications are prepared, staff uses appropriate techniques to avoid contamination during medication preparation, which include, but are not limited, to the following:
    - Using clean or sterile technique as appropriate;
    - Maintaining clean, uncluttered, and functionally separate areas for product preparation to minimize the possibility of contamination;
    - Using a laminar airflow hood or other appropriate environment while preparing any intravenous (IV) admixture in the pharmacy, any sterile product

made from non-sterile ingredients, or any sterile product that will not be used with 24 hours; and

- Visually inspecting the integrity of the medications.

Drug Storage

All drugs and biologicals must be kept in a locked room or container. If the container is mobile or readily portable, when not in use, it must be stored in a locked room, monitored location, or secured location that will ensure the security of the drugs or biologicals.

All drugs and biologicals must be stored in a manner to prevent access by unauthorized individuals. Persons without legal access to drugs and biologicals cannot have unmonitored access to drugs or biologicals.

Persons without legal access to drugs or biologicals cannot have keys to medication storage rooms, carts, cabinets, or containers. Whenever persons without legal access to the drugs or biologicals have unmonitored access to or could gain access to the drugs or biologicals stored in an area, the CAH would not be considered as in compliance with the requirement to store all drugs and biologicals in a locked storage area.

Nursing Medication Carts, Anesthesia Carts, and Other Medication Carts

When not in use, nursing medication carts, anesthesia carts, and other medication carts (hereafter referred to as "carts") containing drugs or biologicals must be locked or stored in a locked storage room. When carts are not in use, locked carts that contain drugs or biologicals must be stored in a locked room, monitored area, or secure location. If a cart containing drugs or biologicals is in use and unlocked, someone with legal access to the drugs and biologicals in the cart must be close by and directly monitoring the cart. That person could be a nurse, a physician, or other individual who in accordance with state and Federal law and CAH policy has legal access to the drugs and biologicals in the cart. That person must monitor the cart and be aware of other people's activities near the cart. He/she is responsible for the security of the drugs and biologicals in the cart.

System for Labeling and Management of Outdated Drugs

The CAH must have a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable drugs and biologicals are not available for patient use.

Survey Procedures §485.635(a)(3)(iv)

- Interview the chief pharmacist or the individual delegated to fulfill the chief pharmacist's functions. Determine that either the medical staff has developed policies and procedures regarding the management of pharmaceuticals or that this function is fulfilled by the pharmacy service.

- Is the staff familiar with the medication-related policies and procedures?
- Is there a method to periodically review and evaluate the actual implementation of pharmaceutical policies and procedures by staff?
- Upon review of patient clinical record are issues with regard to provision of pharmaceutical services identified? Is the facility aware of the issues? Was there a failure to implement a policy and procedure?
- Determine whether the pharmacist is a full-time or part-time employee or employed on a consultative basis.
- Review the implementation of the chief pharmacist's responsibilities by:
    - Reviewing written status reports;
    - Reviewing minutes of meetings (if any) with facility staff regarding pharmaceutical services;
    - Reviewing schedules, time logs, etc.; and
    - Reviewing the job description or the written agreement to see that the responsibilities of the pharmacist are clearly defined and include development, supervision, and coordination of all the activities of pharmacy services.
- Determine whether the pharmacy director is actively involved in those committees responsible for establishing medication-related policies and procedures.
- Determine that the pharmaceutical services staff is sufficient in number and training to provide quality services, including 24 hour, 7-day emergency coverage, or there is an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff. Review any agreements.
- Determine if there are sufficient personnel to provide accurate and timely medication delivery, ensure accurate and safe medication administration and to provide appropriate clinical services as well as the participation in continuous quality improvement programs that meet the needs of the patient population being served.
- Determine if there is a record system in place that provides information on controlled substances in a readily retrievable manner.
- Determine that the pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled.

- Determine if there is a system, delineated in policies and procedures, that tracks movement of all scheduled drugs from the point of entry into the CAH to the point of departure either through administration to the patient, destruction of the drug, or return to the manufacture. Determine if this system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

- Review the records to determine that they trace the movement of scheduled drugs throughout the service.

- Determine if the pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and periodically reconciled.

- Is the CAH system capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual losses or diversion to the time of detection and determination of the extent of loss or diversion?

- Determine if facility policy and procedures minimize scheduled drug diversion.

- Is access to concentrated solutions (e.g. potassium chloride, sodium chloride Solutions greater than 0.9%) restricted?

- Identify and assess the quality assurance procedures for the preparation of sterile products.

- Is appropriate monitoring of medication therapy being conducted?

- Is the pharmacy involved in the evaluation, use and monitoring of drug delivery systems, administration devices and automated drug dispensing machines? The evaluation and monitoring should include the potential for medication errors.

- Review the procedures established to prevent unauthorized usage and distribution. These procedures must provide for an accounting of the receipt and disposition of drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970.

- Determine that only pharmacists or pharmacy supervised personnel compound, label and dispense drugs or biologicals in accordance with State and Federal laws and regulations and as accepted national principles by:

    - Reviewing policies and procedures;

    - Interviewing pharmacy and CAH staff to determine how drugs and biologicals are dispensed;

  - Observing on-site dispensing operations;
  - Reviewing records of drugs and biologicals removed from the pharmacy by non-pharmacy personnel; and
  - Inspecting drug storage areas.

- Verify through interviews of pharmacy and CAH staff, observation of on-site dispensing operations and review of pharmacy records that compounding, dispensing and packaging of drugs and biologicals are performed under the supervision of a pharmacist, in accordance with applicable laws.
- Determine that there is a policy for the safeguarding, transferring and availability of keys to the locked storage area.
- Determine by inspection whether all medications are stored in a manner that prevents unauthorized access.
- Determine if the facility identifies what personnel may have access to medications.
- Spot-check the labels of individual drug containers to verify that they conform to State laws, and/or contain the following minimal information:
  - Each patient's individual drug container bears his/her full name, the prescriber's name, and strength and quantity of the drug dispensed. Appropriate accessory and cautionary statements are included as well as the expiration date.
  - Each floor stock container bears the name and strength of the drug, lot and control number of equivalent, and expiration date.
- If the unit dose system is utilized, verify that each single unit dose package bears name and strength of the drug, lot and control number equivalent, and expiration date.
- Inspect patient-specific and floor stock medications to identify expired, mislabeled or unusable medications.
- Determine through pharmacy records that when the pharmacist is not available, drugs are removed from the pharmacy (drug storage area) only by a designated individual (in accordance with State law if applicable) and only in amounts sufficient for immediate therapeutic needs.
- Review policies and procedures to determine who is designated to remove drugs and biologicals from the pharmacy or storage area and the amount a non-pharmacist may remove in the absence of a pharmacist. The individual(s) designated should be identified by name and qualifications.

- Determine that a system is in place that accurately documents the removal of medications (type and quantity) from either the pharmacy or the after hours supply.
- Determine that the pharmacist reviews all medication removal activity and correlates the removal with current medication orders in the patient medication profile.
- Determine if the pharmacist routinely reviews the contents of the after-hours supply to determine if it is adequate to meet the after-hours needs of the CAH.
- Conduct a spot check of drug use and other inventory records to ensure that drugs are properly accounted for.
- Review reports of pharmaceutical services to determine if there are reported problems with controlled drugs and what actions have been taken to correct the situation.
- Interview the Pharmacy Director, pharmacist and pharmacy employees to determine their understanding of the controlled drug policies. Is there a policy and procedure for handling controlled drug discrepancies?
- Determine if controlled drug losses were reported to appropriate authorities in accordance with State and Federal laws.

C-0277

§485.635(a)(3)(v) Procedures for reporting adverse drug reactions and errors in the administration of drugs.

Interpretive Guidelines §485.635(a)(3)(v)

Written procedures should require that medication errors and adverse drug reactions be reported immediately to the practitioner who ordered the drug. An entry, including the medication administered and the drug reaction, should be entered into the patient's medical record. Unexpected or significant adverse drug reactions should also be reported to the Food and Drug Administration in accordance with the MedWatch program. There must be a process to report serious adverse drug reactions to the FDA in accordance with the MedWatch program.

It is important to flag new types of mistakes as they occur and create systems to prevent their recurrences. The system should work through those mistakes and continually improve and refine things, based on what went wrong.

Reduction of medication errors and adverse reactions can be achieved by effective reporting systems that proactively identify causative factors and are used to implement corrective actions to reduce or prevent reoccurrences. To facilitate reporting, the facility should adopt a

medication error and adverse drug reaction (ADR) definition that is broad enough in scope to capture "near misses" and suspected ADRs as well as actual medication errors and ADRs.

For high risk medications and high-risk patients (pediatric, geriatric or patients with renal or hepatic impairment) there should be systems in place to minimize adverse drug events. Such systems could include but not limited to: checklists, dose limits, pre-printed orders, special packaging, special labeling, double-checks and written guidelines.

One example of a definition is the National Coordinating Council Medication Error Reporting and Prevention definition of a medication error.

> "Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."

In addition to broad scope definitions, the facility must also proactively identify medication errors and adverse drug reactions. Reliance solely on incident reporting fails to identify the majority of adverse drug events. Proactive identification includes observation of medications passes, concurrent and retrospective review of patient's clinical records, ADR surveillance team, implementation of medication usage evaluations for high-alert drugs and identification of indicator drugs or "patient signals" that, when ordered, or noted automatically generate a drug regimen review for a potential adverse drug event.

The facility must have a method by which to measure the effectiveness of its reporting system so as to identify whether or not its system(s) is identifying as many medication errors and adverse drug reactions that would be expected for the size and scope of services provided by their CAH. Such methods could include use of established benchmarks or studies on reporting rates published in peer-reviewed journals.

To improve incident reporting the facility should adopt a non-punitive system with the focus on the system and not the involved health care professionals.

The facility should have immediately available sufficient texts and other resources on drug therapy. The pharmacist also should be readily available by telephone or other means to discuss drug therapy, interactions, side effects, dosage etc., with practitioners to assist in drug selection and with nursing personnel to assist in the identification of drug-induced problems.

The CAH should have policies and procedures to actively identify potential and actual adverse drug events. Proactive identification could include:

- Direct observation of medication administration;

- Review of patient's clinical records; and

- Identification of patient signals that would warrant immediate review of patient's medication therapy and implementation of medication use evaluation studies.

The CAH should have a means to incorporate external alerts and/or recommendations from national associations and governmental agencies for review and facility policy and procedure revision consideration. National associations could include Institute for Safe Medications Practice, National Coordination Council for Medication Error Reporting and Prevention and Joint Commission for Accreditation of Health Care Facilities, Sentinel Event Reports. Governmental agencies may include; Food and Drug Administration, Med Watch Program, and Agency for Health Care Research and Quality.

Provision of pharmaceutical services must meet the needs of the patients' therapeutic goal by promoting a safe medication use process that ensures optimal selection of medications, dose, dosage form, frequency, route, duration of therapy and that substantially reduces or eliminates adverse drug events and duplication of treatment.

The CAH pharmacy must ensure that drug orders are accurate and that medications are administered as ordered. When medications are returned unused, the pharmacy should determine the reason the medication was not used. For example, did the patient refuse the medication, was there a clinical reason the medication was not used, was the medication not used due to error?

Policies and procedures to minimize drug errors should include:

- High-alert medications with dosing limits, administration guidelines, packaging, labeling and storage;

- Limiting the variety of medication-related devices and equipment. For example, limit the types of general-purpose infusion pumps to one or two;

- Availability of up-to-date medication information;

- Availability of pharmacy expertise such as having a pharmacist available on-call when pharmacy does not operate 24 hours a day;

- Standardization of prescribing and communication practices;

- Avoidance of certain abbreviations;

- All elements of the order such as dose, strength, units (metric), route, frequency, and rate;

- Alert systems for look-alike and sound-alike drug names;

- Use of facility approved pre-printed order sheets whenever possible;
- A voluntary, non-punitive, reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions);
- The preparation, distribution, administration and proper disposal of hazardous medications;
- Medication recalls;
- Policies and procedures are reviewed and amended secondary to facility-generated reports of adverse drug events.

Survey Procedures §485.635(a)(3)(v)

- Examine the sources of drug information available at the nursing station and/or drug storage area and determine if they are current.
- Determine whether staff development programs on drug therapy are available to facility staff to cover such topics as new drugs added to the formulary, how to resolve drug therapy problems, and other general information as the need arises.
- Review the pharmaceutical policies and procedures, the CAH'S formulary and, if there is a pharmacy and therapeutic committee, the minutes of the committee meetings.
- Verify that the purpose of pharmaceutical policies and procedures is to minimize drug errors.
- Are there policies and procedures to minimize drug errors?
- Are policies and procedures reviewed and amended secondary to facility-generated reports of adverse drug events?
- Determine that the CAH has an effective procedure that ensures drug administration errors, adverse drug reactions, and drug incompatibilities are immediately reported to the attending physician.
- Review records of medication errors and adverse drug reactions to determine that they are reported immediately in accordance with written procedures, and that medications administered and/or drug reactions are promptly recorded in the patient's medical record.
- Determine if the facility's definition of an adverse drug reaction and medication error will generate sufficient number of reports.

- Review QA activities for medication errors and adverse reaction reports to determine if upon analyses of the reports that potential corrective actions are identified and implemented, if appropriate.

- Determine if the number of medication errors and adverse drug reactions reported is consistent with the size and scope of services provided by the CAH.

- Interview facility staff (nursing, pharmacy and medicine) to ascertain awareness of the facilities policy on reporting and documentation of medication errors and adverse drug reactions.

- Is there a process to report serious adverse drug reactions to the Federal MedWatch program?

C-0278

§485.635(a)(3)(vi) A system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel.

Interpretive Guidelines §485.635(a)(3)(vi)

The CAH must have an active surveillance program that includes specific measures for prevention, early detection, control, education, and investigation of infections and communicable diseases in the CAH. There must be a mechanism to evaluate the effectiveness of the program and to provide corrective action when necessary. The program must include implementation of nationally recognized systems of infection control guidelines to avoid sources and transmission of infections and communicable diseases as recommended by organizations such as the Centers for Disease Control and Prevention (CDC) Guidelines for Prevention and Control of Nosocomial Infections, the CDC Guidelines for Preventing the Transmission of Tuberculosis in Health Care Facilities, the Occupational Health and Safety Administration (OSHA) regulations, and the Association for Professionals in Infection Control and Epidemiology (APIC) infection control guidelines, etc.).

The active infection control program should have policies that address the following:

- Definition of nosocomial infections and communicable diseases;

- Measures for identifying, investigating, and reporting nosocomial infections and communicable diseases;

- Measures for assessing and identifying patients and health care workers, including CAH personnel, contract staff (e.g., agency nurses, housekeeping staff),and volunteers, at risk for infections and communicable diseases;

- Methods for obtaining reports of infections and communicable diseases on inpatients and health care workers, including all CAH personnel, contract such as agency nurses, housekeeping staff, and volunteers, in a timely manner;

- Measures for the prevention of infections, especially infections caused by organisms that are antibiotic resistant or in other ways epidemiologically important; device-related infections (e.g., those associated with intravascular devices, ventilators, tube feeding, indwelling urinary catheters, etc.); surgical site infections; and those infections associated with tracheostomy care, respiratory therapy, burns, immunosuppressed patients, and other factors which compromise a patient's resistance to infection;

- Measures for prevention of communicable disease outbreaks, especially tuberculosis;

- Provision of a safe environment consistent with nationally recognized infection control precautions, such as the current CDC recommendations for the identified infection and/or communicable disease;

- Isolation procedures and requirements for infected or immunosuppressed patients;

- Use and techniques for standard precautions;

- Education of patients, family members and caregivers about infections and communicable diseases;

- Methods for monitoring and evaluating practices of asepsis;

- Techniques for hand washing, respiratory protections, asepsis, sterilization, disinfection, food sanitation, housekeeping, fabric care, liquid and solid waste disposal, needle disposal, separation of clean from dirty, as well as other means for limiting the spread of contagion;

- Authority and indications for obtaining microbiological cultures from patients;

- A requirement that disinfectants, antiseptics, and germicides be used in accordance with the manufacturers' instructions to avoid harming patients, particularly central nervous system effects on children;

- Orientation of all new CAH personnel to infections, communicable diseases, and to the infection control program;

- Measures for the screening and evaluation of health care workers, including all CAH staff, contract workers such as agency nurses, housekeeping staff, and volunteers, for communicable diseases, and for the evaluation of staff and volunteers exposed to patients with non-treated communicable diseases;

- Employee health policies regarding infectious diseases and when infected or ill employees, including contract workers and volunteers, must not render patient care and/or must not report to work;

- A procedure for meeting the reporting requirements of the local health authority;

- Procedures for working with local, State, and Federal health authorities in emergency preparedness situations;

- Policies and procedures developed in coordination with Federal, State, and local emergency preparedness and health authorities to address communicable disease threats and outbreaks; and

- Provision for program evaluation and revision of the program, when indicated.

Designated Infection Control Officer

The CAH must designate in writing an individual or group of individuals, qualified through education, training, experience, and certification or licensure, as an infection control officer or officers.

An infection control committee may delegate responsibility for infection functions, in accordance with CAH policy.

The infection control officer or officers must develop and implement policies governing the control of infections and communicable diseases.

The infection control officer(s) is responsible for:

- Implementing policies governing asepsis and infection control;

- Developing a system for identifying, investigating, reporting, and preventing the spread of infections and communicable diseases among patients and CAH personnel, including contract staff and volunteers;

- Identifying, investigating and reporting infections and outbreaks of communicable diseases among patients and CAH personnel, including contract staff and volunteers, especially those occurring in clusters;

- Preventing and controlling the spread of infections and communicable diseases among patients and staff;

- Cooperating with CAH-wide orientation and inservice education programs;

- Cooperating with other departments and services in the performance of quality assurance activities; and

- Cooperating with disease control activities of the local health authority.

It is recommended that the infection control officer or officers maintain a log of all incidents related to infections and communicable diseases, including those identified through employee health services. The log is not limited to nosocomial infections. All incidents of infection and communicable disease should be included in the log. The log documents infections and communicable diseases of patients and all staff (patient care, non patient care, employees, contract staff and volunteers).

The chief executive officer (CEO), the medical staff and the director of nursing (DON) must ensure that the CAH-wide Quality Assurance (QA) program and staff inservice training programs address problems identified through the infection control program.

The CEO, the medical staff, and the DON are responsible for implementing corrective action plans to address problems identified by the infection control officer(s). These plans should be evaluated for effectiveness and revised if needed, and documentation concerning corrective actions and outcomes should be maintained.

Survey Procedures §485.635(a)(3)(vi)

- Verify that there is a system (policies) for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and CAH personnel, including contract workers and volunteers.

- Determine that this system is an active program, that it is both CAH-wide and program-specific, and that it is implemented correctly.

- Throughout the CAH, observe the environment of care, noting the cleanliness of horizontal surfaces, bedside equipment, and air inlets, etc, because infectious organisms may spread from these places.

- Verify that an infection control officer (or officers) is designated and has the responsibility for the infection control program.

- Review the personnel file of the infection control officer(s) to verify that he/she is qualified through education, training, experience, and certification or licensure to oversee the infection control program.

- Verify that appropriate policies and procedures have been developed and implemented governing the control of infections and communicable diseases.

- Determine that the infection control officer(s) is responsible for the elements specified in the interpretive guidelines.

- Verify that the infection control officer(s) maintains a log of all incidents related to infections and communicable diseases, including those identified through employee health services.

- Determine that the CAH'S QA program and staff inservice training programs address problems identified by the infection control officer(s).

- Determine that problems identified are reported to the medical staff, nursing, and administration, and addressed in the CAH'S quality assurance and inservice training programs.

C-0279

§485.635(a)(3)(vii) If the CAH furnishes inpatient services, procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of §483.25(i) is met with respect to inpatients receiving post CAH SNF care.

Interpretive Guidelines §485.635(a)(3)(vii)

A CAH is not required to prepare meals itself and is free to obtain meals under contract with another supplier, but the CAH is responsible for the quality of arranged services on the same basis as if CAH employees had provided those services.

The food and dietetic services must be organized, directed and staffed in such a manner to ensure that the nutritional needs of the patients are met in accordance with practitioners' orders and recognized dietary practices.

Policies and Procedures for Dietary Services

The CAH should have written policies and procedures that address at least the following:

- Availability of a diet manual and therapeutic diet menus to meet patients' nutritional needs;

- Frequency of meals served;

- System for diet ordering and patient tray delivery;

- Accommodation of non-routine occurrences such as enteral nutrition (tube feeding), total parenteral nutrition, peripheral parenteral nutrition, change in diet orders, early/late trays, nutritional supplements, etc.;

- Integration of the food and dietetic service into the CAH-wide QA and Infection Control programs;

- Guidelines for acceptable hygiene practices of food service personnel; and
- Guidelines for kitchen sanitation.

Compliance with Recognized Dietary Practices

The CAH must be in compliance with Federal and State licensure requirements for food and dietary personnel as well as food service standards, laws and regulations.

Director of Food and Dietetic Services

The CAH must have an employee (either on staff or contracted) who–

- Serves as director of the food and dietetic services;
- Is responsible for daily management of the dietary services; and
- Is qualified by experience or training.

The service director must be either an employee on staff or under contract, who has been granted the authority and delegated responsibility by the CAH'S governing body and medical staff for the operation of the dietary services. This authority and delegated responsibility includes the daily management of the service, implementing training programs for dietary staff, and assuring that established policies and procedures are maintained that address at least the following:

- Safety practices for food handling;
- Emergency food supplies;
- Orientation, work assignments, supervision of work and personnel performance;
- Menu planning, purchasing of foods and supplies, and retention of essential records such as cost, menus, personnel, training records, QA reports, etc.; and
- Dietary service QA program.

Additionally, the service director must demonstrate, through education, experience and/or specialized training, the qualifications necessary to manage the service, appropriate to the scope and complexity of the food service operation.

Qualified Dietitian

A qualified dietitian must supervise the nutritional aspects of patient care. The dietitian can be part of the CAH staff or work under contract (may be full or part time) and is responsible

for all inpatient nutrition including swing bed services. The dietitian must be licensed if required by State law. The dietitian's responsibilities include, but are not limited to:

- Approving patient menus and nutritional supplements;
- Patient, family, and caretaker dietary counseling;
- Performing and documenting nutritional assessments and evaluating patient tolerance to therapeutic diets when appropriate;
- Collaborating with other CAH services (e.g., medical staff, nursing services, pharmacy service, social work service, etc.) to plan and implement patient care as necessary in meeting the nutritional needs of the patients; and
- Maintaining pertinent patient data necessary to recommend, prescribe, or modify therapeutic diets as needed to meet the nutritional needs of the patients.

If the qualified dietitian does not work full-time, and when the dietitian is not available, the CAH must make adequate provisions for dietary consultation that meets the needs of the patients. The frequency of consultation depends on the total number of patients, their nutritional needs and the number of patients requiring therapeutic diets or other nutritional supplementation.

Dietary Support Staff

There must be administrative and technical personnel competent in their respective duties.

This competency is demonstrated through education, experience and specialized training appropriate to the task(s) assigned. Personnel files should include documentation that each staff member is competent in their respective duties.

Recognized Dietary Practices

Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioner responsible for the care of the patients.

Recognized dietary practices include following current national standards for recommended dietary allowances such as the current Recommended Dietary Allowances (RDA) or the Dietary Reference Intake (DRI) of the Food and Nutrition Board of the National Research Council.

Menus provided by the CAH must be nutritionally balanced and meet the needs of the patients. In order to ensure that the CAH is meeting the nutritional needs of its patients, screening criteria should be developed to identify patients at nutritional risk. If a patient is identified as an altered nutritional status, a nutritional assessment should be performed on the patient. In addition to the initial nutritional assessment, the patient should be re-evaluated as

necessary to ensure their ongoing nutritional needs are met. Examples of patients who may require a nutritional assessment include:

- All patients requiring artificial nutrition by any means (i.e., enteral nutrition (tube feeding), total parenteral nutrition, or peripheral parenteral nutrition);
- Patients whose medical condition, surgical intervention, or physical status interferes with their ability to ingest, digest or absorb nutrients;
- Patients whose diagnosis or presenting signs/symptoms indicates a compromised nutritional status (e.g., anorexia nervosa, bulimia, electrolyte imbalances, dysphagia, malabsorption, end stage organ diseases, etc.); and
- Patients whose medical condition can be adversely affected by their nutritional intake (e.g., diabetes, congestive heart failure, patients taking certain medications, renal diseases, etc.).

Therapeutic diets must be prescribed by the practitioner responsible for the care of the patient. Therapeutic diets should be:

- Prescribed in writing by a qualified practitioner or a qualified dietitian;
- Documented in the patient's medical record including information about the patient's tolerance to the therapeutic diet as ordered; and
- Evaluated for nutritional adequacy.

A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.

Survey Procedures §485.635(a)(3)(vii)

- Review CAH personnel files to determine that staff is qualified based on education, experience, specialized training, and, if required by State law, is licensed, certified, or registered by the State.
- If the dietitian is part-time, determine that the number of hours spent working is appropriate to serve the nutritional needs of the patients, and that the CAH makes adequate provisions for qualified consultant coverage when the dietitian is not available.
- Review personnel files for administrative and technical staff to determine if they have appropriate credentials as required and have received adequate training and are competent in their respective duties.

- Ask the CAH to show you what national standard they are following in its menus to meet the nutritional needs of their patients.
- Review patient records to verify that diet orders are provided as prescribed by the practitioner responsible for the care of the patient.
- From the sample patient records, identify patients with special nutritional needs to determine:
    - If their nutritional needs have been met;
    - If appropriate therapeutic diets have been ordered; and
    - If their dietary intake and nutritional status is being monitored, as appropriate.
- Verify that therapeutic diet orders are prescribed and authenticated by the practitioner(s) responsible for the care of the patient.
- Determine that the therapeutic diet manual is current and:
    - Has been approved by both the medical staff and a qualified dietitian;
    - Is readily available to MD/DOs, nursing and food service personnel;
    - Is in accordance with the current national standards, such as RDA or DRI;
    - Includes the different types of therapeutic diets routinely ordered at the CAH; and
    - Is consistently used as guidance for ordering and preparing patient diets.

C-0280

§485.635(a)(4) These policies are reviewed at least annually by the group of professional personnel required under paragraph (a)(2) of this section, and reviewed as necessary by the CAH.

Survey Procedures §485.635(a)(4)

Review the meeting notes and policy and procedure books to verify that the patient care policies are reviewed on an annual basis by the professional group

C-0281

§485.635(b) Standard: Direct Services

(1) General. The CAH staff furnishes, as direct services, those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity CAH outpatient department or emergency department. These direct services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.

Interpretive Guidelines §485.635(b)

The CAH must provide outpatient and emergency room services as direct services at the CAH campus through the use of CAH personnel. The CAH can choose the level of services to be offered. They may offer only the basic services required by this CoP and State law or they may offer a more complex range of services. However, all the outpatient and emergency services offered must be provided at the CAH campus as direct services.

Outpatient Services are a required direct service of the CAH. All outpatient services that the CAH provides to its patients must meet the needs of the patients, in accordance with acceptable standards of practice. The CAH must provide adequate services, equipment, staff, and facilities adequate to provide the outpatient services for the scope of practices appropriate to the scope and complexity of services offered. The outpatient services may be offered at specific times. The CAH is not required to offer outpatient services 24/7 except for emergency room services.

Acceptable standards of practice include standards that are set forth in Federal or State laws, regulations or guidelines, as well as standards and recommendations promoted by nationally recognized professional organizations such as the American Medical Association, American College of Radiology, American College of Surgeons, etc.

The CAH'S outpatient services must be integrated with inpatient services (e.g., medical records, radiology, laboratory, surgical services, anesthesia services, other diagnostic services, etc), as appropriate to the outpatient services offered. The CAH must have written policies in place to ensure the integration of outpatient services, including an established method of communication between outpatient service departments to corresponding inpatient services.

The outpatient services department must be accountable to a single individual who directs the overall operation of the department. The CAH should define in writing the qualifications and competencies necessary to direct the outpatient services. Qualifications include, necessary education, experience and specialized training, consistent with State law, and acceptable standards of practice.

Adequate types and numbers of qualified professional and nonprofessional personnel must be available to provide patients with the appropriate level of care and services offered by the CAH'S outpatient department. The types and numbers of qualified personnel are based on the scope and complexity of outpatient services offered and the number and types of patients treated as outpatients.

Rehabilitation Services

Rehabilitation services are optional CAH services and can include physical therapy, occupational therapy, audiology, and/or speech pathology services. If a CAH provides any degree of rehabilitative services to its patients, either directly or under arrangement, either inpatient or outpatient, the services must be organized and staffed to ensure the health and safety of patients. This includes providing rehabilitative services in accordance with practitioner orders and acceptable standards of practice.

Acceptable standards of practice include any standards that are set forth in Federal or State laws, regulations or guidelines, as well as standards and recommendations promoted by nationally recognized professional organizations such as the American Physical Therapy Association, American Speech and Hearing Association, American Occupational Therapy Association, American College of Physicians, and the American Medical Association etc.

If rehabilitative services are provided, the CAH must provide, or ensure, the appropriate equipment and types and numbers of qualified personnel necessary to furnish the rehabilitation services offered by the CAH in accordance with acceptable standards of practice.

The scope of rehabilitation services offered by the CAH, both directly or under contract, should be defined in written policies and procedures and approved by the Medical staff. Each service, whether provided directly or through a contract, must function with established lines of authority and responsibility to ensure the health and safety of patients. There must be an adequate number of qualified staff available when needed to evaluate each patient, initiate the plan of treatment, and supervise supportive personnel when they furnish rehabilitation services. The number of qualified staff is based on the type of patients treated and the frequency, duration, and complexity of the treatment required.

The rehabilitation service must be accountable to an individual that directs the overall operation of the service. The director of the services must demonstrate through education, experience, and/or specialized training that he/she has the necessary knowledge, experience and capabilities to properly supervise and administer the service. The director may be part-time, full-time, and/or under contract. If part-time, the time spent directing the service should be appropriate with the scope of services provided.

The medical staff must define in writing the required qualifications and competencies for rehabilitation staff in each program or service offered. Qualifications should include the necessary education, experience, specialized training, and if applicable, licensure requirements appropriate for assigned responsibilities consistent with State law.

At least one qualified professional, of the applicable discipline, must be on site when needed to:

- Perform an initial evaluation of each patient for whom rehabilitative services were ordered;
- Initiate the plan of treatment based on the initial evaluation, input from family/caregivers and in accordance with the orders of the practitioner responsible for the care of the patient; and
- Supervise supportive personnel when they furnish services.

Each patient must have an individualized plan of treatment, based on the patient's specific rehabilitation needs, input from family/caregivers and therapeutic treatment goals, that are established in writing prior to the initiation of treatment. At a minimum, the treatment plan must:

- Be established by the practitioner ordering the service in collaboration with an individual qualified to provide the services;
- Be based on the patient's individualized assessment;
- Include the type, amount, frequency and duration of services;
- Include measurable short-term and long-term goals;
- Incorporate patient, family and caregiver goals; and
- Be reviewed and revised as necessary reflect changes in the patient's response to therapeutic intervention. Updated treatment goals should reflect the changes in the patient's status.

Changes to the treatment plan must be documented in writing and supported by clinical record information such as evaluation, test results, interdisciplinary staff conferences or MD/DO orders.

The activities described in the written plan of treatment must be within the scope of practice, State licensure, or certifications of the individual performing the activity.

Survey Procedures §485.635(b)(1)

- Determine the types of outpatient services provided.
- Verify that equipment, staff and facilities are adequate to provide the outpatient services and are in accordance with acceptable standards of practice.

- Verify that the outpatient services are organized in a manner appropriate to the scope and complexity of services offered.
- Verify that the CAH has an established method of communication and established procedures to assure integration with inpatient services to provide continuity of care.
- Review medical records of outpatients who were later admitted to the CAH in order to determine that pertinent information from the outpatient record has been included in the inpatient record.
- Determine that the outpatient services are integrated with the appropriate CAH inpatient services in accordance with the needs of the patient care provided.
- Verify that one person is assigned by the governing body (or responsible individual) to manage and be responsible for outpatient services.
- Review the position description and personnel file of the individual responsible for the outpatient services to ensure that he/she meets the qualifications, in accordance with State law, acceptable standards of practice and CAH policy.
- Review personnel files to verify that the staff qualifications, including education, experience, certifications, current licensure, where appropriate, and competencies are appropriate for assigned responsibilities.
- Verify that sufficient staff are available to provide care.
- Verify that the types and number of qualified personnel are appropriate for the types and numbers of patients receiving care and the complexity of services offered.
- Determine if the CAH provides any degree of rehabilitation services.
- Review the CAH'S policies and procedures to verify that the scope of rehabilitation services offered, either directly or under contract, is defined in writing.
- Review personnel files or contracts to verify current licensure, certifications and training of staff consistent with applicable State laws.
- Determine that adequate types and numbers of qualified staff are available to ensure safe and efficient provision of treatment.
- Review medical records to verify that a qualified professional evaluates the patient and initiates the treatment under medical orders and direction for each episode.

- Verify that each patient has a plan of treatment established in writing and that the plan is established by the practitioner ordering the service and is documented in the patient record along with treatment outcomes achieved.

- If the director of the service does not work full-time, determine that the number of hours spent working is appropriate to the scope of services provided.

- Interview the director to determine if he/she has the necessary knowledge, experience and capabilities to properly supervise and administer the service.

C-0282

§485.635(b)(2) Laboratory Services

The CAH provides, as direct services, basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). (See the laboratory requirements specified in part 493 of this chapter.) The services provided include:

(i) Chemical examination of urine by stick or tablet method or both (including urine ketones);

(ii) Hemoglobin or hematocrit;

(iii) Blood glucose;

(iv) Examination of stool specimens for occult blood;

(v) Pregnancy tests; and

(vi) Primary culturing for transmittal to a certified laboratory.

Interpretive Guidelines §485.635(b)(2)

Basic laboratory services must be provided directly at the CAH campus by CAH staff in order to facilitate the immediate diagnosis and treatment of the patient. The CAH must have a current Clinical Laboratory Improvement Act (CLIA) certificate or waiver for all tests performed.

The provision of laboratory services that exceed the requirements for basic laboratory services is an optional requirement. The CAH must maintain or have available laboratory services, either directly or through arrangement, whenever its patients need those services. The CAH may maintain laboratory services at the CAH or may make laboratory services available through contractual agreements except for the required basic services. The scope and complexity of the CAH laboratory service must be adequate to meet the needs of its patients. All laboratory services, whether direct or contractual must be provided in

accordance with CLIA requirements. Every CAH laboratory must be operating under a current CLIA certificate appropriate to the level of services performed.

The CAH must provide basic emergency laboratory services 24 hours a day, 7 days a week. The medical staff should determine which laboratory services are to be immediately available to meet the emergency laboratory needs of patients who may be currently at the CAH or those patients who may arrive at the CAH in an emergency condition and how the services are to be provided. The emergency laboratory services available should reflect the scope and complexity of the CAH'S operation and be provided in accordance with Federal and State law, regulations and guidelines and acceptable standards of practice.

The laboratory must have written instructions for the collection, preservation, transportation, receipt, and reporting of tissue specimen results.

Survey Procedures §485.635(b)(2)

- Determine which services are provided directly by the facility and which are provided through contractual agreements.
- Determine if the referral laboratory is CLIA certified for the appropriate test specialty.
- Verify that all laboratory services are operating under a current CLIA certificate.
- Examine records and determine if the services, including emergency services, are provided in accordance with the CAH'S policies.
- Review the written description of the emergency laboratory services.
- Review records such as worksheets and test reports to verify the 24 hour availability of emergency services and that those services are provided when required.
- Verify the existence of a written description of the laboratory services provided, including those furnished on routine and stat basis (either directly or under an arrangement with an outside facility). Verify that the description of services is accurate and current.
- Verify that the laboratory has the appropriate CLIA certificate or waiver for the tests performed in the CAH laboratory.
- Verify that the CAH has a procedure in place for obtaining tests that are needed but unavailable at the CAH laboratory.
- Verify that the CAH has written policies and procedures to ensure that all laboratory results are recorded in the medical record.

C-0283

§485.635(b)(3) Radiology services. Radiology services furnished at the CAH are provided as direct services by staff qualified under State law, and do not expose CAH patients or staff to radiation hazards.

Interpretive Guidelines §485.635(b)(3)

Radiological services must be provided by the CAH as direct services at the CAH campus by CAH staff. The CAH must maintain and have available diagnostic radiological services to meet the needs of their patients. These services must be available at all times. The CAH can choose the level of services offered. They may offer only a minimal set of services or a more complex range of services (including nuclear medicine) according to the needs of the patients of the CAH. While the CAH must directly provide all radiology services in the CAH, the interpretation of roentgenograms may be contracted out.

All radiological services provided by the CAH, including diagnostic, therapeutic, and nuclear medicine, must be provided in accordance with acceptable standards of practice and must meet professionally approved standards for safety. The scope and complexity of radiological services offered should be specified in writing and approved by the medical staff and governing body (or responsible individual).

Acceptable standards of practice include maintaining compliance with appropriate Federal and State laws, regulations and guidelines governing radiological services, including facility licensure and/or certification requirements, as well as any standards and recommendations promoted by nationally recognized professions such as the American Medical Association, American College of Radiology, etc.

The CAH must adopt policies and procedures that provide safety for patients and personnel. The CAH must implement and ensure compliance with its established safety standards. The policies should contain safety standards for at least:

- Adequate radiation shielding for patients, personnel and facilities;
- Labeling of radioactive materials, waste, and hazardous areas;
- Transportation of radioactive materials between locations within the CAH;
- Security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials;
- Testing of equipment for radiation hazards;
- Maintenance of personal radiation monitoring devices;

- Storage of radio nuclides and radio pharmaceuticals as well as radioactive waste; and
- Disposal of radio nuclides, unused radio pharmaceuticals, and radioactive waste.

The CAH must have policies and procedures in place to ensure that periodic inspections of radiology equipment are conducted, and that problems identified are corrected in a timely manner. The CAH must have a system in place and qualified employees to correct hazards. The CAH must be able to demonstrate current inspection and proper correction of all hazards.

There must be written policies developed and approved by the medical staff to designate which radiological tests must be interpreted by a radiologist.

Supervision of the radiology services includes, but is not limited, to the following:

- Enforcing safety standards;
- Ensuring that radiology reports are signed by the practitioner who interpreted them;
- Assigning duties to radiology personnel appropriate to their level of training, experience, and licensure if applicable;
- Enforcing infection control standards;
- Ensuring that emergency care is provided to patients who experience an adverse reaction to diagnostic agents in the radiology service;
- Ensuring that files, scans, and other image records are kept in a secure area and are readily retrievable; and
- Training radiology staff on how to operate the equipment safely, perform tests offered by the facility and on the management of emergency radiation hazards and accidents.

There should be written policies, developed and approved by the medical staff, consistent with State law, to designate which personnel are qualified to use the radiological equipment and administer procedures.

The CAH must maintain records for all radiology procedures performed. At a minimum, the records should include copies of reports and printouts, and any films, scans or other image records, as appropriate. The CAH should have written policies and procedures that ensure the integrity of authentication and protect the privacy of radiology records.

Survey Procedures §485.635(b)(3)

- Verify that the CAH maintains, or has available, organized radiology services that meet the needs of the patients, are provided in accordance with accepted standards of practice, and are maintained or available at all times to meet the patient needs.
- Verify that patient shielding (aprons, etc) are properly maintained and routinely inspected.
- Verify that the CAH requires periodic tests of all radiology personnel and that the personnel are knowledgeable about radiation exposure.
- Review records to verify that periodic tests of radiology personnel by exposure meters or test badges are performed.
- Verify that hazardous materials are stored properly in a safe manner.
- Review the inspection records (logs) to verify that periodic inspections are conducted in accordance with manufacturer's instructions, Federal and State laws, regulations, and guidelines, and CAH policy.
- Determine that any problems identified are properly corrected in a timely manner.
- Review medical records to determine that radiological services are provided only on the orders of practitioners with clinical privileges authorized by the medical staff and the governing body (or responsible individual) to order radiological services, consistent with State law.
- Review records to determine that a radiologist interprets those tests that have been designated by the medical staff to require interpretation by a qualified radiologist.
- Verify that supervision of the radiology services is restricted to an individual who is credentialed by the medical staff.
- Review radiological records to determine that reports are signed by the practitioner who reads and evaluates the roentgenogram.
- Verify through observation and document review that radioactive materials, including radioactive waste, are properly stored and disposed of.
- Verify that the CAH maintains accurate records of the receipt and distribution of radio pharmaceuticals.

C-0284

§485.635(b)(4) Emergency procedures. In accordance with the requirements of §485.618, the CAH provides as direct services medical emergency procedures as a first response to common life-threatening injuries and acute illness.

Survey Procedures §485.635(b)(4)

Review policies and procedures for the provision of emergency services.

C-0285

§485.635(c) Standard: Services Provided Through Agreements or Arrangements

(1) The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including--

Interpretive Guidelines §485.635(c)(1)

Individual agreements or arrangements should be well defined, but need not be contractual. They should describe routine procedures (e.g., for obtaining outside laboratory tests); and there should be evidence in the agreement or arrangement that the governing body (or responsible individual) is responsible for these services provided under agreement or arrangement. Individual agreements or arrangements should be revised when the nature and scope of services provided has changed.

The governing body (or responsible individual) has the responsibility for ensuring that CAH services are provided according to acceptable standards of practice, irrespective of whether the services are provided directly by CAH employees or indirectly by arrangement. The governing body must take actions through the CAH'S QA program to: assess the services furnished directly by CAH staff and those services provided under arrangement, identify quality and performance problems, implement appropriate corrective or improvement activities, and to ensure the monitoring and sustainability of those corrective or improvement activities.

Survey Procedures §485.635(c)(1)

Ascertain that all contractor services provided in the CAH are in compliance with the CoP for CAHs.

C-0286

§485.635(c)(1)(i) Inpatient CAH care;

Survey Procedures §485.635(c)(1)(i)

How does the CAH ensure that it has arrangements or agreements with one or more facilities to provide inpatient care to its patients?

C-0287

§485.635(c)(1)(ii) Services of doctors of medicine or osteopathy;

Survey Procedures §485.635(c)(1)(ii)

How does the CAH ensure that it has arrangements or agreements with one or more MD/DOs to meet its requirements at §485.631(b)?

C-0288

§485.635(c)(1)(iii) Additional or specialized diagnostic and clinical laboratory services that are not available at the CAH; and

Interpretive Guidelines §485.635(c)(1)(iii)

Laboratories that provide additional diagnostic and clinical laboratory services to a CAH by agreement or arrangement must be in compliance with CLIA requirements in 42 CFR Part 493 of this chapter. These laboratories will be surveyed separately for compliance with Part 493.

Survey Procedures §485.635(c)(1)(iii)

How does the CAH ensure through arrangements or agreements that it can obtain specialized diagnostic and clinical laboratory services?

C-0289

§485.635(c)(1)(iv) Food and other services to meet inpatients' nutritional needs to the extent these services are not provided directly by the CAH.

Survey Procedures §485.635(c)(1)(iv)

If the CAH has an outside contract for nutritional services, how does the CAH ensure that it has arrangements or agreements for the provision of nutritional services that meet this requirement?

C-0290

§485.635(c)(2) If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated.

Survey Procedures §485.635(c)(2)

- Review a sample of medical records of patients who were treated and transferred from the CAH. What documentation shows that:
    - Transferred patients were accepted and provided with inpatient care, as needed, at CAHs to which they were transferred?
    - Patients referred for diagnostic and/or laboratory tests had these tests performed as requested by the practitioner responsible for the patient?
    - MD/DOs and/or suppliers of services are providing services for the CAH in the manner described in the arrangement or agreement?

C-0291

§485.635(c)(3) The CAH maintains a list of all services furnished under arrangements or agreements. The list describes the nature and scope of the services provided.

Survey Procedures §485.635(c)(3)

- Review the list of contracted services and verify that there is a delineation of contractor responsibility.
- Review any arrangements or agreements to determine if the nature and scope of services defined is being provided to CAH patients and is in compliance with the CAH CoPs.

C-0292

§485.635(c)(4) The person principally responsible for the operation of the CAH under §485.627(b)(2) of this chapter is also responsible for the following:

(i) Services furnished in the CAH whether or not they are furnished under arrangements or agreements.

Survey Procedures §485.635(c)(4)(i)

How does the CAH ensure, (e.g., through operating policies and procedures, by-laws etc.) that the individual responsible for its operations is responsible for all services provided through arrangements or agreements?

C-0293

§485.635(c)(4)(ii) Ensuring that a contractor of services (including one for shared services and joint ventures) furnishes services that enable the CAH to comply with all applicable conditions of participation and standards for the contracted services.

Survey Procedures §485.635(c)(4)(ii)

How does the CAH ensure that contracted services meet all of the CAH Conditions of Participation and standards for contracted services?

C-0294

§485.635(d) Standard: Nursing Services

Nursing services must meet the needs of patients.

Interpretive Guidelines §485.635(d)

In order to meet the needs of patients, nursing services must be a well-organized service of the CAH and under the direction of a registered nurse.

The CAH and the director of the nursing service are responsible for the clinical activities of all nursing to include the clinical activities of all non-CAH nursing personnel (contract, agency, or volunteer). The CAH and the director of nursing service ensure that all CAH nursing staff and each non-CAH nursing staff person is adequately trained and oriented, is adequately supervised, that their clinical activities are evaluated, and that all nursing personnel know the CAH policies and procedures. An appropriately qualified CAH-employed RN should conduct the supervision and evaluation of the clinical activities of each non-CAH nursing staff.

Survey Procedures §485.635(d)

- Observe the nursing care in progress to determine the adequacy of staffing and to assess the delivery of care. Other sources of information to use in the evaluation of the nursing services are: nursing care plans, medical records, accident and investigative reports, staffing schedules, nursing policies and procedures,

credentialing and training files (including contracted staff), and QA activities and reports.

- Review the method for orienting non-CAH staff to CAH policies and procedures. The orientation should include at least the following:
    - The CAH and the unit;
    - Emergency procedures;
    - Nursing services policies and procedures; and
    - Safety policies and procedures.

C-0295

485.635(d)(1) A registered nurse must provide (or assign to other personnel) the nursing care of each patient, including patients at a SNF level of care in a swing-bed CAH. The care must be provided in accordance with the patient's needs and the specialized qualifications and competence of the staff available.

Interpretive Guidelines §485.635(d)(1)

The nursing service ensures that patient needs are met by ongoing assessments of patients' needs and provides nursing staff to meet those needs. There must be sufficient personnel to respond to the appropriate medical needs and care of the patient population being serviced.

An RN must make all patient care assignments. The director of the nursing service and the CAH are to ensure that nursing personnel with the appropriate education, experience, licensure, competence and specialized qualifications are assigned to provide nursing care for each patient in accordance with the individual needs of each patient.

Survey Procedures §485.635(d)(1)

- Review the nursing assignments. Did an RN make the assignments? Determine that the assignments take into consideration the complexity of patient care needs and the competence and specialized qualifications of the nursing staff.
- Determine that there are written staffing schedules that correlate to the number and acuity of patients.
- Verify that there is supervision of personnel performance and nursing care for each nursing unit.
- Interview the registered nurse responsible for supervising the nursing care of the patients and ask the following--

  - How are the specialized needs of patients determined? Who makes this determination?
  - How is staff assigned?
  - How is staff monitored to ensure that appropriately qualified staff provides the care needed?
  - How does the CAH ensure that care provided meets the needs of each patient?
  - If temporary nursing staff is utilized, how are these staff oriented and supervised relative to CAH nursing procedures?
- Interview one or more temporary staff, if available, to determine if they are adequately familiar with CAH nursing requirements.

C-0296

485.635(d)(2) A registered nurse or, where permitted by State law, a physician assistant, must supervise and evaluate the nursing care for each patient, including patients at a SNF level of care in a swing-bed CAH.

Interpretive Guidelines §485.635(d)(2)

An RN (or PA where State law permits) must supervise and evaluate the nursing care for each patient. Evaluation would include assessing the patient's care needs as well as the patient's response to interventions.

Survey Procedures §485.635(d)(2)

- Determine that a registered nurse (or PA where State law permits) supervises and evaluates the nursing care for each patient?
- Interview the RN (or PA where State law permits) who is responsible for supervising and evaluating the nursing care for CAH patients.
- Ask to see staffing schedules as needed to verify information
- Observe the care provided by any non-CAH staff
  - Do they know and adhere to CAH policies?
  - Do they know appropriate emergency procedures?

  - Are they adequately supervised by an appropriately experienced CAH employed RN (or PA where State law permits)?
  - Are their clinical activities being evaluated adequately?
  - Are they licensed in accordance with State law?

- Confirm with the director of nurses that a non-CAH nurse's performance is evaluated at least annually.

C-0297

485.635(d)(3) All drugs, biologicals, and intravenous medications must be administered by or under the supervision of a registered nurse, a doctor of medicine or osteopathy, or, where permitted by State law, a physician assistant, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws.

Interpretive Guidelines §485.635(d)(3)

All drugs and biologicals and intravenous medications must be administered by or under the supervision of a RN, MD, DO or where permitted by State law a PA, in accordance with written or signed orders, accepted standards of practice, and Federal and State laws. As permitted by State law and CAH policy, LPN's may administer medications if they are under the supervision of an RN, MD, DO or if permitted by State law a PA.

Drugs and biologicals must be prepared and administered in accordance with Federal and State laws.

Drugs and biologicals must be prepared and administered in accordance with the orders of the practitioner or practitioners responsible for the patient's care.

Drugs and biologicals must be prepared and administered in accordance with accepted standards of practice.

All orders for drugs and biologicals, including verbal orders, must be legible, timed, dated and authenticated with a signature by the practitioner or practitioners responsible for the care of the patient. All entries in the medical record must be legible, timed, dated and authenticated.

A telephone or verbal order is written in the medical record by a nurse or other professional in accordance with State law and CAH policy as being able to accept verbal orders. The written verbal order must be legible and includes the date, time, the order, the name of the ordering practitioner and the signature of the accepting individual. The ordering practitioner must date and time the order at the time he or she signs the order and must sign a verbal order as soon as possible which would be the earlier of the following:

- The next time the prescribing practitioner provides care to the patient, assesses the patient, or documents information in the patient's medical record, or

- The prescribing practitioner signs or initials the verbal order within time frames consistent with Federal and State law or regulation and CAH policy.

The content of verbal orders should be clearly communicated. The entire verbal order should be repeated back to the prescriber. All verbal orders must be reduced immediately to writing and signed by the individual receiving the order. Verbal orders must be documented in the patient's medical record, and be reviewed and countersigned by the prescriber as soon as possible.

We recognize that in some instances, the ordering practitioner may not be able to authenticate his or her verbal order (e.g., the ordering practitioner gives a verbal order which is written and transcribed, and then is "off duty" for the weekend or an extended period of time). In such cases, it is acceptable for a covering practitioner to co-sign the verbal order of the ordering practitioner. The signature indicates that the covering practitioner assumes responsibility for his/her colleague's order as being complete, accurate and final. This practice must be addressed in the CAH'S policy. However, a qualified practitioner such as a physician assistant or nurse practitioner may not "co-sign" a MD/DO's verbal order or otherwise authenticate a medical record entry for the MD/DO who gave the verbal order.

When used, verbal orders must be used infrequently. Therefore, it is not acceptable to allow covering practitioners to authenticate verbal orders for convenience or to make this common practice. When assessing compliance with this requirement, surveyors review the frequency and practice of using verbal orders within the CAH.

Verbal orders are orders for medications, treatments, intervention or other patient care that are communicated as oral, spoken communications between senders and receivers face to face or by telephone.

Verbal communication of orders should be limited to urgent situations where immediate written or electronic communication is not feasible.

CAHs should establish policies and procedures that:

- Describe limitations or prohibitions on use of verbal orders;

- Provide a mechanism to ensure validity/authenticity of the prescriber;

- List the elements required for inclusion in a complete verbal order;

- Describe situations in which verbal orders may be used;

- List and define the individuals who may send and receive verbal orders; and

- Provide guidelines for clear and effective communication of verbal orders.

CAHs should promote a culture in which it is acceptable, and strongly encouraged, for staff to question prescribers when there are any questions or disagreements about verbal orders. Questions about verbal orders should be resolved prior to the preparation, or dispensing, or administration of the medication.

Elements that should be included in any verbal medication order include:

- Name of patient;
- Age and weight of patient, when appropriate;
- Date and time of the order;
- Drug name;
- Dosage form (e.g., tablets, capsules, inhalants)
- Exact strength or concentration;
- Dose, frequency, and route;
- Quantity and/or duration;
- Purpose or indication;
- Specific instructions for use; and
- Name of prescriber.

Survey Procedures §485.635(d)(3)

- Select patients from the patient sample. Review their medication orders, medication administration records, and appropriate medication documentation in the medical record. Observe the preparation and administration of medications to those patients. Are medications prepared and administered in accordance with Federal and State laws, accepted national standards of practice, manufacturer's directions, and CAH policy?
- Ascertain that there is an effective method for the administration of drugs. Use the following indicators for assessing drug administration:
- Ascertain that there are policies and procedures approved by the medical staff covering who is authorized to administer medications, and that the policies are followed.

- Review a sample of medication administration records to see that they conform to the practitioner's order and that the order is current, and that drug and dosage are correct and administered as ordered.

- Observe the preparation of drugs and their administration to patients in order to verify that procedures are being followed. Are patients addressed by name and/or identiband checked? Does the nurse remain with the patient until medication is taken?

- Verify that nursing staff administering drugs have completed appropriate training courses.

- Check the QA activities to see if the administration of drugs is regularly monitored. The monitoring should include reports of medication irregularities or errors and corrective action taken.

- Determine that all drug orders, including verbal orders, are written in the patient charts and signed by the practitioner caring for the patient. Have verbal orders been signed or initialed by the prescribing practitioner as soon as possible?

- Request to see several patient charts with telephone orders. Check to determine if they are taken by authorized CAH personnel, and are correctly countersigned by the practitioner. Ask several nurses if they are permitted to take telephone and oral orders and how frequently they do so.

- Read the CAH'S policy for practitioner's orders. Does it require that orders must be in writing and signed by the attending practitioner?

- Verify that the prescriber has reviewed and authenticated the orders in accordance with medical staff policy and/or applicable State laws.

C-0298

485.635(d)(4) A nursing care plan must be developed and kept current for each inpatient.

Interpretive Guidelines §485.635(d)(4)

Nursing care planning starts upon admission. It includes planning the patient's care while in the CAH as well as planning for discharge to meet post-CAH needs. A nursing care plan is based on assessing the patient's nursing care needs and developing appropriate nursing interventions in response to those needs. The nursing care plan is kept current by ongoing assessments of the patient's needs and the patient's response to interventions, and updating or revising the patient's nursing care plan in response to assessments. The nursing care plan is

part of the patient's medical record and must comply with the requirements for patient records.

Survey Procedures §485.635(d)(4)

Select a sample of nursing care plans (6-12 as appropriate)

- Are the plans initiated as soon as possible after admission for each patient?
- Does the plan describe patient goals and appropriate physiological and psychosocial factors and patient discharge planning?
- Is the plan consistent with the attending practitioner's plan for medical care?
- Are the plans revised as the needs of the patient change?
- Are the plans implemented?

C-0300

§485.638 Condition of Participation: Clinical Records

C-0301

§485.638(a) Standard: Records System

(1) The CAH maintains a clinical records system in accordance with written policies and procedures.

Interpretive Guidelines §485.638(a)(1)

The CAH must have a system of patient records, pertinent medical information, author identification, and record maintenance that ensures the integrity of the authentication and protects the security of all record entries. The medical record system must correctly identify the author of every medical record entry. The medical record system must protect the security of all medical record entries. The medical record system must ensure that medical record entries are not lost, stolen, destroyed, altered, or reproduced in an unauthorized manner. All locations where medical records are stored or maintained must ensure the integrity, security and protection of the records.

The CAH must have a system in place that ensures that the identity of the author of each entry is correct. The author of every entry must take a specified action to identify himself/herself as the author (or responsible person) of the entry, the time and dating of the entry, that the entry is accurate, and that he/she takes responsibility for accuracy of the entry.

If the CAH uses computer entries there must be security system in place to ensure the integrity of the record system, to ensure that the author of each entry is correctly identified, to ensure that record entries are not altered or lost, that limits access to medical records to only authorized persons, and ensures that records are not released to unauthorized individuals. For the purposes of this regulation, electronic signatures comply with those medical record entries that include a requirements for a signature.

There should be a current list of authenticated signatures, as well as a list of computer codes and signature stamps (when used for authorship purposes) that have been authorized by the governing body and are protected by adequate safeguards. CAH policies and procedures should provide for appropriate sanctions for unauthorized or improper use of computer codes or signature stamps.

The CAH must maintain a medical record for each inpatient and outpatient evaluated or treated in any part or location of the CAH. A unit record for both inpatients and outpatients may be used; however, when two different systems are used they must be appropriately cross referenced. When a patient reimbursement status changes from acute care services to swing bed services, a single medical record may be used for both stays as long as the record is sectioned separately. Both sections must include admission and discharge orders, progress notes, nursing notes, graphics, laboratory support documents, any other pertinent documents, and discharge summaries.

The medical record must be properly filed and retained. The CAH must have a medical recording system that ensures the prompt retrieval of any medical record, of any patient evaluated or treated at any location of the CAH within the past 6 years.

The medical record must be accessible. The CAH must have a medical record system that allows the medical record of any patient, inpatient or outpatient, evaluated and/or treated at any location of the CAH within the past 6 years to be accessible by appropriate staff, 24 hours a day, 7 days a week, whenever that medical record may be needed.

Survey Procedures §485.638(a)(1)

- Verify that a medical record is maintained for each person receiving care.
- Verify that written procedures ensure the integrity of authentication and protect the security of patient records.
- Verify that medical records are stored and maintained in locations where the records are secure, with protection from damage, flood, fire, theft, etc., and limits access to only authorized individuals.
- Verify that records are accurate, completed promptly, easily retrieved and readily accessible, as needed.

- Verify that there is an established system that addresses at least the following activities of the medical records services:
    - Timely processing and retrieval of records;
    - Protecting the confidentiality of medical information;
    - Compiling and retrieval of data of quality assurance activities.
- Verify that the system policies and procedures are reviewed and revised as needed.
- Verify that the CAH employs adequate medical record personnel who possess adequate education, skills, qualifications and experience to ensure the CAH complies with requirements of the medical records regulations and other appropriate Federal and State laws and regulations.
- Are medical records promptly completed in accordance with State law and CAH policy?
- Select a sample of past patients of the CAH (inpatient and/or outpatient). Request those patient's medical records. Can the CAH promptly retrieve those records?

C-0302

§485.638(a)(2) The records are legible, complete, accurately documented, readily accessible, and systematically organized.

Interpretive Guidelines §485.638(a)(2)

All medical records must be accurately written. The CAH must ensure that all medical records accurately and completely document all orders, test results, evaluations, treatments, interventions, care provided and the patient's response to those treatments, interventions and care.

Survey Procedures §485.638(a)(2)

For CAH surveys that are conducted after the initial certification survey, examine a sample of records using an adequate sample size to evaluate the scope of services provided. In a very small CAH, look at all inpatient and outpatients records, if appropriate.

C-0303

§485.638(a)(3) A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.

Interpretive Guidelines §485.638(a)(3)

The CAH must have one unified medical record service with a department head that has been appointed by the governing body (or responsible individual). The director of medical records must have responsibility for all medical records to include both inpatient and outpatient records.

Survey Procedures §485.638(a)(3)

- Verify that the CAH employs adequate medical record personnel.
- Review the organizational structure and policy statements and interview the person responsible for the service to ascertain that the medical records service is structured appropriately to meet the needs of the CAH and the patients.

C-0304

§485.638(a)(4) For each patient receiving health care services, the CAH maintains a record that includes, as applicable--

> **(i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;**

Interpretive Guidelines §485.638(a)(4)(i)

The medical record must include evidence of properly executed informed consent forms for any procedures or surgical procedures specified by the medical staff, or by Federal or State law, if applicable, that require written patient consent.

Informed consent means the patient or patient representative is given the information, explanations, consequences, and options needed in order to consent to a procedure or treatment.

A properly executed consent form contains at least the following:

- Name of patient, and when appropriate, patient's legal guardian;
- Name of CAH;
- Name of procedure(s);
- Name of practitioner(s) performing the procedures(s);
- Signature of patient or legal guardian;

- Date and time consent is obtained;
- Statement that procedure was explained to patient or guardian;
- Signature of professional person witnessing the consent;
- Name/signature of person who explained the procedure to the patient or guardian.

The medical record must contain information such as progress and nursing notes, documentation, records, reports, recordings, test results, assessments etc. to:

- Justify admission;
- Support the diagnosis;
- Describe the patient's progress;
- Describe the patient's response to medications; and
- Describe the patient's response to services such as interventions, care, treatments, etc.

The medical record must contain complete information/documentation regarding medical history, assessment of the health status and health care needs of the patient, and a summary of the episode, disposition, and instructions to the patient. This information and documentation is contained in a discharge summary.

A discharge summary discusses the outcome of the CAH stay, the disposition of the patient, and provisions for follow-up care. Follow-up care provisions include any post CAH appointment, how post CAH patient care needs are to be met, and any plans for post-CAH care by providers such as swing-bed services, home health, hospice, nursing homes, or assisted living. A discharge summary is required following any CAH acute care stay prior to and following a swing-bed admission and discharge.

The MD/DO or other qualified practitioner with admitting privileges in accordance with State law and CAH policy, who admitted the patient is responsible for the patient during the patient's stay in the CAH. This responsibility would include developing and entering the discharge summary.

The MD/DO may delegate writing the discharge summary to other qualified health care personnel such as nurse practitioners and physician assistants to the extent recognized under State law or a State's regulatory mechanism. The MD/DO may also delegate writing the discharge summary to another MD/DO who is familiar with the patient.

Survey Procedures §485.638(a)(4)(i)

- Verify that the medical staff have specified which procedures or treatments require a written informed consent.
- Verify that medical records contain consent forms for all procedures or treatment that are required by CAH policy.
- Verify that consent forms are properly executed.
- Examine a sample of patient records and/or facility records of requests for information contained in patient records to determine if there are signed and dated consent forms, when required, medical history, health status and care needs assessment, and discharge summary in each record, as needed.
- Review of sample of active and closed medical records for completeness and accuracy in accordance with Federal and State laws and regulations and CAH policy. The sample should be at least 10 percent of the average daily census, as appropriate.

C-0305

§485.638(a)(4)(ii) Reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings;

Interpretive Guidelines §485.638(a)(4)(ii)

All or part of the history and physical exam (H & P) may be delegated to other practitioners in accordance with State law and CAH policy, but the MD/DO must sign the H & P and assume full responsibility for the H & P. This means that a nurse practitioner or a physician assistant meeting these criteria may perform the H & P.

Survey Procedures §485.638(a)(4)(ii)

- Determine that the bylaws require a physical examination and medical history be done for each patient.
- For sampled records, does the appropriate practitioner sign reports of physical examinations, diagnostic and laboratory test results, and consultative findings?

C-0306

§485.638(a)(4)(iii) All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature graphics, progress notes describing the patient's response to treatment; and

Interpretive Guidelines §485.638(a)(4)(iii)

The requirement means that the stated information is necessary to monitor the patient's condition and that this and other necessary information must be in the patient's medical record. In order for necessary information to be used it must be promptly filed in the medical record so that health care staff involved in the patient's care can access/retrieve this information in order to monitor the patient's condition and provide appropriate care.

The medical record must contain:

- All practitioner's orders (properly authenticated);
- All nursing notes;
- All reports of treatment (including complications and CAH-acquired infections);
- All medication records (including unfavorable reactions to drugs);
- All radiology reports;
- All laboratory reports;
- All vital signs; and
- All other information necessary to monitor the patient's condition.

All medical records must be promptly completed. Every medical record must be complete with all documentation of orders, diagnosis, evaluations, treatments, test results, consents, interventions, discharge summary, and care provided along with the patient's response to those treatments, interventions, and care.

Survey Procedures §485.638(a)(4)(iii)

- Verify that the patient records contain appropriate documentation of practitioners' orders, interventions, findings, assessments, records, notes, reports and other information necessary to monitor the patient's condition.
- Is necessary information included in patient records in a prompt manner so that health care staff involved in the care of the patient have access to the information necessary to monitor the patient's condition?

C-0307

§485.638(a)(4)(iv) Dated signatures of the doctor of medicine or osteopathy or other health care professional.

Interpretive Guidelines §485.635(a)(4)(iv)

Entries in the medical record may be made only by individuals as specified in CAH and medical staff policies. All entries in the medical record must be timed, dated, and authenticated, and a method established to identify the author. The identification may include written signatures, initials, computer key, or other code.

When rubber stamps are authorized, the individual whose signature the stamp represents shall place in the administrative offices of the CAH a signed statement to the effect that he/she is the only one who has the stamp and uses it. There shall be no delegation to another individual.

A list of computer or other codes and written signatures must be readily available and maintained under adequate safeguards. There shall be sanctions for improper or unauthorized use of stamp, computer key, or other code signatures. The CAH must have policies and procedures in place and operational before an electronic medical record system would be deemed acceptable.

The parts of the medical record that are the responsibility of the MD/DO must be authenticated by this individual. When non-MD/DOs have been approved for such duties as taking medical histories or documenting aspects of physical examination, such information shall be appropriately authenticated by the responsible MD/DO. Any entries in the medical record by house staff or non-MD/DOs that require counter signing by supervisory or attending medical staff members shall be defined in the medical staff rules and regulations.

All entries in the medical record must be authenticated.

Authentication would include at a minimum:

- The CAH has a method to establish the identify of the author of each entry. This would include verification of the author of faxed orders/entries or computer entries.
- The author takes a specific action to verify that the entry is his/her entry or that he/she is responsible for the entry, that the entry is accurate.
- The timing of the entry is noted and correct.

Timing documents the time and date of each entry (orders, reports, notes etc.). Timing establishes when an order was given, when an activity happened or when an activity is to take place. Timing and dating entries are necessary for patient safety and quality of care. Timing and dating of entries establishes a baseline for future actions or assessments and establishes a timeline of events. Many patient interventions or assessments are based on time intervals or time lines of various signs, symptoms, or events. There must be a specific action by the author to indicate that the entry is, in fact, verified and accurate. Failure to disapprove an entry within a specific time period is not acceptable as authentication.

A system of auto-authentication in which a MD/DO or other practitioner authenticates a report before transcription is not consistent with these requirements. There must be a method of determining that the practitioner did, in fact, authenticate the document after it was transcribed.

Survey Procedures §485.635(a)(4)(iv)

- Verify that entries are authenticated.
- Verify that the department maintains a current list of authenticated signatures, written initials, codes, and stamps when such are used for authorship identification.
- Verify that computer or other code signatures are authorized by the CAH'S governing body and that a list of these codes is maintained under adequate safeguards by the CAH administration.
- Verify that the CAH'S policies and procedures provide for appropriate sanctions for unauthorized or improper use of the computer codes.
- Examine the CAH'S policies and procedures for using the system, and determine if documents are being authenticated after transcription.
- For sampled records, are there dated and authenticated signatures by appropriate MD/DOs and/or mid-level practitioners, as needed?

C-0308

§485.638(b) Standard: Protection of Record Information

(1) The CAH maintains the confidentially of record information and provides safeguards against loss, destruction, or unauthorized use.

Interpretive Guidelines §485.638(b)(1)

The CAH has sufficient safeguards to ensure that access to all information regarding patients is limited to those individuals designated by law, regulation, policy; or duly authorized as having a need to know. No unauthorized access or dissemination of clinical records is permitted. Clinical records are kept secure and are only viewed when necessary by those persons having a part in the patient's care.

The right to confidentiality means safeguarding the content of information, including patient paper records, video, audio, and/or computer stored information from unauthorized disclosure without the specific informed consent of the individual, parent of a minor child, or legal guardian. CAH staff and consultants, hired to provide services to the individual, should

have access to only that portion of information that is necessary to provide effective responsive services to that individual.

Confidentiality applies to both central records and clinical record information that may be kept at dispersed locations.

Survey Procedures §485.638(b)(1)

- Verify that only authorized persons are permitted access to records maintained by the medical records department.
- Verify that the CAH has a policy to grant patients direct access to his/her medical record if the responsible official (e.g., practitioner responsible for patient's care) determines that direct access is not likely to have an adverse effect on the patient.
- Verify that medical records are released only for patient care evaluation, utilization review, treatment, quality assurance programs, in-house educational purposes, or in accordance with Federal or State law, court orders, or subpoenas.
- Verify that copies of medical records are released outside the CAH only upon written authorization of the patient, legal guardian, or person with an appropriate "power of attorney" to act on the patient's behalf, or only if there is a properly executed subpoena or court order, or as mandated by statutes.
- Verify that precautions are taken to prevent unauthorized persons from gaining access to or altering patient records.
- Verify that adequate precautions are taken to prevent physical or electronic altering, damaging or deletion/destruction of patient records or information in patient records.

C-0309

§485.638(b)(2) Written policies and procedures govern the use and removal of records from the CAH and the conditions for the release of information.

Interpretive Guidelines §485.638(b)(2)

The CAH'S patient record system must ensure the security of patient records. The CAH must ensure that unauthorized individuals cannot gain access to patient records and that individuals cannot alter patient records. Patient records must be secure at all times and in all locations. This includes open patient records for patients who are currently inpatients in the CAH and outpatients in outpatient clinics.

Survey Procedures §485.638(b)(2)

- Observe the CAH'S security practices for patient records. Are patient records left unsecured or unattended? Are patient records unsecured or unattended in hallways, patient rooms, nurses stations, or on counters where an unauthorized person could gain access to patient records?

- If the CAH uses electronic patient records, are appropriate security safeguards in place? Is access to patient records controlled?

- Verify that the CAH has policies and procedures for the use and release of records and that these policies and procedures are enforced.

C-0310

§485.638(b)(3) The patient's written consent is required for release of information not required by law.

C-0311

§485.638(c) Standard: Retention of Records

The records are retained for at least 6 years from date of last entry, and longer if required by State statute, or if the records may be needed in any pending proceeding.

Interpretive Guidelines §485.638(c)

Medical records are retained in their original form or legally reproduced form in hard copy, microfilm, or computer memory banks. The CAH must be able to promptly retrieve the complete medical record of every individual evaluated or treated in any part or location of the CAH within the last 6 years.

In accordance with Federal and State law and regulations, certain medical records may have retention requirements that exceed 6 years (for example: FDA, OSHA, EPA).

Survey Procedures §485.638(c)

Determine that records are retained for at least 6 years, or more if required by State or local laws.

C-0320

§485.639 Condition of Participation: Surgical Services.

Surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the CAH in accordance with the designation requirements under paragraph (a) of this section.

Interpretive Guidelines §485.639

The provision of surgical services is an optional CAH service. However, if a CAH provides any degree of surgical services to its patients, the services must be organized and staffed in such a manner to ensure the health and safety of patients. Surgical services that are performed in a safe manner would be performed in accordance with acceptable standards of practice. In accordance with acceptable standards of practice includes maintaining compliance with applicable Federal and State laws, regulations and guidelines governing surgical services or surgical service locations, as well as, any standards and recommendations promoted by or established by nationally recognized professional organizations (e.g., the American Medical Association, American College of Surgeons, Association of Operating Room Nurses, Association for Professionals in Infection Control and Epidemiology, etc.) Additionally, the quality of the CAH'S outpatient surgical services must be consistent with the CAH'S inpatient surgical services.

When the CAH offers surgical services, the CAH must provide the appropriate equipment and types and numbers of qualified personnel necessary to furnish the surgical services offered by the CAH in accordance with acceptable standards of practice.

The scope of surgical services provided by the CAH should be defined in writing and approved by the medical staff.

Supervision in the OR

The operating room (inpatient and outpatient) must be supervised by an experienced staff member authorized by State law. The supervisor's experience could include education, background working in surgical services, and specialized training in the provision of surgical services/management of surgical service operations. The CAH should address its required qualifications for the supervisor of the CAH'S operating rooms in its policies.

If the CAH utilizes LPN or operating room technicians as "scrub nurses," those personnel must be under the supervision of an RN who is immediately available to physically intervene and provide care, as required in State law.

Policies and Procedures

Policies governing surgical care should contain:

- Aseptic surveillance and practice, including scrub techniques
- Identification of infected and non-infected cases
- Housekeeping requirements/procedures
- Patient care requirements
    - Preoperative work-up
    - Patient consents and releases
    - Clinical procedures
    - Safety practices
    - Patient identification procedures
- Duties of scrub and circulating nurse
- Safety practices
- The requirement to conduct surgical counts in accordance with accepted standards of practice
- Scheduling of patients for surgery
- Personnel policies unique to the OR
- Resuscitative techniques
- DNR status
- Care of surgical specimens
- Malignant hyperthermia
- Appropriate protocols for all surgical procedures performed. These may be procedure-specific or general in nature and will include a list of equipment, materials, and supplies necessary to properly carry out job assignments.
- Sterilization and disinfection procedures
- Acceptable operating room attire

- Handling infections and biomedical/medical waste

Policies and procedures must be written, implemented and enforced. Surgical services' policies must be in accordance with acceptable standards of medical practice and surgical patient care.

Pre-Operative History and Physical (H & P)

A complete history and physical must be conducted in accordance with acceptable standards of practice, and the written document placed on the medical record, prior to surgery. All or part of the H & P may be delegated to other practitioners in accordance with State law and CAH policy, but the surgeon must sign the H & P and assume full responsibility for the H & P. This means that a nurse practitioner or a physician assistant, meeting these criteria, may perform the H & P.

In all circumstances, when an H & P has been conducted, but is not present on the chart prior to surgery, or in emergency situations where a complete H & P cannot be conducted prior to surgery, a brief admission note on the chart is necessary. The note should include at a minimum critical information about the patient's condition including pulmonary status, cardiovascular status, BP, vital signs, etc.

Informed Consent

A properly executed informed consent form contains at least the following:

- Name of patient, and when appropriate, patient's legal guardian;
- Name of CAH;
- Name of procedure(s);
- Name of practitioner(s) performing the procedure(s) or important aspects of the procedure(s), as well as the name(s) and specific significant surgical tasks that will be conducted by practitioners other than the primary surgeon/practitioner. (Significant surgical tasks include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues.);
- Signature of patient or legal guardian;
- Date and time consent is obtained;
- Statement that procedure was explained to patient or guardian;
- Signature of professional person witnessing the consent; and
- Name/signature of person who explained the procedure to the patient or guardian.

The responsible practitioner must disclose to the patient any information necessary to enable the patient to evaluate a proposed medical or surgical procedure before submitting to it. Informed consent requires that a patient have a full understanding of that to which he or she has consented. An authorization from a patient who does not understand what he/she is consenting to is not informed consent.

Patients must be given sufficient information to allow them to make intelligent choices from among the alternative courses of available treatment for their specific ailments. Informed consent must be given despite a patient's anxiety or indecisiveness.

The responsible practitioner must provide as much information about treatment options as is necessary based on a patient's personal understanding of the practitioner's explanation of the risks of treatment and the probable consequences of the treatment.

Informed consent means the patient or patient representative is given (in a language or means of communication he/she understands) the information needed in order to consent to a procedure or treatment.

An informed consent would include at least: an explanation of the nature and purpose of the proposed procedures, risks and consequences of the procedures, risks and prognosis if no treatment is rendered, the probability that the proposed procedure will be successful, and alternative methods of treatment (if any) and their associated risks and benefits. Furthermore, informed consent would include that the patient is informed as to who will actually perform surgical interventions that are planned. When practitioners other than the primary surgeon will perform important parts of the surgical procedures, even when under the primary surgeon's supervision, the patient must be informed of who these other practitioners are, as well as, what important tasks each will carry out.

Post-Operative Care/Recovery

Adequate provisions for immediate post-operative care means:

- Post operative care must be in accordance with acceptable standards of practice.
- The post-operative care area or recovery room is a separate area of the CAH. Access is limited to authorized personnel.
- Policies and procedures specify transfer requirements to and from the recovery room. Depending on the type of anesthesia and length of surgery, the post-operative check before transferring the patient from the recovery room should include some of the following:
    - Level of activity
    - Respirations

  - Blood pressure
  - Level of consciousness
  - Patient color

- If the patients are not transferred to the recovery room, determine that provisions are made for close observation until they have regained consciousness, e.g., direct observation by an RN in the patient's room.

Operating Room Register

The register should include at least the following information:

- Patient's name
- Patient's CAH identification number
- Date of the operation
- Inclusive or total time of the operation
- Name of the surgeon and any assistant(s)
- Name of nursing personnel (scrub and circulating)
- Type of anesthesia used and name of person administering it
- Operation performed
- Pre and post-op diagnosis
- Age of patient

Operative Report

The operative report would include at least:

- Name and CAH identification number of the patient;
- Date and times of the surgery;
- Name(s) of the surgeon(s) and assistants or other practitioners who performed surgical tasks (even when performing those tasks under supervision);

- Pre-operative and post-operative diagnosis;
- Name of the specific surgical procedure(s) performed;
- Type of anesthesia administered;
- Complications, if any;
- A description of techniques, findings, and tissues removed or altered;
- Surgeons or practitioners name(s) and a description of the specific significant surgical tasks that were conducted by practitioners other than the primary surgeon/practitioner (significant surgical procedures include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues); and
- Prosthetic devices, grafts, tissues, transplants, or devices implanted, if any.

Survey Procedures §485.639

- Inspect all inpatient and outpatient operative rooms/suites. Request the use of proper attire for the inspection. Observe the practices to determine if the services are provided in accordance with acceptable standards of practice. Observe:
    - That access to the operative and recovery area is limited to authorized personnel and that the traffic flow pattern adheres to accepted standards of practice;
    - The conformance to aseptic and sterile technique by all individuals in the surgical area;
    - That there is appropriate cleaning between surgical cases and appropriate terminal cleaning applied;
    - That operating room attire is suitable for the kind of surgical case performed, that persons working in the operating suite must wear only clean surgical costumes, that surgical costumes are designed for maximum skin and hair coverage;
    - That equipment is available for rapid and routine sterilization of operating room materials and that equipment is monitored, inspected, tested, and maintained by the CAH'S biomedical equipment program; and
    - That sterilized materials are packaged, handled, labeled, and stored in a manner that ensures sterility e.g., in a moisture and dust controlled environment and policies and procedures for expiration dates have been developed and are followed in accordance with accepted standards of practice.

- Review the CAH'S organizational chart displaying the relationship of the operating room service to other services. Confirm that the operating room's organization chart indicates lines of authority and delegation of responsibility within the department or service.

- If LPNs and surgical technologists (STs) are performing circulating duties, verify that they do so in accordance with applicable State laws and approved medical staff policies and procedures.

- Verify in situations where LPNs and STs are permitted to circulate that a qualified RN supervisor is immediately available to respond to emergencies.

- Review policies and procedures, to ascertain whether they contain the minimum policies specified in the interpretive guidelines.

- Review a sample of medical records of surgical patients to determine if a complete history and physical examination by a surgeon is completed prior to surgery, except in an emergency, and in accordance with the methodology described above.

- Review a sample of medical records of surgical patients to verify that they contain consent forms. Ascertain that the completed forms contain at least the information specified in the interpretive guidelines.

- Check to determine that the operating room suite has available the items listed.

    - On-call system

    - Cardiac monitor

    - Resuscitator

    - Defibrillator

    - Aspirator (suction equipment)

    - Tracheotomy set (a cricothyroidotomy set is not a substitute)

- Verify that all equipment is working and, as applicable, in compliance with the CAH'S biomedical equipment inspection, testing, and maintenance program.

- Verify that the CAH has provisions for post-operative care.

- Determine that there are policies and procedures that govern the recovery room area.

- Examine the OR register or equivalent record which lists all surgery performed by the surgery service. Determine that the register includes items specified in the interpretive guidelines.

- Review a sample of medical records of patients who had a surgical encounter. Verify that they contain a surgical report that is dated and signed by the responsible surgeon and includes the information specified in the interpretive guidelines.

C-0321

§485.639(a) Standard: Designation of Qualified Practitioners

The CAH designates the practitioners who are allowed to perform surgery for CAH patients, in accordance with its approved policies and procedures, and with State scope of practice laws. Surgery is performed only by--

(1) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(2) A doctor of dental surgery or dental medicine; or

(3) A doctor of podiatric medicine.

Interpretive Guidelines §485.639(a)

Surgical privileges should be reviewed and updated at least every 2 years. A current roster listing each practitioner's specific surgical privileges must be available in the surgical suite and area/location where the scheduling of surgical procedures is done. A current list of surgeons suspended from surgical privileges or whose surgical privileges have been restricted must be retained in these area/locations.

The CAH must delineate the surgical privileges of all practitioners performing surgery and surgical procedures. The medical staff is accountable to the governing body for the quality of care provided to patients. The medical staff bylaws must include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. Surgical privileges are granted in accordance with the competencies of each practitioner. The medical staff appraisal procedures must evaluate each individual practitioner's training, education, experience, and demonstrated competence as established by the CAH'S QA program, credentialing process, the practitioner's adherence to CAH policies and procedures, and in accordance with scope of practice and other State laws and regulations.

The CAH must specify the surgical privileges for each practitioner that performs surgical tasks. This would include practitioners such as MD/DOs, dentists, oral surgeons, podiatrists, RN first assistants, nurse practitioners, surgical physician assistants, surgical technicians, etc. When a practitioner may perform certain surgical procedures under supervision, the specific

tasks/procedures and the degree of supervision (to include whether or not the supervising practitioner is in the same OR in line of sight) be delineated in that practitioner's surgical privileges and included on the surgical roster.

When practitioners whose scope of practice for conducting surgical procedures requires the supervision of an MD/DO surgeon, the term "supervision" would mean the supervising MD/DO surgeon is present in the same room, working with the same patient.

Surgery and all surgical procedures must be conducted by a practitioner who meets the medical staff criteria and procedures for the privileges granted, who has been granted surgical privileges in accordance with those criteria established by the governing body (or responsible individual), and who is working within the scope of those granted and documented privileges.

Survey Procedures §485.639(a)

- Review the CAH'S method for reviewing the surgical privileges of practitioners. This method should require a written assessment of the practitioner's training, experience, health status, and performance.

- Determine that a current roster listing each practitioner's specific surgical privileges is available in the surgical suite and the area where the scheduling of surgical procedures is done.

- Determine that a current list of surgeons suspended from surgical privileges or who have restricted surgical privileges is retained in these areas/locations.

C-0322

§485.639(b) Standard: Anesthetic Risk and Evaluation

(1) A qualified practitioner, as specified in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed.

(2) A qualified practitioner, as specified in paragraph (c) of this section, must examine each patient before surgery to evaluate the risk of anesthesia.

(3) Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (c) of this section.

Interpretive Guidelines §485.639(b)

The pre-anesthesia evaluation must be performed prior to inpatient or outpatient surgery. The pre-anesthesia evaluation must be performed by an individual qualified to administer anesthesia. The pre-operative anesthetic evaluation should include:

- Notation of anesthesia risk
- Anesthesia, drug and allergy history
- Any potential anesthesia problems identified
- Patient's condition prior to induction of anesthesia

The post-anesthesia follow-up report must be written on all inpatients and outpatients prior to discharge from surgery and anesthesia services. The post-anesthesia evaluation must be written by the individual who is qualified to administer the anesthesia. An MD/DO may delegate the post-anesthesia assessment and the writing of the post-anesthesia follow-up report to practitioners qualified to administer anesthesia in accordance with State law and CAH policy. When delegation of the post-anesthesia follow-up report is permitted, the medical staff must address its delegation requirements and methods in its bylaws. The post-anesthesia follow-up report must be documented in the patient's medical record, whether the patient is an inpatient or outpatient of the CAH, and must include at a minimum:

- Cardiopulmonary status;
- Level of consciousness;
- Any follow-up care and/or observations; and
- Any complications occurring during post-anesthesia recovery.

Survey Procedures §485.639(b)

- Review records to determine that each patient has a pre-anesthesia evaluation by an individual qualified to administer anesthesia. The evaluation must be performed prior to surgery.
- Review medical records to determine that a post-anesthesia follow-up report is written for each patient receiving anesthesia services, by the individual who administered the anesthesia prior to discharge from anesthesia services. Documentation should include those items specified in interpretive guidelines.

C-0323

§485.639(c) Standard: Administration of Anesthesia

The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope-of-practice laws.

(1) Anesthesia must be administered by only--

(i) A qualified anesthesiologist;

(ii) A doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(iii) A doctor of dental surgery or dental medicine;

(iv) A doctor of podiatric medicine;

(v) A certified registered nurse anesthetist (CRNA), as defined in Sec. 410.69(b) of this chapter;

(vi) An anesthesiologist's assistant, as defined in Sec. 410.69(b) of this chapter; or

(vii) A supervised trainee in an approved educational program, as described in §§ 413.85 or 413.86 of this chapter.

Interpretive Guidelines §485.639(c)(1)

The medical staff bylaws must include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. The CAH must specify the anesthesia privileges for each practitioner that administers anesthesia, or who supervises the administration of anesthesia by another practitioner. The privileges granted must be in accordance with State law and CAH policy. The type and complexity of procedures for which the practitioner may administer anesthesia, or supervise another practitioner supervising anesthesia, must be specified in the privileges granted to the individual practitioner.

A dentist, oral surgeon, or podiatrist may administer anesthesia in accordance with State law, their scope of practice and CAH policy. The anesthesia privileges of each practitioner must be specified. Anesthesia privileges are granted in accordance with the practitioner's scope of practice, State law, the individual competencies of the practitioner and the practitioner's compliance with the CAH'S credentialing criteria.

When a CAH permits operating practitioners to supervise CRNA administering anesthesia, the medical staff must specify in the statement of privileges for each category of operating practitioner, the type and complexity of procedures they may supervise.
A CRNA may administer anesthesia when under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed (unless supervision is exempted in accordance with §485.639(e)). An anesthesiologist's assistant may administer anesthesia when under the supervision of an anesthesiologist who is immediately available if needed. Available to immediately intervene includes at a minimum, that the supervising anesthesiologist or operating practitioner, as applicable, is:

- Physically located within the operative suite or in the labor and delivery unit; and
- Is prepared to immediately conduct hands-on intervention if needed; and
- Is not engaged in activities that could prevent the supervising practitioner from being able to immediately intervene and conduct hands-on interventions if needed

Survey Procedures §485.639(c)(1)

- Review the qualifications of individuals authorized to deliver anesthesia.
- Determine that there is documentation of current licensure or current certification status for all persons administering anesthesia.

C-0324

§485.639(c)(2) In those cases in which a CRNA administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner except as provided in paragraph (e) of this section. An anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist.

C-0325

§485.639(d) Standard: Discharge

All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure.

Interpretive Guidelines §485.639(d)

Any exceptions to this requirement must be made by the attending practitioner and annotated on the clinical record.

Survey Procedures §485.639(d)

Verify that the CAH has policies and procedures in place to govern discharge procedures and instructions.

C-0326

§485.639(e) Standard: State Exemption

(1) A CAH may be exempted from the requirement for MD/DO supervision of CRNAs as described in paragraph (c)(2) of this section, if the State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from MD/DO supervision for CRNAs. The letter from the Governor must attest that he or she has consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current MD/DO supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time, and are effective upon submission.

C-0330

§485.641 Condition of Participation: Periodic Evaluation and Quality Assurance Review

Interpretive Guidelines §485.641

While conducting the survey, a surveyor may identify a patient care practice or other CAH practice with which the surveyor is unfamiliar. Health care and CAH practice are continually changing due to new laws, regulations and standards of practice. In order for the surveyor to determine compliance with the CAH CoP, the surveyor should interview appropriate CAH staff to gather additional information, such as:

- Tell me about this practice.
- Is the practice a requirement or standard of practice?
- What is your source for this requirement, activity or standard of practice?
- Show me your source material for this practice.

If the CAH produces a law, regulation, or standard of practice from a nationally recognized organization, evaluate whether the CAH'S policies and procedures reflect the law, regulation, or standard of practice. Then, evaluate whether the CAH'S actual practice reflects their policies and procedures, as well as the law, regulation or standard of practice.

C-0331

§485.641(a) Standard: Periodic Evaluation

(1) The CAH carries out or arranges for a periodic evaluation of its total program. The evaluation is done at least once a year and includes review of--

Survey Procedures §485.641(a)(1)

- How is information obtained to be included in the periodic evaluation?
- How does the CAH conduct the periodic evaluation?
- Who is responsible for conducting the periodic evaluation?

C-0332

§485.641(a)(1)(i) The utilization of CAH services, including at least the number of patients served and the volume of services;

Survey Procedures §485.641(a)(1)(i)

How does the CAH ensure that the yearly program evaluation includes a review of all CAH services, the number of patients served and the volume of services provided?

C-0333

§485.641(a)(1)(ii) A representative sample of both active and closed clinical records; and

Interpretive Guidelines §485.641(a)(1)(ii)

"A representative sample of both active and closed clinical records" means not less than 10 percent of both active and closed patient records.

Survey Procedures §485.641(a)(1)(ii)

- Who is responsible for the review of both active and closed clinical records?
- How are records selected and reviewed in the periodic evaluation?
- How does the evaluation process ensure that the sample of records is representative of services furnished?

- What criteria are utilized in the review of both active and closed records?

C-0334

§485.641(a)(1)(iii) The CAH'S health care policies.

Survey Procedures §485.641(a)(1)(iii)

What evidence demonstrates that the health care policies of the CAH are evaluated, reviewed and/or revised as part of the annual program evaluation?

C-0335

§485.641(a)(2) The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and any changes are needed.

Survey Procedures §485.641(a)(2)

- How does the CAH use the results of the yearly program evaluation?
- Were policies, procedures and /or facility practices added, deleted or revised as a result of the yearly program evaluation if needed?

C-0336

§485.641(b) Standard: Quality Assurance

The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. The program requires that--

Interpretive Guidelines §485.641(b)

There is nothing in this requirement to preclude a CAH from obtaining QA through arrangement. Whether the CAH has a freestanding QA program or QA by arrangement, all of the requirements for QA must be met. If a CAH chooses to have a freestanding QA program, the QA program should be facility wide, including all departments and all services provided under contact. For services provided to the CAH under contract, there should be established channels of communication between the contractor and CAH staff.

"An effective quality assurance program" means a QA program that includes:

- Ongoing monitoring and data collection;

- Problem prevention, identification and data analysis;
- Identification of corrective actions;
- Implementation of corrective actions;
- Evaluation of corrective actions; and
- Measures to improve quality on a continuous basis.

Survey Procedures §485.641(b)

Review a copy of the CAH QA plan and other documentation regarding QA activities, (e.g., meeting notes from QA committees, reports produced by the QA director and/or QA committees, if designated, and follow-up communication relative to corrective actions) to become familiar with the scope, methodology and organization of the CAH QA program.

C-0337

§485.641(b)(1) All patient care services and other services affecting patient health and safety, are evaluated;

Survey Procedures §485.641(b)(1)

- Who is responsible to evaluate CAH patient care services?
- How are patient care services evaluated?
- What other services are evaluated?
- How does the CAH ensure quality assurance data is provided to the medical staff and governing body?

C-0338

§485.641(b)(2) Nosocomial infections and medication therapy are evaluated;

Survey Procedures §485.641(b)(2)

- What methodology does the CAH use to evaluate nosocomial infections and medications therapy?
- Review committee meeting minutes for current issues or projects, etc.

C-0339

§485.641(b)(3) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the CAH are evaluated by a member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH;

Survey Procedures §485.641(b)(3)

- How does the CAH ensure that a doctor of medicine or osteopathy evaluates the quality of care provided by mid-level practitioners in the CAH?
- How is clinical performance of mid-level practitioners evaluated?
- What evidence demonstrates that there is an ongoing evaluation of care provided by mid-level practitioners (e.g., reports, periodic written evaluation, QA meeting notes)?
- How does the reviewing MD/DO inform the CAH if he/she determines that there are problems relative to the diagnosis and treatment provided by mid-level practitioners?
- What follow-up actions are called for in the QA plan?

C-0340

§485.641(b)(4) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the CAH are evaluated by--

(i) One hospital that is a member of the network, when applicable;

(ii) One QIO or equivalent entity; or

(iii) One other appropriate and qualified entity identified in the State rural health care plan; and

C-0341

§485.641(b)(5)(i) The CAH staff considers the findings of the evaluations, including any findings or recommendations of the QIO, and takes corrective action if necessary.

C-0342

§485.641(b)(5)(ii) The CAH also takes appropriate remedial action to address deficiencies found through the quality assurance program.

Survey Procedures §485.641(b)(5)(ii)

- How does the CAH ensure that proper remedial actions are taken to correct deficiencies identified in the quality assurance program?
- Who is responsible for implementing remedial actions to correct deficiencies identified by the quality assurance program?

C-0343

§485.641(b)(5)(iii) The CAH documents the outcome of all remedial action.

Survey Procedures §485.641(b)(5)(iii)

How does the CAH document the outcome of any remedial action?

C-0344

§485.643 Condition of Participation: Organ, Tissue, and Eye Procurement

The CAH must have and implement written protocols that:

Interpretive Guidelines §485.643

The CAH must have written policies and procedures to address its organ procurement responsibilities.

C-0345

§485.643(a) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the CAH. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose;

Interpretive Guidelines §485.643(a)

The CAH must have a written agreement with an Organ Procurement Organization (OPO), designated under 42 CFR Part 486. At a minimum, the written agreement must address the following:

- The criteria for referral, including the referral of all individuals whose death is imminent or who have died in the CAH;
- Includes a definition of "imminent death";
- Includes a definition of "timely notification";
- Addresses the OPO's responsibility to determine medical suitability for organ donation;
- Specifies how the tissue and/or eye bank will be notified about potential donors using S notification protocols developed by the OPO in consultation with the CAH-designated tissue and eye bank(s);
- Provides for notification of each individual death in a timely manner to the OPO (or designated third party) in accordance with the terms of the agreement;
- Ensures that the designated requestor training program offered by the OPO has been developed in cooperation with the tissue bank and eye bank designated by the CAH;
- Permits the OPO, tissue bank, and eye bank access to the CAH'S death record information according to a designated schedule, e.g., monthly or quarterly;
- Includes that the CAH is not required to perform credentialing reviews for, or grant privileges to, members of organ recovery teams as long as the OPO sends only "qualified, trained individuals" to perform organ recovery; and
- The interventions the CAH will utilize to maintain potential organ donor patients so that the patient organs remain viable.

CAHs must notify the OPO of every death or imminent death in the CAH. When death is imminent, the CAH must notify the OPO both before a potential donor is removed from a ventilator and while the potential donor's organs are still viable. The CAH should have a written policy, developed in coordination with the OPO and approved by the CAH'S medical staff and governing body, to define "imminent death." The definition for "imminent death" should strike a balance between the needs of the OPO and the needs of the CAH'S care givers to continue treatment of a patient until brain death is declared or the patient's family has made the decision to withdraw supportive measures. Collaboration between OPOs and CAHs will create a partnership that furthers donation, while respecting the perspective of CAH staff.

The definition for "imminent death" might include a patient with severe, acute brain injury who:

- Requires mechanical ventilation;
- Is in an intensive care unit (ICU) or emergency department; **AND**
- Has clinical findings consistent with a Glascow Coma Score that is less than or equal to a mutually-agreed-upon threshold; **or**
- MD/DOs are evaluating a diagnosis of brain death; **or**
- An MD/DO has ordered that life sustaining therapies be withdrawn, pursuant to the family's decision.

CAHs and their OPO should develop a definition of "imminent death" that includes specific triggers for notifying the OPO about an imminent death.

In determining the appropriate threshold for the Glasgow Coma Score (GCS), it is important to remember that if the threshold is too low, there may be too many "premature" deaths or situations where there is a loss of organ viability. Standards for appropriate GCS thresholds may be obtained from the CAH'S OPO or organizations such as the Association of Organ Procurement Organizations.

Note that a patient with "severe, acute brain injury" is not always a trauma patient. For example, post myocardial infarction resuscitation may result in a patient with a beating heart and no brain activity.

The definition agreed to by the CAH and the OPO may include all of the elements listed above or just some of the elements. The definition should be tailored to fit the particular circumstances in each CAH.

CAHs may not use "batch reporting" for deaths by providing the OPO with periodic lists of patient deaths, even if instructed to do so by the OPO. If the patient dies during a transfer from one CAH to another, it is the receiving CAH'S responsibility to notify the OPO.

"**Timely notification**" means a CAH must contact the OPO by telephone as soon as possible after an individual has died, has been placed on a ventilator due to a severe brain injury, or who has been declared brain dead (ideally within 1 hour). That is, a CAH must notify the OPO while a brain dead or severely brain-injured, ventilator-dependent individual is still attached to the ventilator and as soon as possible after the death of any other individual, including a potential non-heart-beating donor. Even if the CAH does not consider an individual who is not on a ventilator to be a potential donor, the CAH must call the OPO as soon as possible after the death of that individual has occurred.

Referral by a CAH to an OPO is timely if it is made:

- As soon as it is anticipated a patient will meet the criteria for imminent death agreed to by the OPO and CAH or as soon as possible after a patient meets the criteria for imminent death agreed to by the OPO and the CAH (ideally, within one hour); **AND**

- Prior to the withdrawal of any life sustaining therapies (i.e., medical **or** pharmacological support).

Whenever possible, referral should be made early enough to allow the OPO to assess the patient's suitability for organ donation before brain death is declared and before the option of organ donation is presented to the family of the potential donor. Timely assessment of the patient's suitability for organ donation increases the likelihood that the patient's organs will be viable for transplantation (assuming there is no disease process identified by the OPO that would cause the organs to be unsuitable), ensures that the family is approached only if the patient is medically suitable for organ donation, and ensures that an OPO representative is available to collaborate with the CAH staff in discussing donation with the family.

It is the OPO's responsibility to determine medical suitability for organ donation, and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose.

Survey Procedures §485.643(a)

- Review the CAH'S written agreement with the OPO to verify that it addresses all required information.

- Verify that the CAH'S governing body has approved the CAH'S organ procurement policies.

- Review a sample of death records to verify that the CAH has implemented its organ procurement policies.

- Interview the staff to verify that they are aware of the CAH'S policies and procedures for organ, tissue and eye procurement.

- Verify that the organ, tissue and eye donation program is integrated into the CAH'S QA program.

C-0346

§485.643(b) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of

tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

Interpretive Guidelines §485.643(b)

The CAH must have an agreement with at least one tissue bank and at least one eye bank. The OPO may serve as a "gatekeeper" receiving notification about every CAH death and should notify the tissue bank chosen by the CAH about potential tissue and eye donors.

It is not necessary for a CAH to have a separate agreement with a tissue bank if it has an agreement with its OPO to provide tissue procurement services; not is it necessary for a CAH to have a separate agreement with an eye bank if its OPO provides eye procurement services. The CAH is not required to use the OPO for tissue or eye procurement but is free to have an agreement with the tissue bank or eye bank of its choice. The tissue banks and eye banks define "usable tissues" and "usable eyes."

The requirements of this regulation may be satisfied through a single agreement with an OPO that provides services for organ, tissue and eye, or by a separate agreement with another tissue and/or eye bank outside the OPO, chosen by the CAH. The CAH may continue current successful direct arrangements with tissue and eye banks as long as the direct arrangement does not interfere with organ procurement.

Survey Procedures §485.643(b)

Verify that the CAH has an agreement with at least one tissue bank and one eye bank that specifies criteria for referral of all individuals who have died in the CAH. The agreement must also acknowledge that it is the OPO's responsibility to determine medical suitability for tissue and eye donation, unless the CAH has an alternative agreement with a different tissue and/or eye bank.

C-0347

§485.643(c) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its option to either donate or not donate organs, tissues, or eyes. The individual designated by the CAH to initiate the request to the family must be a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

Interpretive Guidelines §485.643(c)

It is the responsibility of the OPO to screen for medical suitability in order to select potential donors. Once the OPO has selected a potential donor, that person's family must be informed of the family's donation options.

Ideally, the OPO and the CAH will decide together how and by whom the family will be approached.

The individual designated by the CAH to initiate the request to the family must be a designated requestor.

A "**designated requestor**" is defined as a CAH-designated individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community. If possible, the OPO representative and a designated requestor should approach the family together.

The CAH must ensure that any "designated requestor" for organs, tissues or eyes has completed a training course either offered or approved by the OPO, which addresses methodology for approaching potential donor families.

Survey Procedures §485.643(c)

- Verify that the CAH ensures that the family of each potential donor is informed of its options to donate organs, tissues, or eyes, including the option to decline to donate.
- Review training schedules and personnel files to verify that all designated requestors have completed the required training.
- How does the CAH ensure that only designated requestors are approaching families to ask them to donate?

C-0348

§485.643(d) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the family of potential donors;

Interpretive Guidelines §485.643(d)

Using discretion does not mean a judgment can be made by the CAH that certain families should not be approached about donation. CAHs should approach the family with the belief that a donation is possible and should take steps to ensure the family is treated with respect and care. The staff's perception that a family's grief, race, ethnicity, religion or socioeconomic background would prevent donation should never be used as a reason not to approach a family.

All potential donor families must be approached and informed of their donation rights.

Survey Procedures §485.643(d)

- Interview a CAH-designated requestor regarding approaches to donation requests.
- Review the designated requestor training program to verify that it addresses the use of discretion.
- Review the facility complaint file for any relevant complaints.

C-0349

§485.643(e) Ensure that the CAH works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes takes place.

§485.643(f) For purpose of these standards, the term "organ" means a human kidney, liver, heart, lung, pancreas, or intestines (or multivisceral organs).

Interpretive Guidelines §485.643(e)

Appropriate staff, including all patient care staff, must be trained regarding donation issues and how to work with the OPO, tissue bank and eye bank. Those CAH staff who may have to contact or work with the OPO, tissue bank and eye bank staff, must have appropriate training on donation issues including their duties and roles.

The training program must be developed in cooperation with the OPO, tissue bank and eye bank, and should include, at a minimum:

- Consent process;
- Importance of using discretion and sensitivity when approaching families;
- Role of the designated requestor;
- Transplantation and donation, including pediatrics, if appropriate;
- Quality improvement activities; and
- Role of the organ procurement organization.

Training should be conducted with new employees annually, whenever there are policy/procedure changes, or when problems are determined through the CAH'S QA program.

CAHs must cooperate with OPOs, tissue banks and eye banks in regularly/periodically reviewing death records. This means that a CAH must develop policies and procedures which permit the OPO, tissue bank and eye bank access to death record information that will allow the OPO, tissue bank and eye bank to assess the CAH'S donor potential, ensure that all deaths or imminent deaths are being referred to the OPO in a timely manner, and identify areas where the CAH, OPO, tissue bank and eye bank staff performance might be improved. The policies must address how patient confidentiality will be maintained during the review process.

The CAH must have policies and procedures, developed in cooperation with the OPO, that ensure that potential donors are maintained in a manner that maintain the viability of their organs. The CAH must have policies in place to ensure that potential donors are identified and declared dead within an acceptable time frame by an appropriate practitioner.

Survey Procedures §485.643(e)

- Review inservice training schedules and attendance sheets.
- How does the CAH ensure that all appropriate staff have attended an educational program regarding donation issues and how to work with the OPO, tissue bank, and eye bank?
- Verify by review of policies and records that the CAH works with the OPO, tissue bank, and eye bank in reviewing death records.
- Verify that the effectiveness of any protocols and policies is monitored as part of the CAH'S quality improvement program.
- Validate how often the reviews are to occur. Review the protocols that are in place to guide record reviews and analysis.
- Determine how confidentiality is ensured.
- Verify that there are policies and procedures in place to ensure coordination between the facility staff and the OPO staff in maintaining the potential donor.
- Determine by review, what policies and procedures are in place to ensure that potential donors are identified and declared dead by an appropriate practitioner within an acceptable timeframe.

C-0350

§485.645 Special Requirements for CAH Providers of Long-Term Care Services ("Swing-Beds")

A CAH must meet the following requirements in order to be granted an approval from CMS to provide post-CAH SNF care, as specified in §409.30 of this chapter, and to be paid for SNF-level services, in accordance with paragraph (c) of this section.

Interpretive Guidelines §485.645

The swing-bed concept allows a CAH to use their beds interchangeably for either acute-care or post-acute care. A "swing-bed" is a change in reimbursement status. The patient swings from receiving acute-care services and reimbursement to receiving skilled nursing (SNF) services and reimbursement.

Medicare allows a CAH to operate swing-beds through the issuance of a "swing-bed approval." If the facility fails to meet the swing-bed requirements, and the facility does not develop and implement an accepted plan of correction, the facility loses the approval to operate swing-beds and receive swing-bed reimbursement. The facility does not go on a termination track. If the CAH continues to meet the CoP for the provider type, it continues to operate but loses swing-bed approval.

Swing-beds need not be located in a special section of the CAH. The patient need not change locations in the facility merely because his/her status changes unless the facility requires it.

The change in status from acute care to swing-bed status can occur within one facility or the patient can be transferred from another facility for swing-bed admission.

There must be discharge orders from acute care services, appropriate progress notes, discharge summary, and subsequent admission orders to swing-bed status regardless of whether the patient stays in the same facility or transfers to another facility. If the patient does not change facilities, the same chart can be utilized but the swing-bed section of the chart must be separate with appropriate admission orders, progress notes, and supporting documents.

There is no length of stay restriction for any CAH swing-bed patient. There is no Medicare requirement to place a swing-bed patient in a nursing home and there are no requirements for transfer agreements between CAHs and nursing homes.

Medicare reimbursement requires a 3-day qualifying stay in any CAH or CAH prior to admission to a swing-bed. The swing-bed stay must fall within the same spell of illness as the qualifying stay. This requirement does not apply to patients who are not receiving Medicare reimbursement.

There is no requirement for a CAH to use the MDS form for recording the patient assessment or for nursing care planning.

Swing-bed patients receive a SNF level of care, and the CAH is reimbursed for providing a SNF level of care, however swing-bed patients are not SNF patients. Swing-bed patients in CAHs are considered to be patients of the CAH.

C-0351

§485.645(a) Eligibility

A CAH must meet the following eligibility requirements:

(1) The facility has been certified as a CAH by CMS under §485.606(b) of this subpart; and

(2) The facility provides not more than 25 inpatient beds, and the number of beds used at any time for acute care inpatient services does not exceed 15 beds. Any bed of a unit of the facility that is licensed as a distinct-part SNF at the time the facility applies to the State for designation as a CAH is not counted under paragraph (a) of this section.

C-0352

§485.645(b) Facilities Participating as Rural Primary Care Hospitals (RPCHs) on September 30, 1997

These facilities must meet the following requirements:

(1) Notwithstanding paragraph (a) of this section, a hospital that participated in Medicare as a RPCH on September 30, 1997, and on that date had in effect an approval from CMS to use its inpatient facilities to provide post-hospital SNF care may continue in that status under the same terms, conditions, and limitations that were applicable at the time these approvals were granted..

(2) A CAH that was granted swing-bed approval under paragraph (b)(1) of this section may request that its application to be a CAH and swing-bed provider be reevaluated under paragraph (a) of this section. If this request is approved, the approval is effective not earlier than October 1, 1997. As of the date of approval, the CAH no longer has any status under paragraph (b)(1) of this section and may not request reinstatement under paragraph (b)(1) of this section.

C-0355

§485.645(c) Payment

Payment for inpatient RPCH services to a CAH that has qualified as a CAH under the provisions in paragraph (a) of this section is made in accordance with §413.70 of this chapter. Payment for post-hospital SNF-level of care services is made in accordance with the payment provisions in §413.114 of this chapter.

C-0360

§485.645(d) SNF Services

The CAH is substantially in compliance with the following SNF requirements contained in subpart B of part 483 of this chapter:

(1) Resident rights (§483.10(b)(3) through (b)(6), (d), (e), (h), (i), (j)(1)(vii) and (viii), (1), and (m) of this chapter).

(2) Admission, transfer, and discharge rights (§483.12(a) of this chapter).

(3) Resident behavior and facility practices (§483.13 of this chapter).

(4) Patient activities (§483.15(f) of this chapter), except that the services may be directed either by a qualified professional meeting the requirements of §483.15(f)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy.

(5) Social services (§483.15(g) of this chapter).

(6) Comprehensive assessment, comprehensive care plan, and discharge planning (§483.20(b), (k), and (l) of this chapter, except that the CAH is not required to use the resident assessment instrument (RAI) specified by the State that is required under §483.20(b), or to comply with the requirements for frequency, scope, and number of assessments prescribed in §413.343(b) of this chapter).

(7) Specialized rehabilitative services (§483.45 of this chapter).

(8) Dental services (§483.55 of this chapter).

(9) Nutrition (§483.25(i) of this chapter).

C-0361

§483.10 Resident Rights

The resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility. A facility must protect and promote the rights of each resident, including each of the following rights:

§483.10(a) Exercise of Rights

(1) The resident has the right to exercise his or her rights as a resident of the facility and as a citizen or resident of the United States.

(2) The resident has the right to be free of interference, coercion, discrimination, and reprisal from the facility in exercising his or her rights.

(3) In the case of a resident adjudged incompetent under the laws of a State by a court of competent jurisdiction, the rights of the resident are exercised by the person appointed under State law to act on the resident's behalf.

(4) In the case of a resident who has not been adjudged incompetent by the State court, any legal-surrogate designated in accordance with State law may exercise the resident's rights to the extent provided by State law.

§483.10(b) Notice of Rights and Services

(1) The facility must inform the resident both orally and in writing in a language that the resident understands of his or her rights and all rules and regulations governing resident conduct and responsibilities during the stay in the facility. The facility must also provide the resident with the notice (if any) of the State developed under section 1919(e)(6) of the Act. Such notification must be made prior to or upon admission and during the resident's stay. Receipt of such information, and any amendments to it, must be acknowledged in writing;

(2) The resident or his or her legal representative has the right--

(i) Upon an oral or written request, to access all records pertaining to himself or herself including current clinical records within 24 hours (excluding weekends and holidays); and

(ii) After receipt of his or her records for inspection, to purchase at a cost not to exceed the community standard photocopies of the records or any portions of them upon request and 2 working days advance notice to the facility.

(3) The resident has the right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition;

Interpretive Guidelines §483.10(b)

The intent of this requirement is to assure that each resident knows his or her rights and responsibilities and that the facility communicates this information prior to or upon admission, during the resident's stay, and when the facility's rules changes. A facility must promote the exercise of rights for all residents, including those who face barriers such as

communication problems, hearing problems and cognition limits. These rights include the resident's right to:

- Be informed about what rights and responsibilities the resident has (§483.10(b)(3 through 6));
- Choose a MD/DO (§483.10(d));
- Participate in decisions about treatment and care planning (§483.10(d));
- Have privacy and confidentiality (§483.10(e));
- Work or not work (§483.10(h));
- Have privacy in sending and receiving mail (§483.10(i));
- Visit and be visited by others from outside the facility (§483.10(j)(1)(vii and viii));
- Retain and use personal possessions (§483.10(l));
- Share a room with a spouse (§483.10(m)).

"**Total health status**" includes functional status, medical care, nursing care, nutritional status, rehabilitation and restorative potential, activities potential, cognitive status, oral health status, psychosocial status, and sensory and physical impairments. Information on health status must be presented in language that the resident can understand.

Communicating with the resident in language that the resident can understand includes minimizing the use of technical words, providing interpreters for non-English speaking residents, using sign language when needed, or other interventions, as appropriate.

Survey Procedures §483.10(b)

- Look for on-going efforts on the part of facility staff to keep residents informed.
- Look for evidence that information is communicated in a manner that is understandable to residents.
- Is information available when it is most useful to the residents such as when they are expressing concerns, raising questions, and on an on-going basis?
- Is there evidence in the medical record that the patient was informed of his rights, including the right to accept or refuse medical or surgical treatment?

C-0362

§483.10(b)(4) The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph 8 of this section; and

Interpretive Guidelines §483.10(b)(4)

"**Treatment**" is defined as care provided for purposes of maintaining/restoring health, improving functional level, or relieving symptoms.

"**Experimental research**" is defined as development and testing of clinical treatments, such as an investigational drug or therapy that involve treatment and/or control groups. For example, a clinical trial of an investigational drug would be experimental research.

"**Advance directive**" means a written instruction, such as living will or durable power of attorney for health care, recognized under state law, relating to the provisions of health care when the individual is incapacitated.

A resident who has the capacity to make a health care decision and who withholds consent to treatment or makes an explicit refusal of treatment either directly or through an advance directive, may not be treated against his/her wishes.

The resident has the right to refuse to participate in experimental research. A resident being considered for participation in experimental research must be fully informed of the nature of the experiment and understand the possible consequences of participating. The opportunity to refuse to participate in experimental research must occur prior to the start of the research. Aggregated resident statistics that do not identify individual residents may be used for studies without obtaining resident permission.

Survey Procedures §483.10(b)(4)

If the facility participates in any experimental research involving residents, does it have an Institutional Review Board or other committee that reviews and approves research protocols? The requirement at §483.75(c) Relationship to Other HHC Regulations may apply, see 45 CFR Part 46, Protection of Human Subjects of Research). "Although these regulations at §483.75(c) are not in themselves considered requirements under this part, their violation may result in the termination or suspension of, or the refusal to grant or continue payment with Federal funds."

C-0363

§483.10(b)(5) The facility must--

(i) Inform each resident who is entitled to Medicaid benefits, in writing, at the time of admission to the nursing facility or, when the resident becomes eligible for Medicaid of--

(A) The items and services that are included in nursing facility services under the State plan and for which the resident may not be charged;

(B) Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and

(ii) Inform each resident when changes are made to the items and services specified in paragraphs (5)(i)(A) and (B) of this section.

(6) The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare or by the facility's per diem rate.

Interpretive Guidelines: §483.10(b)(5-6)

If Medicare or Medicaid does not make payment for services, the provider must fully inform the resident of any related charges both at the time of admission and prior to the time that changes will occur in their bills.

Listed below are general categories and examples of items and services that the facility may charge to resident funds, if they are requested and agreed to by a resident.

- Telephone;
- Television/radio for personal use;
- Personal comfort items including smoking materials, notions, novelties, and confection;
- Cosmetic and grooming items and services in excess of those for which payment is made;
- Personal clothing;
- Personal reading matter;

- Gifts purchased on behalf of a resident;
- Flowers and plants;
- Social events and entertainment offered outside the scope of the activities program;
- Non-covered special care services such as privately hired nurses or aides;
- Private room, except when therapeutically required, for example, isolation for infection control;
- Specially prepared or alternative food requested;

NOTE: 42 CFR §483.10(b)(8), containing advance directive requirements, guidelines, procedures and probes, is contained below.

§483.10(b)(8) The facility must comply with the requirements specified in subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. These requirements include provisions to inform and provide written information to all adult residents concerning the right to accept or refuse medical or surgical treatment and, at the individual's option, formulate an advance directive. This includes a written description of the facility's policies to implement advance directives and applicable State law. Facilities are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met. If an adult individual is incapacitated at the time of admission and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, facility may give advance directive information to the individual's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law. The facility is not relieved of its obligation to provide this information to the individual once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.

"Advance directive" means a written instruction, such as a living will or durable power of attorney for health care recognized under State law, relating to the provision of health care when the individual is incapacitated.

Interpretive Guidelines §483.10(b)(8)

This provision applies to residents admitted on or after December 1, 1991. The regulation at 42 CFR §489.102 specifies that at the time of admission of an adult resident, the facility must:

- Maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care;

- Provide written information concerning his or her rights under State law (whether statutory or recognized by the courts of the State) to make decisions concerning medical care, including the right to accept or refuse medical or surgical treatment, and the right to formulate advance directives;

- Document in the resident's medical record whether or not the individual has executed an advance directive;

- Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

- Ensure compliance with requirements of State law regarding advance directives;

- Provide for educating staff regarding the facility's policies and procedures on advance directives; and

- Provide for community education regarding issues concerning advance directives.

The facility is not required to provide care that conflicts with an advance directive. In addition, the facility is also not required to implement an advance directive if, as a matter of conscience, the provider cannot implement an advance directive, and state law allows the provider to conscientiously object.

The sum total of the community education efforts must include a summary of the state law, the rights of residents to formulate advance directives, and the facility's implementation policies regarding advance directives. Video and audiotapes may be used in conducting the community education effort. Individual education programs do not have to address all the requirements if it would be inappropriate for a particular audience.

Survey Procedures §483.10(b)(8)

Review the records of sampled residents admitted on or after December 1, 1991, for facility compliance with advance directive notice requirements.

- Determine to what extent the facility educates its staff regarding advance directives.

- Determine to what extent the facility provides education for the community regarding individual rights under State law to formulate advance directives.

C-0364

§483.10(d) Free Choice

The resident has the right to--

(1) Choose a personal attending MD/DO;

Interpretive Guidelines §483.10(d)(1)

The right to choose a personal MD/DO does not mean that the MD/DO must serve the resident. If the MD/DO of the resident's choosing fails to fulfill a given requirement, such as frequency of MD/DO visits, the facility will have the right, after informing the resident, to seek alternate MD/DO participation to assure provision of appropriate and adequate care and treatment. A facility may not place barriers in the way of residents choosing their own MD/DO. If a resident does not have a MD/DO, or if the resident's MD/DO becomes unable or unwilling to continue providing care to the resident, the facility must assist the resident in exercising his/her choice in finding another MD/DO. A resident can choose his/her own MD/DO, but cannot have a MD/DO who does not have swing-bed admitting privileges.

The requirement for free choice is met if a resident is allowed to choose a personal MD/DO from among those who have practice privileges.

C-0365

§483.10(d)(2) Be fully informed in advance about care and treatment and of any changes in that care or treatment that may affect the resident's well-being; and

Interpretive Guidelines §483.10(d)(2)

"Informed in advance" means that the resident receives information necessary to make a health care decision. The information should include his/her medical condition, changes in his/her medical condition, the benefits and reasonable risks of the recommended treatment, and reasonable alternatives. If there are any financial costs to the resident in the treatment options, they should be disclosed in advance and in writing to the resident prior to his/her decision.

C-0366

§483.10(d)(3) Unless adjudged incompetent or otherwise found to be incapacitated under the laws of the State, participate in planning care and treatment or changes in care and treatment.

Interpretive Guidelines §483.10(d)(3)

"Participates in planning care and treatment" means that the resident is afforded the opportunity to select from alternative treatments, to the level of his ability to understand. This applies both to initial decisions about care and treatment and to decisions about changes in care and treatment. The resident has the right to participate in care planning and to refuse treatment.

Survey Procedures §483.10(d)(3)

- Look for evidence that the resident was afforded the right to participate in care planning or was consulted about care and treatment changes.
- If there appears to be a conflict between a resident's right and the resident's health or safety, determine if the facility attempted to accommodate both the exercise of the resident's rights and the resident's health, including exploration of care alternatives through a thorough care planning process in which the resident may participate.
- If a resident whose ability to make decisions about care and treatment is impaired, was he kept informed and consulted on personal preferences to the level of his ability to understand?

C-0367

§483.10(e) Privacy and Confidentiality

The resident has the right to personal privacy and confidentiality of his or her personal and clinical records.

(1) Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident;

(2) Except as provided in paragraph (e)(3) of this section, the resident may approve or refuse the release of personal and clinical records to any individual outside the facility;

(3) The resident's right to refuse release of personal and clinical records does not apply when--

(i) The resident is transferred to another health care institution; or

(ii) Record release is required by law.

Interpretive Guidelines §483.10(e)

"**Right to personal privacy**" means that the resident has the right to privacy with whomever the resident wishes to be private and that this privacy should include both visual and auditory privacy. Private space may be created flexibly and need not be dedicated solely for visitation purposes.

For example, privacy for visitation or meetings might be arranged by using a dining area between meals, a vacant chapel, office or room; or an activities area when activities are not in progress. Arrangements for private space could be accomplished through cooperation between the facility's administration and resident or family groups so that private space is provided for those requesting it without infringement on the rights of other residents.

Facility staff must examine and treat residents in a manner that maintains the privacy of their bodies. A resident must be granted privacy when going to the bathroom and in other activities of personal hygiene. If an individual requires assistance, authorized staff should respect the individual's need for privacy. Only authorized staff directly involved in treatment should be present when treatments are given. People not involved in the care of the individual should not be present without the individual's consent while he/she is being examined or treated. Staff should pull privacy curtains, close doors, or otherwise remove residents from public view and provide clothing or draping to prevent unnecessary exposure of body parts during the provision of personal care and services.

Survey Procedures §483.10(e)

Document any instances where you observe a resident's privacy being violated. Completely document how the resident's privacy was violated.

Documentation Example: Resident #12 left without gown or bed covers and unattended on 2B Corridor at 3:30 p.m. February 25, 2001. Identify the responsible party, if possible.

C-0368

§483.10(h) Work

The resident has the right to--

(1) Refuse to perform services for the facility;

(2) Perform services for the facility, if he or she chooses, when--

(i) The facility has documented the need or desire for work in the plan of care;

(ii) The plan specifies the nature of the services performed and whether the services are voluntary or paid;

(iii) Compensation for paid services is at or above prevailing rates; and

(iv) The resident agrees to the work arrangement described in the plan of care.

Interpretive Guidelines §483.10(h)

All resident work, whether of a voluntary or paid nature, must be part of the plan of care. A resident's desire for work is subject to medical appropriateness. As part of the plan of care, the resident must agree to a therapeutic work assignment. The resident also has the right to refuse such treatment at any time that he or she wishes. At the time of development or review of the plan, voluntary or paid work can be negotiated.

The "**prevailing rate**" is the wage paid to workers in the community surrounding the facility for the same type, quality, and quantity of work requiring comparable skills.

Survey Procedures §483.10(h)

- Are residents engaged in work (e.g., doing housekeeping, doing laundry, preparing meals)?
- Pay special attention to the possible work activities of residents with mental retardation or mental illness.
- If a resident is performing work, determine whether it is voluntary, and whether it is described in the plan of care. Is the work mutually agreed upon between the resident and the treatment team?

C-0369

§483.10(i) Mail

The resident has the right to privacy in written communications, including the right to--

(1) Send and promptly receive mail that is unopened; and

(2) Have access to stationery, postage, and writing implements at the resident's own expense.

Interpretive Guidelines §483.10(i)

"**Promptly**" means delivery of mail or other materials to the resident within 24 hours of delivery by the postal service (including a post office box) and delivery of outgoing mail to the postal service within 24 hours of regularly scheduled postal delivery and pickup service.

C-0370

§483.10(j) Access and Visitation Rights

(1) The resident has the right and the facility must provide immediate access to any resident by the following:

(vii) Subject to the resident's right to deny or withdraw consent at any time, immediate family or other relatives of the resident; and

(viii) Subject to reasonable restrictions and the resident's right to deny or withdraw consent at any time, others who are visiting with the consent of the resident.

Interpretive Guidelines §483.10(j)(1)(vii)-(viii)

The facility may set reasonable hours for visitation.

If it would violate the rights of a roommate to have visitors in the resident's room, the facility must establish alternate areas in the facility for visiting. These areas could include the chapel, a suitable office area, a dining room, or a porch or patio area.

C-0371

§483.10(l) Personal Property

The resident has the right to retain and use personal possessions, including some furnishings, and appropriate clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.

Interpretive Guidelines §483.10(l)

The intent of this regulation is to encourage residents to bring personal possessions into the facility, as space, safety considerations and fire code permits. All residents' possessions must be treated with respect and safeguarded.

The facility has the right to limit personal property due to space limitations in the facility or for safety considerations.

Survey Procedures §483.10(l)

If residents' rooms have few personal possessions, ask residents and families if--

- They are encouraged to have and to use personal items;

- Their personal property is safe in the facility.

C-0372

§483.10(m) Married Couples

The resident has the right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.

Interpretive Guidelines §483.10(m)

The requirement means that when a room is available for a married couple to share, the facility must permit them to share it if they choose.

C-0373

§483.12 Admission, Transfer and Discharge Rights

§483.12(a) Transfer and Discharge

(1) Definition: Transfer and discharge includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility.

Interpretive Guidelines §483.12(a)(1)

The intent of the regulation on transfer and discharge provisions is to significantly restrict a facility's ability to transfer or discharge a resident once that resident has been admitted to the facility to prevent dumping of high care or difficult residents. This requirement applies to transfer or discharges that are initiated by the facility, not by the resident.

C-0374

§483.12(a)(2) Transfer and discharge requirements. The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless--

(i) The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility;

(ii) The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility;

(iii) The safety of individuals in the facility is endangered;

(iv) The health of individuals in the facility would otherwise be endangered;

(v) The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge a resident only allowable charges under Medicaid; or

(vi) The facility ceases to operate.

Interpretive Guidelines §483.12(a)(2)

If transfer is due to a significant change in the resident's condition, the facility must conduct the appropriate assessment, prior to any transfer or discharge to determine if a new care plan would allow the facility to meet the resident's needs.

If the significant change in the resident's condition is an emergency, immediate transfer should be arranged.

Survey Procedures §483.12(a)(2)

During closed record review, determine the reasons for transfer/discharge.

- Do records document accurate assessments and attempts through care planning to address the resident's needs through multidisciplinary interventions, accommodation of individual needs, and attention to the resident's customary routine?

- Did the resident's MD/DO document the record if the resident was transferred/discharged for the sake of the resident's welfare and the resident's needs could not be met in the facility (e.g., a resident develops an acute condition requiring hospitalization) or the resident's health improved to the extent that the transferred/discharged resident no longer needed the services of the facility?

- Did a MD/DO document the record if residents were transferred because the health of individuals in the facility is endangered?

- Do the records of residents who are transferred/discharged due to safety reasons reflect the process by which the facility concluded that in each instance transfer or discharge was necessary?

- If the entity to which the resident was discharged is another long term care facility, evaluate the extent to which the discharge summary and the resident's MD/DO justify why the facility could not meet the needs of this resident.

C-0376

§483.12(a)(3) Documentation. When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (a)(2)(i) through (v) of this section, the resident's clinical record must be documented. The documentation must be made by--

(i) The resident's MD/DO when transfer or discharge is necessary under paragraph (a)(2)(i) or paragraph (a)(2)(ii) of this section; and

(ii) A MD/DO when transfer or discharge is necessary under paragraph (a)(2)(iv) of this section.

Interpretive Guidelines §483.12(a)(3)

A physician extender may complete documentation of the transfer/discharge unless prohibited by State law or facility policy.

C-0377

§483.12(a)(4) Notice before transfer. Before a facility transfers or discharges a resident, the facility must--

(i) Notify the resident and, if known, a family member or legal representative of the resident of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand.

(ii) Record the reasons in the resident's clinical record; and

(iii) Include in the notice the items described in paragraph (a)(6) of this section.

C-0378

§483.12(a)(5) Timing of the notice.

(i) Except when specified in paragraph (a)(5)(ii) of this section, the notice of transfer or discharge required under paragraph (a)(4) of this section must be made by the facility at least 30 days before the resident is transferred or discharged.

(ii) Notice may be made as soon as practicable before transfer or discharge when--

(A) The safety of individuals in the facility would be endangered under paragraph (a)(2)(iii) of this section;

(B) The health of individuals in the facility would be endangered, under paragraph (a)(2)(iv) of this section;

(C) The resident's health improves sufficiently to allow a more immediate transfer or discharge, under paragraph (a)(2)(ii) of this section;

(D) An immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph (a)(2)(i) of this section; or

(E) A resident has not resided in the facility for 30 days.

C-0379

§483.12(a)(6) Contents of the notice. The written notice specified in paragraph (a)(4) of this section must include the following:

(i) The reason for transfer or discharge;

(ii) The effective date of transfer or discharge;

(iii)The location to which the resident is transferred or discharged;

(iv) A statement that the resident has the right to appeal the action to the State;

(v) The name, address and telephone number of the State long term care ombudsman;

(vi) For nursing facility residents with developmental disabilities, the mailing address and telephone number of the agency responsible for the protection and advocacy of developmentally disabled individuals established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act; and

(vii) For nursing facility residents who are mentally ill, the mailing address and telephone number of the agency responsible for the protection and advocacy of mentally ill individuals established under the Protection and Advocacy for Mentally Ill Individuals Act.

C-0380

§483.12(a)(7) Orientation for transfer or discharge. A facility must provide sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility.

Interpretive Guidelines §483.12(a)(7)

"**Sufficient preparation**" means the facility informs the resident where he or she is going and assures safe transportation. The facility should actively involve the resident and the resident's family in selecting the new residence. Some examples of orientation may include trial visits by the resident to a new location; working with family; and orienting staff in the receiving facility to the resident's daily patterns.

Survey Procedures §483.12(a)(7)

During resident reviews, check social service notes to see if appropriate referrals have been made and, if necessary, if resident counseling has occurred.

C-0381

§483.13 Resident Behavior and Facility Practices

§483.13(a) Restraints

The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms.

Interpretive Guidelines §483.13(a)

The intent of this requirement is for each person to reach his/her highest practicable well being in an environment that prohibits the use of restraints for discipline or convenience and limits restraint use to circumstances in which the resident has medical symptoms that warrant the use of restraints.

"**Physical restraints**" are defined as any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily and that restricts freedom of movement or normal access to one's body.

"**Chemical Restraint**" is defined as a psychopharmacologic drug that is used for discipline or convenience and not required to treat medical symptoms.

"**Discipline**" is defined as any action taken by the facility for the purpose of punishing or penalizing residents.

"**Convenience**" is defined as any action taken by the facility to control resident behavior or maintain residents with a lesser amount of effort by the facility and not in the resident's best interest.

Medical symptoms that would warrant the use of restraints should be reflected in the comprehensive assessment and care planning. The facility must engage in a systematic and

gradual process toward reducing restraints (e.g., gradually increasing the time for ambulation and muscle strengthening activities).

Survey Procedures §483.13(a)

- Determine if the facility follows a systematic process of evaluation and care planning prior to using restraints.
- Determine if the interdisciplinary team addressed the risk of decline at the time restraint use was initiated.
- Did the team institute measures in the care plan to address reversal of any decline in health status?
- Determine the intended use of any restraints. Was the use for convenience or discipline?

C-0382

§483.13(b) Abuse

The resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion.

Interpretive Guidelines §483.13(b)

The intent of this regulation is to assure that each resident is free from abuse, corporal punishment, and involuntary seclusion. The facility is responsible for preventing abuse, but also for those practices and omissions, neglect and misappropriation of property, which if left unchecked, lead to abuse.

Residents must not be subjected to abuse by anyone, including, but not limited to, facility staff, other residents, consultants or volunteers, staff of other agencies serving the individual, family members or legal guardians, friends, or other individuals.

"**Abuse**" is defined as the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm or pain or mental anguish, or deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well being. This presumes that instances of abuse of all residents, even those in a coma, cause physical harm, or pain or mental anguish.

"**Verbal abuse**" is defined as any use of oral, written or gestured language that willfully includes disparaging and derogatory terms to residents or their families, or within their hearing distance, regardless of their age, ability to comprehend, or disability. Examples of verbal abuse include, but are not limited to: threats of harm; and saying things to frighten a resident, such as telling a resident that she will never be able to see her family again.

"**Sexual abuse**" includes, but is not limited to, sexual harassment, sexual coercion, or sexual assault.

"**Physical abuse**" includes hitting, slapping, pinching and kicking. It also includes controlling behavior through corporal punishment and restraints.

"**Mental abuse**" includes, but is not limited to, humiliation, harassment, and threats of punishment or deprivation.

"**Involuntary seclusion**" is defined as separation of a resident from other residents or from his or her room or confinement to his or her room (with or without roommates) against the resident's will, or the will of the resident's legal representative. Emergency or short term monitored separation from other residents will not be considered involuntary seclusion and may be permitted if used for a limited period of time as a therapeutic intervention to reduce agitation until professional staff can develop a plan of care to meet the resident's needs.

Survey Procedures §483.13(b)

- Offsite, pre-survey review of complaints can focus the survey team's on-site review of actual incidents and predisposing factors to abuse or neglect and misappropriation of property.

- Report and record **any** instances where the survey team **observes** an abusive incident. Completely document who committed the abusive act, the nature of the abuse, and where and when it occurred. Ensure that the facility addresses that incident immediately.

- If the survey team's observations and resident's responses signal the presence of abuse, determine how the facility prevents and reports abusive behavior.

- If a resident is being temporarily separated from other residents, for less than 24 hours, as an emergency short-term intervention, answer these questions:

    - What are the symptoms that led to the consideration of the separation?

    - Are these symptoms caused by failure to:

        - Meet individual needs;

        - Provide meaningful activities;

        - Manipulate the resident's environment?

    - Can the cause(s) be removed?

- If the cause(s) cannot be removed, has the facility attempted to use alternatives short of separation?
- Does the facility use the separation for the least amount of time?
- To what extent has the resident, surrogate or representative participated in care planning and made an informed choice about separation?
- Does the facility monitor and adjust care to reduce negative outcomes, while continually trying to find and use less restrictive alternatives?
- If residents are temporarily separated in secured units, staff should carry keys to these units at all times.
- If the purpose of the unit is to provide specialized care for residents who are cognitively impaired (through a program of therapeutic activities designed to enable residents to attain and maintain the highest practicable physical, mental or psychosocial well-being) then placement in the unit is not in violation of resident rights, as long as the resident's individual care plan indicates the need for the stated purpose and services provided in the unit and the resident, surrogate, or representative has participated in the placement decision.

C-0383

§483.13(c) Staff Treatment of Residents

The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property.

(1) The facility must--

(i) Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;

Interpretive Guidelines §483.13(c)

The intent of this regulation is to assure that the facility has in place an effective system that prevents mistreatment, neglect and abuse of residents, and misappropriation of resident's property.

"**Misappropriation of resident's property**" is defined as the patterned or deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a resident's belongings or money without the resident's consent.

C-0384

§483.13(c)(1)(ii) Not employ individuals who have been--

(A) Found guilty of abusing, neglecting, or mistreating residents by a court of law; or
(B) Have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property; and

(iii) Report any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff to the State nurse aide registry or licensing authorities.

(2) The facility must ensure that all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property are reported immediately to the administrator of the facility and to other officials in accordance with State law through established procedures (including to the State survey and certification agency).

(3) The facility must have evidence that all alleged violations are thoroughly investigated, and must prevent further potential abuse while the investigation is in progress.

(4) The results of all investigations must be reported to the administrator or his designated representative and to other officials in accordance with State law (including to the State survey and certification agency) within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.

Interpretive Guidelines §483.13(c)(1-4)

The intent of this regulation is to prevent employment of individuals who have been convicted of abusing, neglecting, or mistreating individuals in a health care related setting.

In addition to inquiry of the State nurse aide registry or other licensing authorities, the facility should check all staff references and make reasonable efforts to uncover information about any past criminal prosecutions.

"Found guilty...by a court of law" applies to situations where the defendant pleads guilty, is found guilty, or pleads nolo contendere.

"**Finding**" is defined as a determination made by the State that validates allegations of abuse, neglect, mistreatment of residents or misappropriation of their property.

Any facility staff found guilty of neglect, abuse, or mistreating residents or misappropriation of property by a court of law must have his or her name entered into the nurse aide registry, or reported to the licensing authority, as appropriate.

Survey Procedures §483.13(c)(1-4)

During Sample Selection--

- If the team has identified a problem in mistreatment, neglect or abuse of residents or misappropriation of their property, then request--
    - A copy of the facility's policies and procedures regarding abuse prevention: Note particularly the extent to which those policies concern the areas uncovered through complaints and/or previous survey;
    - Reports of action(s) by a court of law against employees;
    - Reports of alleged violations involving mistreatment, neglect, abuse, injuries of unknown source, and misappropriation of resident's property;
    - Reports of the results of these investigations; and
    - Records of corrective actions taken.
- Spot check employment applications for questions about convictions or mistreatment, neglect or abuse of residents, or misappropriation of their property. Determine if applicants have answered these questions and if affirmative answers had resulted in rejections of employment candidates.
- Contact the State Nurse Aide Registry or Board of Nursing, as appropriate. Determine if applicants with a finding concerning mistreatment, neglect, and abuse of residents or misappropriation of their property have been rejected.
- Ask for the results of any in-house investigations of mistreatment, neglect, or abuse of residents, misappropriation of their property, or injuries of unknown sources.
    - Was the administrator notified of the incident and when?
    - Did investigations begin promptly after the report of the problem?
    - Is there a record of statements or interviews of the resident, suspect (if one is identified), any eyewitnesses and any circumstantial witnesses?
    - Was relevant documentation reviewed and preserved (e.g., dated dressing which was not changed when treatment recorded change)?

- Was the alleged victim examined promptly (if injury was suspected) and the finding documented in the report?
- What steps were taken to protect the alleged victim from further abuse (particularly where no suspect has been identified)?
- What actions were taken as a result of the investigation?
- What corrective action was taken, including informing the nurse aide registry, State licensure authorities, and other agencies (e.g., long-term care ombudsman; adult protective services; Medicaid fraud and abuse unit)?

C-0385

§483.15(f) Activities

(1) The facility must provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident.

(2) The activities program must be directed by a qualified professional who--

(i) Is a qualified therapeutic recreation specialist or an activities professional who--

(A) Is licensed or registered, if applicable, by the State in which practicing; and

(B) Is eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or

(ii) Has 2 years of experience in a social or recreational program within the last 5 years, 1 of which was full-time in a patient activities program in a health care setting; or

(iii) Is a qualified occupational therapist or occupational therapy assistant; or

(iv) Has completed a training course approved by the State.

Interpretive Guidelines §483.15(f)

A "**recognized accrediting body**" refers to those organizations or associations recognized as such by certified therapeutic recreation specialists or certified activity professionals or registered occupational therapists.

The activities program should be multi-faceted and reflect individual resident's needs on their care plan. Activities can occur at anytime and are not limited to formal activities being provided by activity staff. Others involved may be any facility staff, volunteers, and visitors.

In a Critical Access Hospital, the services at §483.15(f) may be directed either by a qualified professional meeting the requirements of §483.15(f)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy.

Survey Procedures §483.15(f)

- Observe individual, group and bedside activities.
    - Are residents who are confined or choose to remain in their rooms provided with suitable in-room activities (e.g., music, reading, visits with individuals who share their interests)? Do any facility staff members assist the resident with activities?
    - If residents sit for long periods of time with no apparently meaningful activities, is the cause:
        - The resident's choice;
        - Failure of any staff or volunteers either to inform residents when activities are occurring or to encourage resident involvement in activities;
        - Lack of assistance with ambulation;
    - Lack of sufficient supplies and/or staff to facilitate attendance and participation in the activity programs; or
    - Program design that fails to reflect the interests or ability levels of residents, such as activities that are too complex?
    - For residents selected for review, determine to what extent the activities resident's assessment.
    - Review the activity calendar for the month prior to the survey to determine if the formal activity program:
        - Reflects the schedules, choices and rights of the residents;
        - Offers activities at hours convenient to the residents (e.g., morning, afternoon, some evenings and weekends);

- Reflects the cultural and religious interests of the resident population; and
- Would appeal to both men and women and all age groups living in the facility.

o Review clinical records and activity attendance records of residents to determine if:

- Activities reflect individual resident history indicated by the comprehensive assessment;
- Care plans address activities that are appropriate for each resident based on the comprehensive assessment;
- Activities occur as planned; and
- Outcomes/responses to activities interventions are identified in the progress notes of each resident.

o If there are problems with provision of activities, determine if qualified staff provide these service.

C-0386

§483.15(g) Social Services

(1) The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

(2) A facility with more than 120 beds must employ a qualified social worker on a full-time basis.

(3) Qualifications of social worker. A qualified social worker is an individual with--

(i) A bachelor's degree in social work or a bachelor's degree in a human services field including but not limited to sociology, special education, rehabilitation counseling, and psychology; and

(ii) One year of supervised social work experience in a health care setting working directly with individuals.

Interpretive Guidelines §483.15(g)

The intent of this regulation is to assure that all facilities provide for the medically-related social services needs of each resident. This requirement specifies that facilities aggressively identify the need for medically-related social services, and pursue the provision of these services. A qualified social worker need not personally provide all of these services. It is the responsibility of the facility to identify the medically-related social service needs of the resident and assure that the needs are met by the appropriate discipline.

"**Medically-related social services**" means services provided by the facility's staff to assist residents in maintaining or improving their ability to manage their everyday physical, mental, and psychosocial needs. These services could include:

- Making arrangements for obtaining needed adaptive equipment, clothing, and personal items;
- Maintaining contact with family (with resident's permission) to report on changes in health, current goals, discharge planning, and encouragement to participate in care planning;
- Assisting staff to inform residents and those they designate about the resident's health status and health care choices;
- Making referrals and obtaining services from outside entities (e.g., talking books, absentee ballots, community wheelchair transportation);
- Assisting residents with financial and legal matters (e.g., applying for pensions, referrals to lawyers, referrals to funeral homes for preplanning arrangements);
- Discharge planning services (e.g., helping to place a resident on a waiting list for community congregate living, arranging intake for home care services for residents returning home, assisting with transfer arrangements to other facilities);
- Providing or arranging provision of needed counseling services;
- Assisting residents to determine how they would like to make decisions about their health care, and whether or not they would like anyone else to be involved in those decisions;
- Finding options that meet the physical and emotional needs of each resident;
- Meeting the needs of residents who are grieving; and
- Assisting residents with dental/denture care, podiatric care; eye care; hearing services, and obtaining equipment for mobility or assistive eating devices.

Where the Medicaid State Plan does not cover needed services, facilities are still required to attempt to obtain these services.

Survey Procedures §483.15(g)

For residents selected for review:

- How do facility staff implement social services interventions to assist the resident in meeting treatment goals?
- How do staff that are responsible for social work monitor the resident's progress in improving physical, mental and psychosocial functioning? Has goal attainment been evaluated and the care plan changed accordingly?
- How does the care plan link goals to psychosocial functioning/well being?
- Has the staff responsible for social work established and maintained relationships with the resident's family or legal representative?
- What attempts does the facility make to access services for Medicaid recipients when a Medicaid State Plan does not cover those services?
- Look for evidence that social services interventions successfully address residents' needs and link social supports, physical care, and physical environment with residents' needs and individuality.

C-0388

§483.20 Resident Assessment

The facility must conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity.

(b) Comprehensive assessment.

(1) Resident assessment instrument. A facility must make a comprehensive assessment of a resident's needs. The assessment must include at least the following:

(i) Identification and demographic information.

(ii) Customary routine.

(iii) Cognitive patterns.

(iv) Communication.

(v) Vision.

(vi) Mood and behavior patterns.

(vii) Psychosocial well-being.

(viii) Physical functioning and structural problems.

(ix) Continence.

(x) Disease diagnoses and health conditions.

(xi) Dental and nutritional status.

(xii) Skin condition.

(xiii) Activity pursuit.

(xiv) Medications.

(xv) Special treatments and procedures.

(xvi) Discharge potential.

(xvii) Documentation of summary information regarding the additional assessment performed through the resident assessment protocols.

(xviii) Documentation of participation in assessment.

The assessment process must include direct observation and communication with the resident, as well as communication with licensed and non-licensed direct care staff members on all shifts.

Interpretive Guidelines §483.20(b)(1)

The intent of this regulation is to provide the facility with ongoing assessment information necessary to develop a care plan, to provide the appropriate care and services for each resident, and to modify the care plan and care/services based on the resident's status. The facility is expected to use resident observation and communication as the primary source of information when completing the assessment. In addition to direct observation and communication with the resident, the facility should use a variety of other sources, including communication with licensed and non-licensed staff members on all shifts and may include discussions with the resident's MD/DO, family members, or outside consultants and review of the resident's record.

C-0389

§483.20(b)(2) When required. Subject to the timeframes prescribed in §413.343(b) of this chapter, a facility must conduct a comprehensive assessment of a resident in accordance with the timeframes specified in paragraphs (b)(2)(i) through (iii) of this section. The timeframes prescribed in §413.343(b) of this chapter do not apply to CAHs.

> **(i) Within 14 calendar days after admission, excluding readmissions in which there is no significant change in the resident's physical or mental condition. (For purposes of this section, "readmission" means a return to the facility following a temporary absence for hospitalization or for therapeutic leave.)**

Interpretive Guidelines §483.20(b)(2)

The intent of this regulation is to assess residents in a timely manner.

"**Admission**" to the facility is defined as an initial stay or a return stay (not a readmission) in the facility. A "return stay" applies to those residents who are discharged without expectation that they will return to the facility, but who do return to the facility.

A "**readmission**" is an expected return to the facility following a temporary absence for hospitalization, off-site visit or therapeutic leave.

Items in (b)(2) of this section would include comprehensive assessments of a resident which were done within 14 days of admission; within 14 days of a significant change in the resident's physical or mental condition; or done on an annual review. These assessments need to be in the final discharge summary.

C-0390

> **§483.20(b)(2)(ii) Within 14 calendar days after the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition. (For purposes of this section, a "significant change" means a major decline or improvement in the resident's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the resident's health status, and requires inter-disciplinary review or revision of the care plan, or both.)**
>
> **(iii) Not less often than once every 12 months.**

Interpretive Guidelines §483.20(b)(2)(ii)-(iii)

A "**significant change**" may include, but is not limited to, any of the following, or may be determined by a MD/DO's decision if uncertainty exists.

- Deterioration in two of more activities of daily living (ADLs), or any combination of deterioration in two or more areas of ADLs, communication, or cognitive abilities that appear permanent. For example, pronounced deterioration in function and communication following a stroke.

- Loss of ability to ambulate freely or to use hands to grasp small objects to feed or groom oneself, such as spoon, toothbrush, or comb. Temporary loss of ability, such as during an acute illness, is not included.

- Deterioration in behavior or mood, to the point where daily problems arise or relationships have become problematic and staff conclude that these changes in the resident's psychosocial status are not likely to improve without staff intervention.

- Deterioration in a resident's health status, where this change places the resident's life in danger (e.g., stroke, heart disease, metastatic cancer); where the change is associated with a serious clinical complication (e.g., initial development of a stage III pressure sore, prolonged delirious state, or recurrent decline in level of consciousness); or change that is associated with an initial diagnosis of a condition that is likely to affect the resident's physical, mental, or psychosocial well-being over a prolonged period of time (e.g., Alzheimer's disease or diabetes); or the onset of significant, unplanned weight loss (5% in the last 30 days, 10% in the last 180 days).

C-0395

§483.20(k) Comprehensive Care Plans

(1) The facility must develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, mental and psychosocial needs that are identified in the comprehensive assessment. The care plan must describe the following--

(i) The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under §483.25; and

(ii) Any services that would otherwise be required under §483.25 but are not provided due to the resident's exercise of rights under §483.10, including the right to refuse treatment under §483.10(b)(4).

Interpretive Guidelines §483.20(k)(1)

An interdisciplinary team, in conjunction with the resident, resident's family, surrogate, or representative, as appropriate, should develop quantifiable objectives for the highest level of functioning the resident may be expected to attain, based on the comprehensive assessment. The care plan must reflect intermediate steps for each outcome objective if identification of those steps will enhance the resident's ability to meet his/her objectives. Facility staff will use these objectives to follow resident progress. Facilities may, for some residents, need to prioritize needed care. This should be noted in the clinical record or on the plan of care.

The requirements reflect the facility's responsibility to provide necessary care and services to attain or maintain the highest practicable physical, mental and psychosocial well being, in accordance with the comprehensive assessment and plan of care.

However, in some cases, a resident may wish to refuse certain services or treatments that professional staff believe may be indicated to assist the resident in reaching his or her highest practicable level of well-being. Desires of the resident should be documented in the clinical record.

Survey Procedures §483.20(k)(1)

- Does the care plan address the needs, strengths and preferences identified in the comprehensive assessment?
- Is the care plan oriented toward preventing avoidable declines in functioning or functional levels?
- How does the care plan attempt to manage risk factors?
- Does the care plan build on resident strengths?
- Do treatment objectives have measurable outcomes?
- Does the care plan reflect standards of current professional practice?
- Corroborate information regarding the resident's goals and wishes for treatment in the plan of care by interviewing residents; especially those identified as refusing treatment.
- Determine whether the facility has provided adequate information to the resident so that the resident was able to make an informed choice regarding treatment.
- If the resident has refused treatment, does the care plan reflect the facility's efforts to find alternative means to address the problem?

C-0396

§483.20(k)(2) A comprehensive care plan must be--

(i) Developed within 7 days after the completion of the comprehensive assessment;

(ii) Prepared by an interdisciplinary team, that includes the attending MD/DO, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident's needs, and, to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative; and

(iii) Periodically reviewed and revised by a team of qualified persons after each assessment.

Interpretive Guidelines §483.20(k)(2)

"**Interdisciplinary**" means that professional disciplines, as appropriate, will work together to provide the greatest benefit to the resident. It does not mean that every goal must have an interdisciplinary approach. The mechanics of how the interdisciplinary team meets its responsibilities in developing an interdisciplinary care plan (e.g., a face-to-face meeting, teleconference, written communication) are at the discretion of the facility.

The MD/DO must participate as part of the interdisciplinary team, and may arrange with the facility for alternative methods, other than attendance at care planning conferences, of providing his/her input, such as one-to-one discussions and conference calls.

The resident has the right to refuse specific treatments and to select among treatment options before the care plan is instituted. The facility should encourage residents, surrogates, and representatives to participate in care planning, including encouraging attendance at care planning conferences if they so desire.

Survey Procedures §483.20(k)(2)

- Was interdisciplinary expertise utilized to develop a plan to improve the resident's functional abilities?
    - For example, did an occupational therapist design needed adaptive equipment or a speech therapist provide techniques to improve swallowing ability?
    - Do the dietitian and the speech therapist determine, for example, the optimum textures and consistency for the resident's food that provide both a nutritionally adequate diet and effectively use oropharyngeal capabilities of the resident?

- Is there evidence of MD/DO involvement in development of the care plan (e.g., presence at care planning meetings, conversations with team members concerning the care plan, conference calls)?

- In what ways does staff involve residents and families, surrogate, and/or representatives in care planning?
- Does staff make an effort to schedule care plan meetings at the best time of the day for residents and their families?
- Do facility staff attempt to make the process understandable to the resident/family?
- Is the care plan evaluated and revised as the resident's status changes?
- Ask in your resident interviews, "Have you had concerns or questions about your care and brought them to the attention of facility staff?" If yes, "What happened as a result?"

C-0397

§483.20(k)(3) The services provided or arranged by the facility must--

(i) Meet professional standards of quality; and

Interpretive Guidelines §483.20(k)(3)(i)

The intent of this regulation is to assure that persons providing services are qualified to do so, that the resident's plan of care is implemented, and that those services provided meet professional standards of quality and are provided by appropriate qualified persons (e.g., licensed, certified).

"**Professional standards of quality**" means services that are provided according to accepted standards of clinical practice. Standards may apply to care provided by a particular clinical discipline or in a specific clinical situation or setting. Standards regarding quality care practices may be published by a professional organization, licensing board, accreditation body or other regulatory agency. Recommended practices to achieve desired resident outcomes might also be found in clinical literature.

Survey Procedures §483.20(k)(3)(i)

Question those practices that have a negative outcome or have a potential negative outcome.

- Do nurses notify MD/DOs, as appropriate, and show evidence of discussions of acute medical problems?

- Are residents with acute conditions promptly hospitalized, as appropriate?
- Are there errors in medication administration?
- Is there evidence of assessment and care planning sufficient to meet the needs of newly admitted residents, prior to completion of the first comprehensive assessment and care plan?
- Are MD/DOs' orders carried out, unless otherwise indicated by an advanced directive?
- Can staff describe the care, services and expected outcomes of the care they provide?

C-0398

§483.20(k)(3)(ii) Be provided by qualified persons in accordance with each resident's written plan of care.

C-0399

§483.20(l) Discharge Summary

When the facility anticipates discharge a resident must have a discharge summary that includes--

(1) A recapitulation of the resident's stay;

(2) A final summary of the resident's status to include items in paragraph (b)(2) of this section, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or legal representative; and

(3) A post-discharge plan of care that is developed with the participation of the resident and his or her family, which will assist the resident to adjust to his or her new living environment.

Interpretive Guidelines §483.20(l)

The intent of this regulation is to ensure appropriate discharge planning and communication of necessary information to the continuing care provider.

"**Post discharge plan of care**" means the discharge planning process that includes assessing continuing care needs and developing a plan designed to ensure that the individual's needs will be met after discharge from the facility into the community.

When the facility "**anticipates discharge**" the discharge is not an emergency discharge (e.g., hospitalization for an acute condition) and is not due to the resident's death.

"**Adjust to his or her living environment**" means that the post discharge plan should describe the resident's and family's preferences for care, how the resident and family will access these services, and how care should be coordinated if continuing treatment involves multiple care givers. It should identify specific resident needs after discharge such as personal care, sterile dressings, and physical therapy, as well as describe resident/care giver education needs to ensure the resident/care giver is able to meet care needs after discharge.

Survey Procedures §483.20(l)

- Does the discharge summary have information pertinent to continuing care for the resident?
- Is there evidence of discharge planning in the records of discharged residents who had an anticipated discharge or those residents to be discharged shortly (e.g., in the next 7-14 days)?
- Do discharge plans address necessary post discharge care?
- Has the facility aided the resident and his/her family in locating and coordinating post discharge services?
- What types of pre-discharge preparation and education has the facility provided the resident and his/her family?

C-0400

§483.25(i) Nutrition

Based on a resident's comprehensive assessment, the facility must ensure that a resident:

(1) Maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible; and

Interpretive Guidelines §483.25(i)(1)

Parameters of nutritional status that are unacceptable include unplanned weight loss as well as other indices such as peripheral edema, cachexia and laboratory tests indicating malnourishment (e.g., serum albumin levels).

Weight: Since ideal body weight charts have not yet been validated for the institutionalized elderly, weight loss (or gain) is a guide in determining nutritional status. An analysis of

weight loss or gain should consider the loss or gain in light of the individual's former life style as well as the current diagnosis.

C-0401

§483.25(i)(2) Receives a therapeutic diet when there is a nutritional problem.

Interpretive Guidelines §483.25(i)(2)

Suggested parameters for evaluating significance of unplanned and undesired weight loss are:

Interval	Significant Loss	Severe Loss
1 month	5%	Greater than 5%
3 months	7.5%	Greater than 7.5%
6 months	10%	Greater than 10%

The following formula determines percentage of loss:

% of body weight loss = (usual weight - actual weight x 100) divided by usual weight

In evaluating weight loss, consider the resident's usual weight through adult life; the assessment of potential for weight loss; and care plan for weight management. Also, was the resident on a calorie restricted diet, or if newly admitted and obese, and on a normal diet, are fewer calories provided than prior to admission? Was the resident edematous when initially weighed, and with treatment, no longer has edema? Has the resident refused food?

Suggested laboratory values are:

Albumin >60 yr.: 3.4 - 4.8 g/dl (good for examining marginal protein depletion) Plasma Transferrin >60 yr.:180 - 380 g/dl. (Rises with iron deficiency anemia. More persistent indicator of protein status.)

Hemoglobin	Males	14-17 g/dl
	Females:	12-15 g/dl
Hematocrit	Males:	41 - 53
	Females	36 - 46
Potassium	3.5 - 5.0 mEq/L	
Magnesium	1.3 - 2.0 mEq/L	

Some laboratories may have different "normals." Determine range for the specific laboratory. Because some healthy elderly people have abnormal laboratory values, and

because abnormal values can be expected in some disease processes, do not expect laboratory values to be within normal ranges for all residents. Consider abnormal values in conjunction with the resident's clinical condition and baseline normal values.

NOTE: There is no requirement that facilities order the tests referenced above.

Clinical Observations: Potential indicators of malnutrition are pale skin, dull eyes, swollen lips, swollen gums, and swollen and/or dry tongue with scarlet or magenta hue, poor skin turgor, cachexia, bilateral edema, and muscle wasting.

Risk factors for malnutrition are--

- Drug therapy that may contribute to nutritional deficiencies such as--
    - Cardiac glycosides;
    - Diuretics;
    - Anti-inflammatory drugs;
    - Antacids (antacid overuse);
    - Laxatives (laxative overuse);
    - Psychotropic drug overuse;
    - Anticonvulsants;
    - Antineoplastic drugs;
    - Phenothiazines;
    - Oral hypoglycemics;
- Poor oral health status or hygiene, eyesight, motor coordination, or taste alterations;
- Depression or dementia;
- Therapeutic or mechanically altered diet;
- Lack of access to culturally acceptable foods;
- Slow eating pace resulting in food becoming unpalatable, or in staff removing the tray before resident has finished eating; and
- Cancer.

Clinical conditions demonstrating that the maintenance of acceptable nutritional status may not be possible include, but are not limited to--

- Refusal to eat and refusal of other methods of nourishment;
- Advanced disease (i.e., cancer, malabsorption syndrome);
- Increased nutritional/caloric needs associated with pressure sores and wound healing (e.g., fractures, burns);
- Radiation or chemotherapy;
- Kidney disease, alcohol/drug abuse, chronic blood loss, hyperthyroidism;
- Gastrointestinal surgery; and
- Prolonged nausea, vomiting, diarrhea not relieved by treatment given according to accepted standards of practice.

"Therapeutic diet" means a diet ordered by a MD/DO as part of treatment for a disease or clinical condition, to eliminate or decrease certain substances in the diet, (e.g., sodium) or to increase certain substances in the diet (e.g., potassium), or to provide food the resident is able to eat (e.g., a mechanically altered diet).

Survey Procedures §483.25(i)(2)

Determine if residents selected for a comprehensive review, or focused review as appropriate, have maintained acceptable parameters of nutritional status. Where indicated by the resident's medical status, have clinically appropriate therapeutic diets been prescribed?

For sampled residents whose nutritional status is inadequate, do clinical conditions demonstrate that maintenance of inadequate nutritional status was unavoidable--

- Did the facility identify factors that put the resident at risk for malnutrition?
- What routine preventive measures and care did the resident receive to address unique risk factors for malnutrition (e.g., provision of an adequate diet with supplements or modifications as indicated by nutrient needs)?
- Were staff responsibilities for maintaining nutritional status clear, including monitoring the amount of food the resident is eating at each meal and offering substitutes?
- Was this care provided consistently?

- Were individual goals of the plan of care periodically evaluated and if not met, were alternative approaches considered or attempted?

C-0402

§483.45 Specialized Rehabilitative Services

§483.45(a) Provision of Services

If specialized rehabilitative services such as, but not limited to, physical therapy, speech-language pathology, occupational therapy, and mental health rehabilitative services for mental illness and mental retardation, are required in the resident's comprehensive plan of care, the facility must--

(1) Provide the required services; or

(2) Obtain the required services from an outside resource (in accordance with §483.75(h) of this part) from a provider of specialized rehabilitative services.

Interpretive Guidelines §483.45(a)

The intent of this regulation is to assure that residents receive necessary specialized rehabilitative services as determined by the comprehensive assessment and care plan, to prevent avoidable physical and mental deterioration and to assist them in obtaining or maintaining their highest practicable level of functional and psychosocial well being.

Specialized rehabilitative services are considered a facility service and are included within the scope of facility services. They must be provided to residents who need them even when the services are not specifically enumerated in the State plan. No fee can be charged a Medicaid recipient for specialized rehabilitative services because they are covered facility services.

A facility is not obligated to provide **specialized rehabilitative services** if it does not have residents who require these services. If a resident develops a need for these services after admission, the facility must either provide the services, or, where appropriate, obtain the service from an outside resource.

For a resident with mental illness (MI) or mental retardation (MR) to have his or her specialized needs met, the individual must receive all services necessary to assist the individual in maintaining or achieving as much independence and self determination as possible. Specialized services for mental illness or mental retardation refers to those services to be provided by the State which can only be delivered by personnel or programs other than those of the nursing facility (NF) because the overall level of NF services is not as intense as necessary to meet the individuals needs.

"Mental health **rehabilitative services** for MI and MR" refers to those services of lesser frequency or intensity to be implemented by all levels of nursing facility staff who come into contact with the resident who is mentally ill or who has mental retardation. These services are necessary regardless of whether or not they require additional services to be provided for or arranged by the State as specialized services.

Mental health rehabilitative services for MI and MR may include, but are not limited to—

- Consistent implementation during the resident's daily routine and across settings, of systematic plans that are designed to change inappropriate behaviors;
- Drug therapy and monitoring of the effectiveness and side effects of medications which have been prescribed to change inappropriate behavior or to alter manifestations of psychiatric illness;
- Provision of a structured environment for those individuals who are determined to need such structure (e.g., structured socialization activities to diminish tendencies toward isolation and withdrawal);
- Development, maintenance and consistent implementation across settings of those programs designed to teach individuals the daily living skills they need to be more independent and self determining including, but not limited to, grooming, personal hygiene, mobility, nutrition, vocational skills, health, drug therapy, mental health education, money management, and maintenance of the living environment;
- Crisis intervention services;
- Individual, group, and family psychotherapy;
- Development of appropriate personal support networks; and
- Formal behavior modification progress.

Survey Procedures §483.45(a)

Determine the extent of follow through with the comprehensive care plan. Verify from the chart that the resident is receiving frequency and type of therapy as outlined in the care plan.

1. **Physical Therapy**

    - What did the facility do to improve the resident's muscle strength? The resident's balance?
    - What did the facility do to determine if an assistive device would enable the resident to reach or maintain his/her highest practicable level of physical function?

- If the resident has an assistive device, is he/she encouraged to use it on a regular basis?

- What did the facility do to increase the amount of physical activity the resident could do (for example, the number of repetitions of an exercise, the distance walked)?

- What did the facility do to prevent or minimize contractures, which could lead to decreased mobility and increased risk of pressure ulcer occurrence?

2. Occupational Therapy

- What did the facility do to decrease the amount of assistance needed to perform a task?

- What did the facility do to decrease behavioral symptoms?

- What did the facility do to improve gross and fine motor coordination?

- What did the facility do to improve sensory awareness, visual-spatial awareness, and body integration?

- What did the facility do to improve memory, problem solving, attention span, and the ability to recognize safety hazards?

3. Speech, Language Pathology

- What did the facility do to improve auditory comprehension?

- What did the facility do to improve speech production?

- What did the facility do to improve expressive behavior?

- What did the facility do to improve the functional abilities of residents with moderate to severe hearing loss who have received an audiology evaluation?

- For the resident who cannot speak, did the facility assess for a communication board or an alternate means of communication?

4. Rehabilitative Services For MI And MR

- What did the facility do to decrease incidents of inappropriate behaviors, for individuals with MR, or behavioral symptoms for persons with MI? To increase appropriate behavior?

- What did the facility do to identify and treat the underlying factors behind tendencies toward isolation and withdrawal?
- What did the facility do to develop and maintain necessary daily living skills?
- How has the facility modified the training strategies it uses with its residents to account for the special learning needs of its residents with MI or MR?
- Questions to ask individuals with MI or MR--
    - Who do you talk to when you have a problem or need something?
    - What do you do when you feel happy? Sad? Can't sleep at night?
    - In what activities are you involved, and how often?

C-0403

§483.45(b) Qualifications

Specialized rehabilitative services must be provided under the written order of a MD/DO by qualified personnel.

Interpretive Guidelines §483.45(b)

A qualified professional provides specialized rehabilitative services for individuals under a MD/DO's order. Once the assessment for specialized rehabilitative services is completed, a care plan must be developed, followed, and monitored by a licensed professional. Once a resident has met his or her care plan goals, a licensed professional can either discontinue treatment or initiate a maintenance program which either nursing or restorative aides will follow to maintain functional and physical status.

"**Qualified personnel**" means that professional staff are licensed, certified or registered to provide specialized therapy/rehabilitative services in accordance with applicable State laws. Health rehabilitative services for MI and MR must be implemented consistently by all staff unless the nature of the services is such that they are designated or required to be implemented only be licensed or credentialed personnel.

Survey Procedures §483.45(b)

- Determine if there are any problems in quality of care related to maintaining or improving functional abilities. Determine if these problems are attributable in part to the qualifications of specialized rehabilitative services staff.

- Determine from the care plan and record that qualified personnel provide rehabilitative services under the written order of a MD/DO. If a problem in a resident's rehabilitative care is identified that is related to the qualifications of the care providers, it might be necessary to validate the care provider's qualifications.

- If the facility does not employ professional staff who have experience working directly with or designing training or treatment programs to meet the needs of individuals with MI or MR, how has the facility arranged for the necessary direct or staff training services to be provided?

C-0404

§483.55 Dental Services

The facility must assist residents in obtaining routine and 24-hour emergency dental care.

Interpretive Guidelines §483.55

This requirement makes the facility directly responsible for the dental care needs of its residents. The facility must ensure that a dentist is available for residents. It can satisfy this requirement by employing a staff dentist or having a contract/arrangement with a dentist to provide services.

For Medicare and private pay residents, facilities are responsible for having the services available, but they may impose an additional charge for the services. Medicaid residents may not be charged.

For all residents of the facility, if they are unable to pay for needed dental services, the facility should attempt to find alternative funding sources or alternative service delivery systems so that the resident is able to maintain his/her highest practicable level of well being.

C-0405

§483.55(a) Skilled Nursing Facilities

A facility--

(1) Must provide or obtain from an outside resource, in accordance with §483.75(h) of this part, routine and emergency dental services to meet the needs of each resident;

(2) May charge a Medicare resident an additional amount for routine and emergency dental services;

Interpretive Guidelines §483.55(a)(1-2)

"**Routine dental services**" means an annual inspection of the oral cavity for signs of disease, diagnosis of dental disease, dental radiographs as needed, dental cleaning, fillings (new and repairs), minor dental plate adjustments, smoothing of broken teeth, and limited prosthodontic procedures (e.g., taking impressions for dentures and fitting dentures).

"**Emergency dental services**" includes services needed to treat an episode of acute pain in teeth, gums, or palate; broken, or otherwise damaged teeth, or any other problem of the oral cavity that requires immediate attention.

"**Prompt referral**" means, within reason, as soon as the dentures are lost or damaged. Referral does not mean that the resident must see the dentist at that time, but does mean that an appointment (referral) is made, or that the facility is aggressively working at replacing the dentures.

C-0406

§483.55(a)(3) Must if necessary, assist the resident--

(i) In making appointments; and

(ii) By arranging for transportation to and from the dentist's office; and

(4) Promptly refer residents with lost or damaged dentures to a dentist.

Survey Procedures §483.55(a)(3-4)

- Do residents selected for comprehensive or focused reviews, as appropriate, with dentures, use them?
- Are residents missing teeth and may be in need of dentures?
- Do sampled residents have problems eating and maintaining nutritional status because of poor oral health or oral hygiene?
- Are resident's dentures intact? Properly fitted?

NOTE: §483.55(b) Nursing Facilities does not usually apply to Medicare reimbursed swing-bed residents because Medicare swing-bed residents receive skilled nursing care comparable to services provided in a SNF not a NF. If a swing-bed resident is a NF level patient, apply standard §483.55(b) as appropriate.

C-0407

§483.55(b) Nursing Facilities

The facility

(1) Must provide or obtain from an outside resource, in accordance with §483.75(h) of this part, the following dental services to meet the needs of each resident:

(i) Routine dental service (to the extent covered under the State plan); and

(ii) Emergency dental services;

Interpretive Guidelines §483.55(b)(1)

"**Routine dental services**" means an annual inspection of the oral cavity for signs of disease, diagnosis of dental disease, dental radiographs as needed, dental cleaning, fillings (new and repairs), minor dental plate adjustments, smoothing of broken teeth, and limited prosthodontic procedures (e.g., taking impressions for dentures and fitting dentures).

"**Emergency dental services**" includes services needed to treat an episode of acute pain in teeth, gums, or palate; broken, or otherwise damaged teeth, or any other problem of the oral cavity that requires immediate attention.

"**Prompt referral**" means, within reason, as soon as the dentures are lost or damaged. Referral does not mean that the resident must see the dentist at that time, but does mean that an appointment (referral) is made, or that the facility is aggressively working at replacing the dentures.

C-0408

§483.55(b)(2) Must, if necessary, assist the resident--

(i) In making appointments; and

(ii) By arranging for transportation to and from the dentist's office; and

(3) Must promptly refer residents with lost or damaged dentures to a dentist.

Survey Procedures §483.55(b)(2-3)

- Do residents selected for comprehensive or focused reviews, as appropriate, with dentures, use them?

- Are residents missing teeth and may be in need of dentures?
- Do sampled residents have problems eating and maintaining nutritional status because of poor oral health or oral hygiene?
- Are resident's dentures intact? Properly fitted?

Rehabilitation Reference Manual

Tab 25:
CAH Rehabilitation DPU Survey Process

25.1 CAH Rehabilitation DPU Survey Process

25.2 Q&A

25.1 CAH Rehabilitation DPU Survey Process

25.1: CAH Rehabilitation DPU Survey Process

There is no survey process description at this time. It will be developed in the future.

25.2 Q&A

There are no CAH rehabilitation DPU questions and answers at this time.

Rehabilitation Reference Manual

Tab 26: Forms for CAH Rehabilitation DPU Survey

26.1 Form CMS-437A

26.1 Form CMS-437A

FORM APPROVED
OMB NO. 0938-0358

REHABILITATION UNIT CRITERIA WORK SHEET

RELATED MEDICARE PROVIDER NUMBER	ROOM NUMBERS IN THE UNIT	FACILITY NAME AND ADDRESS (City, State, Zip Code)
NUMBER OF BEDS IN THE UNIT	RELATED MEDICARE PROVIDER NUMBER	
REQUEST FOR EXCLUSION FOR COST REPORTING PERIOD: ___/___/_____ to ___/___/_____ (MM DD YYYY MM DD YYYY)		VERIFIED BY

ALL CRITERIA UNDER SUBPART B OF PART 412 OF THE REGULATIONS MUST BE MET FOR EXCLUSION FROM MEDICARE'S ACUTE CARE HOSPITAL PROSPECTIVE PAYMENT SYSTEM

TAG	REGULATION	GUIDANCE	YES	NO	EXPLANATORY STATEMENT
	§412.25 Excluded hospital units: Common requirements.				
	(a) Basis for exclusion. In order to be excluded from the Medicare's Acute Care Hospital Prospective Payment System (PPS) and to be paid under the Inpatient Rehabilitation Facility Prospective Payment System, a rehabilitation unit must meet the following requirements in addition to the all criteria under subpart B of part 412 of the regulations:				
M50	(1) Be part of an institution that — has in effect an agreement under part 489 to participate as a hospital and is not excluded in its entirety from the Acute Care Hospital PPS.	• Has the Fiscal Intermediary (FI) verified the rehab unit meets the 75% rule? • The surveyor should check State Agency (SA) records and/or verify with the Regional Office (RO) to ensure the hospital has an agreement to participate in the Medicare program and to ensure that the hospital is not already excluded in its entirety from PPS, such as a rehabilitation hospital. In other words, the unit seeking exclusion cannot comprise the entire hospital.			
M51	(2) Have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients.	Verify that the hospital has admission criteria and review same. Verify through open and closed record review that the approved admission criteria is being followed for all patients.			
M52	(3) Have admission & discharge records that are separately identified from those of the hospital in which it is located and are readily available.	Verify that medical records are separate and not commingled with other hospital records and are readily available for review.			

TAG	REGULATION	GUIDANCE	YES	NO	EXPLANATORY STATEMENT
M53	(4) Have policies specifying that necessary clinical information is transferred to the unit when a patient of the hospital is transferred to the unit.	Verify that the hospital has a policy detailing the *prompt* transfer of information and that it is being followed. Review records to ensure that the clinical information that should be transferred with the record is actually in the medical record.			
M54	(5) Meet applicable State licensure laws.	• Verify and document that all applicable State licensure laws are met. • Document all unmet State licensure requirements. • Verify the hospital has current licenses for its professional staff. • Are the licenses issued by the State in which the hospital is located? • Does the unit meet special licensing requirements issued by the State?			
M55	(6) Have utilization review standards applicable for the type of care offered in the unit.	Verify that the hospital has a utilization review plan that includes the review of rehab services (No utilization review (UR) standards are required if the QIO is conducting review activities.)			
M56	(7) Have beds physically separate from (that is, not commingled with) the hospital's other beds. **NOTE:** §412.25(a) (8)-(12) are verified by the FI.	Is the space containing the rehab beds separate from the beds in other units of the hospital?			
M57	(13) As part of the first day of the first cost reporting period for which all other exclusion requirements are met, the unit is fully equipped and staffed and is capable of providing hospital inpatient rehabilitation care regardless of whether there are any inpatients in the unit on that date.	Prior to scheduling the survey, verify with the FI that the unit is operational: fully staffed and equipped. (It is not required that the unit has inpatients on the day of the survey, but must demonstrate capability of caring for patients.)			

TAG	REGULATION	GUIDANCE	YES	NO	EXPLANATORY STATEMENT
	§412.29 Excluded rehabilitation units. Additional requirements. In order to be excluded from the Acute Care Hospital PPS, a rehabilitation unit must meet the following requirements:				
M58	(a) Have met either the requirements for: (1) New units under §412.30(b); or (2) Converted units under §412.30(c); or (3) Is excluded for the current cost-reporting period.	The SA will check these provisions with the RO prior to the survey.			
M59	(b) Have in effect a pre-admission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient program or assessment.	Review the pre-admission screening protocol.			
M60	(c) Ensure that the patients receive close medical supervision and furnish, through the use of qualified personnel, rehabilitation nursing, physical therapy, and occupational therapy, plus, as needed, speech therapy, social services or psychological services, and orthotic and prosthetic services.	• Verify that every patient is under the care of a physician and has authenticated orders in the chart. • If the State issues licenses, verify that all licenses are current & are issued by the State in which qualified personnel are providing services. • Determine that the hospital has a means of ensuring that its personnel remain qualified/competent. • Refer to State laws and hospital policies to determine the qualifications of personnel providing rehabilitation services. • Review medical charts if patients have been admitted.			
M61	(d) Have a plan of treatment (POT) for each inpatient that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient.	Ensure that all patients have a POT in their medical record. Verify the physician and other professional personnel participate in the establishment, review, and revision of the POT. (This could be a signature, a record of a conference, or record of consultation.)			

TAG	REGULATION	GUIDANCE	YES	NO	EXPLANATORY STATEMENT
M62	(e) Use a coordinated multidisciplinary team approach in the rehabilitation of each inpatient, as documented by periodic clinical entries made in the patient's medical record to note the patient's status in relationship to goal attainment, and that team conferences are held at least every 2 weeks to determine the appropriateness of treatment.	Review hospital policy regarding multidisciplinary team meetings, frequency, and medical record documentation.			
M63	(f) Have a director of rehabilitation who —	Verify the rehab unit has a director of rehab.			
M64	(1) Provides services to the unit and to its inpatients for at least 20 hours per week;	The 20 hours may be any combination of patient services and administration. Hours cannot be substituted by a Physician Assistant or by any other qualified professional. Verify the 20 hours through review of personnel time cards/logs, etc.			
M65	(2) Is a doctor of medicine or osteopathy;	Ensure license is current and issued by the State in which the service is being provided.			
M66	(3) Is licensed under State law to practice medicine or surgery; and	Ensure license is current and issued by the State in which the service is being provided.			
M67	(4) Has had, after completing a 1 year hospital internship, at least 2 years of training or experience in the medical management of inpatients requiring rehabilitation services.	Review personnel files.			

TAG	REGULATION	GUIDANCE	YES	NO	EXPLANATORY STATEMENT
	§412.30 Exclusion of new distinct part rehabilitation units and expansion of units already excluded.				
M68	(a) **Bed capacity in units.** A decrease in bed capacity must remain in effect for at least a full 12-month cost reporting period before an equal or lesser number of beds can be added to the hospital's licensure and certification and considered "new" under §412.30(b) below.	The SA must verify a previous decrease in State licensed hospital beds. The RO will verify any corresponding reduction in the number of beds for Medicare certification purposes.			
M69	(b) **New units.** A hospital unit is considered a new unit if the hospital has not previously sought exclusion for any rehabilitation unit; and has obtained approval under State licensure and Medicare certification, for an increase in its hospital bed capacity that is greater than 50 percent of the number of beds in the unit. For a hospital seeking exclusion of a new rehabilitation unit, the hospital may provide a written certification that at least 75 percent of the inpatient population it intends the unit to serve will require intensive rehabilitation services for treatment of one or more of the following conditions instead of showing that it has treated such a population during its most recent 12-month cost reporting period: (i) Stroke. (ii) Spinal cord injury (iii) Congenital deformity (iv) Amputation (v) Major multiple trauma. (vi) Fracture of femur (hip fracture). (vii) Brain injury. (viii) Polyarthritis, including rheumatoid arthritis. (ix) Neurological disorders, including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular distrophy, and Parkinson's disease. (x) Burns.	• SA/RO to verify that the hospital has not previously sought exclusion. • SA to verify that hospital received approval for unit under State licensure. • SA to verify that the hospital has provided written certification to the RO/FI. • The regulations at §412.30 state that a hospital unit is considered a converted unit if it doesn't qualify as a new unit. Therefore, existing excluded units are treated as converted units for purposes of reverification of the 75% rule.			

TAG	REGULATION	GUIDANCE	YES	NO	EXPLANATORY STATEMENT
M70	(c) **Converted units** A hospital unit is considered a converted unit if it does not qualify as a new unit and it must have treated, for the hospital's most recent 12-month cost reporting period, an inpatient population of which at least 75 percent required intensive rehabilitation services for the treatment of one or more conditions listed under §412.23(b)(2).	Verify through the RO that the hospital unit provided intensive rehab services to 75% of the unit's population for the most recent 12-month cost reporting period. (The FI is responsible for verifying this criteria.)			
M71	(d) **Expansion of Excluded Rehabilitation Units** (1) The beds that a hospital seeks to add to its excluded rehabilitation unit are considered new only if the State-licensed & Medicare certified bed capacity increases at the start of the cost reporting period (for which the hospital seeks to increase the size of its excluded rehabilitation unit) or at any time after the start of the preceding cost report period; and the hospital has obtained approval, under State licensure and Medicare certification, for an increase in its hospital bed capacity that is greater than 50 percent of the number of beds it seeks to add to the unit. (2) A hospital may increase the size of its excluded rehabilitation unit through conversion of existing bed capacity only if it shows that, for all of the hospital's most recent cost reporting period of at least 12 months, the beds have been used to treat an inpatient population meeting the requirements of §412.23(b)(2).	• Verify the hospital obtained State approval for an increase in its bed capacity. • FI to verify hospital has met the 75% rule for all of the most recent cost reporting period.			

According to the Paperwork Reduction of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0358. The time required to complete this information collection is estimated to average 15 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

Rehabilitation Reference Manual

Tab 27: References for CAH Rehabilitation DPU Survey

27.1 *Code of Federal Regulations*

27.2 *Federal Register*

27.3 Survey & Certification Memoranda

27.4 Social Security Act, Section 1820(c)(2)(E)

27.5 Medicare Modernization Act, Section 405(g)(1)

27.6 *Inpatient Rehabilitation Facility – Patient Assessment Instrument*

27.7 Other Print and Online References

27.1 *Code of Federal Regulations*

42 CFR 410.28
42 CFR 412.25, 29, 30, 600–632
42 CFR 482 Subparts A–D
42 CFR 485.618(d), 647
42 CFR 488.26
42 CFR 489.10(d)

the case of an SNF resident as provided in § 411.15(p) of this chapter;

(ii) As an integral though incidental part of a physician's services; and

(iii) In the hospital or at a location (other than an RHC or an FQHC) that CMS designates as a department of a provider under § 413.65 of this chapter; and

(2) In the case of partial hospitalization services, also meet the conditions of paragraph (d) of this section.

(b) Drugs and biologicals are also subject to the limitations specified in § 410.168.

(c) Rules on emergency services furnished to outpatients by nonparticipating hospitals are specified in § 410.168.

(d) Medicare Part B pays for partial hospitalization services if they are—

(1) Prescribed by a physician who certifies and recertifies the need for the services in accordance with subpart B of part 424 of this chapter; and

(2) Furnished under a plan of treatment as required under subpart B of part 424 of this chapter.

(e) Services furnished by an entity other than the hospital are subject to the limitations specified in § 410.42(a).

(f) Services furnished at a location (other than an RHC or an FQHC) that CMS designates as a department of a provider under § 413.65 of this chapter must be under the direct supervision of a physician. "Direct supervision" means the physician must be present and on the premises of the location and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.

[56 FR 8841, Mar. 1, 1991, as amended at 63 FR 26307, May 12, 1998; 65 FR 18536, Apr. 7, 2000]

§ 410.28 Hospital or CAH diagnostic services furnished to outpatients: Conditions.

(a) Medicare Part B pays for hospital or CAH diagnostic services furnished to outpatients, including drugs and biologicals required in the performance of the services (even if those drugs or biologicals are self-administered), if those services meet the following conditions:

(1) They are furnished by or under arrangements made by a participating hospital or participating CAH, except in the case of an SNF resident as provided in § 411.15(p) of this chapter.

(2) They are ordinarily furnished by, or under arrangements made by, the hospital or CAH to its outpatients for the purpose of diagnostic study.

(3) They would be covered as inpatient hospital services if furnished to an inpatient.

(b) Drugs and biologicals are also subject to the limitations specified in § 410.29(b) and (c).

(c) Diagnostic services furnished by an entity other than the hospital or CAH are subject to the limitations specified in § 410.42(a).

(d) Rules on emergency services furnished to outpatients by nonparticipating hospitals are set forth in subpart G of part 424 of this chapter.

(e) Medicare Part B makes payment under section 1833(t) of the Act for diagnostic services furnished at a facility (other than an RHC or an FQHC) that CMS designates as having provider-based status only when the diagnostic services are furnished under the appropriate level of physician supervision specified by CMS in accordance with the definitions in § 410.32(b)(3)(i), (b)(3)(ii), and (b)(3)(iii). Under general supervision at a facility accorded provider-based status, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the facility.

(f) The rules for clinical diagnostic laboratory tests set forth in §§ 410.32(a) and (d)(2) through (d)(4) of this subpart are applicable to those tests when furnished in hospitals and CAHs.

[51 FR 41339, Nov. 14, 1986, as amended at 58 FR 30668, May 26, 1993; 63 FR 26307, May 12, 1998; 65 FR 18536, Apr. 7, 2000; 66 FR 58809, Nov. 23, 2001]

§ 410.29 Limitations on drugs and biologicals.

Medicare part B does not pay for the following:

(a) Except as provided in § 410.28(a) for outpatient diagnostic services and § 410.63(b) for blood clotting factors,

inpatient hospital services if it is reimbursed under special arrangement as provided in § 412.22(c).

(i) *Changes in classification of hospitals.* For purposes of exclusions from the prospective payment system, the classification of a hospital is effective for the hospital's entire cost reporting period. Any changes in the classification of a hospital are made only at the start of a cost reporting period.

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 35688, Sept. 3, 1985; 51 FR 22041, June 17, 1986; 51 FR 31496, Sept. 3, 1986; 52 FR 33057, Sept. 1, 1987; 55 FR 36068, Sept. 4, 1990; 55 FR 46887, Nov. 7, 1990; 56 FR 43240, Aug. 30, 1991; 57 FR 39820, Sept. 1, 1992; 59 FR 45396, Sept. 1, 1994; 60 FR 45846, Sept. 1, 1995; 62 FR 46026, Aug. 29, 1997; 66 FR 39933, Aug. 1, 2001; 66 FR 41386, Aug. 7, 2001; 67 FR 56048, Aug. 30, 2002; 68 FR 45469, Aug. 1, 2003; 69 FR 25720, May 7, 2004; 69 FR 25775, May 7, 2004]

§ 412.25 Excluded hospital units: Common requirements.

(a) *Basis for exclusion.* In order to be excluded from the prospective payment systems specified in § 412.1(a)(1), a psychiatric or rehabilitation unit must meet the following requirements.

(1) Be part of an institution that—

(i) Has in effect an agreement under part 489 of this chapter to participate as a hospital;

(ii) Is not excluded in its entirety from the prospective payment systems; and

(iii) Has enough beds that are not excluded from the prospective payment systems to permit the provision of adequate cost information, as required by § 413.24(c) of this chapter.

(2) Have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients.

(3) Have admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.

(4) Have policies specifying that necessary clinical information is transferred to the unit when a patient of the hospital is transferred to the unit.

(5) Meet applicable State licensure laws.

(6) Have utilization review standards applicable for the type of care offered in the unit.

(7) Have beds physically separate from (that is, not commingled with) the hospital's other beds.

(8) Be serviced by the same fiscal intermediary as the hospital.

(9) Be treated as a separate cost center for cost finding and apportionment purposes.

(10) Use an accounting system that properly allocates costs.

(11) Maintain adequate statistical data to support the basis of allocation.

(12) Report its costs in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital.

(13) As of the first day of the first cost reporting period for which all other exclusion requirements are met, the unit is fully equipped and staffed and is capable of providing hospital inpatient psychiatric or rehabilitation care regardless of whether there are any inpatients in the unit on that date.

(b) *Changes in the size of excluded units.* For purposes of exclusions from the prospective payment systems under this section, changes in the number of beds and square footage considered to be part of each excluded unit are allowed as specified in paragraphs (b)(1) through (b)(3) of this section.

(1) *Increase in size.* Except as described in paragraph (b)(3) of this section, the number of beds and square footage of an excluded unit may be increased only at the start of a cost reporting period.

(2) *Decrease in size.* Except as described in paragraph (b)(3) of this section, the number of beds and square footage of an excluded unit may be decreased at any time during a cost reporting period if the hospital notifies its fiscal intermediary and the CMS Regional Office in writing of the planned decrease at least 30 days before the date of the decrease, and maintains the information needed to accurately determine costs that are attributable to the excluded unit. Any decrease in the number of beds or square footage considered to be part of an excluded unit made during a cost reporting period must remain in effect for the rest of that cost reporting period.

(3) *Exception to changes in square footage and bed size.* The number of beds in an excluded unit may be decreased, and

the square footage considered to be part of the unit may be either increased or decreased, at any time, if these changes are made necessary by relocation of a unit—

(i) To permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility; or

(ii) Because of catastrophic events such as fires, floods, earthquakes, or tornadoes.

(c) *Changes in the status of hospital units.* For purposes of exclusions from the prospective payment systems under this section, the status of each hospital unit (excluded or not excluded) is determined as specified in paragraphs (c)(1) and (c)(2) of this section.

(1) The status of a hospital unit may be changed from not excluded to excluded only at the start of the cost reporting period. If a unit is added to a hospital after the start of a cost reporting period, it cannot be excluded from the prospective payment systems before the start of a hospital's next cost reporting period.

(2) The status of a hospital unit may be changed from excluded to not excluded at any time during a cost reporting period, but only if the hospital notifies the fiscal intermediary and the CMS Regional Office in writing of the change at least 30 days before the date of the change, and maintains the information needed to accurately determine costs that are or are not attributable to the excluded unit. A change in the status of a unit from excluded to not excluded that is made during a cost reporting period must remain in effect for the rest of that cost reporting period.

(d) *Number of excluded units.* Each hospital may have only one unit of each type (psychiatric or rehabilitation) excluded from the prospective payment systems.

(e) *Satellite facilities.* (1) For purposes of paragraphs (e)(2) through (e)(4) of this section, a satellite facility is a part of a hospital unit that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital.

(2) Except as provided in paragraphs (e)(3) and (e)(5) of this section, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period:

(i) In the case of a unit excluded from the prospective payment systems for the most recent cost reporting period beginning before October 1, 1997, the unit's number of State-licensed and Medicare-certified beds, including those at the satellite facility, does not exceed the unit's number of State-licensed and Medicare-certified beds on the last day of the unit's last cost reporting period beginning before October 1, 1997.

(ii) The satellite facility independently complies with—

(A) For a rehabilitation unit, the requirements under §412.23(b)(2); or

(B) For a psychiatric unit, the requirements under §412.27(a).

(iii) The satellite facility meets all of the following requirements:

(A) Effective for cost reporting periods beginning on or after October 1, 2002, it is not under the control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the control of the medical staff or chief medical officer of the hospital in which it is located.

(B) It maintains admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.

(C) It has beds that are physically separate from (that is, not commingled with) the beds of the hospital in which it is located.

(D) It is serviced by the same fiscal intermediary as the hospital unit of which it is a part.

(E) It is treated as a separate cost center of the hospital unit of which it is a part.

(F) For cost reporting and apportionment purposes, it uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of allocation.

(G) It reports its costs on the cost report of the hospital of which it is a part, covering the same fiscal period and using the same method of apportionment as the hospital of which it is a part.

(3) Except as specified in paragraph (e)(4) of this section, the provisions of paragraph (e)(2) of this section do not apply to any unit structured as a satellite facility on September 30, 1999, and excluded from the prospective payment systems on that date, to the extent the unit continues operating under the same terms and conditions, including the number of beds and square footage considered to be part of the unit, in effect on September 30, 1999.

(4) In applying the provisions of paragraph (e)(3) of this section, any unit structured as a satellite facility as of September 30, 1999, may increase or decrease the square footage of the satellite facility or may decrease the number of beds in the satellite facility at any time, if these changes are made necessary by relocation of the facility—

(i) To permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility; or

(ii) Because of catastrophic events such as fires, floods, earthquakes, or tornadoes.

(5) The provisions of paragraph (e)(2)(i) of this section do not apply to any inpatient rehabilitation facility that is subject to the inpatient rehabilitation facility prospective payment system under subpart P of this part, effective for cost reporting periods beginning on or after October 1, 2003.

(f) *Changes in classification of hospital units.* For purposes of exclusions from the prospective payment system under this section, the classification of a hospital unit is effective for the unit's entire cost reporting period. Any changes in the classification of a hospital unit is made only at the start of a cost reporting period.

(g) *CAH units not meeting applicable requirements.* If a psychiatric or rehabilitation unit of a CAH does not meet the requirements of § 485.647 with respect to a cost reporting period, no payment may be made to the CAH for services furnished in that unit for that period. Payment to the CAH for services in the unit may resume only after the start of the first cost reporting period beginning after the unit has demonstrated to CMS that the unit meets the requirements of § 485.647.

[50 FR 12741, Mar. 29, 1985, as amended at 57 FR 39820, Sept. 1, 1992; 58 FR 46337, Sept. 1, 1993; 59 FR 45400, Sept. 1, 1994; 64 FR 41540, July 30, 1999; 66 FR 39933, Aug. 1, 2001; 66 FR 41387, Aug. 7, 2001; 67 FR 50111, Aug. 1, 2002; 68 FR 45469 and 45698, Aug. 1, 2003; 69 FR 49241, Aug. 11, 2004]

§ 412.27 Excluded psychiatric units: Additional requirements.

In order to be excluded from the prospective payment systems, a psychiatric unit must meet the following requirements:

(a) Admit only patients whose admission to the unit is required for active treatment, of an intensity that can be provided appropriately only in an inpatient hospital setting, of a psychiatric principal diagnosis that is listed in the Third Edition of the American Psychiatric Association's Diagnostic and Statistical Manual, or in Chapter Five ("Mental Disorders") of the International Classification of Diseases, Ninth Revision, Clinical Modification.

(b) Furnish, through the use of qualified personnel, psychological services, social work services, psychiatric nursing, occupational therapy, and recreational therapy.

(c) Maintain medical records that permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the unit, and that meet the following requirements:

(1) *Development of assessment/diagnostic data.* Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit.

(i) The identification data must include the inpatient's legal status.

(ii) A provisional or admitting diagnosis must be made on every inpatient at the time of admission, and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.

(3) *Nursing services.* The unit must have a qualified director of psychiatric nursing services. In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each inpatient's active treatment program and to maintain progress notes on each inpatient.

(i) The director of psychiatric nursing services must be a registered nurse who has a master's degree in psychiatric or mental health nursing, or its equivalent, from a school of nursing accredited by the National League for Nursing, or be qualified by education and experience in the care of the mentally ill. The director must demonstrate competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished.

(ii) The staffing pattern must ensure the availability of a registered nurse 24 hours each day. There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each inpatient's active treatment program.

(4) *Psychological services.* The unit must provide or have available psychological services to meet the needs of the inpatients. The services must be furnished in accordance with acceptable standards of practice, service objectives, and established policies and procedures.

(5) *Social services.* There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished. The services must be furnished in accordance with accepted standards of practice and established policies and procedures. Social service staff responsibilities must include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate information with sources outside the hospital.

(6) *Therapeutic activities.* The unit must provide a therapeutic activities program.

(i) The program must be appropriate to the needs and interests of inpatients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.

(ii) The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each inpatient's active treatment program.

[50 FR 12741, Mar. 29, 1985, as amended at 57 FR 39820, Sept. 1, 1992; 59 FR 45397, 45400, Sept. 1, 1994]

§ 412.29 Excluded rehabilitation units: Additional requirements.

In order to be excluded from the prospective payment systems described in § 412.1(a)(1) and to be paid under the prospective payment system specified in § 412.1(a)(2), a rehabilitation unit must meet the following requirements:

(a) Have met either the requirements for—

(1) New units under § 412.30(a); or

(2) Converted units under § 412.30(c).

(b) Have in effect a preadmission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient program or assessment.

(c) Ensure that the patients receive close medical supervision and furnish, through the use of qualified personnel, rehabilitation nursing, physical therapy, and occupational therapy, plus, as needed, speech therapy, social services or psychological services, and orthotic and prosthetic services.

(d) Have a plan of treatment for each inpatient that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient.

(e) Use a coordinated multidisciplinary team approach in the rehabilitation of each inpatient, as documented by periodic clinical entries made in the patient's medical record to note the patient's status in relationship to goal attainment, and that team conferences are held at least every two weeks to determine the appropriateness of treatment.

(f) Have a director of rehabilitation who—

(1) Provides services to the unit and to its inpatients for at least 20 hours per week;

(2) Is a doctor of medicine or osteopathy;

(3) Is licensed under State law to practice medicine or surgery; and

(4) Has had, after completing a one-year hospital internship, at least two years of training or experience in the medical management of inpatients requiring rehabilitation services.

[50 FR 12741, Mar. 29, 1985, as amended at 57 FR 39821, Sept. 1, 1992; 59 FR 45397, 45400, Sept. 1, 1994; 60 FR 45847, Sept. 1, 1995; 66 FR 41387, Aug. 7, 2001; 68 FR 45699, Aug. 1, 2003]

§ 412.30 Exclusion of new rehabilitation units and expansion of units already excluded.

(a) *Bed capacity in units.* A decrease in bed capacity must remain in effect for at least a full 12-month cost reporting period before an equal or lesser number of beds can be added to the hospital's licensure and certification and considered "new" under paragraph (b) of this section. Thus, when a hospital seeks to establish a new unit under the criteria under paragraph (b) of this section, or to enlarge an existing unit under the criteria under paragraph (d) of this section, the regional office will review its records on the facility to determine whether any beds have been delicensed and decertified during the 12-month cost reporting period before the period for which the hospital seeks to add the beds. To the extent bed capacity was removed from the hospital's licensure and certification during that period, that amount of bed capacity may not be considered "new" under paragraph (b) of this section.

(b) *New units.* (1) A hospital unit is considered a new unit if the hospital—

(i) Has not previously sought exclusion for any rehabilitation unit; and

(ii) Has obtained approval, under State licensure and Medicare certification, for an increase in its hospital bed capacity that is greater than 50 percent of the number of beds in the unit.

(2) A hospital that seeks exclusion of a new rehabilitation unit may provide a written certification that the inpatient population the hospital intends the unit to serve meets the requirements of § 412.23(b)(2) instead of showing that the unit has treated such a population during the hospital's most recent cost reporting period.

(3) The written certification described in paragraph (b)(2) of this section is effective for the first full cost reporting period during which the unit is used to provide hospital inpatient care.

(4) If a hospital that has not previously participated in the Medicare program seeks exclusion of a rehabilitation unit, it may designate certain beds as a new rehabilitation unit for the first full 12-month cost reporting period that occurs after it becomes a Medicare-participating hospital. The written certification described in paragraph (b)(2) of this section also is effective for any cost reporting period of not less than 1 month and not more than 11 months occurring between the date the hospital began participating in Medicare and the start of the hospital's regular 12-month cost reporting period.

(5) A hospital that has undergone a change of ownership or leasing as defined in § 489.18 of this chapter is not considered to have participated previously in the Medicare program.

(c) *Converted units.* A hospital unit is considered a converted unit if it does not qualify as a new unit under paragraph (a) of this section. A converted unit must have treated, for the hospital's most recent, consecutive, and appropriate 12-month time period (as defined by CMS or the fiscal intermediary), an inpatient population meeting the requirements of § 412.23(b)(2).

(d) *Expansion of excluded rehabilitation units.*—(1) *New bed capacity.* The beds that a hospital seeks to add to its excluded rehabilitation unit are considered new beds only if—

(i) The hospital's State-licensed and Medicare-certified bed capacity increases at the start of the cost reporting period for which the hospital seeks to increase the size of its excluded rehabilitation unit, or at any time after the start of the preceding cost reporting period; and

(ii) The hospital has obtained approval, under State licensure and Medicare certification, for an increase in its hospital bed capacity that is greater than 50 percent of the number of beds it seeks to add to the unit.

(2) *Conversion of existing bed capacity.* (i) Bed capacity is considered to be existing bed capacity if it does not meet the definition of new bed capacity under paragraph (d)(1) of this section.

(ii) A hospital may increase the size of its excluded rehabilitation unit through the conversion of existing bed capacity only if it shows that, for the hospital's most recent, consecutive, and appropriate 12-month time period (as defined by CMS or the fiscal intermediary), the beds have been used to treat an inpatient population meeting the requirements of § 412.23(b)(2).

(e) *Retroactive adjustments for certain units.* For cost reporting periods beginning on or after October 1, 1991, if a hospital has a new rehabilitation unit excluded from the prospective payment systems for a cost reporting period under paragraph (a) of this section or expands an existing rehabilitation unit under paragraph (c) of this section, but the inpatient population actually treated in the new unit or the beds added to the existing unit during that cost reporting period does not meet the requirements in § 412.23(b)(2), CMS adjusts payments to the hospital retroactively in accordance with the provisions in § 412.130 of this part.

[50 FR 12741, Mar. 29, 1985, as amended at 56 FR 43420, Aug. 30, 1991; 57 FR 39821, Sept. 1, 1992; 59 FR 45400, Sept. 1, 1994; 60 FR 45847, Sept. 1, 1995; 62 FR 46027, Aug. 29, 1997; 68 FR 45699, Aug. 1, 2003; 69 FR 25776, May 7, 2004]

Subpart C—Conditions for Payment Under the Prospective Payment Systems for Inpatient Operating Costs and Inpatient Capital-Related Costs

§ 412.40 General requirements.

(a) A hospital must meet the conditions of this subpart to receive payment under the prospective payment systems for inpatient hospital services furnished to Medicare beneficiaries.

(b) If a hospital fails to comply fully with these conditions with respect to inpatient hospital services furnished to one or more Medicare beneficiaries, CMS may, as appropriate—

(1) Withhold Medicare payment (in full or in part) to the hospital until the hospital provides adequate assurances of compliance; or

(2) Terminate the hospital's provider agreement.

[50 FR 12741, Mar. 29, 1985, as amended at 57 FR 39821, Sept. 1, 1992]

§ 412.42 Limitations on charges to beneficiaries.

(a) *Prohibited charges.* A hospital may not charge a beneficiary for any services for which payment is made by Medicare, even if the hospital's costs of furnishing services to that beneficiary are greater than the amount the hospital is paid under the prospective payment systems.

(b) *Permitted charges—Stay covered.* A hospital receiving payment under the prospective payment systems for a covered hospital stay (that is, a stay that includes at least one covered day) may charge the Medicare beneficiary or other person only for the following:

(1) The applicable deductible and coinsurance amounts under §§ 409.82, 409.83, and 409.87 of this chapter.

(2) Noncovered items and services, furnished at any time during a covered stay, unless they are excluded from coverage only on the basis of the following:

(i) The exclusion of custodial care under § 405.310(g) of this chapter (see paragraph (c) of this section for when charges may be made for custodial care).

(ii) The exclusion of medically unnecessary items and services under § 405.310(k) of this chapter (see paragraphs (c) and (d) of this section for when charges may be made for medically unnecessary items and services).

(iii) The exclusion under § 405.310(m) of this chapter of nonphysician services furnished to hospital inpatients by other than the hospital or a provider or supplier under arrangements made by the hospital.

(iv) The exclusion of items and services furnished when the patient is not entitled to Medicare Part A benefits under subpart A of part 406 of this

weeks after the end of the biweekly period of service as described in §413.64(h)(6) of this subchapter. The interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if a long-term care hospital receives interim payments for less than a full reporting period. These payments are subject to final cost settlement.

(d) *Special interim payment for unusually long lengths of stay.*

(1) *First interim payment.* A hospital that is not receiving periodic interim payments under paragraph (b) of this section may request an interim payment 60 days after a Medicare beneficiary has been admitted to the hospital. Payment for the interim bill is determined as if the bill were a final discharge bill and includes any outlier payment determined as of the last day for which services have been billed.

(2) *Additional interim payments.* A hospital may request additional interim payments at intervals of at least 60 days after the date of the first interim bill submitted under paragraph (d)(1) of this section. Payment for these additional interim bills, as well as the final bill, is determined as if the bill were the final bill with appropriate adjustments made to the payment amount to reflect any previous interim payment made under the provisions of this paragraph.

(e) *Outlier payments.* Additional payments for outliers are not made on an interim basis. The outlier payments are made based on the submission of a discharge bill and represent final payment.

(f) *Accelerated payments.* (1) *General rule.* Upon request, an accelerated payment may be made to a long-term care hospital that is receiving payment under this subpart and is not receiving PIP under paragraph (b) of this section if the hospital is experiencing financial difficulties because of the following:

(i) There is a delay by the intermediary in making payment to the long-term care hospital.

(ii) Due to an exceptional situation, there is a temporary delay in the hospital's preparation and submittal of bills to the intermediary beyond its normal billing cycle.

(2) *Approval of payment.* A request by a long-term care hospital for an accelerated payment must be approved by the intermediary and by CMS.

(3) *Amount of payment.* The amount of the accelerated payment is computed as a percentage of the net payment for unbilled or unpaid covered services.

(4) *Recovery of payment.* Recovery of the accelerated payment is made by recoupment as long-term care hospital bills are processed or by direct payment by the long-term care hospital.

[67 FR 56049, Aug. 30, 2002, as amended at 68 FR 10988, Mar. 7, 2003]

Subpart P—Prospective Payment for Inpatient Rehabilitation Hospitals and Rehabilitation Units

SOURCE: 66 FR 41388, Aug. 7, 2001, unless otherwise noted.

§412.600 Basis and scope of subpart.

(a) *Basis.* This subpart implements section 1886(j) of the Act, which provides for the implementation of a prospective payment system for inpatient rehabilitation hospitals and rehabilitation units (in this subpart referred to as "inpatient rehabilitation facilities").

(b) *Scope.* This subpart sets forth the framework for the prospective payment system for inpatient rehabilitation facilities, including the methodology used for the development of payment rates and associated adjustments, the application of a transition phase, and related rules. Under this system, for cost reporting periods beginning on or after January 1, 2002, payment for the operating and capital costs of inpatient hospital services furnished by inpatient rehabilitation facilities to Medicare Part A fee-for-service beneficiaries is made on the basis of prospectively determined rates and applied on a per discharge basis.

§412.602 Definitions.

As used in this subpart—

Assessment reference date means the specific calendar day in the patient assessment process that sets the designated endpoint of the common patient observation period, with most patient assessment items usually referring back in time from this endpoint.

CMS stands for the Centers for Medicare & Medicaid Services.

Comorbidity means a specific patient condition that is secondary to the patient's principal diagnosis that is the primary reason for the inpatient rehabilitation stay.

Discharge. A Medicare patient in an inpatient rehabilitation facility is considered discharged when—

(1) The patient is formally released from the inpatient rehabilitation facility; or

(2) The patient dies in the inpatient rehabilitation facility.

Encode means entering data items into the fields of the computerized patient assessment software program.

Functional-related groups refers to the distinct groups under which inpatients are classified using proxy measurements of inpatient rehabilitation relative resource usage.

Interrupted stay means a stay at an inpatient rehabilitation facility during which a Medicare inpatient is discharged from the inpatient rehabilitation facility and returns to the same inpatient rehabilitation facility within 3 consecutive calendar days. The duration of the interruption of the stay of 3 consecutive calendar days begins with the day of discharge from the inpatient rehabilitation facility and ends on midnight of the third day.

Outlier payment means an additional payment beyond the standard Federal prospective payment for cases with unusually high costs.

Patient assessment instrument refers to a document that contains clinical, demographic, and other information on a patient.

Rural area means an area as defined in § 412.62(f)(1)(iii).

Transfer means the release of a Medicare inpatient from an inpatient rehabilitation facility to another inpatient rehabilitation facility, a short-term, acute-care prospective payment hospital, a long-term care hospital as described in § 412.23(e), or a nursing home that qualifies to receive Medicare or Medicaid payments.

Urban area means an area as defined in § 412.62(f)(1)(ii).

[66 FR 41388, Aug. 7, 2001, as amended at 67 FR 44077, July 1, 2002; 68 FR 45699, Aug. 1, 2003]

§ 412.604 Conditions for payment under the prospective payment system for inpatient rehabilitation facilities.

(a) *General requirements.* (1) Effective for cost reporting periods beginning on or after January 1, 2002, an inpatient rehabilitation facility must meet the conditions of this section to receive payment under the prospective payment system described in this subpart for inpatient hospital services furnished to Medicare Part A fee-for-service beneficiaries.

(2) If an inpatient rehabilitation facility fails to comply fully with these conditions with respect to inpatient hospital services furnished to one or more Medicare Part A fee-for-service beneficiaries, CMS or its Medicare fiscal intermediary may, as appropriate—

(i) Withhold (in full or in part) or reduce Medicare payment to the inpatient rehabilitation facility until the facility provides adequate assurances of compliance; or

(ii) Classify the inpatient rehabilitation facility as an inpatient hospital that is subject to the conditions of subpart C of this part and is paid under the prospective payment systems specified in § 412.1(a)(1).

(b) *Inpatient rehabilitation facilities subject to the prospective payment system.* Subject to the special payment provisions of § 412.22(c), an inpatient rehabilitation facility must meet the general criteria set forth in § 412.22 and the criteria to be classified as a rehabilitation hospital or rehabilitation unit set forth in §§ 412.23(b), 412.25, and 412.29 for exclusion from the inpatient hospital prospective payment systems specified in § 412.1(a)(1).

(c) *Completion of patient assessment instrument.* For each Medicare Part A fee-for-service patient admitted to or discharged from an IRF on or after January 1, 2002, the inpatient rehabilitation

facility must complete a patient assessment instrument in accordance with §412.606.

(d) *Limitation on charges to beneficiaries*—(1) *Prohibited charges.* Except as provided in paragraph (d)(2) of this section, an inpatient rehabilitation facility may not charge a beneficiary for any services for which payment is made by Medicare, even if the facility's costs of furnishing services to that beneficiary are greater than the amount the facility is paid under the prospective payment system.

(2) *Permitted charges.* An inpatient rehabilitation facility receiving payment under this subpart for a covered hospital stay (that is, a stay that includes at least one covered day) may charge the Medicare beneficiary or other person only for the applicable deductible and coinsurance amounts under §§409.82, 409.83, and 409.87 of this subchapter and for items or services as specified under §489.20(a) of this chapter.

(e) *Furnishing of inpatient hospital services directly or under arrangement.* (1) Subject to the provisions of §412.622(b), the applicable payments made under this subpart are payment in full for all inpatient hospital services, as defined in §409.10 of this subchapter. Inpatient hospital services do not include the following:

(i) Physicians' services that meet the requirements of §415.102(a) of this subchapter for payment on a fee schedule basis.

(ii) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(iii) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(iv) Certified nurse midwife services, as defined in section 1861(gg) of the Act.

(v) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(vi) Services of an anesthetist, as defined in §410.69 of this chapter.

(2) Medicare does not pay any provider or supplier other than the inpatient rehabilitation facility for services furnished to a Medicare beneficiary who is an inpatient of the inpatient rehabilitation facility, except for services described in paragraphs (e)(1)(i) through (e)(1)(vi) of this section.

(3) The inpatient rehabilitation facility must furnish all necessary covered services to the Medicare beneficiary either directly or under arrangements (as defined in §409.3 of this subchapter).

(f) *Reporting and recordkeeping requirements.* All inpatient rehabilitation facilities participating in the prospective payment system under this subpart must meet the recordkeeping and cost reporting requirements of §§413.20 and 413.24 of this subchapter.

[66 FR 41388, Aug. 7, 2001, as amended at 67 FR 44077, July 1, 2002; 68 FR 45699, Aug. 1, 2003]

§412.606 Patient assessments.

(a) *Admission orders.* At the time that each Medicare Part A fee-for-service patient is admitted, the inpatient rehabilitation facility must have physician orders for the patient's care during the time the patient is hospitalized.

(b) *Patient assessment instrument.* An inpatient rehabilitation facility must use the CMS inpatient rehabilitation facility patient assessment instrument to assess Medicare Part A fee-for-service inpatients who—

(1) Are admitted on or after January 1, 2002; or

(2) Were admitted before January 1, 2002, and are still inpatients as of January 1, 2002.

(c) *Comprehensive assessments.* (1) A clinician of the inpatient rehabilitation facility must perform a comprehensive, accurate, standardized, and reproducible assessment of each Medicare Part A fee-for-service inpatient using the inpatient rehabilitation facility patient assessment instrument specified in paragraph (b) of this section as part of his or her patient assessment in accordance with the schedule described in §412.610.

(2) A clinician employed or contracted by an inpatient rehabilitation facility who is trained on how to perform a patient assessment using the inpatient rehabilitation facility patient assessment instrument specified in paragraph (b) of the section must record appropriate and applicable data accurately and completely for each item on the patient assessment instrument.

(3) The assessment process must include—

(i) Direct patient observation and communication with the patient; and

(ii) When appropriate and to the extent feasible, patient data from the patient's physician(s), family, someone personally knowledgeable about the patient's clinical condition or capabilities, the patient's clinical record, and other sources.

§ 412.608 Patients' rights regarding the collection of patient assessment data.

(a) Before performing an assessment using the inpatient rehabilitation facility patient assessment instrument, a clinician of the inpatient rehabilitation facility must give a Medicare inpatient—

(1) The form entitled "Privacy Act Statement—Health Care Records"; and

(2) The simplified plain language description of the Privacy Act Statement—Health Care Records which is a form entitled "Data Collection Information Summary for Patients in Inpatient Rehabilitation Facilities."

(b) The inpatient rehabilitation facility must document in the Medicare inpatient's clinical record that the Medicare inpatient has been given the documents specified in paragraph (a) of this section.

(c) By giving the Medicare inpatient the forms specified in paragraph (a) of this section the inpatient rehabilitation facility will inform the Medicare patient of—

(1) Their privacy rights under the Privacy Act of 1974 and 45 CFR 5b.4(a)(3); and

(2) The following rights:

(i) The right to be informed of the purpose of the collection of the patient assessment data;

(ii) The right to have the patient assessment information collected be kept confidential and secure;

(iii) The right to be informed that the patient assessment information will not be disclosed to others, except for legitimate purposes allowed by the Federal Privacy Act and Federal and State regulations;

(iv) The right to refuse to answer patient assessment questions; and

(v) The right to see, review, and request changes on his or her patient assessment.

(d) The patient rights specified in this section are in addition to the patient rights specified in § 82.13 of this chapter.

[68 FR 45699, Aug. 1, 2003]

§ 412.610 Assessment schedule.

(a) *General.* For each Medicare Part A fee-for-service inpatient, an inpatient rehabilitation facility must complete a patient assessment instrument as specified in § 412.606 that covers a time period that is in accordance with the assessment schedule specified in paragraph (c) of this section.

(b) *Starting the assessment schedule day count.* The first day that the Medicare Part A fee-for-service inpatient is furnished Medicare-covered services during his or her current inpatient rehabilitation facility hospital stay is counted as day one of the patient assessment schedule.

(c) *Assessment schedules and reference dates.* The inpatient rehabilitation facility must complete a patient assessment instrument upon the Medicare Part A fee-for-service patient's admission and discharge as specified in paragraphs (c)(1) and (c)(2) of this section.

(1) *Admission assessment.*

(i) *General rule.* The admission assessment—

(A) Time period is a span of time that covers calendar days 1 through 3 of the patient's current Medicare Part A fee-for-service hospitalization;

(B) Has an admission assessment reference date that is the third calendar day of the span of time specified in paragraph (c)(1)(i)(A) of this section; and

(C) Must be completed by the calendar day that follows the admission assessment reference day.

(ii) *Exception to the general rule.* We may specify in the patient assessment instrument item-by-item guide and in other issued instructions, items that have a different admission assessment time period to most appropriately capture patient information for payment and quality of care monitoring objectives.

(2) *Discharge assessment.*

(i) *General rule.* The discharge assessment—

(A) Time period is a span of time that covers 3 calendar days, and is the discharge assessment reference date itself specified in paragraph (c)(2)(ii) of this section and the 2 calendar days prior to the discharge assessment reference date; and

(B) Must be completed on the 5th calendar day that follows the discharge assessment reference date specified in paragraph (c)(2)(ii) of this section with the discharge assessment reference date itself being counted as the first day of the 5 calendar day time span.

(ii) *Discharge assessment reference date.* The discharge assessment reference date is the actual day that the first of either of the following two events occurs:

(A) The patient is discharged from the inpatient rehabilitation facility; or

(B) The patient stops being furnished Medicare Part A fee-for-service inpatient rehabilitation services.

(iii) *Exception to the general rule.* We may specify in the patient assessment instrument item-by-item guide and in other issued instructions, items that have a different discharge assessment time period to most appropriately capture patient information for payment and quality of care monitoring objectives.

(d) *Encoding dates.* The admission and discharge patient assessments must be encoded by the 7th calendar day from the completion dates specified in paragraph (c) of this section.

(e) *Accuracy of the patient assessment data.* The encoded patient assessment data must accurately reflect the patient's clinical status at the time of the patient assessment.

(f) *Patient assessment instrument record retention.* An inpatient rehabilitation facility must maintain all patient assessment data sets completed on Medicare Part A fee-for-service patients within the previous 5 years either in a paper format in the patient's clinical record or in an electronic computer file format that the inpatient rehabilitation facility can easily obtain.

[66 FR 41388, Aug. 7, 2001, as amended at 67 FR 44077, July 1, 2002; 68 FR 45699, Aug. 1, 2003]

§412.612 Coordination of the collection of patient assessment data.

(a) *Responsibilities of the clinician.* A clinician of an inpatient rehabilitation facility who has participated in performing the patient assessment must have responsibility for—

(1) The accuracy and thoroughness of the specific data recorded by that clinician on the patient's assessment instrument; and

(2) The accuracy of the assessment reference date inserted on the patient assessment instrument completed under §412.610(c).

(b) *Penalty for falsification.*

(1) Under Medicare, an individual who knowingly and willfully—

(i) Completes a material and false statement in a patient assessment is subject to a civil money penalty of not more than $1,000 for each assessment; or

(ii) Causes another individual to complete a material and false statement in a patient assessment is subject to a civil money penalty of not more than $5,000 for each assessment.

(2) Clinical disagreement does not constitute a material and false statement.

§412.614 Transmission of patient assessment data.

(a) *Data format. General rule.* The inpatient rehabilitation facility must encode and transmit data for each Medicare Part A fee-for-service inpatient—

(1) Using the computerized version of the patient assessment instrument available from us; or

(2) Using a computer program(s) that conforms to our standard electronic record layout, data specifications, and data dictionary, includes the required patient assessment instrument data set, and meets our other specifications.

(3) *Exception to the general rule.* When the inpatient rehabilitation facility does not submit claim data to Medicare in order to be paid for any of the services it furnished to a Medicare Part A fee-for-service inpatient, the inpatient rehabilitation facility is not required to, but may, transmit to Medicare the inpatient rehabilitation facility patient assessment data associated with the services furnished to that

same Medicare Part A fee-for-service inpatient.

(b) *How to transmit data.* The inpatient rehabilitation facility must—

(1) Electronically transmit complete, accurate, and encoded data from the patient assessment instrument for each Medicare Part A fee-for-service inpatient to our patient data system in accordance with the data format specified in paragraph (a) of this section; and

(2) Transmit data using electronic communications software that provides a direct telephone connection from the inpatient rehabilitation facility to the our patient data system.

(c) *Transmission dates.* The inpatient rehabilitation facility must transmit both the admission patient assessment and the discharge patient assessments at the same time to the our patient data system by the 7th calendar day in the period beginning with the applicable patient assessment instrument encoding date specified in § 412.610(d).

(d) *Late transmission penalty.* (1) We assess a penalty when an inpatient rehabilitation facility does not transmit the required data from the patient assessment instrument to the our patient data system in accordance with the transmission timeframe in paragraph (c) of this section.

(2) If the actual patient assessment data transmission date is later than 10 calendar days from the transmission date specified in paragraph (c) of this section, the patient assessment data is considered late and the inpatient rehabilitation facility receives a payment rate that is 25 percent less than the payment rate associated with a case-mix group.

(e) *Exemption to being assessed a penalty for transmitting the IRF–PAI data late.* CMS may waive the penalty specified in paragraph (d) of this section when, due to an extraordinary situation that is beyond the control of an inpatient rehabilitation facility, the inpatient rehabilitation facility is unable to transmit the patient assessment data in accordance with paragraph (c) of this section. Only CMS can determine if a situation encountered by an inpatient rehabilitation facility is extraordinary and qualifies as a situation for waiver of the penalty specified in paragraph (d)(2) of this section. An extraordinary situation may be due to, but is not limited to, fires, floods, earthquakes, or similar unusual events that inflict extensive damage to an inpatient rehabilitation facility. An extraordinary situation may be one that produces a data transmission problem that is beyond the control of the inpatient rehabilitation facility, as well as other situations determined by CMS to be beyond the control of the inpatient rehabilitation facility. An extraordinary situation must be fully documented by the inpatient rehabilitation facility.

[66 FR 41388, Aug. 7, 2001, as amended at 68 FR 45699, Aug. 1, 2003]

§ 412.616 Release of information collected using the patient assessment instrument.

(a) *General.* An inpatient rehabilitation facility may release information from the patient assessment instrument only as specified in § 482.24(b)(3) of this chapter.

(b) *Release to the inpatient rehabilitation facility's agent.* An inpatient rehabilitation facility may release information that is patient-identifiable to an agent only in accordance with a written contract under which the agent agrees not to use or disclose the information except for the purposes specified in the contract and only to the extent the facility itself is permitted to do so under paragraph (a) of this section.

§ 412.618 Assessment process for interrupted stays.

For purposes of the patient assessment process, if a Medicare Part A fee-for-service patient has an interrupted stay, as defined under § 412.602, the following applies:

(a) *Assessment requirements.* (1) The initial case-mix group classification from the admission assessment remains in effect (that is, no new admission assessment is performed).

(2) When the patient has completed his or her entire rehabilitation episode stay, a discharge assessment must be performed.

(b) *Recording and encoding of data.* The clinician must record the interruption of the stay on the patient assessment instrument.

(c) If the interruption in the stay occurs during the admission assessment time period, the assessment reference date, completion date, and encoding date for the admission assessment are advanced by the same number of calendar days as the length of the patient's interruption in the stay.

[66 FR 41388, Aug. 7, 2001, as amended at 67 FR 44077, July 1, 2002]

§412.620 Patient classification system.

(a) *Classification methodology.*

(1) A patient classification system is used to classify patients in inpatient rehabilitation facilities into mutually exclusive case-mix groups.

(2) For purposes of this subpart, case-mix groups are classes of Medicare patient discharges by functional-related groups that are based on a patient's impairment, age, comorbidities, functional capabilities, and other factors that may improve the ability of the functional-related groups to estimate variations in resource use.

(3) Data from admission assessments under §412.610(c)(1) are used to classify a Medicare patient into an appropriate case-mix group.

(4) Data from the discharge assessment under §412.610(c)(2) are used to determine the weighting factors under paragraph (b)(4) of this section.

(b) *Weighting factors.*

(1) *General.* An appropriate weight is assigned to each case-mix group that measures the relative difference in facility resource intensity among the various case-mix groups.

(2) *Short-stay outliers.* We will determine a weighting factor or factors for patients that are discharged and not transferred (as defined in §412.602) within a number of days from admission as specified by us.

(3) *Patients who expire.* We will determine a weighting factor or factors for patients who expire within a number of days from admission as specified by us.

(4) *Comorbidities.* We will determine a weighting factor or factors to account for the presence of a comorbidity, as defined in §412.602, that is relevant to resource use in the classification system.

(c) *Revision of case-mix group classifications and weighting factors.* We may periodically adjust the case-mix groups and weighting factors to reflect changes in—

(1) Treatment patterns;

(2) Technology;

(3) Number of discharges; and

(4) Other factors affecting the relative use of resources.

§412.622 Basis of payment.

(a) *Method of payment.*

(1) Under the prospective payment system, inpatient rehabilitation facilities receive a predetermined amount per discharge for inpatient services furnished to Medicare Part A fee-for-service beneficiaries.

(2) The amount of payment under the prospective payment system is based on the Federal payment rate, including adjustments described in §412.624 and, if applicable, during a transition period, on a blend of the Federal payment rate and the facility-specific payment rate described in §412.626.

(b) *Payment in full.* (1) The payment made under this subpart represents payment in full (subject to applicable deductibles and coinsurance as described in subpart G of part 409 of this subchapter) for inpatient operating and capital-related costs associated with furnishing Medicare covered services in an inpatient rehabilitation facility, but not for the cost of an approved medical education program described in §§413.85 and 413.86 of this chapter.

(2) In addition to payments based on prospective payment rates, inpatient rehabilitation facilities receive payments for the following:

(i) Bad debts of Medicare beneficiaries, as provided in §413.80 of this chapter; and

(ii) A payment amount per unit for blood clotting factor provided to Medicare inpatients who have hemophilia.

§412.624 Methodology for calculating the Federal prospective payment rates.

(a) *Data used.* To calculate the prospective payment rates for inpatient hospital services furnished by inpatient rehabilitation facilities, we use—

(1) The most recent Medicare data available, as of the date of establishing the inpatient rehabilitation facility prospective payment system, to estimate payments for inpatient operating and capital-related costs made under part 413 of this subchapter;

(2) An appropriate wage index to adjust for area wage differences;

(3) An increase factor to adjust for the most recent estimate of increases in the prices of an appropriate market basket of goods and services included in covered inpatient rehabilitation services; and

(4) Patient assessment data described in § 412.606 and other data that account for the relative resource utilization of different patient types.

(b) *Determining the average costs per discharge for fiscal year 2001.* We determine the average inpatient operating and capital costs per discharge for which payment is made to each inpatient rehabilitation facility using the available data specified under paragraph (a)(1) of this section. The cost per discharge is adjusted to fiscal year 2001 by an increase factor, described in paragraph (a)(3) of this section, under the update methodology described in section 1886(b)(3)(B)(ii) of the Act for each year through the midpoint of fiscal year 2001.

(c) *Determining the Federal prospective payment rates*—(1) *General.* The Federal prospective payment rates will be established using a standard payment amount referred to as the standard payment conversion factor. The standard payment conversion factor is a standardized payment amount based on average costs from a base year that reflects the combined aggregate effects of the weighting factors, various facility and case level adjustments, and other adjustments.

(2) *Update the cost per discharge.* CMS applies the increase factor described in paragraph (a)(3) of this section to the facility's cost per discharge determined under paragraph (b) of this section to compute the cost per discharge for fiscal year 2002. Based on the updated cost per discharge, CMS estimates the payments that would have been made to the facility for fiscal year 2002 under part 413 of this chapter without regard to the prospective payment system implemented under this subpart.

(3) *Computation of the standard payment conversion factor.* The standard payment conversion factor is computed as follows:

(i) *For fiscal year 2002.* Based on the updated costs per discharge and estimated payments for fiscal year 2002 determined in paragraph (c)(2) of this section, CMS computes a standard payment conversion factor for fiscal year 2002, as specified by CMS, that reflects, as appropriate, the adjustments described in paragraph (d) of this section.

(ii) *For fiscal years after 2002.* The standard payment conversion factor for fiscal years after 2002 will be the standardized payments for the previous fiscal year updated by the increase factor described in paragraph (a)(3) of this section, including adjustments described in paragraph (d) of this section as appropriate.

(4) *Determining the Federal prospective payment rate for each case-mix group.* The Federal prospective payment rates for each case-mix group is the product of the weighting factors described in § 412.620(b) and the standard payment conversion factor described in paragraph (c)(3) of this section.

(d) *Adjustments to the standard payment conversion factor.* The standard payment conversion factor described in paragraph (c)(3) of this section will be adjusted for the following:

(1) *Outlier payments.* CMS determines a reduction factor equal to the estimated proportion of additional outlier payments described in paragraph (e)(4) of this section.

(2) *Budget neutrality.* CMS adjusts the Federal prospective payment rates for fiscal year 2002 so that aggregate payments under the prospective payment system, excluding any additional payments associated with elections not to be paid under the transition period methodology under § 412.626(b), are estimated to equal the amount that would have been made to inpatient rehabilitation facilities under part 413 of this chapter without regard to the prospective payment system implemented under this subpart.

(3) *Coding and classification changes.* CMS adjusts the standard payment conversion factor for a given year if

CMS determines that revisions in case-mix classifications or weighting factors for a previous fiscal year (or estimates that those revisions for a future fiscal year) did result in (or would otherwise result in) a change in aggregate payments that are a result of changes in the coding or classification of patients that do not reflect real changes in case-mix.

(e) *Calculation of the adjusted Federal prospective payment.* For each discharge, an inpatient rehabilitation facility's Federal prospective payment is computed on the basis of the Federal prospective payment rate that is in effect for its cost reporting period that begins in a Federal fiscal year specified under paragraph (c) of this section. A facility's Federal prospective payment rate will be adjusted, as appropriate, to account for area wage levels, payments for outliers and transfers, and for other factors as follows:

(1) *Adjustment for area wage levels.* The labor portion of a facility's Federal prospective payment is adjusted to account for geographical differences in the area wage levels using an appropriate wage index. The application of the wage index is made on the basis of the location of the facility in an urban or rural area as defined in §412.602. Adjustments or updates to the wage data used to adjust a facility's Federal prospective payment rate under paragraph (e)(1) of this section will be made in a budget neutral manner. CMS determines a budget neutral wage adjustment factor, based on any adjustment or update to the wage data, to apply to the standard payment conversion factor.

(2) *Adjustments for low-income patients.* We adjust the Federal prospective payment, on a facility basis, for the proportion of low-income patients that receive inpatient rehabilitation services as determined by us.

(3) *Adjustments for rural areas.* We adjust the Federal prospective payment by a factor, as specified by us for facilities located in rural areas, as defined in §412.602.

(4) *Adjustment for high-cost outliers.* CMS provides for an additional payment to an inpatient rehabilitation facility if its estimated costs for a patient exceeds a fixed dollar amount (adjusted for area wage levels and factors to account for treating low-income patients and for rural locations) as specified by CMS. The additional payment equals 80 percent of the difference between the estimated cost of the patient and the sum of the adjusted Federal prospective payment computed under this section and the adjusted fixed dollar amount. Effective for discharges occurring on or after October 1, 2003, additional payments made under this section will be subject to the adjustments at §412.84(i), except that national averages will be used instead of statewide averages. Effective for discharges occurring on or after October 1, 2003, additional payments made under this section will also be subject to adjustments at §412.84(m).

(5) *Adjustments related to the patient assessment instrument.* An adjustment to a facility's Federal prospective payment amount for a given discharge will be made, as specified under §412.614(d), if the transmission of data from a patient assessment instrument is late.

(f) *Special payment provision for patients that are transferred.*

(1) A facility's Federal prospective payment will be adjusted to account for a discharge of a patient who—

(i) Is transferred from the inpatient rehabilitation facility to another site of care, as defined in §412.602; and

(ii) Stays in the facility for a number of days that is less than the average length of stay for nontransfer cases in the case-mix group to which the patient is classified.

(2) We calculate the adjusted Federal prospective payment for patients who are transferred in the following manner:

(i) By dividing the Federal prospective payment by the average length of stay for nontransfer cases in the case-mix group to which the patient is classified to equal the payment per day.

(ii) By multiplying the payment per day under paragraph (f)(2)(i) of this section by the number of days the patient stayed in the facility prior to being discharged to equal the per day payment amount.

(iii) By multiplying the payment per day under paragraph (f)(2)(i) by 0.5 to

equal an additional one half day payment for the first day of the stay before the discharge.

(iv) By adding the per day payment amount under paragraph (f)(2)(ii) and the additional one-half day payment under paragraph (f)(2)(iii) to equal the unadjusted payment amount.

(v) By applying the adjustments described in paragraphs (e)(1), (e)(2), and (e)(3) of this section to the unadjusted payment amount determined in paragraph (f)(2)(iv) of this section to equal the adjusted transfer payment amount.

(g) *Special payment provision for interrupted stays.* When a patient in an inpatient rehabilitation facility has one or more interruptions in the stay, as defined in § 412.602 and as indicated on the patient assessment instrument in accordance with § 412.618(b), we will make payments in the following manner:

(1) *Patient is discharged and returns on the same day.* Payment for a patient who is discharged and returns to the same inpatient rehabilitation facility on the same day will be the adjusted Federal prospective payment under paragraph (e) of this section that is based on the patient assessment data specified in § 412.618(a)(1). Payment for a patient who is discharged and returns to the same inpatient rehabilitation facility on the same day will only be made to the inpatient rehabilitation facility.

(2) *Patient is discharged and does not return by the end of the same day.* Payment for a patient who is discharged and does not return on the same day but does return to the same inpatient rehabilitation facility by or on midnight of the third day, defined as an interrupted stay under § 412.602, will be—

(i) The adjusted Federal prospective payment under paragraph (e) of this section that is based on the patient assessment data specified in § 412.618(a)(1) made to the inpatient rehabilitation facility; and

(ii) If the reason for the interrupted patient stay is to receive inpatient acute care hospital services, an amount based on the prospective payment systems described in § 412.1(a)(1) made to the acute care hospital.

[66 FR 41388, Aug. 7, 2001, as amended at 67 FR 44077, July 1, 2002; 68 45700, Aug. 1, 2003]

§ 412.626 Transition period.

(a) *Duration of transition period and proportion of the blended transition rate.* (1) Except for a facility that makes an election under paragraph (b) of this section, for cost reporting periods beginning on or after January 1, 2002 and before October 1, 2002, an inpatient rehabilitation facility receives a payment comprised of a blend of the adjusted Federal prospective payment, as determined under § 412.624(e) or § 412.624(f) and a facility-specific payment as determined under paragraph (a)(2) of this section.

(i) For cost reporting periods beginning on or after January 1, 2002 and before October 1, 2002, payment is based on 33⅓ percent of the facility-specific payment and 66⅔ percent of the adjusted FY 2002 Federal prospective payment.

(ii) For cost reporting periods beginning on or after October 1, 2002, payment is based entirely on the adjusted Federal prospective payment.

(2) *Calculation of the facility-specific payment.* The facility-specific payment is equal to the payment for each cost reporting period in the transition period that would have been made without regard to this subpart. The facility's Medicare fiscal intermediary calculates the facility-specific payment for inpatient operating costs and capital-related costs in accordance with part 413 of this chapter.

(b) *Election not to be paid under the transition period methodology.* An inpatient rehabilitation facility may elect a payment that is based entirely on the adjusted Federal prospective payment for cost reporting periods beginning before fiscal year 2003 without regard to the transition period percentages specified in paragraph (a)(1)(i) of this section.

(1) *General requirement.* An inpatient rehabilitation facility will be required to request the election under this paragraph (b) within 30 days of its first cost reporting period for which payment is based on the inpatient rehabilitation facility prospective payment system for cost reporting periods beginning on or after January 1, 2002 and before October 1, 2002.

(2) *Notification requirement to make election.* The request by the inpatient

rehabilitation facility to make the election under this paragraph (b) must be made in writing to the Medicare fiscal intermediary. The intermediary must receive the request on or before the 30th day before the applicable cost reporting period begins, regardless of any postmarks or anticipated delivery dates. Requests received, postmarked, or delivered by other means after the 30th day before the cost reporting period begins will not be approved. If the 30th day before the cost reporting period begins falls on a day that the postal service or other delivery sources are not open for business, the inpatient rehabilitation facility is responsible for allowing sufficient time for the delivery of the request before the deadline. If an inpatient rehabilitation facility's request is not received timely or is otherwise not approved, payment will be based on the transition period rate specified in paragraph (a)(1)(i) of this section.

[66 FR 41388, Aug. 7, 2001, as amended at 67 FR 44077, July 1, 2002]

§412.628 Publication of the Federal prospective payment rates.

We publish information pertaining to the inpatient rehabilitation facility prospective payment system effective for each fiscal year in the FEDERAL REGISTER. This information includes the unadjusted Federal payment rates, the patient classification system and associated weighting factors, and a description of the methodology and data used to calculate the payment rates. This information is published on or before August 1 prior to the beginning of each fiscal year.

§412.630 Limitation on review.

Administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, is prohibited with regard to the establishment of the methodology to classify a patient into the case-mix groups and the associated weighting factors, the unadjusted Federal per discharge payment rates, additional payments for outliers and special payments, and the area wage index.

§412.632 Method of payment under the inpatient rehabilitation facility prospective payment system.

(a) *General rule.* Subject to the exceptions in paragraphs (b) and (c) of this section, an inpatient rehabilitation facility receives payment under this subpart for inpatient operating costs and capital-related costs for each discharge only following submission of a discharge bill.

(b) *Periodic interim payments.*

(1) *Criteria for receiving periodic interim payments.*

(i) An inpatient rehabilitation facility receiving payment under this subpart may receive periodic interim payments (PIP) for Part A services under the PIP method subject to the provisions of §413.64(h) of this subchapter.

(ii) To be approved for PIP, the inpatient rehabilitation facility must meet the qualifying requirements in §413.64(h)(3) of this subchapter.

(iii) Payments to a rehabilitation unit are made under the same method of payment as the hospital of which it is a part as described in §412.116.

(iv) As provided in §413.64(h)(5) of this chapter, intermediary approval is conditioned upon the intermediary's best judgment as to whether payment can be made under the PIP method without undue risk of its resulting in an overpayment to the provider.

(2) *Frequency of payment.* For facilities approved for PIP, the intermediary estimates the inpatient rehabilitation facility's Federal prospective payments net of estimated beneficiary deductibles and coinsurance and makes biweekly payments equal to 1/26 of the total estimated amount of payment for the year. If the inpatient rehabilitation facility has payment experience under the prospective payment system, the intermediary estimates PIP based on that payment experience, adjusted for projected changes supported by substantiated information for the current year. Each payment is made 2 weeks after the end of a biweekly period of service as described in §413.64(h)(6) of this subchapter. The interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if an inpatient rehabilitation facility receives interim payments for

less than a full reporting period. These payments are subject to final settlement.

(3) *Termination of PIP.* (i) *Request by the inpatient rehabilitation facility.* Subject to the provisions of paragraph (b)(1)(iii) of this section, an inpatient rehabilitation facility receiving PIP may convert to receiving prospective payments on a non-PIP basis at any time.

(ii) *Removal by the intermediary.* An intermediary terminates PIP if the inpatient rehabilitation facility no longer meets the requirements of §413.64(h) of this chapter.

(c) *Interim payments for Medicare bad debts and for Part A costs not paid under the prospective payment system.* For Medicare bad debts and for costs of an approved education program and other costs paid outside the prospective payment system, the intermediary determines the interim payments by estimating the reimbursable amount for the year based on the previous year's experience, adjusted for projected changes supported by substantiated information for the current year, and makes biweekly payments equal to 1/26 of the total estimated amount. Each payment is made 2 weeks after the end of a biweekly period of service as described in §413.64(h)(6) of this chapter. The interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if an inpatient rehabilitation facility receives interim payments for less than a full reporting period. These payments are subject to final cost settlement.

(d) *Outlier payments.* Additional payments for outliers are not made on an interim basis. The outlier payments are made based on the submission of a discharge bill and represent final payment.

(e) *Accelerated payments.* (1) *General rule.* Upon request, an accelerated payment may be made to an inpatient rehabilitation facility that is receiving payment under this subpart and is not receiving PIP under paragraph (b) of this section if the inpatient rehabilitation facility is experiencing financial difficulties because of the following:

(i) There is a delay by the intermediary in making payment to the inpatient rehabilitation facility.

(ii) Due to an exceptional situation, there is a temporary delay in the inpatient rehabilitation facility's preparation and submittal of bills to the intermediary beyond its normal billing cycle.

(2) *Approval of payment.* An inpatient rehabilitation facility's request for an accelerated payment must be approved by the intermediary and us.

(3) *Amount of payment.* The amount of the accelerated payment is computed as a percentage of the net payment for unbilled or unpaid covered services.

(4) *Recovery of payment.* Recovery of the accelerated payment is made by recoupment as inpatient rehabilitation facility bills are processed or by direct payment by the inpatient rehabilitation facility.

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

Subpart A—Introduction and General Rules

Sec.
413.1 Introduction.
413.5 Cost reimbursement: General.
413.9 Cost related to patient care.
413.13 Amount of payment if customary charges for services furnished are less than reasonable costs.
413.17 Cost to related organizations.

Subpart B—Accounting Records and Reports

413.20 Financial data and reports.
413.24 Adequate cost data and cost finding.

Subpart C—Limits on Cost Reimbursement

413.30 Limitations on payable costs.
413.35 Limitations on coverage of costs: Charges to beneficiaries if cost limits are applied to services.
413.40 Ceiling on the rate of increase in hospital inpatient costs.

Subpart D—Apportionment

413.50 Apportionment of allowable costs.
413.53 Determination of cost of services to beneficiaries.

SUBCHAPTER G—STANDARDS AND CERTIFICATION

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

Subpart A—General Provisions

Sec.
482.1 Basis and scope.
482.2 Provision of emergency services by nonparticipating hospitals.

Subpart B—Administration

482.11 Condition of participation: Compliance with Federal, State and local laws.
482.12 Condition of participation: Governing body.
482.13 Condition of participation: Patients' rights.

Subpart C—Basic Hospital Functions

482.21 Condition of participation: Quality assessment and performance improvement program.
482.22 Condition of participation: Medical staff.
482.23 Condition of participation: Nursing services.
482.24 Condition of participation: Medical record services.
482.25 Condition of participation: Pharmaceutical services.
482.26 Condition of participation: Radiologic services.
482.27 Condition of participation: Laboratory services.
482.28 Condition of participation: Food and dietetic services.
482.30 Condition of participation: Utilization review.
482.41 Condition of participation: Physical environment.
482.42 Condition of participation: Infection control.
482.43 Condition of participation: Discharge planning.
482.45 Condition of participation: Organ, tissue, and eye procurement.

Subpart D—Optional Hospital Services

482.51 Condition of participation: Surgical services.
482.52 Condition of participation: Anesthesia services.
482.53 Condition of participation: Nuclear medicine services.
482.54 Condition of participation: Outpatient services.
482.55 Condition of participation: Emergency services.
482.56 Condition of participation: Rehabilitation services.
482.57 Condition of participation: Respiratory care services.

Subpart E—Requirements for Specialty Hospitals

482.60 Special provisions applying to psychiatric hospitals.
482.61 Condition of participation: Special medical record requirements for psychiatric hospitals.
482.62 Condition of participation: Special staff requirements for psychiatric hospitals.
482.66 Special requirements for hospital providers of long-term care services ("swing-beds").

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 51 FR 22042, June 17, 1986, unless otherwise noted.

Subpart A—General Provisions

§ 482.1 Basis and scope.

(a) *Statutory basis.* (1) Section 1861(e) of the Act provides that—

(i) Hospitals participating in Medicare must meet certain specified requirements; and

(ii) The Secretary may impose additional requirements if they are found necessary in the interest of the health and safety of the individuals who are furnished services in hospitals.

(2) Section 1861(f) of the Act provides that an institution participating in Medicare as a psychiatric hospital must meet certain specified requirements imposed on hospitals under section 1861(e), must be primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons, must maintain clinical records and other records that the Secretary finds necessary, and must meet staffing requirements that the Secretary finds necessary to carry out an active program of treatment for individuals who are furnished services in the hospital. A distinct part of an institution can participate as a psychiatric hospital if the institution meets the specified 1861(e) requirements and is primarily engaged in providing psychiatric services, and if the

distinct part meets the records and staffing requirements that the Secretary finds necessary.

(3) Sections 1861(k) and 1902(a)(30) of the Act provide that hospitals participating in Medicare and Medicaid must have a utilization review plan that meets specified requirements.

(4) Section 1883 of the Act sets forth the requirements for hospitals that provide long term care under an agreement with the Secretary.

(5) Section 1905(a) of the Act provides that "medical assistance" (Medicaid) payments may be applied to various hospital services. Regulations interpreting those provisions specify that hospitals receiving payment under Medicaid must meet the requirements for participation in Medicare (except in the case of medical supervision of nurse-midwife services. See §§440.10 and 440.165 of this chapter.).

(b) *Scope.* Except as provided in subpart A of part 488 of this chapter, the provisions of this part serve as the basis of survey activities for the purpose of determining whether a hospital qualifies for a provider agreement under Medicare and Medicaid.

[51 FR 22042, June 17, 1986, as amended at 60 FR 50442, Sept. 29, 1995]

§ 482.2 Provision of emergency services by nonparticipating hospitals.

(a) The services of an institution that does not have an agreement to participate in the Medicare program may, nevertheless, be reimbursed under the program if—

(1) The services are emergency services; and

(2) The institution meets the requirements of section 1861(e) (1) through (5) and (7) of the Act. Rules applicable to emergency services furnished by nonparticipating hospitals are set forth in subpart G of part 424 of this chapter.

(b) Secton 440.170(e) of this chapter defines emergency hospital services for purposes of Medicaid reimbursement.

[51 FR 22042, June 17, 1986, as amended at 53 FR 6648, Mar. 2, 1988]

Subpart B—Administration

§ 482.11 Condition of participation: Compliance with Federal, State and local laws.

(a) The hospital must be in compliance with applicable Federal laws related to the health and safety of patients.

(b) The hospital must be—

(1) Licensed; or

(2) Approved as meeting standards for licensing established by the agency of the State or locality responsible for licensing hospitals.

(c) The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.

§ 482.12 Condition of participation: Governing body.

The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.

(a) *Standard: Medical staff.* The governing body must:

(1) Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff;

(2) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff;

(3) Assure that the medical staff has bylaws;

(4) Approve medical staff bylaws and other medical staff rules and regulations;

(5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients;

(6) Ensure the criteria for selection are individual character, competence, training, experience, and judgment; and

(7) Ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon

certification, fellowship, or membership in a specialty body or society.

(b) *Standard: Chief executive officer.* The governing body must appoint a chief executive officer who is responsible for managing the hospital.

(c) *Standard: Care of patients.* In accordance with hospital policy, the governing body must ensure that the following requirements are met:

(1) Every Medicare patient is under the care of:

(i) A doctor of medicine or osteopathy (This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or a State's regulatory mechanism.);

(ii) A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State and who is acting within the scope of his or her license;

(iii) A doctor of podiatric medicine, but only with respect to functions which he or she is legally authorized by the State to perform;

(iv) A doctor of optometry who is legally authorized to practice optometry by the State in which he or she practices;

(v) A chiropractor who is licensed by the State or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist; and

(vi) A clinical psychologist as defined in § 410.71 of this chapter, but only with respect to clinical psychologist services as defined in § 410.71 of this chapter and only to the extent permitted by State law.

(2) Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital. If a Medicare patient is admitted by a practitioner not specified in paragraph (c)(1) of this section, that patient is under the care of a doctor of medicine or osteopathy.

(3) A doctor of medicine or osteopathy is on duty or on call at all times.

(4) A doctor of medicine or osteopathy is responsible for the care of each Medicare patient with respect to any medical or psychiatric problem that—

(i) is present on admission or develops during hospitalization; and

(ii) Is not specifically within the scope of practice of a doctor of dental surgery, dental medicine, podiatric medicine, or optometry; a chiropractor; or clinical psychologist, as that scope is—

(A) Defined by the medical staff;

(B) Permitted by State law; and

(C) Limited, under paragraph (c)(1)(v) of this section, with respect to chiropractors.

(d) *Standard: Institutional plan and budget.* The institution must have an overall institutional plan that meets the following conditions:

(1) The plan must include an annual operating budget that is prepared according to generally accepted accounting principles.

(2) The budget must include all anticipated income and expenses. This provision does not require that the budget identify item by item the components of each anticipated income or expense.

(3) The plan must provide for capital expenditures for at least a 3-year period, including the year in which the operating budget specified in paragraph (d)(2) of this section is applicable.

(4) The plan must include and identify in detail the objective of, and the anticipated sources of financing for, each anticipated capital expenditure in excess of $600,000 (or a lesser amount that is established, in accordance with section 1122(g)(1) of the Act, by the State in which the hospital is located) that relates to any of the following:

(i) Acquisition of land;

(ii) Improvement of land, buildings, and equipment; or

(iii) The replacement, modernization, and expansion of buildings and equipment.

(5) The plan must be submitted for review to the planning agency designated in accordance with section 1122(b) of the Act, or if an agency is not designated, to the appropriate health planning agency in the State. (See part 100 of this title.) A capital expenditure is not subject to section 1122 review if 75 percent of the health care facility's

patients who are expected to use the service for which the capital expenditure is made are individuals enrolled in a health maintenance organization (HMO) or competitive medical plan (CMP) that meets the requirements of section 1876(b) of the Act, and if the Department determines that the capital expenditure is for services and facilities that are needed by the HMO or CMP in order to operate efficiently and economically and that are not otherwise readily accessible to the HMO or CMP because—

(i) The facilities do not provide common services at the same site;

(ii) The facilities are not available under a contract of reasonable duration;

(iii) Full and equal medical staff privileges in the facilities are not available;

(iv) Arrangements with these facilities are not administratively feasible; or

(v) The purchase of these services is more costly than if the HMO or CMP provided the services directly.

(6) The plan must be reviewed and updated annually.

(7) The plan must be prepared—

(i) Under the direction of the governing body; and

(ii) By a committee consisting of representatives of the governing body, the administrative staff, and the medical staff of the institution.

(e) *Standard: Contracted services.* The governing body must be responsible for services furnished in the hospital whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services.

(1) The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.

(2) The hospital must maintain a list of all contracted services, including the scope and nature of the services provided.

(f) *Standard: Emergency services.* (1) If emergency services are provided at the hospital, the hospital must comply with the requirements of § 482.55.

(2) If emergency services are not provided at the hospital, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

(3) If emergency services are provided at the hospital but are not provided at one or more off-campus departments of the hospital, the governing body of the hospital must assure that the medical staff has written policies and procedures in effect with respect to the off-campus department(s) for appraisal of emergencies and referral when appropriate.

[51 FR 22042, June 17, 1986; 51 FR 27847, Aug. 4, 1986, as amended at 53 FR 6549, Mar. 1, 1988; 53 FR 18987, May 26, 1988; 56 FR 8852, Mar. 1, 1991; 56 FR 23022, May 20, 1991; 59 FR 46514, Sept. 8, 1994; 63 FR 20130, Apr. 23, 1998; 63 FR 33874, June 22, 1998; 68 FR 53262, Sept. 9, 2003]

§ 482.13 Condition of participation: Patients' rights.

A hospital must protect and promote each patient's rights.

(a) *Standard: Notice of rights.* (1) A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

(2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The hospital's governing body must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization. At a minimum:

(i) The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.

(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.

(iii) In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

(b) *Standard: Exercise of rights.* (1) The patient has the right to participate in the development and implementation of his or her plan of care.

(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

(3) The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with § 489.100 of this part (Definition), § 489.102 of this part (Requirements for providers), and § 489.104 of this part (Effective dates).

(4) The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.

(c) *Standard: Privacy and safety.* (1) The patient has the right to personal privacy.

(2) The patient has the right to receive care in a safe setting.

(3) The patient has the right to be free from all forms of abuse or harassment.

(d) *Standard: Confidentiality of patient records.* (1) The patient has the right to the confidentiality of his or her clinical records.

(2) The patient has the right to access information contained in his or her clinical records within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its recordkeeping system permits.

(e) *Standard: Restraint for acute medical and surgical care.* (1) The patient has the right to be free from restraints of any form that are not medically necessary or are used as a means of coercion, discipline, convenience, or retaliation by staff. The term "restraint" includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body. A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for the patient's medical or psychiatric condition.

(2) A restraint can only be used if needed to improve the patient's well-being and less restrictive interventions have been determined to be ineffective.

(3) The use of a restraint must be—

(i) Selected only when other less restrictive measures have been found to be ineffective to protect the patient or others from harm;

(ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital to order a restraint. This order must—

(A) Never be written as a standing or on an as needed basis (that is, PRN); and

(B) Be followed by consultation with the patient's treating physician, as soon as possible, if the restraint is not ordered by the patient's treating physician;

(iii) In accordance with a written modification to the patient's plan of care;

(iv) Implemented in the least restrictive manner possible;

(v) In accordance with safe and appropriate restraining techniques; and

(vi) Ended at the earliest possible time.

(4) The condition of the restrained patient must be continually assessed, monitored, and reevaluated.

(5) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of restraints.

(f) *Standard: Seclusion and restraint for behavior management.* (1) The patient has the right to be free from seclusion and restraints, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. The term "restraint" includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body. A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for the patient's medical or psychiatric condition. Seclusion is the involuntary confinement of a person in a room or an area where the person is physically prevented from leaving.

(2) Seclusion or a restraint can only be used in emergency situations if needed to ensure the patient's physical safety and less restrictive interventions have been determined to be ineffective.

(3) The use of a restraint or seclusion must be—

(i) Selected only when less restrictive measures have been found to be ineffective to protect the patient or others from harm;

(ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital to order seclusion or restraint. The following requirements will be superseded by existing State laws that are more restrictive:

(A) Orders for the use of seclusion or a restraint must never be written as a standing order or on an as needed basis (that is, PRN).

(B) The treating physician must be consulted as soon as possible, if the restraint or seclusion is not ordered by the patient's treating physician.

(C) A physician or other licensed independent practitioner must see and evaluate the need for restraint or seclusion within 1 hour after the initiation of this intervention.

(D) Each written order for a physical restraint or seclusion is limited to 4 hours for adults; 2 hours for children and adolescents ages 9 to 17; or 1 hour for patients under 9. The original order may only be renewed in accordance with these limits for up to a total of 24 hours. After the original order expires, a physician or licensed independent practitioner (if allowed under State law) must see and assess the patient before issuing a new order.

(iii) In accordance with a written modification to the patient's plan of care;

(iv) Implemented in the least restrictive manner possible;

(v) In accordance with safe appropriate restraining techniques; and

(vi) Ended at the earliest possible time.

(4) A restraint and seclusion may not be used simultaneously unless the patient is—

(i) Continually monitored face-to-face by an assigned staff member; or

(ii) Continually monitored by staff using both video and audio equipment. This monitoring must be in close proximity the patient.

(5) The condition of the patient who is in a restraint or in seclusion must continually be assessed, monitored, and reevaluated.

(6) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of seclusion and restraint application and techniques and alternative methods for handling behavior, symptoms, and situations that traditionally have been treated through the use of restraints or seclusion.

(7) The hospital must report to CMS any death that occurs while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion.

[64 FR 36088, July 2, 1999]

Subpart C—Basic Hospital Functions

§ 482.21 Condition of participation: Quality assessment and performance improvement program.

The hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.

(a) *Standard: Program scope.* (1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors.

(2) The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations.

(b) *Standard: Program data.* (1) The program must incorporate quality indicator data including patient care data, and other relevant data, for example, information submitted to, or received from, the hospital's Quality Improvement Organization.

(2) The hospital must use the data collected to—

(i) Monitor the effectiveness and safety of services and quality of care; and

(ii) Identify opportunities for improvement and changes that will lead to improvement.

(3) The frequency and detail of data collection must be specified by the hospital's governing body.

(c) *Standard: Program activities.* (1) The hospital must set priorities for its performance improvement activities that—

(i) Focus on high-risk, high-volume, or problem-prone areas;

(ii) Consider the incidence, prevalence, and severity of problems in those areas; and

(iii) Affect health outcomes, patient safety, and quality of care.

(2) Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital.

(3) The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained.

(d) *Standard: Performance improvement projects.* As part of its quality assessment and performance improvement program, the hospital must conduct performance improvement projects.

(1) The number and scope of distinct improvement projects conducted annually must be proportional to the scope and complexity of the hospital's services and operations.

(2) A hospital may, as one of its projects, develop and implement an information technology system explicitly designed to improve patient safety and quality of care. This project, in its initial stage of development, does not need to demonstrate measurable improvement in indicators related to health outcomes.

(3) The hospital must document what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

(4) A hospital is not required to participate in a QIO cooperative project, but its own projects are required to be of comparable effort.

(e) *Standard: Executive responsibilities.* The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:

(1) That an ongoing program for quality improvement and patient safety,

including the reduction of medical errors, is defined, implemented, and maintained.

(2) That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety; and that all improvement actions are evaluated.

(3) That clear expectations for safety are established.

(4) That adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients.

(5) That the determination of the number of distinct improvement projects is conducted annually.

[68 FR 3454, Jan. 24, 2003]

§ 482.22 Condition of participation: Medical staff.

The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital.

(a) *Standard: Composition of the medical staff.* The medical staff must be composed of doctors of medicine or osteopathy and, in accordance with State law, may also be composed of other practitioners appointed by the governing body.

(1) The medical staff must periodically conduct appraisals of its members.

(2) The medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates.

(b) *Standard: Medical staff organization and accountability.* The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to patients.

(1) The medical staff must be organized in a manner approved by the governing body.

(2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.

(3) The responsibility for organization and conduct of the medical staff must be assigned only to an individual doctor of medicine or osteopathy or, when permitted by State law of the State in which the hospital is located, a doctor of dental surgery or dental medicine.

(c) *Standard: Medical staff bylaws.* The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:

(1) Be approved by the governing body.

(2) Include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, etc.)

(3) Describe the organization of the medical staff.

(4) Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.

(5) Include a requirement that a physical examination and medical history be done no more than 7 days before or 48 hours after an admission for each patient by a doctor of medicine or osteopathy, or, for patients admitted only for oromaxillofacial surgery, by an oromaxillofacial surgeon who has been granted such privileges by the medical staff in accordance with State law.

(6) Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.

(d) *Standard: Autopsies.* The medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. The mechanism for documenting permission to perform an autopsy must be defined. There must be a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed.

[51 FR 22042, June 17, 1986, as amended at 59 FR 64152, Dec. 13, 1994]

§ 482.23 Condition of participation: Nursing services.

The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.

(a) *Standard: Organization.* The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

(b) *Standard: Staffing and delivery of care.* The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.

(1) The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times, except for rural hospitals that have in effect a 24-hour nursing waiver granted under § 405.1910(c) of this chapter.

(2) The nursing service must have a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licensure.

(3) A registered nurse must supervise and evaluate the nursing care for each patient.

(4) The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient.

(5) A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.

(6) Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing service.

(c) *Standard: Preparation and administration of drugs.* Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under § 482.12(c), and accepted standards of practice.

(1) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

(2) All orders for drugs and biologicals must be in writing and signed by the practitioner or practitioners responsible for the care of the patient as specified under § 482.12(c) with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment for contraindications. When telephone or oral orders must be used, they must be—

(i) Accepted only by personnel that are authorized to do so by the medical staff policies and procedures, consistent with Federal and State law;

(ii) Signed or initialed by the prescribing practitioner as soon as possible; and

(iii) Used infrequently.

(3) Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures. If blood transfusions and intravenous medications are administered by personnel other than doctors of medicine or osteopathy, the personnel must have special training for this duty.

(4) There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

[51 FR 22042, June 17, 1986, as amended at 67 FR 61814, Oct. 2, 2002]

§ 482.24 Condition of participation: Medical record services.

The hospital must have a medical record service that has administrative responsibility for medical records. A

medical record must be maintained for every individual evaluated or treated in the hospital.

(a) *Standard: Organization and staffing.* The organization of the medical record service must be appropriate to the scope and complexity of the services performed. The hospital must employ adequate personnel to ensure prompt completion, filing, and retrieval of records.

(b) *Standard: Form and retention of record.* The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentification and protects the security of all record entries.

(1) Medical records must be retained in their original or legally reproduced form for a period of at least 5 years.

(2) The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.

(3) The hospital must have a procedure for ensuring the confidentiality of patient records. In-formation from or copies of records may be released only to authorized individuals, and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released by the hospital only in accordance with Federal or State laws, court orders, or subpoenas.

(c) *Standard: Content of record.* The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.

(1) All entries must be legible and complete, and must be authenticated and dated promptly by the person (identified by name and discipline) who is responsible for ordering, providing, or evaluating the service furnished.

(i) The author of each entry must be identifed and must authenticate his or her entry.

(ii) Authentication may include signatures, written initials or computer entry.

(2) All records must document the following, as appropriate:

(i) Evidence of a physical examination, including a health history, performed no more than 7 days prior to admission or within 48 hours after admission.

(ii) Admitting diagnosis.

(iii) Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.

(iv) Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia.

(v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.

(vi) All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.

(vii) Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow-up care.

(viii) Final diagnosis with completion of medical records within 30 days following discharge.

§ 482.25 Condition of participation: Pharmaceutical services.

The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

(a) *Standard: Pharmacy management and administration.* The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

(1) A full-time, part-time, or consulting pharmacist must be responsible

for developing, supervising, and coordinating all the activities of the pharmacy services.

(2) The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.

(3) Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.

(b) *Standard: Delivery of services.* In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

(1) All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.

(2) Drugs and biologicals must be kept in a locked storage area.

(3) Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.

(4) When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law.

(5) Drugs and biologicals not specifically prescribed as to time or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.

(6) Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital-wide quality assurance program.

(7) Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

(8) Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff.

(9) A formulary system must be established by the medical staff to assure quality pharmaceuticals at reasonable costs.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

§ 482.26 Condition of participation: Radiologic services.

The hospital must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.

(a) *Standard: Radiologic services.* The hospital must maintain, or have available, radiologic services according to needs of the patients.

(b) *Standard: Safety for patients and personnel.* The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

(1) Proper safety precutions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.

(2) Periodic inspection of equipment must be made and hazards identified must be promptly corrected.

(3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

(4) Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.

(c) *Standard: Personnel.* (1) A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

(2) Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.

(d) *Standard: Records.* Records of radiologic services must be maintained.

(1) The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.

(2) The hospital must maintain the following for at least 5 years:

(i) Copies of reports and printouts.

(ii) Films, scans, and other image records, as appropriate.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

§ 482.27 Condition of participation: Laboratory services.

(a) The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with part 493 of this chapter.

(b) *Standard: Adequacy of laboratory services.* The hospital must have laboratory services available, either directly or through a contractual agreement with a certified laboratory that meets requirements of part 493 of this chapter.

(1) Emergency laboratory services must be available 24 hours a day.

(2) A written description of services provided must be available to the medical staff.

(3) The laboratory must make provision for proper receipt and reporting of tissue specimens.

(4) The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.

(c) *Standard: Potentially infectious blood and blood products*—(1) *Potentially HIV infectious blood and blood products* are prior collections from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to the human immunodeficiency virus (HIV) on a later donation, and the FDA-licensed, more specific test or other followup testing recommended or required by FDA is positive and the timing of seroconversion cannot be precisely estimated.

(2) *Services furnished by an outside blood bank.* If a hospital regularly uses the services of an outside blood bank, it must have an agreement with the blood bank that governs the procurement, transfer, and availability of blood and blood products. The agreement must require that the blood bank promptly notify the hospital of the following:

(i) If it supplied blood and blood products collected from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to HIV on a later donation; and

(ii) The results of the FDA-licensed, more specific test or other followup testing recommended or required by FDA completed within 30 calendar days after the donor's repeatedly reactive screening test. (FDA regulations concerning HIV testing and lookback procedures are set forth at 21 CFR 610.45-et seq.)

(3) *Quarantine of blood and blood products pending completion of testing.* If the blood bank notifies the hospital of the repeatedly reactive HIV screening test results as required by paragraph (c)(2)(i) of this section, the hospital must determine the disposition of the blood or blood product and quarantine all blood and blood products from previous donations in inventory.

(i) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other followup testing recommended or required by FDA is negative, absent other informative test results, the hospital may release the blood and blood products from quarantine.

(ii) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other followup testing recommended or required by FDA is positive, the hospital must dispose of the blood and blood products in accordance with 21 CFR 606.40 and notify patients in accordance with paragraph (c)(4) of this section.

(4) *Patient notification.* If the hospital has administered potentially HIV infectious blood or blood products (either directly through its own blood bank or under an agreement described in paragraph (c)(2) of this section) or released such blood or blood products to another entity or appropriate individual,

the hospital must take the following actions:

(i) Promptly make at least three attempts to notify the patient's attending physician (that is, the physician of record) or the physician who ordered the blood or blood product that potentially HIV infectious blood or blood products were transfused to the patient.

(ii) Ask the physician to immediately notify the patient, or other individual as permitted under paragraph (c)(8) of this section, of the need for HIV testing and counseling.

(iii) If the physician is unavailable, declines to make the notification, or later informs the hospital that he or she was unable to notify the patient, promptly make at least three attempts to notify the patient, or other individual as permitted under paragraph (c)(8) of this section, of the need for HIV testing and counseling.

(iv) Document in the patient's medical record the notification or attempts to give the required notification.

(5) *Timeframe for notification.* The notification effort begins when the blood bank notifies the hospital that it received potentially HIV infectious blood and blood products and continues for 8 weeks unless—

(i) The patient is located and notified; or

(ii) The hospital is unable to locate the patient and documents in the patient's medical record the extenuating circumstances beyond the hospital's control that caused the notification timeframe to exceed 8 weeks.

(6) *Content of notification.* The notification given under paragraphs (c)(4) (ii) and (iii) of this section must include the following information:

(i) A basic explanation of the need for HIV testing and counseling.

(ii) Enough oral or written information so that the transfused patient can make an informed decision about whether to obtain HIV testing and counseling.

(iii) A list of programs or places where the patient can obtain HIV testing and counseling, including any requirements or restrictions the program may impose.

(7) *Policies and procedures.* The hospital must establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for confidentiality and medical records.

(8) *Notification to legal representative or relative.* If the patient has been adjudged incompetent by a State court, the physician or hospital must notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or hospital must notify the patient or his or her legal representative or relative. If the patient is deceased, the physician or hospital must continue the notification process and inform the deceased patient's legal representative or relative.

[57 FR 7136, Feb. 28, 1992, as amended at 61 FR 47433, Sept. 9, 1996]

§ 482.28 Condition of participation: Food and dietetic services.

The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel. However, a hospital that has a contract with an outside food management company may be found to meet this Condition of participation if the company has a dietitian who serves the hospital on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.

(a) *Standard: Organization.* (1) The hospital must have a full-time employee who—

(i) Serves as director of the food and dietetic service;

(ii) Is responsible for the daily management of the dietary services; and

(iii) Is qualified by experience or training.

(2) There must be a qualified dietitian, full-time, part-time, or on a consultant basis.

(3) There must be administrative and technical personnel competent in their respective duties.

(b) *Standard: Diets.* Menus must meet the needs of the patients.

(1) Therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the patients.

(2) Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the patients.

(3) A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.

§ 482.30 Condition of participation: Utilization review.

The hospital must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs.

(a) *Applicability*. The provisions of this section apply except in either of the following circumstances:

(1) A Utilization and Quality Control Quality Improvement Organization (QIO) has assumed binding review for the hospital.

(2) CMS has determined that the UR procedures established by the State under title XIX of the Act are superior to the procedures required in this section, and has required hospitals in that State to meet the UR plan requirements under §§ 456.50 through 456.245 of this chapter.

(b) *Standard: Composition of utilization review committee.* A UR committee consisting of two or more practitioners must carry out the UR function. At least two of the members of the committee must be doctors of medicine or osteopathy. The other members may be any of the other types of practitioners specified in § 482.12(c)(1).

(1) Except as specified in paragraphs (b) (2) and (3) of this section, the UR committee must be one of the following:

(i) A staff committee of the institution;

(ii) A group outside the institution—

(A) Established by the local medical society and some or all of the hospitals in the locality; or

(B) Established in a manner approved by CMS.

(2) If, because of the small size of the institution, it is impracticable to have a properly functioning staff committee, the UR committee must be established as specified in paragraph (b)(1)(ii) of this section.

(3) The committee's or group's reviews may not be conducted by any individual who—

(i) Has a direct financial interest (for example, an ownership interest) in that hospital; or

(ii) Was professionally involved in the care of the patient whose case is being reviewed.

(c) *Standard: Scope and frequency of review*. (1) The UR plan must provide for review for Medicare and Medicaid patients with respect to the medical necessity of—

(i) Admissions to the institution;

(ii) The duration of stays; and

(iii) Professional services furnished, including drugs and biologicals.

(2) Review of admissions may be performed before, at, or after hospital admission.

(3) Except as specified in paragraph (e) of this section, reviews may be conducted on a sample basis.

(4) Hospitals that are paid for inpatient hospital services under the prospective payment system set forth in Part 412 of this chapter must conduct review of duration of stays and review of professional services as follows:

(i) For duration of stays, these hospitals need review only cases that they reasonably assume to be outlier cases based on extended length of stay, as described in § 412.80(a)(1)(i) of this chapter; and

(ii) For professional services, these hospitals need review only cases that they reasonably assume to be outlier cases based on extraordinarily high costs, as described in § 412.80(a)(1)(ii) of this chapter.

(d) *Standard: Determination regarding admissions or continued stays.* (1) The determination that an admission or continued stay is not medically necessary—

(i) May be made by one member of the UR committee if the practitioner or practitioners responsible for the care of the patient, as specified of

§ 482.12(c), concur with the determination or fail to present their views when afforded the opportunity; and

(ii) Must be made by at least two members of the UR committee in all other cases.

(2) Before making a determination that an admission or continued stay is not medically necessary, the UR committee must consult the practitioner or practitioners responsible for the care of the patient, as specified in § 482.12(c), and afford the practitioner or practitioners the opportunity to present their views.

(3) If the committee decides that admission to or continued stay in the hospital is not medically necessary, written notification must be given, no later than 2 days after the determination, to the hospital, the patient, and the practitioner or practitioners responsible for the care of the patient, as specified in § 482.12(c);

(e) *Standard: Extended stay review.* (1) In hospitals that are not paid under the prospective payment system, the UR committee must make a periodic review, as specified in the UR plan, of each current inpatient receiving hospital services during a continuous period of extended duration. The scheduling of the periodic reviews may—

(i) Be the same for all cases; or

(ii) Differ for different classes of cases.

(2) In hospitals paid under the prospective payment system, the UR committee must review all cases reasonably assumed by the hospital to be outlier cases because the extended length of stay exceeds the threshold criteria for the diagnosis, as described in § 412.80(a)(1)(i). The hospital is not required to review an extended stay that does not exceed the outlier threshold for the diagnosis.

(3) The UR committee must make the periodic review no later than 7 days after the day required in the UR plan.

(f) *Standard: Review of professional services.* The committee must review professional services provided, to determine medical necessity and to promote the most efficient use of available health facilities and services.

§ 482.41 Condition of participation: Physical environment.

The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.

(a) *Standard: Buildings.* The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.

(1) There must be emergency power and lighting in at least the operating, recovery, intensive care, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available.

(2) There must be facilities for emergency gas and water supply.

(b) *Standard: Life safety from fire.* (1) Except as otherwise provided in this section—

(i) The hospital must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to hospitals.

(2) After consideration of State survey agency findings, CMS may waive

specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protects patients in hospitals.

(4) Beginning March 13, 2006, a hospital must be in compliance with Chapter 19.2.9, Emergency Lighting.

(5) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to hospitals.

(6) The hospital must have procedures for the proper routine storage and prompt disposal of trash.

(7) The hospital must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities.

(8) The hospital must maintain written evidence of regular inspection and approval by State or local fire control agencies.

(c) *Standard: Facilities.* The hospital must maintain adequate facilities for its services.

(1) Diagnostic and therapeutic facilities must be located for the safety of patients.

(2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

(3) The extent and complexity of facilities must be determined by the services offered.

(4) There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

[51 FR 22042, June 17, 1986, as amended at 53 FR 11509, Apr. 7, 1988; 68 FR 1386, Jan. 10, 2003; 69 FR 49267, Aug. 11, 2004]

§ 482.42 Condition of participation: Infection control.

The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

(a) *Standard: Organization and policies.* A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases.

(1) The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

(2) The infection control officer or officers must maintain a log of incidents related to infections and communicable diseases.

(b) *Standard: Responsibilities of chief executive officer, medical staff, and director of nursing services.* The chief executive officer, the medical staff, and the director of nursing services must—

(1) Ensure that the hospital-wide quality assurance program and training programs address problems identified by the infection control officer or officers; and

(2) Be responsible for the implementation of successful corrective action plans in affected problem areas.

§ 482.43 Condition of participation: Discharge planning.

The hospital must have in effect a discharge planning process that applies to all patients. The hospital's policies and procedures must be specified in writing.

(a) *Standard: Identification of patients in need of discharge planning.* The hospital must identify at an early stage of hospitalization all patients who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning.

(b) *Standard: Discharge planning evaluation.* (1) The hospital must provide a discharge planning evaluation to the patients identified in paragraph (a) of this section, and to other patients upon the patient's request, the request of a person acting on the patient's behalf, or the request of the physician.

(2) A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, the evaluation.

(3) The discharge planning evaluation must include an evaluation of the likelihood of a patient needing post- hospital services and of the availability of the services.

(4) The discharge planning evaluation must include an evaluation of the likelihood of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the hospital.

(5) The hospital personnel must complete the evaluation on a timely basis so that appropriate arrangements for post-hospital care are made before discharge, and to avoid unnecessary delays in discharge.

(6) The hospital must include the discharge planning evaluation in the patient's medical record for use in establishing an appropriate discharge plan and must discuss the results of the evaluation with the patient or individual acting on his or her behalf.

(c) *Standard: Discharge plan.* (1) A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, a discharge plan if the discharge planning evaluation indicates a need for a discharge plan.

(2) In the absence of a finding by the hospital that a patient needs a discharge plan, the patient's physician may request a discharge plan. In such a case, the hospital must develop a discharge plan for the patient.

(3) The hospital must arrange for the initial implementation of the patient's discharge plan.

(4) The hospital must reassess the patient's discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan.

(5) As needed, the patient and family members or interested persons must be counseled to prepare them for post-hospital care.

(6) The hospital must include in the discharge plan a list of HHAs or SNFs that are available to the patient, that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, in the geographic area requested by the patient. HHAs must request to be listed by the hospital as available.

(i) This list must only be presented to patients for whom home health care or post-hospital extended care services are indicated and appropriate as determined by the discharge planning evaluation.

(ii) For patients enrolled in managed care organizations, the hospital must indicate the availability of home health and posthospital extended care services through individuals and entities that have a contract with the managed care organizations.

(iii) The hospital must document in the patient's medical record that the list was presented to the patient or to the individual acting on the patient's behalf.

(7) The hospital, as part of the discharge planning process, must inform the patient or the patient's family of their freedom to choose among participating Medicare providers of posthospital care services and must, when possible, respect patient and family preferences when they are expressed. The hospital must not specify or otherwise limit the qualified providers that are available to the patient.

(8) The discharge plan must identify any HHA or SNF to which the patient is referred in which the hospital has a disclosable financial interest, as specified by the Secretary, and any HHA or SNF that has a disclosable financial interest in a hospital under Medicare. Financial interests that are disclosable under Medicare are determined in accordance with the provisions of Part 420, Subpart C, of this chapter.

(d) *Standard: Transfer or referral.* The hospital must transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for followup or ancillary care.

(e) *Standard: Reassessment.* The hospital must reassess its discharge planning process on an on-going basis. The reassessment must include a review of discharge plans to ensure that they are responsive to discharge needs.

[59 FR 64152, Dec. 13, 1994, as amended at 69 FR 49268, Aug. 11, 2004]

§ 482.45 Condition of participation: Organ, tissue, and eye procurement.

(a) *Standard: Organ procurement responsibilities.* The hospital must have and implement written protocols that:

(1) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose;

(2) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

(3) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its options to donate organs, tissues, or eyes or to decline to donate. The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

(4) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

(5) Ensure that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.

(b) *Standard: Organ transplantation responsibilities.* (1) A hospital in which organ transplants are performed must be a member of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274) and abide by its rules. The term "rules of the OPTN" means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS Act which are enforceable under 42 CFR 121.10. No hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act, or with the requirements of this paragraph, unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing.

(2) For purposes of these standards, the term "organ" means a human kidney, liver, heart, lung, or pancreas.

(3) If a hospital performs any type of transplants, it must provide organ-transplant-related data, as requested by the OPTN, the Scientific Registry, and the OPOs. The hospital must also provide such data directly to the Department when requested by the Secretary.

[63 FR 33875, June 22, 1998]

Subpart D—Optional Hospital Services

§ 482.51 Condition of participation: Surgical services.

If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

(a) *Standard: Organization and staffing.* The organization of the surgical services must be appropriate to the scope of the services offered.

(1) The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.

(2) Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as "scrub nurses" under the supervision of a registered nurse.

(3) Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the surpervision of a qualified registered nurse who is immediately available to respond to emergencies.

(4) Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.

(b) *Standard: Delivery of service.* Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

(1) There must be a complete history and physical work-up in the chart of every patient prior to surgery, except in emergencies. If this has been dictated, but not yet recorded in the patient's chart, there must be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient.

(2) A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies.

(3) The following equipment must be available to the operating room suites: call-in-system, cardiac monitor, resuscitator, defibrillator, aspirator, and tracheotomy set.

(4) There must be adequate provisions for immediate post-operative care.

(5) The operating room register must be complete and up-to-date.

(6) An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.

§ 482.52 Condition of participation: Anesthesia services.

If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.

(a) *Standard: Organization and staffing.* The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered only by—

(1) A qualified anesthesiologist;

(2) A doctor of medicine or osteopathy (other than an anesthesiologist);

(3) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;

(4) A certified registered nurse anesthetist (CRNA), as defined in § 410.69(b) of this chapter, who, unless exempted in accordance with paragraph (c)of this section, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or

(5) An anesthesiologist's assistant, as defined in § 410.69(b) of this chapter, who is under the supervision of an anesthesiologist who is immediately available if needed.

(b) *Standard: Delivery of services.* Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of preanesthesia and post anesthesia responsibilities. The policies must ensure that the following are provided for each patient:

(1) A preanesthesia evaluation by an individual qualified to administer anesthesia under paragraph (a) of this section performed within 48 hours prior to surgery.

(2) An intraoperative anesthesia record.

(3) With respect to inpatients, a postanesthesia followup report by the individual who administers the anesthesia that is written within 48 hours after surgery.

(4) With respect to outpatients, a postanesthesia evaluation for proper anesthesia recovery performed in accordance with policies and procedures approved by the medical staff.

(c) *Standard: State exemption.* (1) A hospital may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (a)(4) of this section, if the State in which the hospital is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.

[51 FR 22042, June 17, 1986 as amended at 57 FR 33900, July 31, 1992; 66 FR 56769, Nov. 13, 2001]

§ 482.53 Condition of participation: Nuclear medicine services.

If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.

(a) *Standard: Organization and staffing.* The organization of the nuclear medicine service must be appropriate to the scope and complexity of the services offered.

(1) There must be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.

(2) The qualifications, training, functions, and responsibilities of nuclear medicine personnel must be specified by the service director and approved by the medical staff.

(b) *Standard: Delivery of service.* Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.

(1) In-house preparation of radiopharmaceuticals is by, or under, the direct supervision of an appropriately trained registered pharmacist or a doctor of medicine or osteopathy.

(2) There is proper storage and disposal of radioactive material.

(3) If laboratory tests are performed in the nuclear medicine service, the service must meet the applicable requirement for laboratory services specified in § 482.27.

(c) *Standard: Facilities.* Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance. The equipment must be—

(1) Maintained in safe operating condition; and

(2) Inspected, tested, and calibrated at least annually by qualified personnel.

(d) *Standard: Records.* The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.

(1) The hospital must maintain copies of nuclear medicine reports for at least 5 years.

(2) The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretation of these tests.

(3) The hospital must maintain records of the receipt and disposition of radiopharmaceuticals.

(4) Nuclear medicine services must be ordered only by practitioner whose scope of Federal or State licensure and whose defined staff privileges allow such referrals.

[51 FR 22042, June 17, 1986, as amended at 57 FR 7136, Feb. 28, 1992]

§ 482.54 Condition of participation: Outpatient services.

If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.

(a) *Standard: Organization.* Outpatient services must be appropriately organized and integrated with inpatient services.

(b) *Standard: Personnel.* The hospitals must—

(1) Assign an individual to be responsible for outpatient services; and

(2) Have appropriate professional and nonprofessional personnel available.

§ 482.55 Condition of participation: Emergency services.

The hospital must meet the emergency needs of patients in accordance with acceptable standards of practice.

(a) *Standard: Organization and direction.* If emergency services are provided at the hospital—

(1) The services must be organized under the direction of a qualified member of the medical staff;

(2) The services must be integrated with other departments of the hospital;

(3) The policies and procedures governing medical care provided in the emergency service or department are established by and are a continuing responsibility of the medical staff.

(b) *Standard: Personnel.* (1) The emergency services must be supervised by a qualified member of the medical staff.

(2) There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.

§ 482.56 Condition of participation: Rehabilitation services.

If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients.

(a) *Standard: Organization and staffing.* The organization of the service must be appropriate to the scope of the services offered.

(1) The director of the services must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

(2) Physical therapy, occupational therapy, or speech therapy, or audiology services, if provided, must be provided by staff who meet the qualifications specified by the medical staff, consistent with State law.

(b) *Standard: Delivery of services.* Services must be furnished in accordance with a written plan of treatment. Services must be given in accordance with orders of practitioners who are authorized by the medical staff to order the services, and the orders must be incorporated in the patient's record.

§ 482.57 Condition of participation: Respiratory care services.

The hospital must meet the needs of the patients in accordance with acceptable standards of practice. The following requirements apply if the hospital provides respiratory care service.

(a) *Standard: Organization and Staffing.* The organization of the respiratory care services must be appropriate to the scope and complexity of the services offered.

(1) There must be a director of respiratory care services who is a doctor of medicine or osteopathy with the knowledge experience, and capabilities to supervise and administer the service properly. The director may serve on either a full-time or part-time basis.

(2) There must be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with State law.

(b) *Standard: Delivery of Services.* Services must be delivered in accordance with medical staff directives.

(1) Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures must be designated in writing.

(2) If blood gases or other laboratory tests are performed in the respiratory care unit, the unit must meet the applicable requirements for laboratory services specified in § 482.27.

(3) Services must be provided only on, and in accordance with, the orders of a doctor of medicine or osteopathy.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986, as amended at 57 FR 7136, Feb. 28, 1992]

Subpart E—Requirements for Specialty Hospitals

§ 482.60 Special provisions applying to psychiatric hospitals.

Psychiatric hospital must—

(a) Be primarily engaged in providing, by or under the supervision of a doctor of medicine or osteopathy, psychiatric services for the diagnosis and treatment of mentally ill persons;

(b) *Standard: Location in a rural area or treatment as rural.* The CAH meets the requirements of either paragraph (b)(1) or (b)(2) or (b)(3) of this section.

(1) The CAH meets the following requirements:

(i) The CAH is located outside any area that is a Metropolitan Statistical Area, as defined by the Office of Management and Budget, or that has been recognized as urban under § 412.62(f) of this chapter;

(ii) The CAH is not deemed to be located in an urban area under § 412.63(b) of this chapter; and

(iii) The CAH has not been classified as an urban hospital for purposes of the standardized payment amount by CMS or the Medicare Geographic Classification Review Board under § 412.230(e) of this chapter, and is not among a group of hospitals that have been redesignated to an adjacent urban area under § 412.232 of this chapter.

(2) The CAH is located within a Metropolitan Statistical Area, as defined by the Office of Management and Budget, but is being treated as being located in a rural area in accordance with § 412.103 of this chapter.

(3) Effective only for October 1, 2004 through September 30, 2006, the CAH does not meet the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, in FY 2004, was not part of a Metropolitan Statistical Area as defined by the Office of Management and Budget, but as of FY 2005 was included as part of such an MSA as a result of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003.

(c) *Standard: Location relative to other facilities or necessary provider certification.* The CAH is located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH, or before January 1, 2006, the CAH is certified by the State as being a necessary provider of health care services to residents in the area. A CAH that is designated as a necessary provider as of October 1, 2006, will maintain its necessary provider designation after January 1, 2006.

[62 FR 46036, Aug. 29, 1997, as amended at 65 FR 47052, Aug. 1, 2000; 66 FR 39938, Aug. 1, 2001; 69 FR 49271, Aug. 11, 2004; 69 FR 60252, Oct. 7, 2004]

§ 485.612 Condition of participation: Compliance with hospital requirements at the time of application.

Except for recently closed facilities as described in § 485.610(a)(2), or health clinics or health centers as described in § 485.610(a)(3), the facility is a hospital that has a provider agreement to participate in the Medicare program as a hospital at the time the hospital applies for designation as a CAH.

[66 FR 32196, June 13, 2001]

§ 485.616 Condition of participation: Agreements.

(a) *Standard: Agreements with network hospitals.* In the case of a CAH that is a member of a rural health network as defined in § 485.603 of this chapter, the CAH has in effect an agreement with at least one hospital that is a member of the network for—

(1) Patient referral and transfer;

(2) The development and use of communications systems of the network, including the network's system for the electronic sharing of patient data, and telemetry and medical records, if the network has in operation such a system; and

(3) The provision of emergency and nonemergency transportation between the facility and the hospital.

(b) *Standard: Agreements for credentialing and quality assurance.* Each CAH that is a member of a rural health network shall have an agreement with respect to credentialing and quality assurance with at least—

(1) One hospital that is a member of the network;

(2) One QIO or equivalent entity; or

(3) One other appropriate and qualified entity identified in the State rural health care plan.

[62 FR 46036, Aug. 29, 1997]

§485.618 Condition of participation: Emergency services.

The CAH provides emergency care necessary to meet the needs of its inpatients and outpatients.

(a) *Standard: Availability.* Emergency services are available on a 24-hours a day basis.

(b) *Standard: Equipment, supplies, and medication.* Equipment, supplies, and medication used in treating emergency cases are kept at the CAH and are readily available for treating emergency cases. The items available must include the following:

(1) *Drugs and biologicals* commonly used in life-saving procedures, including analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarrythmics, cardiac glycosides, antihypertensives, diuretics, and electrolytes and replacement solutions.

(2) *Equipment and supplies* commonly used in life-saving procedures, including airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, immobilization devices, nasogastric tubes, splints, IV therapy supplies, suction machine, defibrillator, cardiac monitor, chest tubes, and indwelling urinary catheters.

(c) *Standard: Blood and blood products.* The facility provides, either directly or under arrangements, the following:

(1) Services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hours a day basis.

(2) Blood storage facilities that meet the requirements of 42 CFR part 493, subpart K, and are under the control and supervision of a pathologist or other qualified doctor of medicine or osteopathy. If blood banking services are provided under an arrangement, the arrangement is approved by the facility's medical staff and by the persons directly responsible for the operation of the facility.

(d) *Standard: Personnel.* (1) Except as specified in paragraph (d)(2) of this section, there must be a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care on call and immediately available by telephone or radio contact, and available onsite within the following timeframes:

(i) Within 30 minutes, on a 24-hour a day basis, if the CAH is located in an area other than an area described in paragraph (d)(1)(ii) of this section; or

(ii) Within 60 minutes, on a 24-hour a day basis, if all of the following requirements are met:

(A) The CAH is located in an area designated as a frontier area (that is, an area with fewer than six residents per square mile based on the latest population data published by the Bureau of the Census) or in an area that meets the criteria for a remote location adopted by the State in its rural health care plan, and approved by CMS, under section 1820(b) of the Act.

(B) The State has determined, under criteria in its rural health care plan, that allowing an emergency response time longer than 30 minutes is the only feasible method of providing emergency care to residents of the area served by the CAH.

(C) The State maintains documentation showing that the response time of up to 60 minutes at a particular CAH it designates is justified because other available alternatives would increase the time needed to stabilize a patient in an emergency.

(2) A registered nurse satisfies the personnel requirement specified in paragraph (d)(1) of this section for a temporary period if—

(i) The CAH has no greater than 10 beds;

(ii) The CAH is located in an area designated as a frontier area or remote location as described in paragraph (d)(1)(ii)(A) of this section;

(iii) The State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation on the issue of using RNs on a temporary basis as part of their State rural healthcare plan with the State Boards of Medicine and Nursing, and in accordance with State law, requesting that a registered nurse with training and experience in emergency care be included in the list of personnel specified in paragraph (d)(1) of this section. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and

the quality of emergency services in the States. The letter from the Governor must also describe the circumstances and duration of the temporary request to include the registered nurses on the list of personnel specified in paragraph (d)(1) of this section;

(iv) Once a Governor submits a letter, as specified in paragraph (d)(2)(iii) of this section, a CAH must submit documentation to the State survey agency demonstrating that it has been unable, due to the shortage of such personnel in the area, to provide adequate coverage as specified in this paragraph (d).

(3) The request, as specified in paragraph (d)(2)(iii) of this section, and the withdrawal of the request, may be submitted to us at any time, and are effective upon submission.

(e) *Standard: Coordination with emergency response systems.* The CAH must, in coordination with emergency response systems in the area, establish procedures under which a doctor of medicine or osteopathy is immediately available by telephone or radio contact on a 24-hours a day basis to receive emergency calls, provide information on treatment of emergency patients, and refer patients to the CAH or other appropriate locations for treatment.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997; 64 FR 41544, July 30, 1999; 67 FR 80041, Dec. 31, 2002; 69 FR 49271, Aug. 11, 2004]

§ 485.620 Condition of participation: Number of beds and length of stay.

(a) *Standard: Number of beds.* Except as permitted for CAHs having distinct part units under § 485.647, the CAH maintains no more than 25 inpatient beds after January 1, 2004, that can be used for either inpatient or swing-bed services.

(b) *Standard: Length of stay.* The CAH provides acute inpatient care for a period that does not exceed, on an annual average basis, 96 hours per patient.

[62 FR 46036, Aug. 29, 1997, as amended at 65 FR 47052, Aug. 1, 2000; 69 FR 49271, Aug. 11, 2004; 69 FR 60252, Oct. 7, 2004]

§ 485.623 Condition of participation: Physical plant and environment.

(a) *Standard: Construction.* The CAH is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of direct services.

(b) *Standard: Maintenance.* The CAH has housekeeping and preventive maintenance programs to ensure that—

(1) All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition;

(2) There is proper routine storage and prompt disposal of trash;

(3) Drugs and biologicals are appropriately stored;

(4) The premises are clean and orderly; and

(5) There is proper ventilation, lighting, and temperature control in all pharmaceutical, patient care, and food preparation areas.

(c) *Standard: Emergency procedures.* The CAH assures the safety of patients in non-medical emergencies by—

(1) Training staff in handling emergencies, including prompt reporting of fires, extinguishing of fires, protection and, where necessary, evacuation of patients, personnel, and guests, and cooperation with fire fighting and disaster authorities;

(2) Providing for emergency power and lighting in the emergency room and for battery lamps and flashlights in other areas;

(3) Providing for an emergency fuel and water supply; and

(4) Taking other appropriate measures that are consistent with the particular conditions of the area in which the CAH is located.

(d) *Standard: Life safety from fire.* (1) Except as otherwise provided in this section—

(i) The CAH must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or

will not become effective until approval has been given by the Office of Management and Budget.

§ 488.20 Periodic review of compliance and approval.

(a) Determinations by CMS to the effect that a provider or supplier is in compliance with the conditions of participation, or requirements (for SNFs and NFs), or the conditions for coverage are made as often as CMS deems necessary and may be more or less than a 12-month period, except for SNFs, NFs and HHAs. (See § 488.308 for special rules for SNFs and NFs.)

(b) The responsibilities of State survey agencies in the review and certification of compliance are as follows:

(1) Resurvey providers or suppliers as frequently as necessary to ascertain compliance and confirm the correction of deficiencies;

(2) Review reports prepared by a Professional Standards Review Organization (authorized under Part B Title XI of the Act) or a State inspection of care team (authorized under Title XIX of the Act) regarding the quality of a facility's care;

(3) Evaluate reports that may pertain to the health and safety of patients; and

(4) Take appropriate actions that may be necessary to achieve compliance or certify noncompliance to CMS.

(c) A State survey agency certification to CMS that a provider or supplier is no longer in compliance with the conditions of participation or requirements (for SNFs and NFs) or conditions for coverage will supersede the State survey agency's previous certification.

(Secs. 1102, 1814, 1861, 1863 through 1866, 1871, and 1881; 42 U.S.C. 1302, 1395f, 1395x, 1395z through 1395cc, 1395hh, and 1395rr)

[45 FR 74833, Nov. 12, 1981. Redesignated and amended at 53 FR 23100, June 17, 1988, and further amended at 54 FR 5373, Feb. 2, 1989; 56 FR 48879, Sept. 26, 1991; 59 FR 56237, Nov. 10, 1994]

§ 488.24 Certification of noncompliance.

(a) Special rules for certification of noncompliance for SNFs and NFs are set forth in § 488.330.

(b) The State agency will certify that a provider or supplier is not or is no longer in compliance with the conditions of participation or conditions for coverage where the deficiencies are of such character as to substantially limit the provider's or supplier's capacity to furnish adequate care or which adversely affect the health and safety of patients; or

(c) If CMS determines that an institution or agency does not qualify for participation or coverage because it is not in compliance with the conditions of participation or conditions for coverage, or if a provider's agreement is terminated for that reason, the institution or agency has the right to request that the determination be reviewed. (Appeals procedures are set forth in Part 498 of this chapter.)

[59 FR 56237, Nov. 10, 1994]

§ 488.26 Determining compliance.

(a) Additional rules for certification of compliance for SNFs and NFs are set forth in § 488.330.

(b) The decision as to whether there is compliance with a particular requirement, condition of participation, or condition for coverage depends upon the manner and degree to which the provider or supplier satisfies the various standards within each condition. Evaluation of a provider's or supplier's performance against these standards enables the State survey agency to document the nature and extent of deficiencies, if any, with respect to a particular function, and to assess the need for improvement in relation to the prescribed conditions.

(c) The State survey agency must adhere to the following principles in determining compliance with participation requirements:

(1) The survey process is the means to assess compliance with Federal health, safety and quality standards;

(2) The survey process uses resident outcomes as the primary means to establish the compliance status of facilities. Specifically surveyors will directly observe the actual provision of care and services to residents, and the effects of that care, to assess whether the care provided meets the needs of individual residents;

(3) Surveyors are professionals who use their judgment, in concert with

Federal forms and procedures, to determine compliance;

(4) Federal procedures are used by all surveyors to ensure uniform and consistent application and interpretation of Federal requirements;

(5) Federal forms are used by all surveyors to ensure proper recording of findings and to document the basis for the findings.

(d) The State survey agency must use the survey methods, procedures, and forms that are prescribed by CMS.

(e) The State survey agency must ensure that a facility's actual provision of care and services to residents and the effects of that care on residents are assessed in a systematic manner.

[59 FR 56237, Nov. 10, 1994]

§ 488.28 Providers or suppliers, other than SNFs and NFs, with deficiencies.

(a) If a provider or supplier is found to be deficient with respect to one or more of the standards in the conditions of participation or conditions for coverage, it may participate in or be covered under the Health Insurance for the Aged and Disabled Program only if the facility has submitted an acceptable plan of correction for achieving compliance within a reasonable period of time acceptable to the Secretary.

(b) The existing deficiencies noted either individually or in combination neither jeopardize the health and safety of patients nor are of such character as to seriously limit the provider's capacity to render adequate care.

(c)(1) If it is determined during a survey that a provider or supplier is not in compliance with one or more of the standards, it is granted a reasonable time to achieve compliance.

(2) The amount of time depends upon the—

(i) Nature of the deficiency; and

(ii) State survey agency's judgment as to the capabilities of the facility to provide adequate and safe care.

(d) Ordinarily a provider or supplier is expected to take the steps needed to achieve compliance within 60 days of being notified of the deficiencies but the State survey agency may recommend that additional time be granted by the Secretary in individual situations, if in its judgment, it is not reasonable to expect compliance within 60 days, for example, a facility must obtain the approval of its governing body, or engage in competitive bidding.

[59 FR 56237, Nov. 10, 1994]

Subpart B—Special Requirements

§ 488.52 [Reserved]

§ 488.54 Temporary waivers applicable to hospitals.

(a) *General provisions.* If a hospital is found to be out of compliance with one or more conditions of participation for hospitals, as specified in part 482 of this chapter, a temporary waiver may be granted by CMS. CMS may extend a temporary waiver only if such a waiver would not jeopardize or adversely affect the health and safety of patients. The waiver may be issued for any one year period or less under certain circumstances. The waiver may be withdrawn earlier if CMS determines this action is necessary to protect the health and safety of patients. A waiver may be granted only if:

(1) The hospital is located in a rural area. This includes all areas not delineated as "urban" by the Bureau of the Census, based on the most recent census;

(2) The hospital has 50 or fewer inpatient hospital beds;

(3) The character and seriousness of the deficiencies do not adversely affect the health and safety of patients; and

(4) The hospital has made and continues to make a good faith effort to comply with personnel requirements consistent with any waiver.

(b) *Minimum compliance requirements.* Each case will have to be decided on its individual merits, and while the degree and extent of compliance will vary, the institution must, as a minimum, meet all of the statutory conditions in section 1861(e)(1)–(8), in addition to meeting such other requirements as the Secretary finds necessary under section 1861(e)(9). (For further information relating to the exception in section 1861(e)(5) of the Act, see paragraph (c) of this section.)

(c) *Temporary waiver of 24-hour nursing requirement of 24-hour registered nurse requirement.* CMS may waive the requirement contained in section

(4) Clinics, rehabilitation agencies, and public health agencies.

(5) Comprehensive outpatient rehabilitation facilities (CORFs).

(6) Hospices.

(7) Critical access hospital (CAHs).

(8) Community mental health centers (CMHCs).

(9) Religious nonmedical health care institutions (RNHCIs).

(c)(1) Clinics, rehabilitation agencies, and public health agencies may enter into provider agreements only for furnishing outpatient physical therapy, and speech pathology services.

(2) CMHCs may enter into provider agreements only to furnish partial hospitalization services.

[45 FR 22937, Apr. 4, 1980, as amended at 47 FR 56297, Dec. 15, 1982; 48 FR 56036, Dec. 15, 1983; 51 FR 24492, July 3, 1986; 58 FR 30676, May 26, 1993; 59 FR 6578, Feb. 11, 1994; 62 FR 46037, Aug. 29, 1997; 68 FR 66720, Nov. 28, 2003]

§ 489.3 Definitions.

For purposes of this part—

Immediate jeopardy means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.

Provider agreement means an agreement between CMS and one of the providers specified in § 489.2(b) to provide services to Medicare beneficiaries and to comply with the requirements of section 1866 of the Act.

[48 FR 39837, Sept. 1, 1983, as amended at 51 FR 24492, July 3, 1986; 54 FR 5373, Feb. 2, 1989; 59 FR 56250, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 489.10 Basic requirements.

(a) Any of the providers specified in § 489.2 may request participation in Medicare. In order to be accepted, it must meet the conditions of participation or requirements (for SNFs) set forth in this section and elsewhere in this chapter. The RNHCIs must meet the conditions for coverage, conditions for participation and the requirements set forth in this section and elsewhere in this chapter.

(b) In order to participate in the Medicare program, the provider must meet the applicable civil rights requirements of:

(1) Title VI of the Civil Rights Act of 1964, as implemented by 45 CFR part 80, which provides that no person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subject to discrimination under, any program or activity receiving Federal financial assistance (section 601);

(2) Section 504 of the Rehabilitation Act of 1973, as implemented by 45 CFR part 84, which provides that no qualified handicapped person shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subject to discrimination under any program or activity receiving Federal financial assistance;

(3) The Age Discrimination Act of 1975, as implemented by 45 CFR part 90, which is designed to prohibit discrimination on the basis of age in programs or activities receiving Federal financial assistance. The Age Discrimination Act also permits federally assisted programs and activities, and recipients of Federal funds, to continue to use certain age distinctions, and factors other than age, that meet the requirements of the Age Discrimination Act and 45 CFR part 90; and

(4) Other pertinent requirements of the Office of Civil Rights of HHS.

(c) In order for a hospital, SNF, HHA, hospice, or RNHCI to be accepted, it must also meet the advance directives requirements specified in subpart I of this part.

(d) The State survey agency will ascertain whether the provider meets the conditions of participation or requirements (for SNFs) and make its recommendations to CMS.

(e) In order for a home health agency to be accepted, it must also meet the surety bond requirements specified in subpart F of this part.

(f) In order for a home health agency to be accepted as a new provider, it must also meet the capitalization requirements specified in subpart B of this part.

[58 FR 61843, Nov. 23, 1993, as amended at 59 FR 6578, Feb. 11, 1994; 63 FR 312, Jan. 5, 1998; 68 FR 66720, Nov. 28, 2003]

27.2 *Federal Register*

69 Fed. Reg. 28330–1 (2001)

69 Fed. Reg. 49214-222, 49272

Letter No. 0414, issued December 11, 2003.) Therefore, effective January 1, 2004, this provision allows any currently participating CAH, or applicant for CAH approval, to maintain up to 25 inpatient beds. If swing-bed approval has been granted, all 25 beds can be used interchangeably for acute care or swing-bed services. However, no CAH will be considered to have had 25 acute care beds prior to January 1, 2004. We are proposing to amend our regulations at §§ 485.620(a) and 485.645(a)(2) to reflect the increase in the number of beds permitted in a CAH, in accordance with the amendments made by section 405(e) of Public Law 108–173.

7. Authority To Establish Psychiatric and Rehabilitation Distinct Part Units of CAHs (Section 405(g)(1) of Public Law 108–173 and Proposed New § 485.646 of the Regulations)

As stated earlier, sections 1820(c)(2)(B) and 1861(mm) of the Act set forth the criteria for designating a CAH. Under this authority, the Secretary has established in regulations the minimum requirements a CAH must meet to participate in Medicare (42 CFR Part 485, Subpart F). The CAH designation is targeted to small rural hospitals with a low patient census and short patient stays.

Under the law in effect prior to Public Law 108–173, CAHs are excluded from operating distinct part units (that is, separate sections of hospitals that are dedicated to providing inpatient rehabilitation or psychiatric care and are paid under payment methods different from those used for the acute care areas of the hospitals). The statute (section 1886(d)(l)(B) of the Act) and implementing regulations under 42 CFR Part 412, Subpart B require distinct part units to be units of ''subsection (d) hospitals,'' which are hospitals paid under the IPPS. Because CAHs are not ''subsection (d) hospitals'' paid under IPPS, but instead are paid for inpatient care on a reasonable cost basis under section 1814(l) of the Act, they are effectively prohibited from having distinct part units.

Section 405(g)(1) of Public Law 108–173 modified the statutory requirements for CAHs under section 1814(l) and section 1820(c)(2) of the Act to allow CAHs to establish distinct part rehabilitation and psychiatric units of up to 10 beds each, which will not be included in the revised total 25 CAH bed count under section 405(e) of Public Law 108–173 (discussed in detail in section VI.D.6. of this preamble. In addition, as explained more fully below, the average 96-hour stay does not apply to the 10 beds in the distinct part units and inpatient admissions; days of inpatient care in these distinct part units are not taken into account in determining the facility's compliance with the requirement for a facility-wide average length of stay that does not exceed 96 hours.

Section 405(g)(1) of Public Law 108–173 provides under section 1820(c)(2)(E)(i) of the Act that a distinct part rehabilitation or psychiatric unit of a CAH must meet the conditions of participation that would otherwise apply to the distinct part unit of a hospital if the distinct part unit were established by a subsection (d) hospital in accordance with the matter following clause (v) of section 1886(d)(1)(B) of the Act, including any applicable regulations adopted by the Secretary. CAHs will now be permitted to operate distinct-part psychiatric and rehabilitation units, and it is clear that the law, consistent with this change, requires the same level of health and safety protection for patients in distinct part units of a CAH that is currently required for patients in distinct part units operated by an acute care hospital.

The amendments to section 405(g)(1) are effective for the cost reporting periods beginning on or after October 1, 2004.

As CAHs were excluded from operating distinct part units prior to the enactment of section 405(g), the CAH conditions of participation did not address the necessary requirements and standards for operating such units. As noted previously, section 1820(c)(2)(E)(i) of the Act makes it clear that the requirements, including conditions of participation, for operating these units in a CAH are to be the same as is currently required for these units operated by an acute care hospital. Accordingly, we are proposing that, in accordance with the requirements of section 405(g), a rehabilitation or psychiatric distinct part unit of a CAH must meet all of the hospital conditions of participation at 42 CFR Part 482, Subparts A, B, C, and D and the criteria for exclusion from the IPPS at 42 CFR Part 412 as described below. These requirements will only apply to the services provided in the distinct part unit of a CAH and not the entire CAH.

Currently, psychiatric distinct part units of hospitals are subject to specific Medicare regulations established in 42 CFR 412.27 regarding the types of patients admitted, the scope of services furnished, and the qualifications of staff. For example, psychiatric distinct part units may admit only patients whose condition requires inpatient hospital care for a psychiatric principal diagnosis. The regulations at § 412.27(b) further requires a hospital that wishes to establish a psychiatric distinct part unit to furnish, through the use of qualified personnel, psychological services, social work services, psychiatric nursing, and occupational and recreational therapy. The hospital must maintain medical records for the unit that permit determination of the degree and intensity of services to individuals treated in the unit. Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program, and who is board certified in psychiatry (42 CFR 412.27(d)(2)). The distinct part unit must have a director of social services, a qualified director of psychiatric nursing services who is a registered nurse with a master's degree in psychiatric or mental health nursing, or its equivalent from an accredited school of nursing, or is qualified by education and experience in the care of individuals with mental illness. There must also be an adequate number of registered nurses to provide 24-hour coverage as well as licensed practical nurses and mental health workers. These and other applicable requirements are set forth in greater detail in § 412.27.

Rehabilitation distinct part units of hospitals are currently subject to criteria in 42 CFR 412.29. This section specifies that such a unit must meet either the requirements for new units (§ 412.30(a)) or those for existing units (§ 412.30(c)). In addition, the units must furnish through qualified personnel rehabilitation nursing, physical and occupational therapy, and as needed, speech therapy and social services or psychological services, and orthotics and prosthetics. The unit must have a director of rehabilitation services who is trained or experienced in medical management of inpatients who require rehabilitation services and is a doctor of medicine or a doctor of osteopathy. Rehabilitation distinct part units may treat only patients likely to benefit significantly from an intensive inpatient program, utilizing services such as physical, occupational, or speech therapy. These and other applicable requirements are set forth in greater detail in §§ 412.29 and 412.30.

To implement the requirements of section 1820(c)(2)(E)(i) of the Act, as added by section 405(g)(1) of Public Law 108–173, we are proposing to add a new § 485.647 to 42 CFR Part 485, Subpart F. In proposed § 485.647(a)(1), we would specify that if a CAH provides

inpatient psychiatric services in a distinct part unit, the services provided in that unit must comply with the hospital requirements specified in Subparts A, B, C, and D of Part 482, with the common requirements for IPPS-excluded units in § 412.25(a)(2) through (f), and with the additional requirements of § 412.27 for psychiatric units excluded from the IPPS. In proposed § 485.647(a)(2), we would specify that if a CAH provides inpatient rehabilitation services in a distinct part unit, the services provided in that unit must comply with the hospital requirements specified in Subparts A, B, C, and D of Part 482, with the common requirements for IPPS-excluded units in § 412.25(a)(2) through (f), and with the additional requirements of §§ 412.29 and 412.30, which relate specifically to rehabilitation units excluded from the IPPS. To provide for consistent application of section 405(g)(1) and avoid any confusion, we also are proposing to revise § 412.22, which contains the common requirements for excluded hospital units, to state that, for purposes of 42 CFR Part 412, Subpart B, the term ''hospital'' includes a CAH.

As noted earlier, sections 1820(c)(2)(E)(ii) and (c)(2)(E)(iii) of the Act, as added by section 405(g)(1) of the MMA, provide that each distinct part unit of a CAH may have up to 10 beds and that, in determining the number of beds a CAH has for purposes of compliance with the 25-bed limit described earlier, the beds in a distinct part unit are not to be taken into account. We interpret the exclusion of these beds from consideration for purposes of the 25-bed limit as also indicating that the admissions and lengths of stay in distinct part unit beds are not to be considered in determining the facility-wide average length stay of a CAH for purposes of the 96-hour limitation on CAH's average length of inpatient stay. These rules would be codified in paragraphs (b)(1) through (b)(3) of proposed § 485.647.

Section 1820(c)(2)(E)(iv) of the Act, as added by section 405(g)(1) of Public Law 108–173, imposes severe sanctions on CAHs that fail to operate their distinct part units in compliance with applicable requirements. That section states that if a psychiatric or rehabilitation unit of a CAH does not meet the requirements of section 1820(c)(2)(E)(i) with respect to a cost reporting period, no payment may be made to the CAH for services furnished in that unit for that period. Payment to the CAH for services in the unit may resume only after the unit has demonstrated to CMS that the unit meets the requirements of § 485.645. We are proposing to codify this requirement by adding a new paragraph (g) to § 412.25.70, which contains the common requirements for excluded units.

Section 405(g)(1) of Public Law 108–173 amended section 1814(l) of the Act by adding a new paragraph (2) to that provision. New section 1814(l)(2) states that, in the case of a distinct-part psychiatric or rehabilitation unit of a CAH, the amount of payment for inpatient CAH services of such a unit is to equal the amount that would be paid if these services were inpatient hospital services of a psychiatric or rehabilitation unit, respectively, of the kind described in the matter following clause (v) of section 1886(d)(1)(B) of the Act. To implement the requirements of section 1814(1)(2) of the Act, we are proposing that, for CAHs that establish rehabilitation or psychiatric distinct part units, or both, in their facility, Medicare payment for inpatient services provided in those units would be made under the applicable existing payment methodology described below for IRFs and IPFs.

Presently, IRFs are paid under a per discharge PPS that became effective for cost reporting periods beginning on or after January 1, 2002. The regulations governing the IRF PPS are located under 42 CFR Part 412, Subpart P (§§ 412.600 through 412.632).

At this time psychiatric hospitals and units that are excluded from the IPPS are paid for their inpatient operating costs on a reasonable cost basis, subject to a hospital-specific limit. However, as required by statute, a per diem PPS for Medicare payments for inpatient hospital services furnished in psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)) was proposed in the **Federal Register** on November 28, 2003 (68 FR 66920). We are in the process of developing the final rule for this proposed rule. When finalized, the IPF PPS will replace the reasonable cost based payment system currently in effect.

To clarify the requirements of section 1814(1)(2) of the Act regarding payment for inpatient CAH services of a distinct part psychiatric or rehabilitation unit of a CAH, we are proposing to revise the title and first sentence of paragraph (a)(1) of § 413.70, and to add a new paragraph (a)(4) to that section, to clarify that payment for inpatient services of a CAH distinct part unit is not made in accordance with the otherwise applicable rules for payment for inpatient CAH services, but under other rules described in new § 413.70(e). We propose also in new paragraph § 413,70(e), that payment for inpatient services of distinct part rehabilitation units of CAHs is made in accordance with regulations governing the IRF PPS at 42 CFR Part 412, Subpart F (§§ 412.600 through 412.632). We also would state that payment for inpatient services of distinct part psychiatric units of CAHs is made in accordance with regulations governing IPPS-excluded psychiatric units of hospitals at 42 CFR 413.40.

8. Waiver Authority for Designation of a CAH as a Necessary Provider

Section 405(h) of Public Law 108–173 amended section 1820(c)(B)(i)(II) of the Act by adding language that terminates a State's authority to waive the location requirement for a CAH by designating the CAH as a necessary provider, effective January 1, 2006. Currently, a CAH is required to be located more than a 35-mile drive (or in the case of mountainous terrain or secondary roads, a 15-mile drive) from a hospital or another CAH, unless the CAH is certified by the State as a necessary provider of health care services to residents in the area. Under this provision, after January 1, 2006, States will no longer be able to designate a CAH based upon a determination it is a necessary provider of health care.

In addition, section 405(h) of Public Law 108–173 amended section 1820(h) of the Act to include a grandfathering provision for CAHs that are certified as necessary providers prior to January 1, 2006. Under this provision, any CAH that is designated as a necessary provider in its State's rural health plan prior to January 1, 2006, will be permitted to maintain its necessary provider designation.

In this proposed rule, we are proposing to revise our regulations at § 485.610(c) to incorporate the amendments made by section 405(h) of Public Law 108–173.

9. Payment for Clinical Diagnostic Laboratory Tests

Medicare payment for clinical diagnostic laboratory tests provided to the outpatients of CAHs was established through the regulatory process and published in the **Federal Register** as part of the FY 2004 IPPS final rule (68 FR 45346, August 1, 2003). Payment to a CAH for clinical diagnostic laboratory tests for outpatients is made on a reasonable cost basis only if the individuals for whom the tests are performed are outpatients of the CAH and are physically present at the CAH at the time specimens are collected. Otherwise, payment for these tests is made on a fee schedule basis.

percentage of the threshold will be the lesser of the percentage of their discharges admitted from their host for their cost reporting period beginning on or after October 1, 2003 or 50 percent, and for cost reporting periods beginning on or after October 1, 2007, the percentage threshold will be 25 percent or the applicable percentage.

Technical Change. In § 412.22(e) of our regulations, we refer to a hospital-within-a-hospital as a hospital that ''occupies space in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital'' (emphasis added). The reference to ''entire'' buildings is incorrect. We should have referred to ''separate'' buildings. Therefore, in the May 18, 2004 proposed rule, we proposed to correct this error.

C. Critical Access Hospitals (CAHs)

1. Background

Section 1820 of the Act provides for the establishment of Medicare Rural Hospital Flexibility Programs, under which individual States may designate certain facilities as critical access hospitals (CAHs). Facilities that are so designated and meet the CAH conditions of participation in 42 CFR Part 485, Subpart F, will be certified as CAHs by CMS. Regulations governing payments to CAHs for services to Medicare beneficiaries are located in 42 CFR Part 413.

2. Payment Amounts for CAH Services (Section 405(a) of Public Law 108–173 and §§ 413.70 and 413.114 of the Regulations)

Prior to the enactment of Public Law 108–173, section 1814(l) of the Act provides that the Medicare payment amount for inpatient services furnished by a CAH is the reasonable costs of the CAH in providing the services. Section 1834(g)(1) of the Act provides that the Medicare amount of payment for outpatient services furnished by a CAH is also made on a reasonable cost basis, unless the CAH makes an election, under section 1834(g) of the Act, to receive a payment amount that is the sum of the reasonable cost of hospital outpatient facility services plus 115 percent of the amount otherwise paid for professional services. Section 1883(a)(3) of the Act provides for payment to a CAH for covered skilled nursing facility services furnished under an agreement entered into under section 1883 of the Act on the basis of the reasonable costs of such services. Regulations implementing these provisions are set forth in § 413.70(a), for inpatient CAH services; in § 413.70(b), for payment under the standard method for the reasonable costs of facility services, and outpatient CAH services; in § 413.70(b)(3), for the optional method of payment for outpatient services (reasonable costs for facility services plus fee schedule for professional services); and in § 413.114, for SNF services of a CAH with a swing-bed agreement.

Section 405(a) of Public Law 108–173 amended sections 1814(l), 1834(g)(1), and 1883(a)(3) of the Act to provide that, effective for services furnished during cost reporting periods beginning on or after January 1, 2004, the amount of the payment for inpatient, outpatient, and SNF services, respectively, furnished by a CAH is equal to 101 percent of the reasonable cost of the CAH in providing these services.

In the May 18, 2004 proposed rule (69 FR 28327–28328), we proposed to revise §§ 413.70(a)(1), (b)(2), and (b)(3) and § 413.114 of our regulations to incorporate the change in the payment percentage made by section 405(a) of Public Law 180–173. We also proposed to make a technical correction to § 413.70(b)(2)(i) to remove paragraphs (b)(2)(i)(C) and (D). We proposed to delete these paragraphs to conform the regulations to provisions of the outpatient hospital PPS.

We note that in the IPPS final rule published in the **Federal Register** on August 1, 2001 (66 FR 39936), we added a new paragraph (a)(1)(iv) to § 413.70. However, when the change was incorporated into the Code of Federal Regulations, paragraphs (a)(1)(i), (a)(1)(ii), and (a)(1)(iii) were inadvertently omitted. Our proposed revision of § 413.70(a)(1) would correct the omission of these three paragraphs.

We did not receive any public comments on our proposals. Accordingly, in this final rule, we are adopting the proposals as final without modification.

3. Condition for Application of Special Professional Service Payment Adjustment (Section 405(d) of Public Law 108–173 and § 413.70(b) of the Regulations)

As stated earlier, section 1834(g) of the Act provides for two methods of payment for outpatient CAH services. Under the provisions of section 1834(g) of the Act, a CAH will be paid under a reasonable cost method unless it elects payment under an optional method. Under the reasonable cost payment method, facility services are paid on a reasonable cost payment basis by the fiscal intermediary to the CAH, and physician and other professional services to CAH outpatients are paid for under the physician fee schedule, with payments being made by the carrier. Under the optional method (frequently referred to as ''method 2''), CAHs submit bills for both facility and professional services to the fiscal intermediary. If a CAH elects the optional method of billing for outpatient services, Medicare payment for its facility services are made at the same level as would apply under the reasonable cost reimbursement method, but services of professionals to outpatients are paid for at 115 percent of the amounts that would otherwise be paid for under the physician fee schedule. To make the optional method election feasible and to help prevent possible duplicate billing, we require practitioners furnishing services to outpatients of a CAH to agree to reassign to the CAH their rights to bill the Medicare program for those services.

Existing regulations at § 413.70(b) set forth these payment options and specify that an election of the optional method, once made for a cost reporting period, remains in effect for all of that period and applies to all services furnished to CAH outpatients during that period. This means that, under existing regulations, a CAH may elect the optional method payment only if all of its practitioners agree to reassign their billing rights for outpatient services to the CAH.

Section 405(d)(1) of Public Law 108–173 amended section 1834(g)(2) of the Act by adding a sentence after paragraph (B) to specify that the Secretary may not require, as a condition for a CAH to make an election of the optional method of payment, that each physician or other practitioner providing professional services in the CAH must assign billing rights with respect to the services. However, the optional payment method does not apply to those physicians and practitioners who have not assigned such billing rights. In other words, section 405(d) of Public Law 108–173 amended the Medicare law to authorize CAHs to elect the optional payment method even if some practitioners do not reassign to the CAH their rights to bill for professional services to CAH outpatients. However, it also specifies that the 15-percent increase in payment for those services is not available for professional services for which billing rights are not reassigned to the CAH.

The provisions of section 405(d)(1) of Public Law 108–173 are effective for cost reporting periods beginning on or after July 1, 2004. However, section 405(d)(2)(B) of Public Law 108–173 also states, in a special rule of application,

that in the case of a CAH that made an election before November 1, 2003, the provisions of section 405(d)(1) of Public Law 108–173 are effective for cost reporting periods beginning on or after July 1, 2001.

Consistent with section 405(d)(2)(B) of Public Law 108–173, we do not intend to attempt recovery of certain amounts paid improperly in the past to CAHs for professional services that the CAHs billed under the optional payment method, even though the CAHs had not obtained reassignments of billing rights from all physicians and other practitioners furnishing professional services to their outpatients, as required by § 413.70 as in effect at that time. However, in the May 18, 2004 proposed rule (69 FR 28328), we proposed to clarify that the special rule of application in section 405(d)(2)(B) of Public Law 108–173 is not to be interpreted to permit a CAH to obtain payment under the optional payment method for any cost reporting period based on an election made for a prior period or on an optional payment method election that was withdrawn or revoked prior to the start of the cost reporting period for which it was made.

To illustrate the application of section 405(d)(2)(B) of Public Law 108–173, assume that on October 1, 2002, a CAH elected method 2 for its cost reporting period starting on January 1, 2003, but did not obtain reassignments from all physicians treating its outpatients, as required by regulations in effect at that time. Under section 405(d)(2)(B) of Public Law 108–173, CMS would not recover any amounts from the CAH for payments for services furnished during that cost reporting period (January 1, 2003, through December 31, 2004) that are attributable to that election, even though the election was inappropriate based on the regulations that were in effect at the time it was made. Assume further that the same CAH recognized its error and did not make a method 2 election for its cost reporting period beginning January 1, 2004, thus receiving payment under method 1. The fact that the election of October 1, 2002, was made prior to November 1, 2003, is not material in this case and cannot be interpreted to justify method 2 payment for the cost reporting period beginning January 1, 2004, because that method 2 election related to an earlier cost reporting period and not to the cost reporting period beginning January 1, 2004. The same result would occur if the CAH had elected method 2 on October 1, 2003, but subsequently revoked that election on October 15, 2004.

In the proposed rule, we proposed to revise § 413.70(b)(3)(i) to reflect the changes made by section 405(d) of Public Law 108–173. We proposed to specify in § 413.70(b)(3)(i) that a CAH may elect to be paid for outpatient services in any cost reporting period beginning on or after July 1, 2004, under the method described in §§ 413.70(b)(3)(ii) and (b)(3)(iii). In § 413.70(b)(3)(i)(A), we proposed to clarify that such an election is to be made at least 30 days before the start of the cost reporting period for which the election is made. In § 413.70(b)(3)(i)(B), we proposed to specify that the provision applies to all services furnished to outpatients during that cost reporting period by a physician or other practitioner who has reassigned his or her rights to bill for those services to the CAH in accordance with the reassignment regulations under 42 CFR Part 424, Subpart F. In that paragraph, we also proposed to specify that if a physician or other practitioner does not reassign his or her billing rights to the CAH in accordance with 42 CFR Part 424, Subpart F, payment for the physician's or practitioner's services to CAH outpatients will be made on a fee schedule or other applicable basis specified in 42 CFR Part 414, Subpart B. We also proposed to add a new paragraph (C) to § 413.70(b)(3)(i) to state that, in case of a CAH that made an election under § 413.70(b)(3) before November 1, 2003, for a cost reporting period beginning before December 1, 2004, the rules in paragraph (b)(3)(i)(B) are effective for cost reporting periods beginning on or after July 1, 2001. In addition, we proposed in § 413.70(b)(3)(i)(B) to clarify that an election for the optional method would be effective only for any cost reporting period for which it was made and does not apply to an election that was withdrawn or revoked before the start of the cost reporting period for which it was made.

We did not receive any public comments on our proposals. Accordingly, in this final rule, we are adopting the proposals as final without modification.

4. Coverage of Costs for Certain Emergency Room On-Call Providers (Section 405(b) of Public Law 108–173 and §§ 413.70(b)(4) and 485.618 of the Regulations)

Under existing regulations at § 413.70(b)(4), which implement section 1834(g)(5) of the Act, Medicare payments to a CAH may include the costs of compensation and related costs of on-call emergency room physicians who are not present on the premises of a CAH, are not otherwise furnishing services, and are not on-call at any other provider or facility when determining the reasonable cost of outpatient CAH services. Section 405(b) of Public Law 108–173 amended section 1834(g)(5) of the Act to expand the reimbursement to a CAH of compensation costs for on-call emergency room providers beyond physicians to include physician assistants, nurse practitioners, and clinical nurse specialists for the costs associated with covered Medicare services furnished on or after January 1, 2005.

In the May 18, 2004 proposed rule (69 FR 28329), we proposed to revise § 413.70(b)(4)(i) and (ii) to include the expanded list of emergency room on-call providers for whom reimbursement for reasonable compensation and related costs in a CAH would be available. We also proposed to make a conforming change to § 485.618(d) governing the standard for emergency room personnel who are on call under the CAH conditions of participation.

Comment: One commenter recommended that the proposed change to § 485.618(d), under which a clinical nurse specialist is added to the list of practitioners who may be on call to provide emergency services to CAH patients, be revised by adding a comma after the phrase ''clinical nurse specialist.'' The commenter believed this change will help to clarify that all practitioners who have on-call responsibilities, and not only clinical nurse specialties, should have training or experience in emergency care.

Response: We agree and have made this change to § 485.618(d) and a conforming change to § 413.70(b)(4)(ii)(B) in this final rule.

Accordingly, in this final rule, we are adopting the proposed changes to § 485.618(d) as final with one further technical change, as discussed above, to clarify that all practitioners who have on-call responsibilities should have training or experience in emergency care.

5. Authorization of Periodic Interim Payments for CAHs (Section 405(c) of Public Law 108–173 and Proposed §§ 413.64(h)(2)(vi) and 413.70(d) of the Regulations)

Section 1815(e)(2) of the Act provides that payments may be made on a periodic interim payment (PIP) basis for specified covered Medicare services. Section 405(c)(1) of Public Law 108–173 amended section 1815(e)(2) of the Act by adding a new subsection (E) to provide for payments for inpatient services furnished by CAHs on a PIP basis, effective for payments made on or

after July l, 2004. Section 405(c)(2) of Public Law 108–173 directs the Secretary to develop alternative methods for the timing of the payments under the PIP method.

We have already established in existing regulations under § 413.64(h) provisions for making payments under the PIP method to providers for certain Medicare covered services. The principles and rules of § 413.64 have been incorporated into regulations governing payment on a PIP basis to acute care IPPS hospitals as well as to other providers, such as SNFs and LTCHs, that are paid on a prospective basis. We believe these principles and rules could be equally applied to CAHs. Therefore, in the May 18, 2004 proposed rule (69 FR 28329), to implement the provisions of section 405(c) of Public Law 108–173, we proposed to add a new § 413.64(h)(2)(vi) to specify inpatient services furnished by CAHs as an additional type of covered service for which PIP is available, effective for payments made on or after July 1, 2004.

It has been our longstanding policy under § 413.64(h)(6) that payment will be made biweekly under the PIP method, unless the provider requests a longer fixed interval (not to exceed 1 month) between payments. We believe that this provision grants adequate flexibility for the timing of payments under the PIP method to all qualifying providers, including CAHs. Under the proposed policy for CAHs, if a CAH chooses to receive its payments less frequently than biweekly, it could inform its Medicare fiscal intermediary. Section 413.64(h)(6) does not provide for the payments to be made more frequently than biweekly to providers for which PIP is currently available. We believe this is equally appropriate for the payments for inpatient services furnished by CAHs.

In summary, we proposed to apply the same rules and procedures for payments under the PIP method that we apply to acute care hospitals and certain other Medicare providers. Therefore, CAHs, in applying for and receiving payments for inpatient services under the PIP provision, would be operating under the same rules as other providers for which PIP is available under § 413.64(h), including the flexibility discussed above of the timing of their payments as provided for under § 413.64(h)(6). We also proposed to establish a new paragraph (d) under § 413.70 to provide that, for payments on or after July l, 2004, a CAH may elect to receive PIP for inpatient services furnished by CAHs, subject to the provisions of § 413.64(h). The new § 413.70(d) summarizes the application of the PIP provisions under § 413.64(h)(6) for CAH inpatient services and notes the availability of accelerated payments for CAHs that are not receiving PIPs.

Comment: Two commenters noted that section 405(c) of Public Law 108–173 provides that PIP for CAHs applies to payments made on or after July 1, 2004. One commenter believed that the new paragraph (d) under § 413.70 providing for PIP for CAHs ''subject to the provisions of § 413.64(h)'' suggests that payment of PIP would be for cost reports beginning on or after July 1, 2004. The commenters stated that some fiscal intermediaries have indicated that existing CAH facilities will not be able to receive PIP until the start of their first cost reporting period beginning on or after July 1, 2004 and that a CMS regional office has provided direction that the election of PIP is limited to the beginning of a CAH cost reporting period. The commenters asked CMS to clarify that qualifying CAHs are eligible for PIP, effective for payments made on or after July 1, 2004, not for cost reports beginning on or after that date.

Response: Qualifying CAHs are eligible for PIP for payments made on or after July 1, 2004. New § 413.64(h)(2)(vi) specifies that for inpatient CAH services furnished by a CAH, PIP is available for qualifying CAHs, effective for payments made on or after July 1, 2004. New § 413.70(d) also provides that a CAH may elect to receive PIP effective for payments made on or after July 1, 2004. Section 413.64(h)(3) has long provided that a provider that establishes to the satisfaction of its fiscal intermediary that it meets the requirements to receive PIP may elect to receive PIP, beginning with the first month after its request that the fiscal intermediary finds administratively feasible. This provision provides fiscal intermediaries some flexibility in beginning PIP for a provider, but we expect that fiscal intermediaries will begin PIP for providers, including CAHs, within a reasonable period of time after the fiscal intermediary has determined that the provider qualifies for PIP.

Comment: One commenter indicated that some fiscal intermediaries have interpreted the regulations at § 413.64(h) that a new CAH cannot receive PIP until at least one CAH cost report has been filed. Another commenter indicated that one CMS regional office has suggested that PIP is only available to those CAHs that have at least one full 12-month cost report under cost-based reimbursement.

Response: Section 413.64(h)(3)(ii) has long contained the requirement that, to qualify for PIP, the provider has filed at least one completed Medicare cost report accepted by the fiscal intermediary as providing an accurate basis for computation of payment. However, the requirement contains an exception in the case of a provider requesting payment under PIP upon first entering the Medicare program. Therefore, a new CAH to the Medicare program need not have filed a cost report to be able to qualify for PIP. However, in the absence of a completed cost report, the fiscal intermediary must have other information in order to satisfy itself that it can make accurate PIP payments. A provider without a completed cost report needs to supply all information that the fiscal intermediary requests in order for the intermediary to make its determination as to whether it can make accurate payments to the provider under the PIP method. Section 413.64(h)(5) provides that approval of PIP is conditioned upon the intermediary's best judgment as to whether accurate payments can be made under the PIP method. Therefore, if the fiscal intermediary is satisfied with the information it has received that it can make accurate payments under the PIP method, it will approve PIP for the provider. If the fiscal intermediary is not satisfied that it can make accurate payments, it is not to approve PIP for the provider.

A CAH need not have at least one full 12-month cost report under cost-based reimbursement to qualify for PIP. However, as discussed above, a fiscal intermediary is not to approve PIP unless it is satisfied that PIP will result in accurate payments. For a provider without a full 12-month cost report under cost reimbursement, the fiscal intermediary may request additional information from the provider in order to assure itself that it can make accurate payment to the provider under PIP. If the fiscal intermediary is satisfied with the information it has received that it can make accurate payments under the PIP method, it will approve PIP for the provider. If the fiscal intermediary is not satisfied, it is not to approve PIP for the provider.

After careful consideration of the comments received, we do not believe any changes are necessary, and we are adopting our proposal as final without modification.

Technical Changes to § 413.64. In the May 18, 2004 proposed rule, we proposed to use this opportunity to remove §§ 413.64(h)(3)(iv) and 413.64(h)(4), which contain an outdated requirement that a provider must repay any outstanding current financing payments before being permitted to be paid under the PIP method. Current financing payments have not been

available since 1973. We did not receive any public comments on this proposed technical change. Therefore, we are adopting it as final.

6. Revision of the Bed Limit for CAHs (Section 405(e) of Pub. L. 108–173 and §§ 485.620(a) and 485.645(a)(2) of the Regulations)

Prior to the enactment of Public Law 108–173, sections 1820(c)(2)(B)(iii) and 1820(f) of the Act restricted CAHs to 15 acute care beds and a total of 25 beds if the CAH had been granted swing-bed approval. The number of beds used at any time for acute care inpatient services could not exceed 15 beds.

Section 405(e) of Public Law 108–173 amended sections 1820(c)(2)(B)(iii) and 1820(f) of the Act to allow CAHs a maximum of 25 acute care beds for inpatient services, regardless of the swing-bed approval. This amendment is effective on January 1, 2004 and applies to CAHs designated before, on, or after this date. However, section 405(e)(3) of Public Law 108–173 also notes that any election made in accordance with the regulations promulgated to carry out the bed size amendments only applies prospectively.

We implemented this provision via a survey and certification letter on January 1, 2004. (See Survey and Certification Letter No. 0414, issued December 11, 2003.) Effective January 1, 2004, this provision allows any currently participating CAH, or applicant for CAH approval, to maintain up to 25 inpatient beds. If swing-bed approval has been granted, all 25 beds can be used interchangeably for acute care or swing-bed services. However, no CAH will be considered to have had 25 acute care beds prior to January 1, 2004. In the May 18, 2004 proposed rule (69 FR 28329), we proposed to amend our regulations at §§ 485.620(a) and 485.645(a)(2) to reflect the increase in the number of beds permitted in a CAH, in accordance with the amendments made by section 405(e) of Public Law 108–173.

We received no comments within the scope of this proposal and, in this final rule, we are adopting as final, without modification, our proposed amendments to §§ 485.620(a) and 485.645(a)(2) to reflect the increase in the number of beds to 25 permitted in a CAH, in accordance with the amendments made by section 405(e) of Public Law 108–173.

7. Authority to Establish Psychiatric and Rehabilitation Distinct Part Units of CAHs (Section 405(g)(1) of Pub. L. 108–173 and New § 485.646 of the Regulations)

As stated earlier, sections 1820(c)(2)(B) and 1861(mm) of the Act set forth the criteria for designating a CAH. Under this authority, the Secretary has established in regulations the minimum requirements a CAH must meet to participate in Medicare (42 CFR Part 485, Subpart F). The CAH designation is targeted to small rural hospitals with a low patient census and short patient stays.

Under the law in effect prior to Public Law 108–173, CAHs are excluded from operating distinct part units (that is, separate sections of hospitals that are dedicated to providing inpatient rehabilitation or psychiatric care and are paid under payment methods different from those used for the acute care areas of the hospitals). The statute (section 1886(d)(l)(B) of the Act) and implementing regulations under 42 CFR Part 412, Subpart B require distinct part units to be units of ''subsection (d) hospitals,'' which are hospitals paid under the IPPS. Because CAHs are not ''subsection (d) hospitals'' paid under IPPS, but instead are paid for inpatient care on a reasonable cost basis under section 1814(l) of the Act, they are effectively prohibited from having distinct part units.

Section 405(g)(1) of Public Law 108–173 modified the statutory requirements for CAHs under section 1814(l) and section 1820(c)(2) of the Act to allow CAHs to establish distinct part rehabilitation and psychiatric units of up to 10 beds each, which will not be included in the revised total 25 CAH bed count under section 405(e) of Public Law 108–173 (discussed in detail in section VI.D.6. of this preamble). In addition, as explained more fully below, the average 96-hour stay does not apply to the 10 beds in the distinct part units and inpatient admissions; days of inpatient care in these distinct part units are not taken into account in determining the facility's compliance with the requirement for a facility-wide average length of stay that does not exceed 96 hours.

Section 405(g)(1) of Public Law 108–173 provides under section 1820(c)(2)(E)(i) of the Act that a distinct part rehabilitation or psychiatric unit of a CAH must meet the conditions of participation that would otherwise apply to the distinct part unit of a hospital if the distinct part unit were established by a subsection (d) hospital in accordance with the matter following clause (v) of section 1886(d)(1)(B) of the Act, including any applicable regulations adopted by the Secretary. CAHs will now be permitted to operate distinct-part psychiatric and rehabilitation units, and it is clear that the law, consistent with this change, requires the same level of health and safety protection for patients in distinct part units of a CAH that is currently required for patients in distinct part units operated by an acute care hospital. The amendments to section 405(g)(1) Public Law 108–173 are effective for the cost reporting periods beginning on or after October 1, 2004.

As CAHs were excluded from operating distinct part units prior to the enactment of section 405(g) Public Law 108–173, the CAH conditions of participation did not address the necessary requirements and standards for operating such units. As noted previously, section 1820(c)(2)(E)(i) of the Act makes it clear that the requirements, including conditions of participation, for operating these units in a CAH are to be the same as is currently required for these units operated by an acute care hospital. Accordingly, we proposed that, in accordance with the requirements of section 405(g) Public Law 108–173, a rehabilitation or psychiatric distinct part unit of a CAH must meet all of the hospital conditions of participation at 42 CFR Part 482, Subparts A, B, C, and D and the criteria for exclusion from the IPPS at 42 CFR Part 412 as described below. These requirements will only apply to the services provided in the distinct part unit of a CAH and not the entire CAH.

Currently, psychiatric distinct part units of hospitals are subject to specific Medicare regulations established in 42 CFR 412.27 regarding the types of patients admitted, the scope of services furnished, and the qualifications of staff. For example, psychiatric distinct part units may admit only patients whose condition requires inpatient hospital care for a psychiatric principal diagnosis. The regulations at § 412.27(b) further requires a hospital that wishes to establish a psychiatric distinct part unit to furnish, through the use of qualified personnel, psychological services, social work services, psychiatric nursing, and occupational and recreational therapy. The hospital must maintain medical records for the unit that permit determination of the degree and intensity of services provided to individuals treated in the unit. Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership

required for an intensive treatment program, and who is board certified in psychiatry (42 CFR 412.27(d)(2)). The distinct part unit must have a director of social services, a qualified director of psychiatric nursing services who is a registered nurse with a master's degree in psychiatric or mental health nursing, or its equivalent from an accredited school of nursing, or is qualified by education and experience in the care of individuals with mental illness. There must also be an adequate number of registered nurses to provide 24-hour coverage as well as licensed practical nurses and mental health workers. These and other applicable requirements are set forth in greater detail in § 412.27.

Rehabilitation distinct part units of hospitals are currently subject to criteria in 42 CFR 412.29. This section specifies that such a unit must meet either the requirements for new units (§ 412.30(a)) or those for existing units (§ 412.30(c)). In addition, the units must furnish through qualified personnel rehabilitation nursing, physical and occupational therapy, and, as needed, speech therapy and social services or psychological services, and orthotics and prosthetics. The unit must have a director of rehabilitation services who is trained or experienced in medical management of inpatients who require rehabilitation services and is a doctor of medicine or a doctor of osteopathy. Rehabilitation distinct part units may treat only patients likely to benefit significantly from an intensive inpatient program, utilizing services such as physical, occupational, or speech therapy. These and other applicable requirements are set forth in greater detail in § 412.29 and § 412.30.

To implement the requirements of section 1820(c)(2)(E)(i) of the Act, as added by section 405(g)(1) of Public Law 108–173, in the May 18, 2004 proposed rule (69 FR 28330), we proposed to add a new § 485.647 to 42 CFR Part 485, Subpart F. In proposed § 485.647(a)(1), we proposed to specify that if a CAH provides inpatient psychiatric services in a distinct part unit, the services provided in that unit must comply with the hospital requirements specified in Subparts A, B, C, and D of Part 482, with the common requirements for IPPS-excluded units in § 412.25(a)(2) through (f), and with the additional requirements of § 412.27 for psychiatric units excluded from the IPPS. In proposed § 485.647(a)(2), we proposed to specify that if a CAH provides inpatient rehabilitation services in a distinct part unit, the services provided in that unit must comply with the hospital requirements specified in Subparts A, B, C, and D of Part 482, with the common requirements for IPPS-excluded units in § 412.25(a)(2) through (f), and with the additional requirements of § 412.29 and § 412.30, which relate specifically to rehabilitation units excluded from the IPPS. To provide for consistent application of section 405(g)(1) Public Law 108–173 and avoid any confusion, we also proposed to revise § 412.22, which contains the common requirements for excluded hospital units, to state that, for purposes of 42 CFR Part 412, Subpart B, the term ''hospital'' includes a CAH.

As noted earlier, sections 1820(c)(2)(E)(ii) and (c)(2)(E)(iii) of the Act, as added by section 405(g)(1) of Public Law 108–173, provide that each distinct part unit of a CAH may have up to 10 beds and that, in determining the number of beds a CAH has for purposes of compliance with the 25-bed limit described earlier, the beds in a distinct part unit are not to be taken into account. We interpret the exclusion of these beds from consideration for purposes of the 25-bed limit as also indicating that the admissions and lengths of stay in distinct part unit beds are not to be considered in determining the facility-wide average length stay of a CAH for purposes of the 96-hour limitation on CAH's average length of inpatient stay. We proposed to codify these rules in paragraphs (b)(1) through (b)(3) of proposed § 485.647.

Section 1820(c)(2)(E)(iv) of the Act, as added by section 405(g)(1) of Public Law 108–173, imposes severe sanctions on CAHs that fail to operate their distinct part units in compliance with applicable requirements. That section states that if a psychiatric or rehabilitation unit of a CAH does not meet the requirements of section 1820(e)(2)(E)(i) of the Act with respect to a cost reporting period, no payment may be made to the CAH for services furnished in that unit for that period. Payment to the CAH for services in the unit may resume only after the CAH unit has demonstrated to CMS that the unit meets the requirement of section 1820(e)(2)(E)(1) of the Act. We proposed to codify this requirement by adding a new paragraph (g) to § 412.25, which contains the common requirements for excluded units.

Section 405(g)(1) of Public Law 108–173 amended section 1814(l) of the Act by adding a new paragraph (2) to that provision. New section 1814(l)(2) of the Act states that, in the case of a distinct-part psychiatric or rehabilitation unit of a CAH, the amount of payment for inpatient CAH services of such a unit is to equal the amount that would be paid if these services were inpatient hospital services of a psychiatric or rehabilitation unit, respectively, of the kind described in the matter following clause (v) of section 1886(d)(1)(B) of the Act. To implement the requirements of section 1814(1)(2) of the Act, we proposed that, for CAHs that establish rehabilitation or psychiatric distinct part units, or both, in their facility, Medicare payment for inpatient services provided in those units would be made under the applicable existing payment methodology described below for IRFs and IPFs.

Presently, IRFs are paid under a per discharge PPS that became effective for cost reporting periods beginning on or after January 1, 2002. The regulations governing the IRF PPS are located under 42 CFR Part 412, Subpart P (§ 412.600 through § 412.632).

At this time psychiatric hospitals and units that are excluded from the IPPS are paid for their inpatient operating costs on a reasonable cost basis, subject to a hospital-specific limit. However, as required by statute, a per diem PPS for Medicare payments for inpatient hospital services furnished in psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)) was proposed in the **Federal Register** on November 28, 2003 (68 FR 66920). We are in the process of developing the final rule for this proposed rule. When finalized, the IPF PPS will replace the reasonable cost based payment system currently in effect.

To clarify the requirements of section 1814(1)(2) of the Act regarding payment for inpatient CAH services of a distinct part psychiatric or rehabilitation unit of a CAH, in the May 18, 2004 proposed rule, we proposed to revise the title and first sentence of paragraph (a)(1) of § 413.70, and to add a new paragraph (a)(4) to that section, to clarify that payment for inpatient services of a CAH distinct part unit is not made in accordance with the otherwise applicable rules for payment for inpatient CAH services, but under other rules described in new § 413.70(e). We also proposed in new paragraph § 413.70(e), that payment for inpatient services of distinct part rehabilitation units of CAHs is made in accordance with regulations governing the IRF PPS at 42 CFR Part 412, Subpart F (§ 412.600 through § 412.632). We also proposed to state that payment for inpatient services of distinct part psychiatric units of CAHs is made in accordance with regulations governing IPPS-excluded psychiatric units of hospitals at 42 CFR 413.40.

Comment: One commenter expressed concern with the requirement that a CAH must have an ''adequate'' number of doctors with appropriate qualifications ''to provide essential psychiatric services.'' The commenter was concerned that, due to the small size of CAHs and the limited number of psychiatrists in rural areas, CAHs may hire psychiatrists who spend only a small portion of their time at the CAH. The commenter suggested that we consider requiring clinical directors to devote a specified minimum amount of time to each psychiatric unit they serve to offset the possibility of an inadequate supply of physicians.

Response: We believe the clinical director must devote the appropriate amount of time to meet the needs of the patients in the unit. We stated in the proposed rule that CAHs that operate a distinct-part psychiatric unit must comply with the same health and safety requirements as other Medicare-certified acute care hospitals that operate distinct-part psychiatric units. Currently, distinct-part psychiatric units of hospitals are subject to specific Medicare regulations regarding the staff and scope of services for psychiatric inpatient care. In addition to a clinical director, the distinct-part psychiatric unit must have a director of social services, a qualified director of psychiatric nursing services who is a registered nurse with a master's degree in psychiatric or mental health nursing, or its equivalent from an accredited school of nursing, or is qualified by education and experience in the care of individuals with mental illness. We believe that these requirements, and others set forth in greater detail in § 412.27, are required to l safeguard the care of individuals in a CAH distinct-part psychiatric unit.

Comment: One commenter stated that requiring CAH distinct part psychiatric and rehabilitation units to meet all of the hospital conditions of participation at 42 CFR Part 42, Subparts A, B, C and D will require both the JCAHO and the State survey agencies to conduct two surveys when assessing CAHs. The commenter stated that this requirement would result in a burdensome oversight strategy that would cause CAHs to decide not to add distinct part units.

Response: Section 405(g)(1) of Public Law 108–173 states that a distinct-part rehabilitation or psychiatric unit of a CAH must meet the conditions of participation that would otherwise apply to a distinct-part unit of a hospital. Therefore, we believe that it is clear that the Congress wants the same level of health and safety protection for patients in a distinct-part unit operated by a CAH as those that are currently required for patients in a distinct-part unit operated by an acute care hospital.

Therefore, it will be necessary for a distinct-part psychiatric or rehabilitation unit of a CAH to undergo a survey to demonstrate compliance with the requirements stipulated in the statute. Until a CAH receives approval and a provider number from CMS for any DPUs, the services furnished in those units will not be eligible for Medicare reimbursement. The CAH is not required to furnish such uncompensated services to Medicare beneficiaries prior to its approval.

Comment: As previously noted, proposed § 412.25(g) would require denial of payment to a CAH for services of a distinct-part psychiatric or rehabilitation unit of a CAH if that unit does not meet the requirements of proposed § 485.647 with respect to a cost reporting period. Under the proposal, no payment may be made to the CAH for services furnished in that unit for that period. The section further states that payment to the CAH for services in the unit may resume only after the unit has demonstrated to CMS that the unit meets the requirements of § 485.647.

One commenter stated that the rule is unclear as to whether, if a failure to meet proposed § 485.647 is both noted and corrected in the same cost reporting period, would payment resume as soon as the noncompliance is corrected. The commenter recommended that the section be revised to state that payment will be denied only from the date on which the deficiency was noted to the date on which it was corrected.

Response: We do not believe that the commenter's recommendation is supported by the statute. As noted above, section 405(g)(1) of Public Law 108–173, states that if a psychiatric or rehabilitation unit of a CAH does not meet the requirements of section 1820(c)(2)(E)(i) of the Act with respect to a cost reporting period, no payment may be made to the CAH for services furnished in that unit for that period. Because the law is so specific on this issue, we do not have the flexibility to resume payment for services of a unit during any part of the same period in which the unit fails to meet applicable requirements of section 1820(c)(2)(E)(i) of the Act, as implemented by the regulations in new § 485.649. On the contrary, the law would permit payment to the CAH for services for such a unit to resume only after the start of the first cost reporting period beginning after the unit has demonstrated to CMS that the unit meets the requirements of § 485.647. We have revised § 412.25(g) to clarify that. Payment to the CAH for services provided in such a unit may resume only after the start of the first cost reporting period beginning after the unit has demonstrated to CMS that the unit meets the requirements of § 485.647.

Although we considered carefully the comments received regarding distinct-part units of CAHs, we concluded that they did not raise considerations that would require changes to the proposed rule. Therefore, in this final rule, we are adopting as final the proposed amendments to § 413.70(a)(1) and the proposed addition of § 413.70(a)(4), § 413.70(e), and § 485.647 to implement the requirements under section 405(g)(1) of Public Law 108–173 for CAHs to establish and receive payment under Medicare for psychiatric and rehabilitation distinct part units. In the May 18 2004, proposed rule, we proposed to implement this provision under proposed § 485.647. However, the statute would permit payment to the CAH for services of such a unit to resume only after the start of the first cost reporting period beginning after the unit has demonstrated to CMS that the unit meets the requirements of proposed § 485.647. In this final rule, we are revising § 412.25(g) to clarify that payments to the CAH for services provided in such a unit may resume only after the start of the first cost reporting period beginning after the unit has demonstrated to CMS that the unit meets the requirements of § 485.647.

Comment: Several commenters questioned how distinct-part unit beds are to be classified in a CAH if the facility had distinct-part unit beds prior to converting to a CAH. The commenters inquired if the distinct-part unit beds will be considered new or converted beds.

Response: In order for Medicare to classify a provider as a CAH, the provider must meet specific regulatory requirements. Therefore, we believe a CAH evolved into a different provider classification from the type of provider it was prior to converting to a CAH. Under the statute in effect prior to Public Law 108–173, a CAH was not allowed to establish an inpatient rehabilitation DPU. Section 405(g)(1) of Public Law 108–173 modified the statutory requirements for CAHs under section 1820(c)(2) of the Act to allow a CAH to establish a rehabilitation DPU of up to 10 beds. A CAH that meets all inpatient rehabilitation DPU regulatory requirements, on or after the effective date of this final rule, will be allowed to establish an inpatient rehabilitation DPU whose size does not exceed 10 beds. According to § 412.30(b)(1)(i), a

new unit is a hospital unit that the hospital has not previously sought to exclude from the IPPS. In addition, before the hospital unit may be considered a new unit, § 412.30(b)(1)(ii) of our regulations requires that the hospital have ''obtained approval, under State licensure and Medicare certification, for an increase in its hospital bed capacity that is greater than 50 percent of the number of beds in the unit.'' Because a CAH is a different provider from the entity it was prior to converting to being a CAH, and was not previously allowed to establish an inpatient rehabilitation DPU, a CAH never sought exclusion for any inpatient rehabilitation unit. Therefore, if a CAH establishes an inpatient rehabilitation DPU, that DPU will be considered to be a new unit in accordance with § 412.30(b)(1)(i) of our regulations, as long as the CAH also meets the requirements specified in § 412.30(b)(1)(ii) of our regulations.

Comment: One commenter requested that their hospital be grandfathered into the CAH program and be allowed to maintain a 15-bed psychiatric distinct-part unit.

Response: We do not have the authority to grandfather a hospital into the CAH program. A facility can be certified as a CAH if the facility is designated as a CAH by the State survey agency or by CMS and found to meet the conditions of participation in 42 CFR Part 485, Subpart F. Regardless, the statute does not allow CAHs to exceed the 10-bed limit for distinct-part units.

We considered carefully the comments received regarding distinct-part units of CAHs. To implement the requirements under section 405(g)(1) of Public Law 108–173 for CAHs to establish and receive payment under Medicare for psychiatric and rehabilitation distinct part units, in this final rule, we are adopting the proposed amendments to § 413.70(a)(1) and the proposed addition of §§ 413.70(a)(4), 413.70(e), and 485.647 as final, with one modification. That is, we are revising § 412.25(g) to clarify that payments to the CAH for services provided in such a unit may resume only after the start of the first cost reporting period beginning after the unit has demonstrated to CMS that the unit meets the requirements of § 485.647.

8. Waiver Authority for Designation of a CAH as a Necessary Provider

Section 405(h) of Public Law 108–173 amended section 1820(c)(B)(i)(II) of the Act by adding language that terminates a State's authority to waive the location requirement for a CAH by designating the CAH as a necessary provider, effective January 1, 2006. Currently, a CAH is required to be located more than a 35-mile drive (or in the case of mountainous terrain or secondary roads, a 15-mile drive) from a hospital or another CAH, unless the CAH is certified by the State as a necessary provider of health care services to residents in the area. Under this provision, after January 1, 2006, States will no longer be able to designate a CAH based upon a determination that it is a necessary provider of health care.

In addition, section 405(h) of Public Law 108–173 amended section 1820(h) of the Act to include a grandfathering provision for CAHs that are certified as necessary providers prior to January 1, 2006. Under this provision, any CAH that is designated as a necessary provider in its State's rural health plan prior to January 1, 2006, will be permitted to maintain its necessary provider designation.

In the May 18, 2004 proposed rule (69 FR 28331), we proposed to revise our regulations at § 485.610(c) to incorporate the amendments made by section 405(h) of Public Law 108–173.

Comment: Commenters were concerned that some hospitals may receive the necessary provider designation by the State before January 1, 2006, but would not have had enough time to complete the State survey and certification process in order to be fully converted to a CAH by January 1, 2006. The commenters recommended that we grandfather a hospital that is certified as a necessary provider by January 1, 2006, as long as that hospital is continuing the process toward conversion to a CAH.

Response: Both the preamble and the regulations text concerning this issue in the proposed rule state that a CAH that is designated as a necessary provider in its State's rural health plan as of January 1, 2006, will maintain its necessary provider designation after January 1, 2006. However, in keeping with the clear intent of section 405(h) of Public Law 108–173, if a facility is not a CAH as of January 1, 2006, the ability to be designated as a necessary provider before becoming a CAH will no longer exist after January 1, 2006. Extending the time to allow for such a facility to convert to a CAH would violate this intent. Therefore, we are not accepting these commenters' recommendation.

Comment: One commenter stated several CAHs in Nebraska are considering replacing their aged facilities and wanted to know if a CAH could retain its necessary provider status if it relocates. The commenter inquired if the necessary provider status would remain with the provider number and not be determined by the physical location of the building.

Response: There are many factors involved with a relocation of a CAH that may or may not change a CAH's status as a necessary provider. It is not possible to make a statement in this final rule that would apply to all situations. The issue of retaining a necessary provider status after a CAH relocates is a local certification issue that the regional offices will evaluate on a case-by-case basis.

In this final rule, we are adopting as final, without modification, the provisions of § 485.610(c) that incorporates the amendments made by section 405(h) of Public Law 108–173.

9. Payment for Clinical Diagnostic Laboratory Tests

Medicare payment for clinical diagnostic laboratory tests provided to the outpatients of CAHs was established through the regulatory process and published in the **Federal Register** as part of the FY 2004 IPPS final rule (68 FR 45346, August 1, 2003). Payment to a CAH for clinical diagnostic laboratory tests for outpatients is made on a reasonable cost basis only if the individuals for whom the tests are performed are outpatients of the CAH and are physically present at the CAH at the time specimens are collected. Otherwise, payment for these tests is made on a fee schedule basis.

We published this final rule to clarify our policy in this area and ensure that all relevant issues were publicly noted. For reasons which are set forth in detail in the FY 2004 IPPS final rule, we do not agree that providing reasonable cost payment to individuals who are not present at the CAH when the specimen is collected is appropriate. We believe that extending reasonable cost payment in these instances is inconsistent with Medicare law and regulations and duplicates existing coverage. It also creates confusion for beneficiaries and others by blurring the distinction between CAHs and other types of providers (for example, SNFs and HHAs) and increases the costs of providing care to Medicare patients without enhancing either the quality or the availability of that care.

Following publication of the FY 2004 IPPS final rule, we received a number of letters and statements in Open Door Calls indicating that some commenters continue to believe that this policy will impose a hardship on Medicare beneficiaries in rural areas. Several of these commenters argued that it might cause frail elderly nursing home patients to have to be moved to a CAH to have blood drawn or other specimen

collection performed instead of sending a laboratory technician to the patient's bedside for the same purpose. We agree with the commenters that this would not be an appropriate result. However, we would note that there are also alternative ways in which specimen collection and travel are payable under Medicare (for example, the laboratory benefit under Part B or HHAs that have laboratory provider numbers). Therefore, we do not expect beneficiaries to face reduced access to services under this policy.

In response to continuing claims of potential access problems, we invited commenters to submit further, more specific comments that provide specific information on actual, rather than merely potential or anticipated access problems. In response, we received many communications asserting that these problems would occur, but no credible documentation that they actually are occurring. As a result of these responses, we did not propose any further change in policy on this issue in the May 18, 2004 proposed rule (69 FR 28331–28332). We indicated that we would like to renew our request for specific, verifiable documentation as to any actual access problems being generated by this policy, and would review carefully any such documentation we receive to determine whether current policy should be reconsidered.

Comment: Some commenters asserted that CMS policy in this area is shortsighted and not in the best interest of rural beneficiaries or hospitals, or that it would restrict access to laboratory services in rural areas, but provided no documentation of access problems or other evidence to support their assertions.

Response: While we read the commenters' letters with interest, we noted that they merely restated former comments, but did not provide any objective evidence in support of their comments that maintaining the current policy regarding payment for clinical diagnostic laboratory tests would compromise access to these tests in rural areas. Therefore, we made no changes in our policy in this area based on these comments.

Comment: One commenter stated that five CAHs in the commenter's State (Kansas) have either eliminated or seriously limited the processing of specimens drawn from off-site locations in response to the payment policy for clinical diagnostic laboratory tests.

Response: We appreciate this additional information and will take it into account as we consider whether any revision should be made to this policy.

10. Continued Participation by CAHs in Counties Reclassified as Urban Based on the 2000 Census

Under section 1820(c)(2)(B)(i) of the Act, a facility is eligible for designation as a CAH only if it is located in a county or equivalent unit of local government in a rural area (as defined in section 1886(d)(2)(D) of the Act), or is being treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act. The regulations implementing this location requirement are located at 42 CFR 485.610(b)(2). As previously noted, some facilities currently participating as CAHs are located in counties which are located in areas considered as ''rural areas'' in FY 2004 under the definition in section 1886(d)(2)(D) of the Act but will, as of October 1, 2004, be considered to be located in MSAs because of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003. We received a number of comments on this issue.

Comment: Several commenters recommended that CMS exercise executive discretion to allow continued CAH participation by facilities which are currently (that is, for FY 2004) participating as CAHs but are located in counties which will be considered part of MSAs effective October 1, 2004, as a result of data from the 2000 census and implementation of the new MSA definitions announced by OMB on June 6, 2003. The commenters stated that if such facilities' CAH participation were terminated, they would be likely to again seek State licensure and Medicare participation as hospitals in order to be able to continue operations. However, this change to hospital status would not be automatic but would require the facility either to be re-licensed as a hospital by the State and to successfully demonstrate compliance with the hospital conditions of participation (COPs) based either on a CMS survey conducted by the State survey agency under contract with CMS, or on hospital accreditation by the JCAHO or the American Osteopathic Association (AOA). Once the facility has resumed participation as defined under section 1886(d) of the Act, the facility could then be treated as a ''rural'' hospital under section 1886(d)(8)(E)(ii)(II) of the Act, which provides such treatment for any hospital located in an area designated by law or regulation of the State as a rural area. If the facility were to obtain such a designation and met other criteria for CAH conversion, it would then be qualified for designation by the State and certification by CMS as a CAH, notwithstanding its location in an MSA. The commenters believed such a sequence of changes in the status of a facility (that is, from being a CAH to being a hospital to again being a CAH) would be costly and time consuming for both the facility and CMS, and would not serve any useful purpose, because at the conclusion of the process the facility would resume participating as a CAH, as it did during FY 2004. Therefore, some of these commenters recommended that CMS continue to treat CAHs in such counties as being rural for an indefinite time period. Other commenters recommended that CAHs in such counties be considered rural until at least January 1, 2006, in order to allow them an opportunity to obtain rural designations under applicable State law or regulations from their State legislatures or regulatory agencies.

Another commenter did not recommend any particular course of action to be taken by CMS, but asked whether there were any plans to develop a grandfather provision to avoid a break in CAH participation by facilities affected by the new census results.

Response: We agree with the commenters' concerns and are revising § 485.610 by adding a new paragraph (b)(3) to provide special treatment for such facilities. Under the new paragraph, a CAH that is located in a county that, in FY 2004, was not part of a MSA as defined by the OMB, but as of FY 2005 was included as part of a MSA as a result of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003, would nevertheless be considered to meet the rural location requirement and, therefore, could continue participating without interruption as a CAH from October 1, 2004, through the earlier of the date on which the CAH obtains a rural designation under § 412.103, or December 31, 2005. Such a facility would be allowed to continue participating as a CAH and would not be required to convert back to being a hospital unless it was not able to obtain a rural designation under § 412.103. We are also amending § 412.103 to clarify that such a CAH is eligible for rural designation under that section.

Comment: One commenter suggested that changes in the status of an area from rural to urban as a result of the most recent census data and implementation of the new MSA definitions be applied only for purposes of determining the wage index values for providers paid under a system that

uses a wage index adjustment, and not for determining a rural location for purposes of eligibility of a facility to participate in Medicare as a CAH.

Response: We reviewed this suggestion but concluded that section 1820 of the Act, which specifically refers to rural areas as, defined in sections 1886(d)(2)(D) and 1886(d)(8)(E) of the Act, do not authorize us to implement the new census results and MSA designation rules in such a selective way. Therefore, in this final rule, we are not adopting this recommendation.

11. Proposed Technical Changes in Part 489

In several sections of Part 489, we have discovered a need to update cross-references to conform them to the redesignation of the Medicare transfer rules from § 489.24(d) to § 489.24(d). Specifically, as we proposed in the May 18, 2004 proposed rule (69 FR 28332), we are correcting the cross-reference to ''§ 489.24(d)'' in §§ 489.20(m) and 489.53(b)(2) to read ''§ 489.24(e)''.

12. Issues Beyond the Scope of the Proposed Rule

In the proposed rule published on May 18, 2004, we proposed changes affecting CAHs only if they were related to MSA definitions and the results of the 2000 census, or to the provisions of section 405 of Public Law 108–173. In addition, as previously noted, we requested documentation regarding the effects of the rule on payment for clinical diagnostic laboratory tests by a CAH, but did not propose any change in that rule.

In response to the proposed rule, many commenters chose to raise issues that are beyond the scope of our proposals. In this final rule, we are not summarizing or responding to those comments in this document. However, we will review the comments and consider whether to take other actions, such as revising or clarifying CMS program operating instructions or procedures, based on the information and recommendations in the comments.

VII. Changes to the Disclosure of Information Requirements for Quality Improvement Organizations (QIOs)

A. Background

Section 1152 of the Act defines a utilization and quality control peer review organization (now referred to as a quality improvement organization (QIO). Section 1153 provides for contracts with such organizations to review items and services furnished by physicians, other practitioners, and providers to Medicare patients to verify that the items and services are reasonable, medically necessary, and allowable under the Act; meet professionally recognized standards of health care; and are furnished in the appropriate setting. Section 1154 of the Act outlines the functions of a QIO, which include responsibility for: (1) Collecting and maintaining information necessary to carry out its responsibilities; (2) examining pertinent records maintained by the practitioner or provider verifying the medical necessity and quality of services provided by any practitioner or provider of health care services to Medicare patients; (3) ensuring that health care practitioners and providers maintain evidence of medical necessity and quality of health care services provided to Medicare patients; and (4) exchanging information with intermediaries, carriers, and other public or private review organizations as appropriate. Section 1160 of the Act provides that information acquired by QIOs in the exercise of their duties and functions must be held in confidence. Information cannot be disclosed except as allowed under section 1160 of the Act and the existing regulations governing the release of QIO peer review information in 42 CFR Part 480. Specifically, Part 480 sets forth the policies and procedures for disclosure of information collected, acquired, or generated by a QIO (or the review component of a QIO subcontractor) in the performance of its responsibilities under the Act and the Medicare regulations, as well as the acquisition and maintenance of information needed by a QIO to comply with its responsibilities under the Act.

QIOs assist institutions and practitioners seeking to improve the quality of care given to Medicare beneficiaries. CMS aims to ensure that adequate protections of information collected by QIOs are in place and, at the same time, to ensure that the quality improvement activities of these institutions and practitioners are not unnecessarily hindered by regulations. It has come to our attention that the existing regulations omit information disclosure procedures that would allow for the effective and efficient exchange of information that is an essential part of quality improvement activities. In addition, it has come to our attention that, although the QIO does not need the consent of the institution to release nonconfidential information, the existing 30-day advance notice requirement to an institution prior to releasing public information or any other nonconfidential information that identifies an institution, when an institution consents to or requests the release of information, impedes the ability of QIOs to conduct quality improvement work. If the institution requests or consents to the release of the information, the institution is already aware of the QIO's intention to disclose the nonconfidential information. Therefore, we see no reason to require the additional 30-day advance notice. Likewise, there is no reason to require a 30-day notice for practitioners who request the release of information for quality improvement activities or other permissible releases under the regulations.

B. Provisions of the May 18, 2004 Proposed Regulations

In the May 18, 2004 IPPS proposed rule (69 FR 28332), we proposed to make several changes in the regulations in Part 480 to expedite the exchange of information and minimize delays and expenditures currently required of QIOs, institutions, and practitioners as discussed below.

Existing § 480.105(a) requires that a QIO must notify an identified institution of its intent to disclose nonconfidential information about the institution and provide a copy of the information at least 30 calendar days before the disclosure. Section 480.105 also includes certain notice requirements a QIO must meet before disclosing confidential information that identifies practitioners and physicians. Section 480.106 presently includes several exceptions to these notice requirements. We proposed to revise § 480.106 to establish additional exceptions to the notice requirements in § 480.105(a) and (b)(2). We proposed to specify that the notice requirements in § 480.105(a) and (b)(2) would not apply if (1) the institution or practitioner has requested, in writing, that the QIO make the disclosure; (2) the institution or practitioner has provided written consent for the disclosure; or (3) the information is public information as defined in § 480.101 and specified in § 480.120.

Existing § 480.133(a)(2)(iii) specifies that a QIO may disclose to any person, agency, or organization confidential information on a particular practitioner or reviewer with the consent of that practitioner or reviewer, provided that the information does not identify other individuals. In the May 18, 2004 IPPS proposed rule (69 FR 28369), we proposed to revise § 480.133(a)(2)(iii) to allow for the release of information at the written request of the practitioner or reviewer, in addition to information releasable with the consent of the

1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the **Federal Register** to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the Life Safety Code does not apply to a CAH.

* * * * *

(5) Beginning March 13, 2006, a critical access hospital must be in compliance with Chapter 9.2.9, Emergency Lighting.

(6) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to critical access hospitals.

■ 6. Section 485.645 is amended by republishing the introductory text of paragraph (a) and revising paragraph (a)(2) to read as follows:

§ 485.645 Special requirements for CAH providers of long-term care services (''swing-beds'').

* * * * *

(a) *Eligibility.* A CAH must meet the following eligibility requirements:

* * * * *

(2) The facility provides not more than 25 inpatient beds. Any bed of a unit of the facility that is licensed as a distinct-part SNF at the time the facility applies to the State for designation as a CAH is not counted under paragraph (a) of this section.

* * * * *

■ 7. A new § 485.647 is added under subpart F to read as follows:

§ 485.647 Condition of participation: psychiatric and rehabilitation distinct part units.

(a) *Conditions.*

(1) If a CAH provides inpatient psychiatric services in a distinct part unit, the services furnished by the distinct part unit must comply with the hospital requirements specified in Subparts A, B, C, and D of Part 482 of this subchapter, the common requirements of § 412.25(a)(2) through (f) of Part 412 of this chapter for hospital units excluded from the prospective payment systems, and the additional requirements of § 412.27 of Part 412 of this chapter for excluded psychiatric units.

(2) If a CAH provides inpatient rehabilitation services in a distinct part unit, the services furnished by the distinct part unit must comply with the hospital requirements specified in Subparts A, B, C, and D of Part 482 of this subchapter, the common requirements of § 412.25(a)(2) through (f) of Part 412 of this chapter for hospital units excluded from the prospective payments systems, and the additional requirements of §§ 412.29 and § 412.30 of Part 412 of this chapter related specifically to rehabilitation units.

(b) *Eligibility requirements.*

(1) To be eligible to receive Medicare payments for psychiatric or rehabilitation services as a distinct part unit, the facility provides no more than 10 beds in the distinct part unit.

(2) The beds in the distinct part are excluded from the 25 inpatient-bed count limit specified in § 485.620(a).

(3) The average annual 96-hour length of stay requirement specified under § 485.620(b) does not apply to the 10 beds in the distinct part units specified in paragraph (b)(1) of this section, and admissions and days of inpatient care in the distinct part units are not taken into account in determining the CAH's compliance with the limits on the number of beds and length of stay in § 485.620.

■ K. Part 489 is amended as follows:

PART 489—PROVIDER AGREEMENT AND SUPPLIER APPROVAL

■ 1. The authority citation for part 489 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 489.20 is amended as follows:

■ A. In paragraph (m), the cross-reference ''§ 489.24(d)'' is removed and the cross-reference ''§ 489.24(e)'' is added in its place.

■ B. A new paragraph (t) is added.

§ 489.20 Basic commitments.

* * * * *

(t) Hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970 (or a State occupational safety and health plan that is approved under section 18(b) of the Occupational Safety and Health Act) must comply with the bloodborne pathogens (BBP) standards under 29 CFR 1910.1030. A hospital that fails to comply with the BBP standards may be subject to a civil money penalty in accordance with section 17 of the Occupational Safety and Health Act of 1970, including any adjustments of the civil money penalty amounts under the Federal Civil Penalties Inflation Adjustment Act, for a violation of the BBP standards. A civil money penalty will be imposed and collected in the same manner as civil money penalties under section 1128A(a) of the Social Security Act.

§ 489.53 [Amended]

■ 3. In § 489.53(b)(2), the cross-reference ''489.24(d)'' is removed and the cross-reference ''489.24(e)'' is added in its place.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 2, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Dated: August 2, 2004.

Tommy G. Thompson,

Secretary.

[**Editorial Note:** The following Addendum and appendixes will not appear in the Code of Federal Regulations.]

Addendum—Schedule of Standardized Amount Effective with Discharges Occurring On or After October 1, 2004 and Update Factors and Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning On or After October 1, 2004

I. Summary and Background

In this Addendum, we are setting forth the amounts and factors for determining prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs. We are also setting forth rate-of-increase percentages for updating the target amounts for hospitals and hospital units excluded from the IPPS.

For discharges occurring on or after October 1, 2004, except for SCHs, MDHs, and hospitals located in Puerto Rico, each hospital's payment per discharge under the IPPS will be based on 100 percent of the Federal national rate, which will be based on the national adjusted standardized amount. This amount reflects the national average hospital costs per case from a base year, updated for inflation.

SCHs are paid based on whichever of the following rates yields the greatest

27.3 Survey & Certification Memoranda

Implementation of CAH DPUs for Psychiatric and Rehabilitation Services

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-04-48

DATE: **September 29, 2004**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Implementation of Critical Access Hospital (CAH) Distinct Part Units (DPUs) for Psychiatric and Rehabilitation Services

Letter Summary

- A PPS Hospital with a PPS-excluded Psychiatric Unit or Rehabilitation Unit that meets criteria as an Inpatient Rehabilitation Facility (IRF), may convert to CAH provider status with the same DPU(s) at any date on or after October 1, 2004. Each such DPU may have up to 10 beds.
- A current CAH wishing to add a DPU(s) may add the DPU on the beginning of a CAH cost reporting period on or after October 1, 2004.
- New provider numbers for the CAH DPUs billing will be effective with CAH DPU approval effective date on or after October 1, 2004.
- CAH DPU must meet certain Conditions of Participation and Other Requirements, and compliance is subject to onsite verification.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), enacted on December 8, 2003, contained a number of modifications to the CAH statutory requirements including a new provision allowing the addition of CAH distinct part units (DPUs) for psychiatric and rehabilitation services. (Section 1820(c)(2)(E) of the Social Security Act) The purpose of this memorandum is to summarize how CMS will implement the establishment of DPUs in CAHs.

Common Requirements for the Establishment of DPUs in CAHs

Compliance with the Conditions of Participation (CoPs): All DPUs that are established in any CAH are new units for the CAH provider type and must undergo a survey by CMS, or its designee, in order to demonstrate compliance with the CAH DPU Conditions of Participation at §485.647. (42 CFR §489.10(a))

- **In the case of a currently participating PPS hospital with a compliant PPS-excluded psychiatric unit and/or rehabilitation unit, converting to CAH status with the same distinct part unit(s):**

    - The application for change in provider status can occur at any time of the year on or after October 1, 2004.

    - The entire facility, including any DPUs, must be surveyed for compliance with all of the CAH CoPs. All hospitals converting to a CAH and all new DPUs are subject to an initial survey and a one-year follow-up survey for compliance.

    - The initial survey by the State agency can be scheduled and completed at any time during the application process.

    - A PPS Hospital with an attached PPS-exempt Psychiatric Unit and/or a Rehabilitation Unit that meets criteria as an Inpatient Rehabilitation Facility (IRF), may convert to CAH provider status with the same DPU(s) at any date on or after October 1, 2004.

    - A final cost report must be filed after changing provider type in accordance with directions from the Fiscal Intermediary.

    - Payment as a CAH provider type will not commence until on or after the date that all requirements have been met and an effective date for certification has been granted.

    - Medicare will not pay for services furnished under the CAH provider number to Medicare participants prior to the effective date of certification.

    - The CAH is not required to admit Medicare patients prior to the issuance of an effective date of Medicare participation.

- **In the case of a currently existing CAH that wishes to establish a DPU:**

    - The DPU(s) must be surveyed for compliance with the CAH DPU CoP at §485.647. All new CAH DPUs are subject to an initial survey and a one-year follow-up survey for compliance.

    - A current CAH wishing to add a DPU(s) may begin operating the DPU at the beginning of the CAH cost reporting period on or after October 1, 2004.

    - The State agency will conduct an initial survey of the DPU(s) as soon as is practicable.

    - Medicare payment to the CAH DPU(s) may only commence on the first day of a CAH's cost reporting period if all requirements are met by or on that date.

    - Medicare will not pay for services furnished to Medicare beneficiaries prior to the effective date of certification.

    - The CAH is not required to admit Medicare patients to any DPU prior to the issuance of an effective date of Medicare participation.

- The CAH is limited on changing cost report periods by regulation. (42 CFR §413.24(f)(3)

New Conditions of Participation for DPUs have been added at 42 CFR §485.647 to implement the addition of DPUs to CAHs. (Final Rule for Changes to the Hospital PPS (IPPS-FR) published in the Federal Register/ Vol. 69, No. 154/ Wednesday, August 11, 2004/ Rules and Regulations, page 49272)

There are two CoPs for CAH DPUs at §485.647. One CoP applies to a Psychiatric DPU and one applies to a Rehabilitation DPU. Surveyors will select the appropriate CoP for the type of unit being surveyed.

§485.647 Condition of Participation: Psychiatric Distinct Part Unit

- Compliance with Part 482, Subparts A-D Hospital Conditions of Participation
- Compliance with §412.25 (a)(2) through (g) Excluded hospital units: common requirements
- Compliance with §412.27 Excluded psychiatric units: additional requirements
- Eligibility requirements

§485.647 Condition of Participation: Rehabilitation Distinct Part Unit

- Compliance with Part 482, Subparts A-D Hospital Conditions of Participation
- Compliance with §412.25 (a)(2) through (g) Excluded hospital units: common requirements
- Compliance with §412.29 Excluded rehabilitation units: additional requirements
- Compliance with §412.30 Exclusion of new rehabilitation units and expansion of units already excluded
- Eligibility requirements

Determining Compliance: The survey process is the means to assess compliance with Federal health, safety and quality standards. Surveyors will directly observe the actual provision of care and services to patients, and the effects of that care, to assess whether the care provided meets the needs of individual patients. (42 CFR §488.26(c))

Each CMS Regional Office (RO) will assign the determination of compliance with the common requirements to the appropriate fiscal intermediary or State agency.

The surveyor will apply the appropriate CAH and/or CAH DPU CoPs according to the established CAH Survey Protocol as allowed at 42 CFR §488.2(d). This protocol and the CAH CoPs can be found in the Appendix W to the State Operations Manual on the web at www.cms.hhs.gov/manuals/107_som/som107_appendixtoc.asp.

The State survey agency will conduct a survey as soon as is practicable. If the survey determines the requirements were not met at the CoP level, the CAH will be denied payment for the applicable DPU for the full cost reporting period. (42 CFR §412.25(g)).

If the survey determines the requirements were not met at the standard level, the facility may participate in Medicare by submitting an acceptable Plan of Correction for achieving compliance within a reasonable period of time. If an acceptable Plan of Correction is received and approved

within 60 days, the CAH and its DPU(s) will be considered in compliance and payment of the DPU services will commence as of the effective date that is established by the CMS regional office in accordance with guidance in the State Operations Manual. If an acceptable Plan of Correction is not received and approved within 60 days, the CAH will be denied payment for the applicable DPU(s) of the CAH for the full cost reporting period (Ref: 42 CFR §412.25(g)).

Note on Accreditation Status

A CAH may choose to be accredited by either Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) or the American Osteopathic Association (AOA) under either organization's CMS approved critical access hospital accreditation program and be deemed to meet CAH conditions of participation. This accreditation does not confer deemed status for the CAH Condition of Participation at 42 CFR §485.647 for distinct part units. A CAH may elect to become accredited under the JCAHO or AOA hospital accreditation program for the hospital services in its distinct part units, and may be deemed to meet the hospital Conditions of Participation for those units at 42 CFR §482.

In summary, a CAH that will provide services in a distinct part unit, psychiatric or rehabilitation, must be surveyed for compliance with the CMS hospital conditions of participation at 42 CFR §482. To demonstrate compliance with the hospital Conditions of Participation, the CAH may elect JCAHO or AOA hospital accreditation.

Interim Survey Procedures

Until a CAH ASPEN update (that includes the CAH DPU CoPs) and corresponding Interpretive Guidelines are developed, surveyors are to use the following methods to conduct surveys of CAH Psychiatric and Rehabilitation DPU.

- Use Appendix A (Hospital Survey Protocol and Interpretive Guidelines) to determine compliance with the Hospital CoPs at §482. Use the current version of ASPEN for hospitals to record survey findings regarding the DPU's compliance with the hospital CoP. A separate Form CMS-2567 will be produced.

- Use Form CMS-437 "Psychiatric Unit Criteria Worksheet" to conduct the survey of the CAH Psychiatric DPU Common Requirements (§412.25) and the CAH Excluded Psychiatric Unit Requirements (§412.27). Use the Psychiatric Hospital Interpretive Guidelines in Appendix AA to determine compliance with the Excluded Psychiatric Unit Requirements. Use the current version of CAH ASPEN to record survey findings. Surveyors must select a 9999 ASPEN Code and write in the regulation text.

- Use Form CMS-437A "Rehabilitation Unit Criteria Worksheet" to conduct the survey of the CAH Rehabilitation DPU Common Requirements (§412.25), the CAH Excluded Rehabilitation Unit Requirements (§412.29), and the DPU New/Expansion Requirements (§412.30). Use the current version of CAH ASPEN to record survey findings. Surveyors must select a 9999 ASPEN Code and write in the regulation text.

- For the Eligibility Requirements CoP, enter survey findings in the current version of CAH ASPEN. Select a 9999 ASPEN Code and write in the regulation text.

- The completed Form CMS-437 and/or Form CMS-437A is to be forwarded to the CAH Survey and Certification staff at the applicable CMS RO.

- Forms can be obtained from the web at www.cms.hhs.gov/forms.

Effective Date: An effective date for participation in the Medicare program will be established by the CMS regional office following compliance with all Medicare requirements. The effective date for a DPU for participation will be the date the provider meets all Federal requirements for that DPU but can be no sooner than either the last day of the on-site survey if there are no deficiencies, or the date of receipt of an acceptable Plan of Correction from the facility for any standard level deficiencies. (42 CFR §489.13)

In the case of a current CAH who is adding a DPU, the effective date must begin on the first day of the cost-reporting year of the CAH. If the effective date occurs later than the first day of the cost reporting year, the CAH will not be able to receive Medicare payment for the DPU until the beginning of the following cost reporting year, assuming all Federal requirements are met at that time.

Downsizing a current DPU to 10 beds: A PPS hospital that wishes to convert to CAH status makes the decision when it wishes to reduce the size of its PPS-excluded distinct part rehabilitation or psychiatric unit, in order to qualify as a CAH. The qualifying change to the maximum of 10 beds per unit can occur at any time prior to the initial CAH certification survey but would have to be in place on the date of the initial CAH survey. Downsizing is a Federal requirement and is managed as part of the application process for conversion of a hospital to a CAH provider.

Eligibility for DPUs: (42 CFR §485.647)

- A CAH may have one psychiatric DPU and/or one rehabilitation DPU of 10 beds each
- The DPU beds are NOT part of the maximum bed count of the CAH
- The CAH 96-hour average annual length of stay for acute care patients does NOT apply to the DPUs
- The CAH must only admit patients with a qualifying psychiatric diagnosis (42 CFR §412.27(a)) or rehabilitation diagnosis (42 CFR §412.29(b)) who are likely to benefit by being placed in the specialty units.

Provider Agreement: In most instances, there is no requirement to issue a new Medicare provider agreement because the conversion from a PPS hospital to a CAH provider type is considered to be a change in provider status but the provider is not a new Medicare provider. Exceptions are to be managed on a case-by-case basis according to established certification guidelines in the State Operations Manual.

Provider Billing Numbers: For each area shown below, a CAH will be issued a distinct Medicare provider number to be used for billing purposes. In all instances the number will consist of 6 digits, the first two digits of which identify the State. The CAH provider numbers are in the 1300 series. The last four digits of the CAH DPU provider number will begin with "M" for a psychiatric unit or "R" for a rehabilitation unit, followed by the last three digits of the parent CAH provider number.

CAH billing number	XX**13XX** (1300-1399)
Psychiatric DPU billing number	XX**M**XXX
Rehabilitation DPU billing number	XX**R**XXX

CAH Psychiatric DPU Payment: Psychiatric DPUs will be paid at cost with a TEFRA Cap until the Psychiatric PPS regulation is implemented.

CAH Rehabilitation DPU Payment: Inpatient Rehabilitation Facilities (IRFs) will be paid under the IRF PPS. The IRF PPS payment is contingent on the requirement that IRFs complete a patient assessment upon admission and discharge for Medicare patients. The patient assessment instrument (PAI) form OMB-0938-0842 and instructions can be found on the web at www.cms.hhs.gov/providers/irfpps/irfpai.asp.

All rehabilitation beds are considered "new" beds for the CAH provider, regardless of whether a current CAH adds a rehabilitation unit, or a PPS hospital with an existing rehabilitation unit (meeting IRF requirements) converts to CAH status and maintains its rehabilitation unit as part of the CAH. In either instance, the IRF unit beds will be considered as “new” rehabilitation beds. The facility is permitted to attest that the “new” unit meets and will continue to meet, the requirement at 42 CFR §412.30(b)(2) by using the attached attestation statement or submitting an attestation statement on their letterhead.

The attestation statement does not negate the requirement for an on-site survey to validate whether the facility is in compliance with the CAH CoP for a rehabilitation DPU.

State Licensure: All CAHs with a DPU must amend the State license for the facility, as appropriate, according to the licensure laws of the State. Note that this process must be complete prior to any effective date for participation as a CAH DPU.

If you have any questions that cannot be resolved by the appropriate State Agency, CMS regional office, or Fiscal Intermediary, please contact Marjorie Eddinger at (410) 786-0375 or via E-mail at MEddinger@cms.hhs.gov.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)
Attachment

Critical Access Hospital
Attestation Statement for Distinct Part Unit
for Rehabilitation Services

This attestation statement must be signed and dated by the Administrator/ Chief Executive Officer of the critical access hospital (CAH).

False, fictitious or fraudulent statement or representations can result in a $10,000 fine, imprisonment for 5 years, or both. (18 U.S.C. Section 1001)

Based upon my personal knowledge and belief, I attest that the

_____

(Name of CAH)

currently meets and will continue to meet the requirements in 42 CFR §412.30(b)(2) for the cost report period beginning _____. The CAH intends for the rehabilitation distinct part unit to serve the inpatient population in the requirements.

I understand that the Centers for Medicare and Medicaid Services (CMS), or its representative, will conduct an on-site survey during the cost report period to validate whether the facility is in compliance with the CAH Condition of Participation for a rehabilitation distinct part unit.

If the on-site survey determines that the facility is not in compliance at the Condition level, no payment will be made for the full cost-reporting year as required by Section 1820(c)(2)(E)(iv) of the Social Security Act, 42 U.S.C. 1395i-4(c)(2)(E)(iv), and implementing regulations at 42 C.F.R. 412.25(g).

Signature _____

Title _____ **Date** _____

27.4 Social Security Act, Section 1820(c)(2)(E): Critical Access Hospital Distinct Part Units

Social Security Act, Section 1820(c)(2)(E): Critical Access Hospital Rehabilitation Distinct Part Units

(E)[83] AUTHORITY TO ESTABLISH PSYCHIATRIC AND REHABILITATION DISTINCT PART UNITS.—

(i) IN GENERAL.—Subject to the succeeding provisions of this subparagraph, a critical access hospital may establish—

(I) a psychiatric unit of the hospital that is a distinct part of the hospital; and

(II) a rehabilitation unit of the hospital that is a distinct part of the hospital, if the distinct part meets the requirements (including conditions of participation) that would otherwise apply to the distinct part if the distinct part were established by a subsection (d) hospital in accordance with the matter following clause (v) of section 1886(d)(1)(B), including any regulations adopted by the Secretary under such section.

(ii) LIMITATION ON NUMBER OF BEDS.—The total number of beds that may be established under clause (i) for a distinct part unit may not exceed 10.

(iii) EXCLUSION OF BEDS FROM BED COUNT.—In determining the number of beds of a critical access hospital for purposes of applying the bed limitations referred to in subparagraph (B)(iii) and subsection (f), the Secretary shall not take into account any bed established under clause (i).

(iv) EFFECT OF FAILURE TO MEET REQUIREMENTS.—If a psychiatric or rehabilitation unit established under clause (i) does not meet the requirements described in such clause with respect to a cost reporting period, no payment may be made under this title to the hospital for services furnished in such unit during such period. Payment to the hospital for services furnished in the unit may resume only after the hospital has demonstrated to the Secretary that the unit meets such requirements.

[83] P.L. 108-173, §405(g)(1), added subparagraph (E), applicable to cost reporting periods beginning on or after October 1, 2004.

27.5 Medicare Modernization Act, Section 405(g)(1)

Medicare Modernization Act, Section 405(g)(1)

(g) Authority To Establish Psychiatric and Rehabilitation Distinct Part Units.—

(1) In general.—Section 1820(c)(2) (42 U.S.C. 1395i-4(c)(2)) is amended by adding at the end the following:

"(E) Authority to establish psychiatric and rehabilitation distinct part units.—

"(i) In general.—Subject to the succeeding provisions of this subparagraph, a critical access hospital may establish—

"(I) a psychiatric unit of the hospital that is a distinct part of the hospital; and

"(II) a rehabilitation unit of the hospital that is a distinct part of the hospital, if the distinct part meets the requirements (including conditions of participation) that would otherwise apply to the distinct part if the distinct part were established by a subsection (d) hospital in accordance with the matter following clause (v) of section 1886(d)(1)(B), including any regulations adopted by the Secretary under such section.

"(ii) Limitation on number of beds.—The total number of beds that may be established under clause (i) for a distinct part unit may not exceed 10.

"(iii) Exclusion of beds from bed count.—In determining the number of beds of a critical access hospital for purposes of applying the bed limitations referred to in subparagraph (B)(iii) and subsection (f), the Secretary shall not take into account any bed established under clause (i).

"(iv) Effect of failure to meet requirements.—If a psychiatric or rehabilitation unit established under clause (i) does not meet the requirements described in such clause with respect to a cost reporting period, no payment may be made under this title to the hospital for services furnished in such unit during such period. Payment to the hospital for services furnished in the unit may resume only after the hospital has demonstrated to the Secretary that the unit meets such requirements.".

27.6 *Inpatient Rehabilitation Facility – Patient Assessment Instrument*

INPATIENT REHABILITATION FACILITY - PATIENT ASSESSMENT INSTRUMENT

Identification Information*

1. Facility Information
   A. Facility Name
   _____
   _____
   _____
   B. Facility Medicare Provider Number _____

2. Patient Medicare Number _____

3. Patient Medicaid Number _____

4. Patient First Name _____

5A. Patient Last Name _____

5B. Patient Identification Number _____

6. Birth Date _____/_____/_____ (MM / DD / YYYY)

7. Social Security Number _____

8. Gender (*1 - Male; 2 - Female*) _____

9. Race/Ethnicity *(Check all that apply)*
   - *American Indian or Alaska Native* A. _____
   - *Asian* B. _____
   - *Black or African American* C. _____
   - *Hispanic or Latino* D. _____
   - *Native Hawaiian or Other Pacific Islander* E. _____
   - *White* F. _____

10. Marital Status _____
    (*1 - Never Married; 2 - Married; 3 - Widowed; 4 - Separated; 5 - Divorced*)

11. Zip Code of Patient's Pre-Hospital Residence _____

Admission Information*

12. Admission Date _____/_____/_____ (MM / DD / YYYY)

13. Assessment Reference Date _____/_____/_____ (MM / DD / YYYY)

14. Admission Class _____
    (*1 - Initial Rehab; 2 - Evaluation; 3 - Readmission; 4 - Unplanned Discharge; 5 - Continuing Rehabilitation)*

15. Admit From _____
    (*01 - Home; 02 - Board & Care; 03 - Transitional Living; 04 - Intermediate Care; 05 - Skilled Nursing Facility; 06 - Acute Unit of Own Facility; 07 - Acute Unit of Another Facility; 08 - Chronic Hospital; 09 - Rehabilitation Facility; 10 - Other; 12 - Alternate Level of Care Unit; 13 – Subacute Setting; 14 - Assisted Living Residence*)

16. Pre-Hospital Living Setting _____
    (*Use codes from item 15 above*)

17. Pre-Hospital Living With _____
    (*Code only if item 16 is 01 - Home; Code using 1 - Alone; 2 - Family/Relatives; 3 - Friends; 4 - Attendant; 5 - Other*)

18. Pre-Hospital Vocational Category _____
    (*1 - Employed; 2 - Sheltered; 3 - Student; 4 - Homemaker; 5 - Not Working; 6 - Retired for Age; 7 - Retired for Disability*)

19. Pre-Hospital Vocational Effort _____
    (*Code only if item 18 is coded 1 - 4; Code using 1 - Full-time; 2 - Part-time; 3 - Adjusted Workload*)

Payer Information*

20. Payment Source
    A. Primary Source _____
    B. Secondary Source _____

    (*01 - Blue Cross; 02 - Medicare non-MCO; 03 - Medicaid non-MCO; 04 - Commercial Insurance; 05 - MCO HMO; 06 - Workers' Compensation; 07 - Crippled Children's Services; 08 – Developmental Disabilities Services; 09 - State Vocational Rehabilitation; 10 - Private Pay; 11 - Employee Courtesy; 12 - Unreimbursed; 13 - CHAMPUS; 14 - Other; 15 - None; 16 – No-Fault Auto Insurance; 51 – Medicare MCO; 52 - Medicaid MCO)*

Medical Information*

21. Impairment Group _____ Admission _____ Discharge
    Condition requiring admission to rehabilitation; code according to Appendix A, attached.

22. Etiologic Diagnosis _____
    (*Use an ICD-9-CM code to indicate the etiologic problem that led to the condition for which the patient is receiving rehabilitation*)

23. Date of Onset of Impairment _____/_____/_____ (MM / DD / YYYY)

24. Comorbid Conditions; Use ICD-9-CM codes to enter up to ten medical conditions

    A. _____ B. _____
    C. _____ D. _____
    E. _____ F. _____
    G. _____ H. _____
    I. _____ J. _____

Medical Needs

25. Is patient comatose at admission? _____ (0 - No, 1 - Yes)

26. Is patient delirious at admission? _____ (0 - No, 1 - Yes)

27. Swallowing Status _____ Admission _____ Discharge

    3 - Regular Food: solids and liquids swallowed safely without supervision or modified food consistency
    2 - Modified Food Consistency/ Supervision: subject requires modified food consistency and/or needs supervision for safety
    1 - Tube /Parenteral Feeding: tube / parenteral feeding used wholly or partially as a means of sustenance

28. Clinical signs of dehydration _____ Admission _____ Discharge

    (Code 0 – No; 1 – Yes) e.g., e*vidence of oliguria, dry skin, orthostatic hypotension, somnolence, agitation*

*The FIM data set, measurement scale and impairment codes incorporated or referenced herein are the property of U B Foundation Activities, Inc. ©1993, 2001 U B Foundation Activities, Inc. The FIM mark is owned by UBFA, Inc.

OMB-0938-0842 (expires: 07-31-2005)

INPATIENT REHABILITATION FACILITY - PATIENT ASSESSMENT INSTRUMENT

Function Modifiers*

Complete the following specific functional items prior to scoring the FIM™ Instrument:

	ADMISSION	DISCHARGE
29. Bladder Level of Assistance (Score using FIM Levels 1 - 7)		
30. Bladder Frequency of Accidents (Score as below)		

7 - No accidents
6 - No accidents; uses device such as a catheter
5 - One accident in the past 7 days
4 - Two accidents in the past 7 days
3 - Three accidents in the past 7 days
2 - Four accidents in the past 7 days
1 - Five or more accidents in the past 7 days

Enter in Item 39G (Bladder) the lower (more dependent) score from Items 29 and 30 above.

	ADMISSION	DISCHARGE
31. Bowel Level of Assistance (Score using FIM Levels 1 - 7)		
32. Bowel Frequency of Accidents (Score as below)		

7 - No accidents
6 - No accidents; uses device such as an ostomy
5 - One accident in the past 7 days
4 - Two accidents in the past 7 days
3 - Three accidents in the past 7 days
2 - Four accidents in the past 7 days
1 - Five or more accidents in the past 7 days

Enter in Item 39H (Bowel) the lower (more dependent) score of Items 31 and 32 above.

	ADMISSION	DISCHARGE
33. Tub Transfer		
34. Shower Transfer		

(Score Items 33 and 34 using FIM Levels 1 - 7; use 0 if activity does not occur) *See training manual for scoring of Item 39K (Tub/Shower Transfer)*

	ADMISSION	DISCHARGE
35. Distance Walked		
36. Distance Traveled in Wheelchair		

(Code items 35 and 36 using: 3 - 150 feet; 2 - 50 to 149 feet; 1 - Less than 50 feet; 0 – activity does not occur)

	ADMISSION	DISCHARGE
37. Walk		
38. Wheelchair		

(*Score Items 37 and 38 using FIM Levels 1 - 7; 0 if activity does not occur) See training manual for scoring of Item 39L (Walk/ Wheelchair)*

*The FIM data set, measurement scale and impairment codes incorporated or referenced herein are the property of U B Foundation Activities, Inc. ©1993, 2001 U B Foundation Activities, Inc. The FIM mark is owned by UBFA, Inc.

39. FIM™ Instrument*

	ADMISSION	DISCHARGE	GOAL
SELF-CARE			
A. Eating			
B. Grooming			
C. Bathing			
D. Dressing - Upper			
E. Dressing - Lower			
F. Toileting			
SPHINCTER CONTROL			
G. Bladder			
H. Bowel			
TRANSFERS			
I. Bed, Chair, Whlchair			
J. Toilet			
K. Tub, Shower			
LOCOMOTION (W - Walk; C - wheelChair; B - Both)			
L. Walk/Wheelchair			
M. Stairs			
COMMUNICATION (A - Auditory; V - Visual; B - Both)			
N. Comprehension			
O. Expression (V - Vocal; N - Nonvocal; B - Both)			
SOCIAL COGNITION			
P. Social Interaction			
Q. Problem Solving			
R. Memory			

FIM LEVELS

No Helper

7 Complete Independence (Timely, Safely)

6 Modified Independence (Device)

Helper - Modified Dependence

5 Supervision (Subject = 100%)

4 Minimal Assistance (Subject = 75% or more)

3 Moderate Assistance (Subject = 50% or more)

Helper - Complete Dependence

2 Maximal Assistance (Subject = 25% or more)

1 Total Assistance (Subject less than 25%)

0 Activity does not occur; Use this code only at admission

OMB-0938-0842 (expires: 07-31-2005)

Discharge Information*

40. Discharge Date _____/_____/_____
MM / DD / YYYY

41. Patient discharged against medical advice? _____
(*0 - No, 1 - Yes*)

42. Program Interruption(s) _____
(*0 - No; 1 - Yes*)

43. Program Interruption Dates
(Code only if Item 42 is 1 - Yes)

A. 1st Interruption Date _____ MM / DD / YYYY

B. 1st Return Date _____ MM / DD / YYYY

C. 2nd Interruption Date _____ MM / DD / YYYY

D. 2nd Return Date _____ MM / DD / YYYY

E. 3rd Interruption Date _____ MM / DD / YYYY

F. 3rd Return Date _____ MM / DD / YYYY

44A. Discharge to Living Setting _____
(*01 - Home; 02 - Board and Care; 03 - Transitional Living; 04 - Intermediate Care; 05 - Skilled Nursing Facility; 06 - Acute Unit of Own Facility; 07 - Acute Unit of Another Facility; 08 - Chronic Hospital; 09 - Rehabilitation Facility; 10 - Other; 11 - Died; 12 - Alternate Level of Care Unit; 13 - Subacute Setting; 14 - Assisted Living Residence)*

44B. Was patient discharged with Home Health Services? _____
(*0 - No; 1 - Yes*)
(Code only if Item 44A is 01 - Home, 02 - Board and Care, 03 - Transitional Living, or 14 - Assisted Living Residence)

45. Discharge to Living With _____
(*Code only if Item 44A is 01 - Home; Code using 1 - Alone; 2 - Family / Relatives; 3 - Friends; 4 - Attendant; 5 - Other*

46. Diagnosis for Interruption or Death _____
(Code using ICD-9-CM code)

47. Complications during rehabilitation stay
(*Use ICD-9-CM codes to specify up to six conditions that began with this rehabilitation stay*)

A. _____ B. _____

C. _____ D. _____

E. _____ F. _____

Quality Indicators

RESPIRATORY STATUS
(*Score items 48 to 50 as 0 - No; 1 - Yes*)

	Admission	Discharge
48. Shortness of breath with exertion	_____	_____
49. Shortness of breath at rest	_____	_____
50. Weak cough and difficulty clearing airway secretions	_____	_____

Quality Indicators

PAIN
51. Rate the highest level of pain reported by the patient within the assessment period:
Admission: _____ Discharge: _____

(*Score using the scale below; report whole numbers only)*

0 1 2 3 4 5 6 7 8 9 10
No Pain — Moderate Pain — Worst Possible Pain

Pressure Ulcers

52A. Highest current pressure ulcer stage
Admission _____ Discharge _____

(*0 - No pressure ulcer; 1 - Any area of persistent skin redness (Stage 1); 2 - Partial loss of skin layers (Stage 2); 3 - Deep craters in the skin (Stage 3); 4 - Breaks in skin exposing muscle or bone (Stage 4); 5 - Not stageable (necrotic eschar predominant; no prior staging available*)

52B. Number of current pressure ulcers
Admission _____ Discharge _____

PUSH Tool v. 3.0 ã

SELECT THE CURRENT LARGEST PRESSURE ULCER TO CODE THE FOLLOWING. Calculate three components (C through E) and code total score in F.

52C. Length multiplied by width (open wound surface area)
Admission _____ Discharge _____

(*Score as 0 - 0 cm^2; 1 - < 0.3 cm^2; 2 - 0.3 to 0.6 cm^2; 3 - 0.7 to 1.0 cm^2; 4 - 1.1 to 2.0 cm^2; 5 - 2.1 to 3.0 cm^2; 6 - 3.1 to 4.0 cm^2; 7 - 4.1 to 8.0 cm^2; 8 - 8.1 to 12.0 cm^2; 9 - 12.1 to 24.0 cm^2; 10 - > 24 cm^2)*

52D. Exudate amount
Admission _____ Discharge _____
0 - None; 1 - Light; 2 - Moderate; 3 - Heavy

52E. Tissue type
Admission _____ Discharge _____
0 - Closed/resurfaced: The wound is completely covered with epithelium (new skin); 1 - Epithelial tissue: For superficial ulcers, new pink or shiny tissue (skin) that grows in from the edges or as islands on the ulcer surface. 2 - Granulation tissue: Pink or beefy red tissue with a shiny, moist, granular appearance. 3- Slough: Yellow or white tissue that adheres to the ulcer bed in strings or thick clumps or is mucinous. 4 - Necrotic tissue (eschar): Black, brown, or tan tissue that adheres firmly to the wound bed or ulcer edges.

52F. TOTAL PUSH SCORE (Sum of above three items – C, D and E)
Admission _____ Discharge _____

SAFETY	Admission	Discharge
53. Balance problem (*0 - No; 1 - Yes*) *e.g., dizziness, vertigo, or light-headedness*	_____	_____
		Discharge
54. Total number of falls during the rehabilitation stay		_____

* The FIM data set, measurement scale and impairment codes incorporated or referenced herein are the property of U B Foundation Activities, Inc. ©1993, 2001 U B Foundation Activities, Inc. The FIM mark is owned by UBFA, Inc.

27.7 Other Print and Online References

CMS forms:
http://www.cms.hhs.gov/forms/

Clarification of Hyperbaric Oxygen Therapy for the Treatment of Diabetic Wounds of the Lower Extremities:
http://new.cms.hhs.gov/QuarterlyProviderUpdates/JUL2003/list.asp#TopOfPage
Note: This is in the QPU July 2003 list. This list has 634 items. To go to the article, enter "Coverage of Hyperbaric Oxygen" in the "Show only articles containing keywords" box.

Code of Federal Regulations search page:
http://www.gpoaccess.gov/cfr/index.html

Federal Register search page:
http://www.gpoaccess.gov/fr/index.html

Medicare Modernization Act text on the Social Security Agency website:
http://www.ssa.gov/OP_Home/comp2/F108-173.html

Social Security Act index:
http://www.ssa.gov/OP_Home/ssact/comp-ssa.htm

State Operations Manual Appendix index:
http://new.cms.hhs.gov/manuals/downloads/som107c09_appendixtoc.pdf

Survey & Certification Guidance for Laws and Regulations, CAH survey:
http://new.cms.hhs.gov/GuidanceforLawsAndRegulations/04_CAHs.asp

Survey & Certification letters:
http://www.cms.hhs.gov/SurveyCertificationGenInfo/01_Overview.asp#TopOfPage

Rehabilitation Reference Manual

Tab 28: Survey Documentation for CAH DPUs

28.1 Examples

28.2 Survey Tools: CAH DPUs

28.1 Examples

There are no examples specific to CAH DPUs as of the date of this reference manual.

28.2 Survey Tools: CAH DPUs

28.2: Survey Tools: CAH DPUs

If	Then
CAH is new and has new DPU.	Survey CAH using tags from Appendix W and DPU with A tags from Appendix A.

CAH C Tags and C-Tag Identifiers

Tag	Identifier
C0150	***Compliance w/Fed, State & Local Laws/Regulations***
C0151	Standard: Compliance w/Federal laws/regulations
C0152	Standard: Compliance w/State, local laws/regulations
C0153	Standard: Licensure of CAH
C0154	Standard: Licens., Cert. or Registration Personnel
C0160	***Status & Location***
C0161	Standard: Status
C0162	Standard: location rural area or treatment as rural
C0165	Standard: location relative other facilities/prov. cert.
C0170	***Compliance w/CAH, Req. at Time of Application***
C0190	***Agreements***
C0191	Standard: Agreement w/Network Hospitals
C0192	Patient referral & transfer
C0193	Dvmt./use network communication systems
C0194	Transp. emer./non-emer between facility & hospital
C0195	Standard: Agreements Credentialing Quality Assur.
C0200	***Emergency Services***
C0201	Standard: Availability
C0202	Standard: Equipment, Supplies & Medication
C0203	Drugs/biologicals commonly used in life-saving proc.
C0204	Equip./supplies commonly used in life-saving proced.
C0205	Standard: Blood & Blood Products
C0206	Blood storage facilities 42 CFR 493 K sup. patholog.
C0207	Standard: Personnel
C0209	Standard: Coordination Emerg. Response Systems
C0210	***Number of Beds & Length of Stay***
C0211	Standard: Number of Beds
C0212	Length of Stay
C0220	***Physical Plant & Environment***
C0221	Standard: Construction
C0222	Standard: Maintenance
C0223	Proper routine storage, prompt disposal of trash
C0224	Drugs/biologicals appropriately stored
C0225	Premises clean & orderly
C0226	Proper vent./light./temp. in pharm, pt care, food prep.
C0227	Standard: Emergency Procedures
C0228	Emergency power/light in ER, bat lamps/flashlights
C0229	Emergency fuel/water supply
C0230	Other approp. measures location of CAH
C0231	Standard: Life Safety From Fire
C0232	CMS may allow State fire & safety instead of LSC
C0233	CMS may waive specific LSC if hardship on CAH
C0234	CAH maintains evid. reg. State/local fire inspection
C0235	Critical Acc. CAH 19.3.6.3.2, 19.2.9 Mar 13, 2006
C0240	***Organizational Structure***
C0241	Standard: Gov. body, responsible indiv.
C0242	Standard: Disclosure
C0243	Principle person responsible for CAH
C0244	Person responsible for medication direction
C0250	***Staffing & Staff Responsibilities***
C0251	Standard: Staffing
C0252	Auxiliary personnel supervised by professional staff
C0253	Staff sufficient to provide essential CAH services
C0254	Dr. med/osteo, nurse prac, clin nurse avail all times
C0255	RN, clinical nurse spec., LPN CAH 1 or more pts.
C0256	Standard: Respons Dr. Medicine or Osteopathy
C0257	Dr. med./osteo medical dir. CAH active., supv. staff
C0258	Develop./execute CAH written policies of services
C0259	Review CAH pt records, provide med. orders, care pts.
C0260	Review/sign record of pt. care by NP, CNS or PA
C0261	Dr. med./osteo present sufficient periods, once 2 wks.
C0262	Standard: PA, NP, CNS Responsibilities
C0263	PA, NP, CNS participate in rev, exec written policies
C0264	Partic. dr. of med./osteo. periodic rev. pt health record
C0265	PA, NP, CNS provide srvs. accordance CAH policies
C0267	Arrange/refer pts. services not provided at CAH
C0268	Dr. med/osteo. notified of pt. admit. by NP, PA, CNS
C0270	***Provision of Services***
C0271	Standard: Patient Care Policies
C0272	Policies dvp. w/advice professional personnel group
C0273	Descrip. services CAH furnishes direct./arrange
C0274	Policies & procedures emergency medical services
C0275	Guidelines med. management of health problems
C0276	Rules storage/dispens./handling drugs & biologicals
C0277	Procedures adverse drug reactions/admin. errors
C0278	System id., report, invest. inf./commun. diseases pt/per
C0279	CAH inpatient nutritional needs w/orders
C0280	Policies reviewed annually professional personnel
C0281	Standard: Direct Services
C0282	Laboratory Services: basic services for diagnosis
C0283	Radiology services at CAH by qualified staff
C0284	Emer. proced. 1st response life threat. inj./acute illness
C0285	Standard Services provided through agrmt./arrang.
C0286	Inpatient CAH care
C0287	Services of doctors of medicine or osteopathy
C0288	Addit. speci. diag. & clinical lab. serv. not at CAH
C0289	Food/other serv. to meet pt. nutr. needs not at CAH
C0290	If aggr/arrg not in writing, pt referred CAH are accept.
C0291	CAH maintains list of services under agrmt/arrange.
C0292	Person resp. oper. all CAH services incl. agrm/arrange
C0293	Contractor furn. serv. allow CAH to comply w/CoP
C0294	Standard: Nursing Services
C0295	RN prov./assign care all pts. incl. SNF & swing-bed
C0296	RN supv./eval. nursing care each pt. incl. SNF/swing
C0297	All drugs, bio, intrv. meds. suprv. RN/Dr. med./osteo.
C0298	Nursing care plan devolped & kept current each pt.
C0300	***Clinical Records***
C0301	Standard: Records System
C0302	Recs. legible, compt., accurate, readily avail, syst. org.
C0303	Member prof. staff responsible record maintenance
C0304	CAH pt. social data, consnt forms, med. hist., hlth stat
C0305	Reports of phys. exam, diagnostics, lab test results
C0306	All orders dr. med/osteo, nurses notes, treatm., med.
C0307	Dated signat. dr. med./osteo. other health professionals
C0308	Standard: Protection of Record Information
C0309	Writ. policies/proc. use/removal of records from CAH
C0310	Pt. written consent release info. not required by law
C0311	Standard: Retention of Records
C0320	***Surgical Services***
C0321	Standard: Designation of Qualified Practitioners
C0322	Standard: Anesthetic Risk & Evaluation
C0323	Standard: Administration of Anesthesia
C0324	CRNA under supv. oper. pract. when admin. anesthesia
C0325	Standard: Discharge
C0326	Standard: State Exemption
C0330	***Periodic Evaluation & Quality Assurance Review***
C0331	Standard: Periodic Evaluation
C0332	Utiliz. of CAH services incl. at least no. pt. served, vol.
C0333	A representative sample active/closed clinical records
C0334	CAH health care policies
C0335	Purpose of eval. determine utilz. of service appropriate
C0336	Standard: Quality Assurance
C0337	All pt. services/othr. services affecting pt. health/safety
C0338	Nonosocomial infections/medication therapy evaluated
C0339	Quality & appropriateness treatment by NP, CNS, PA
C0340	Quality & appropriateness treatment by Dr. med./osteo.
C0341	CAH considers findings incl. QIO, corrective measures
C0342	CAH remedial action address deficiencies in QA prog.
C0343	CAH documents outcome of all remedial action
C0344	***Organ, Tissue & Eye Procurement***
C0345	Incorporate agrmt. w/OPO to notify immin death pt.
C0346	Incorp. agrmt. minim. 1 tissue, 1 eye bank for retrieval
C0347	Collab. w/OPO inform family option to donate or not
C0348	Discr./sensitivity circum., views, beliefs of donor's fam
C0349	Coop. OPO educate staff donation issues, death records
C0350	Spec. Req. CAH providers LTC services (swing-beds)
C0351	Eligibility
C0352	Facilities Partic. Rural Primary Care Hospitals 9/30/97
C0355	Payment
C0360	SNF Services
C0361	Resident Rights
C0362	Res. right to refuse trmt./esp. research, create adv. dir.
C0363	Inf. res. writ. who entitled Medicare srvs., chg. to serv.
C0364	Free Choice
C0365	Fully inf. in adv. care/trtm, chgs. affect res well-being
C0366	Unless incomp./incapac. part. plan. care, trtmt, changes
C0367	Privacy & Confidentiality
C0368	Work
C0369	Mail
C0370	Access & visitation rights
C0371	Personal Property
C0372	Married Couples
C0373	Admission, transfer & discharge rights
C0374	Permit res to remain facility unless transf./disch. necess
C0376	Documentation resident record transfer/discharge
C0377	Notice before transfer or discharge
C0378	Timing of the notice
C0379	Contents of notice: reason, date, location
C0380	Orientation for transfer or discharge
C0381	Resident behavior & facility policies
C0382	Abuse
C0383	Staff treatment of residents
C0384	Not employ indiv. found guilty of abuse/finding abuse
C0385	Activities
C0386	Social Services
C0388	Resident Assessment
C0389	When required subject to timeframes in 413.343(b)
C0390	Within 14 calendar days decline pt mental/phys condit.

Tag	*Identifier*
C0395	Comprehensive Care Plans
C0396	Comp. Care Plan within 7 days care assessment
C0397	Services provid. arrang. facility prof. stands. quality
C0398	Prov. qualified persons accordance res. written PoC
C0399	Discharge Summary
C0400	Nutrition
C0401	Receives therapeutic diet when nutritional problem
C0402	Specialized rehabilitative services
C0403	Qualification
C0404	Dental Services
C0405	Skilled Nursing Facilities
C0406	Assist res. w/appts., transp. to dentist, ref to dentist
C0407	Nursing Facilities
C0408	Assist res. w/appts., transp. to dentist, ref to dentist

Hospital A Tags and A-Tag Identifiers

Tag	*Identifier*
A0001	Provision of emergency services
A0002	***Compliance w/Fed., State & Local Laws***
A0003	Compliance w/ fed. health & safety laws
A0004	Hospital licensed/approv. by licensing agency
A0005	Hospital personnel licens./meet State, local laws
A0006	***Governing Body***
A0007	Standard: Medical Staff
A0008	Eligibility of practitioners for medical staff
A0009	Appoint members w/med. staff recommendations
A0010	Assure that medical staff has bylaws
A0011	Approve med. staff bylaws, rules & regulations
A0012	Med. staff accountable to gov. body for patient QoC
A0013	Selec. criteria: char., competence, train., exp., judg.
A0014	Prvlg. not solely for cert., fellowship/society member
A0015	Standard: Chief Executive Officer
A0016	Standard: Care of Patients
A0017	Medicare pt.med./osteo, dent., pod., opt., chiro., psyc.
A0018	Pts. admitted by State approved licensed practitioner
A0019	Pt. admitted by med./osteo. if not by licensed pract.
A0020	Dr. of medicine or osteo. on duty/on call at all times
A0021	Med/osteo responsible pt. prob. before/during stay
A0022	Standard: Institutional Plan & Budget
A0023	Plan submitted to designated agency for review
A0024	Capital expenditure not subject to 1122 review
A0025	Plan must be reviewed & updated annually
A0026	Gov. body & committee prepare plan
A0027	Standard: Contracted Services
A0028	Contracted services performed safely & effectively
A0029	List/scope/nature of services maintained by hospital
A0030	Standard: Emergency Services
A0031	Compliance w/§482.55 emergency services provided
A0032	Med. staff has policies if no emergency services
A0033	Med. staff policies off-campus w/out emergency srvs.
A0038	***Patients' Rights***
A0039	Standard: Notice of Rights
A0040	Pt. informed of rights before care/discontinuing care
A0041	Prompt resol. pt. griev./pt. informed w/whom to file
A0042	Gov. body responsible for effective grievance process
A0043	Griev. proc. timely referral QoC/premature discharge
A0044	Clearly explained procedure for writ/verbal grievance
A0045	Griev. process specify review/response timeframe
A0046	Grievance resolution in writing w/contact info. to pt.
A0047	Standard: Excersis of Rights
A0048	Right of pt. participate in development of plan of care
A0049	Pt. has right to make informed decisions for care
A0050	Pt. rights include being informed of health status
A0051	Pt. involved in care planning/treatment
A0052	Pt. able to request/refuse treatment med. appropriate
A0053	Pt. right to form advanced directives w/ compliance
A0054	Pt. right to family/doctor notified hospital admission
A0055	Standard: Privacy & Safety
A0056	Pt. right to personal privacy
A0057	Pt. right to care in safe setting
A0058	Pt. right to be free of abuse/harassment
A0059	Standard: Confidentiality of Patient Records
A0060	Pt. right to confidentiality of clinical records

Tag	*Identifier*
A0061	Pt. right to information in clinical records
A0062	Standard: Restraint Acute Medical & Surgical Care
A0063	Pt. right to free from unnecessary restraints
A0064	Restraint used only to improve pt. well being
A0065	Restraint if other means ineffective/harm self & others
A0066	Physician/licensed indp. practitioner restraint order
A0067	Never written as a standing or on an as needed basis
A0068	Consultation w/treating physician if they didn't order
A0069	In accordance w/written modification to pt. PoC
A0070	Implemented in least restrictive manner possible
A0071	Accordance w/safe/appropriate restraining techniques
A0072	Ended at earliest possible time
A0073	Condition of restrained pt. continually assessed
A0074	Staff direct contact w/pt. trained in safe restraint use
A0075	Standard: Seclusion & Restraint for Behavior Mgmt.
A0076	Pt. free from seclusion/restraints: discipline/retaliation
A0077	Seclusion/restraint only used for emergency/pt. safety
A0078	Use of restraint/seclusion less restrictive ineffective
A0079	Physician/licensed practitioner orders restraints
A0080	Restraints never written as standing order/as needed
A0081	If not ordered by treating physician, contacted ASAP
A0082	Need for restraint evaluated within 1 hr. by physician
A0083	Restraint limited: 4 hrs. 18+yrs/2 hrs. -18yrs/1 hr -9yrs
A0084	Original order renewed up to total 24 hours
A0085	Assessed by physician/licensed prt. before new order
A0086	In accordance with a written modification to pt. PoC
A0087	Implemented in least restrictive manner possible
A0088	In accordance w/safe/appropriate techniques
A0089	Ended at earliest possible time
A0090	Restraint & seclusion not used simultaneously
A0091	Continually monitored w/video/audio close to patient
A0092	Condition continually monitored/assessed/reevaluated
A0093	Ongoing restraint training of staff direct contact w/pt.
A0094	Ongoing alt. methods training staff direct contact w/pt.
A0095	Report death of restrained/secluded pt. to CMS
A0141	***Quality Assessment & Performance Improvement***
A0142	Standard: Program Scope
A0143	Ongoing prog. showing improvement health outcomes
A0144	Ongoing prog. showing improv. reduce medical errors
A0145	Must measure, analyze & track quality indicators
A0146	Standard: Program Data
A0147	Prg. quality ind. pt. care date, & other relevant data
A0148	Use data collected to monitor effectiveness, QoC
A0149	Use data collected to identify opt. improvement
A0150	Freq./detail of data collection specified by gov. body
A0151	Standard: Program Activities
A0152	High risk/high volume, incidence, severity, QoC
A0153	High risk/high volume, incidence, severity, pt. safety
A0154	Impv. actv. track medical errors/adverse pt. evts.
A0155	Impv. actv. track medical errors/adverse evts./causes
A0156	Perf. Imp. implement actions that include feedback
A0157	Must take actions aimed at performance improvement
A0158	After implementing actions, must measure success
A0159	Track performance ensure improvements sustained
A0160	Standard: Performance Improvement Projects
A0161	No./scope distinct imp. proj. annually propor. services

Tag	*Identifier*
A0162	May implement info. tech syst. to improve pt. safety
A0163	Must doc. what quality imprvt. proj. being conducted
A0164	Must document reasons for conducting these projects
A0165	Must doc. measurable progress achieved on these projs
A0166	Not req. to partic. in a QIO coop. proj.
A0167	Standard: Executive Responsibilities
A0168	Ongoing proj quality improve. def./impld/maintained
A0169	Ongoing prg. pt. safety/red. med. errors maintained
A0170	Hospital-wide QA address priorities for imprv. pt QoC
A0171	Hospital-wide QA address priorities for imprv. pt safety
A0172	That clear expectations for safety are established
A0173	Adequate resources allocated: asses, imprv. perfor.
A0174	Determ. # of distinct imprv. projs. conducted annually
A0181	***Medical Staff***
A0182	Standard: Composition of the Medical Staff
A0183	Med. staff periodically conduct appraisal of members
A0184	Staff examine candidate credentials med.membership
A0185	Standard: Medical Staff Organization & Accountability
A0186	Standard: Medical Staff Bylaws
A0187	Be approved by the governing body
A0188	Include statement of duties/privileges of med. staff
A0189	Describe the organization of the medical staff
A0190	Qualif. to be met by candidate for med. staff recomd.
A0191	Req. phys. exam, med hist. for each pt. dr. med./osteo
A0192	Criteria for privg. to ind. pract. & procedure for request
A0193	Standard: Autopsies
A0199	***Nursing Services***
A0200	Standard: Organization
A0201	Standard: Staffing & Delivery of Care
A0202	Provide 24 hr. on duty RN/LPN, services./sup RN
A0203	Nurse service ensure nurse personnel valid licensure
A0204	RN must supervise/evaluate care for each patient
A0205	Hosp. ensure nurse staff develop/keep plan each patient
A0206	RN must assign care to nurses according to pt. need
A0207	Non-employee LN adhere to hospital policies
A0208	Standard: Preparation& Administration of Drugs
A0209	Drugs/biolog. admin. by/supv. nuring/personnel by law
A0210	Orders drugs/biolog. in writing & signed by practitioner
A0211	Accepted only authorized personnel by Fed/State law
A0212	Signed or initialed by prescribing practitioner ASAP
A0213	Used frequently
A0214	Blood tranf./IV meds. admin accordance w/ State law
A0215	Hospital procedure reporting transf., reactions, errors
A0221	***Medical Record Services***
A0222	Standard: Organization & Staffing
A0223	Standard: Form & Retention of Record
A0224	Med. records retained original/legal copy min. 5 yrs.
A0225	System of coding/indexing medical records
A0226	Procedure for confidentiality of records
A0227	Unauthorized indv. can't gain access to pt. records
A0228	Org. med. records released in accord. Fed/ State laws
A0229	Standard: Content of Record
A0230	All entries legible/complete authenticated/dated
A0231	Author of each entry identified entry authenticated
A0232	Authentication : signatures, written initials, pc entry
A0233	All record must document following as appropriate

Tag	Identifier
A0234	Evid. physical examination &health history
A0235	Admitting diagnosis
A0236	Results of consul. evaluations of pt. & findings
A0237	Doc. of complic., hospital acq. infections, reactions
A0238	Properly executed consent forms for procedures
A0239	All pract. ords., nurse notes, med. recs. to monitor pt.
A0240	Discharge summary w/outcome of hospitalization
A0241	Final diagnosis w/complt. of med. rec. within 30 days
A0247	***Pharmaceutical Services***
A0248	Standard: Pharmacy Management @ Administration
A0249	All pharmacists respons. develp./sup./coord services
A0250	Pharm. service adequate personnel quality services
A0251	Current/accurate records receipt/disposition drugs
A0252	Standard: Delivery of Services
A0253	Pkg., disp., drugs/biolog. under pharmacist superv.
A0254	Drugs and biologicals kept in locked storage area
A0255	Outdated/mislabeled/unlabeled not for pt. use
A0256	Drugs/biolog. removed only by design. personnel
A0257	Drugs/biolog not specf. presc. to time/# auto. stopped
A0258	Drug admin errors, reactions, incomp. report immd.
A0259	Abuse/loss of controlled substances report by law
A0260	Info. relating drug interact./therapy/effects aval. staff
A0261	Formulary system established by med. staff
A0267	***Radiological Services***
A0268	Standard: Radiology Services
A0269	Standard: Safety for Patients & Personnel
A0270	Proper Safety Precautions maintained agst. radiation
A0271	Periodic inspection of equip. hazards identified
A0272	Radiation workers checked periodically
A0273	Radiology services only by order of practitioners
A0274	Standard: Personnel
A0275	Radiologist supervise services interp. tests detr. staff
A0276	Med. staff designated personnel radiological equip.
A0277	Standard: Records
A0278	Services by Radiologist/practitioner sign reports
A0279	Copies reports, printouts, films, scans, images 5 yrs.
A0284	***Laboratory Services***
A0285	Standard: Adequacy of Laboratory Services
A0286	Emergency lab services available 24 hrs a day
A0287	Written description of services available med. staff
A0288	Lab. must make provisions receipt/report tissue spec.
A0289	Med. staff/pathol. determine spec. macro/micro exam
A0290	Standard: Potentially Infectious Blood & Blood Prod.
A0295	***Food & Dietetic Services***
A0296	Standard: Organization
A0297	Dir. food/dietetic serv., mgmt. dietary svc. full time
A0298	Qualified dietitian full/part time or consultant basis
A0299	Admin/tech personnel competent in respective duties
A0300	Standard: Diets
A0301	Therapeutic diets prescribed by practitioner
A0302	Nutr. needs met accord. recog. practices/prac orders
A0304	Current therapeutic diet manual apprv. dietician/staff
A0308	***Utilization Review***
A0309	Standard: Applicability
A0310	Standard: Composition Utilization Rev. Committee
A0311	Standard: Scope & Frequency Review
A0312	Standard: Determ. Regarding Admis. or Cont. Stays
A0313	Standard: Extended Stay Review
A0314	Standard: Review of Professional Services
A0317	***Physical Environment***
A0318	Standard: Buildings
A0319	Emergency Power: operating, recovery, IC, ER, stairs
A0320	There must be facilities emergency gas/water supply
A0321	Standard: Life Safety From Fire
A0322	Meet applicable provisions 2000 ed. LSC NFPA
A0323	CMS waive specific provisions LSC hardship facility
A0324	CMS may allow State's fire safety code instead LSC
A0325	March 13, 2006 in comp. w/19.3.3.3.2 & 19.2.9
A0326	Procedures proper routine storage & trash disposal
A0327	Fire control plans prompt reporting fires, pt protection
A0328	Maintain written evidence regular inspection
A0329	Standard: Facilities
A0330	Diagnostic/therapeutic facilities located pt. safety
A0331	Facilities, supplies, equip. maintained
A0332	Extent/complexity of facilities deter. services offered
A0333	Proper vent., light, temp. controls in pharm, food prep
A0338	***Infection Control***
A0339	Standard: Organization & Policies
A0340	IC officer system identify, report, investigate, control
A0341	IC officer maintain log incidents infect./com. diseases
A0342	Std.: Resp. Chief Exec. Off., Med Staff, Dir. Nursing
A0349	***Discharge Planning***
A0350	Standard: Identification of Pts. Need of Discharge
A0351	Standard: Discharge Planning Evaluation
A0352	Nurse/social work. develop/supervise devp. evaluation
A0353	Discharge planning evaluation, post hospital services
A0354	Pt. self-care/cared in env. from which entered hospital
A0355	Personnel cmpt. eval. tmely for post-hospital arrang.
A0356	Discharge planning included in pts. med. record
A0357	Standard: Discharge Plan
A0358	RN/social worker develop discharge plan when indic.
A0359	Pt. physician may req. discharge plan
A0360	Must arrange initial implementation pt. discharge plan
A0361	Reassess pt. discharge plan if factors cont. care needs
A0362	Pt/fam/interested persons must be counseled post-hosp
A0363	Standard: Transfer or Referral
A0364	Standard: Reassessment
A0369	Organ, Tissue & Eye Procurement
A0371	OPO medical suitability tissue, eye
A0372	Agrmt. at least 1 tissue bank: retrieval, proces, storage
A0373	Family informed options to donate or decline
A0374	Designated requestor for family
A0375	Discretion/sensitivity w/respect circumstances/beliefs
A0376	Hospital works w/ designated OPP educating staff
A0377	Reviewing death records improve id. potential donors
A0378	Maintain potential donors testing/placement organs
A0379	Standard: Organ Transplantation Responsibilities
A0384	***Surgical Services***
A0385	Standard: Organization & Staffing
A0386	ORs supervised by exp. RN or dr. med./osteopathy
A0387	LPNs/surg. tech. serve "scrub nurses" under RN sup.
A0388	RN circulating duties in OR accord. State law
A0389	Surg. priv. delineate. all practit. performing surgery
A0390	Standard: Delivery of Service
A0391	Complete history /phys work-up in chart pt prior surg.
A0392	Informed consent form operation in pt chart prior surg.
A0393	OR: call-in sys., cardi. mon., resus., defib., asp., trach.
A0394	Adequate provisions for post-OP care
A0395	OR register complete/ up to date
A0396	OR report: techn., findings, tissues remov./alter.
A0416	***Anesthesia Services***
A0417	Standard: Organization & Staffing
A0418	Standard: Delivery of Systems
A0419	Pre-anesthesia eval. qualified indiv. to admin anes.
A0420	An intraoperative anesthesia record
A0421	Inpatients post-anesthesia follow-up report
A0422	Outpatients post-anesthesia evaluation for proper recov.
A0428	***Nuclear Medicine Services***
A0429	Standard: Organization & Staffing
A0430	Dir. who is dr. medicine/osteo. qualified nuclear med.
A0431	Qualif./train./funct./resp. nuclear med. staff spec. by dir
A0432	Standard: Delivery of Service
A0433	In-house prep. radio pharma. trained, regis. pharm./doc
A0434	There is proper storage & disposal of radioactive mater.
A0435	Lab tests in nuc. med. srv. meet requirement lab srvs.
A0436	Standard: Facilities
A0437	Equip. safe oper. cond./insp, tested, calibrated annually
A0438	Standard: Records
A0439	Hosp. maintain copies nuc med. reports at least 5yrs.
A0440	Pract. approv. med, staff interpret diag. proc. sign, date
A0441	Hospital maintain records receipt distr. radio pharma.
A0442	Nuc. ordered practitioners Fed/State licensure referrals
A0446	***Outpatient Services***
A0447	Standard: Organization
A0448	Standard: Personnel
A0452	***Emergency Services***
A0453	Standard: Organization & Direction
A0454	Service organized dir. qualified member med. staff
A0455	Services integrated w/other depts. of hospital
A0456	Polic. med care prov. in emer. serv. dept. est. med. staff
A0457	Standard: Personnel
A0458	Emer services. supervised qualified member med. staff
A0459	Adeq. med./nursing personnel qual. in emr. care facility
A0463	***Rehabilitation Services***
A0464	Standard: Organization & Staffing
A0465	Dir. of serv. knwlg., exp., capab. administer services
A0466	Phys/occup/speech/audio therapy staff State law
A0467	Standard: Delivery of Services
A0471	***Respiratory Services***
A0472	Standard: Organization & Staffing
A0473	Dir of resp. is dr. med./osteo w/knwlg admin. service
A0474	Adeq. # resp. therapists/technicians consist. w/law
A0475	Standard: Delivery of Services
A0476	Personnel qualif. perform spec. procedures/sup. req.
A0477	Blood gases/clinical lab tests, unit meet lab services
A0478	Services provided accord w/orders dr. med or osteo