

Quick Reference to Certification and Enforcement Requirements in the CFR, SOM, and Survey and Certification (S&C) Letters (Draft—December 11, 2007)

Introduction

This Quick Reference is primarily intended for use by persons in the CMS Regional Offices or States who perform tasks required for Medicare provider/supplier certification and enforcement.

The reference is designed to help these individuals quickly identify major certification and enforcement requirements in the *Code of Federal Regulations (CFR)*, the *CMS State Operations Manual (SOM)*, and the *CMS Survey and Certification (S&C) Letters*. While there are other important sources for policy and procedural information, these are among the most commonly used resources with guidance relevant to all provider/supplier types and all CMS Regions and States.

As shown in the Table of Contents on the next page, this Quick Reference consists of two sections:

- **Section I: Certification**
Organized by type of health services provider/supplier; identifies the locations of key requirements related to certification of providers/suppliers.
- **Section II: Enforcement and Other Program Activities**
Organized by type of action/activity; identifies the locations of key requirements related to other commonly performed types of program actions. This includes initial denials of participation, enforcement activities (involuntary termination, mandatory and optional remedies, etc.), sample validation surveys, complaints/reported incidents, and change of ownership (CHOW).

Internet Website Links for Resources Cited

Listed below are web addresses for resources cited in Quick Reference.

- (1) **Code of Federal Regulations, Title 42**—Public Health
Index to Chapter IV, parts 400–413:
http://www.access.gpo.gov/nara/cfr/waisidx_06/42cfrv2_06.html
Index to Chapter IV, parts 414–429:
http://www.access.gpo.gov/nara/cfr/waisidx_06/42cfrv3_06.html
Index to Chapter IV, parts 430–505:
http://www.access.gpo.gov/nara/cfr/waisidx_06/42cfrv4_06.html
- (2) **CMS State Operations Manual (SOM)**¹
<http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=99&sortByDID=1&sortOrder=ascending&itemID=CMS1201984&intNumPerPage=10>
- (3) **CMS Survey and Certification (S&C) Letters**²
<http://www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp>

While the **Social Security Act (SSA)** is not cited in this Quick Reference, the SSA provides the statutory basis for Medicare/Medicaid regulations and policy. The SSA may be accessed at these websites:

Title XVIII—Medicare

http://www.ssa.gov/OP_Home/ssact/title18/1800.htm

Title XIX—Medicaid

http://www.ssa.gov/OP_Home/ssact/title19/1900.htm

¹**Note:** Chapters and sections of the SOM cited in this Quick Reference were published by CMS as of December, 2007.

²**Note:** This reference does not contain all S&C Letters, since the content of many of the letters representing permanent changes to CMS policy or procedures has been incorporated into the SOM.

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to Certification and Enforcement Requirements
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Provider/Supplier Types	Code of Federal Regulations (CFR)	CMS State Operations Manual (SOM)	CMS Survey & Certification (S&C) Letters
Long-Term Care Providers			
<p>Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs)</p> <p><i>(Note: Includes citations for Distinct Part SNFs and NFs)</i></p>	<ul style="list-style-type: none"> • 42 CFR 483 Subpart B • 42 CFR 488 • 42 CFR 489.3 <p><i>(Immediate jeopardy defined)</i></p>	<ul style="list-style-type: none"> • Ch. 2, 2000–2005A3—General Process Identification of Providers and Suppliers; Initial Certification “Kits”; Designation; Enrollment; Initial Certifications; Approval/Denial • Ch. 2, 2026 Certification of Parts of Institutions as Hospitals (Other Than Psychiatric Hospitals) See 2026A for information about survey of hospital components appropriately certified as other kinds of providers/suppliers, such as a Distinct Part SNF or NF; for more on Distinct Part SNF or NF, see also 2762B, 2764, and 7203B • Ch. 2, 2470–2490—Fire/Life Safety Code (LSC) • Ch. 2, 2700–2800—Survey Process General information on survey and certification process, not provider-specific; includes Summary of SA Certification Actions Performed After Survey, Objectives of RO Certification Review, and RO Assignment of Provider and Supplier Identification Numbers—see LTC Provider Identification Numbers, 2279D 	<ul style="list-style-type: none"> • (12/07/2007) S&C 08-06—Revisions to State Operations Manual (SOM) Exhibits • (09/28/07) S&C 07-39—Medication Pass Clarification for Surveying F Tags 332 and 333 During Nursing Home Surveys • (09/28/07) S&C 07-38—Pre-Admission Screening and Resident Review (PASRR) and the Nursing Home Survey Process • (08/10/07) S&C 07-30 (revised)— Issuance of New Tag F373 (Paid Feeding Assistants) as Part of Appendix PP, State Operations Manual • (07/13/07) S&C 07-29—Canopy and Overhang Sprinkler Requirements and the Use of the Fire Safety Evaluation System • (07/06/07) S&C 07-26—Communication between State Survey Agencies and State Long-Term Care Ombudsman • (07/06/07) S&C 07-25—Issuance of Revised Guidance for Nursing Homes: Accidents and Supervision • (06/22/07) S&C 07-22—Clarification of 'Physical Restraints' as Applied to the Requirements for LTC Facilities • (12/21/06) S&C 07-07—Nursing Home Culture Change Regulatory Compliance Questions and Answers • (09/15/06) S&C 06-29 (revised)—Issuance of

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		<ul style="list-style-type: none"> • Ch. 7—Survey Process for SNFs/NFs <ul style="list-style-type: none"> – 7000–7010—Citations and Descriptions; Types of Facilities that May Qualify; Special Waivers – 7200–7212—Survey Process (Survey Protocol; Survey Frequency; Unannounced Surveys; Finding Substandard Quality of Care; Informal Dispute Resolution) – 7300—Certification of Compliance and Non-Compliance (<i>see Section II of Quick Reference for more on non-compliance/Enforcement Process</i>) – 7800–7907—Program Management; Disclosure • Appendix P—Survey Protocol for Long-Term Care Facilities • Appendix PP—Interpretive Guidelines for Long-Term Care Facilities • Appendix Q—Guidelines for Determining Immediate Jeopardy • Exhibit 63—List of Documents in Certification Packet 	<p>Revised Surveyor Guidance for Unnecessary Medications (F329) and entire Pharmacy section</p> <ul style="list-style-type: none"> • (09/29/06) S&C 06-30—Exceptions to the Observation Requirement When Determining Significant Medication Errors • (09/14/06) S&C 06-26—Clarification of Tag 58 on Form CMS-437A • (09/14/06) S&C 06-24—Revisions to Tasks 2 and 5 as Part of App P, SOM, and New Tag F334 (Flu and Pneumonia), App PP • (06/15/06) S&C 06-20—Implementation of the New Psychosocial Outcome Severity Guide • (05/26/06) S&C 06-19—Nursing Homes - Issuance of New Tag F356 • (05/26/06) S&C 06-18—Clarification of the Amount of Air Movement Allowed Between Corridors and Resident Rooms • (05/11/06) S&C 06-16—Nursing Homes and Medicare Part D • (05/01/06) S&C 06-13—Issuance of Revised Appendix P, SOM, Survey Protocol for LTC Facilities • (03/10/06) S&C 06-11—Issuance of Revised Surveyor Guidance for QAA (Tags F520 and F521) as Part of App PP, SOM • (03/10/06) S&C 06-10—Issuance of the New Psychosocial Outcome Severity Guide as Part of Appendix P, SOM • (03/10/06) S&C 06-09—Issuance of Revised Activities Guidance (Tags F248 and F249) as Part of Appendix PP, SOM • (03/10/06) S&C 06-08—Compliance Date for Installation of Emergency Lighting and Replacement of Existing Roller Latches • (11/14/05) S&C 06-06—The Use of Foreign

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			<p>Acquired Drugs in Long-Term Care Facilities</p> <ul style="list-style-type: none"> • (6/2/04) S&C 04-30—Clarification of the Scoring for Measure 5 (Medication Investigation) of the Federal Oversight Support Survey (FOSS) Protocol for LTC • (6/2/04) S&C 04-27—Opening of New Centers for Medicare & Medicaid Web Site Resource for LTC Surveyors and Providers • (4/8/04) S&C 04-25—Upcoming Criminal Background Checks Pilot Program • (3/11/04) S&C 04-23—Procedures in the Event of a Fire in a Medicare- or Medicaid-Certified Health Care Facility • (1/16/04) S&C 04-17—Clarification on Nursing Homes Requiring Promissory Notes or Deposit Fees as a Condition of Admission, and Implications Related to Surety Bonds
<p>Intermediate Care Facility/Mental Retardation (ICF/MR)</p>	<ul style="list-style-type: none"> • 42 CFR 435 Subpart K • 42 CFR 440 Subpart A • 42 CFR 442 • 42 CFR 483 Subpart I • 42 CFR 488 	<ul style="list-style-type: none"> • Ch. 2, 2000–2005A3—General Process Identification of Providers and Suppliers; Initial Certification “Kits”; Designation; Enrollment; Initial Certifications; Approval/Denial • Ch. 2, 2130–2141 Citations and Description; Distinct Part ICFs/MR; Approval Procedures for ICFs/MR; Assessment of ICFs/MR Based on Conditions of Participation (CoPs) for Active Treatment; Waiver/Variance of ICF/MR Requirements; Time-Limited Certifications (TLAs) of ICF/MR • Ch. 2, 2700–2800—Survey Process General information on survey and certification process, not provider-specific; includes Summary of SA Certification Actions Performed After Survey, Objectives of RO Certification Review, and RO 	<ul style="list-style-type: none"> • (6/09/05) S&C 05-33—Multiple Providers—Adoption of a New Fire Safety Amendment for the Use of Alcohol-Based Hand Rubs (ABHRs) • (4/29/02) S&C 02-26—Intermediate Care Facilities for Persons with Mental Retardation (ICFs/MR) (Contains Form-3070G Revisions—ACTION) • (2/06/02) S&C 02-18—Intermediate Care Facilities for Persons with Mental Retardation (ICFs/MR) Form 3070G Revisions • (12/21/01) S&C 02-08—Intermediate Care Facilities for Persons with Mental Retardation (ICFs/MR) Federal Monitoring and Oversight Survey Data • (10/10/01) S&C 02-01—Abuse and Neglect Detection and Prevention Training

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		Assignment of Provider and Supplier Identification Numbers <ul style="list-style-type: none"> • Appendix J—Intermediate Care Facilities for Persons with Mental Retardation • Appendix Q—Guidelines for Determining Immediate Jeopardy • Exhibit 63—List of Documents in Certification Packet 	
Non-Long-Term Care Providers			
<p>Hospitals (Includes Short-Term Acute Hospitals, Children’s Hospitals, Psychiatric Hospitals, and Non-Participating Emergency Hospitals; also includes citations for Distinct Parts)</p> <p><i>(Note: Also see separate listings for Critical Access Hospitals, Hospitals and Units Excluded from Prospective Payment System (PPS), and Hospital Providers of Extended Care Services—Swing Beds)</i></p>	<ul style="list-style-type: none"> • 42 CFR 482 • 42 CFR 488 • 42 CFR 489.12, 489.13, 489.24, 489.3 	<ul style="list-style-type: none"> • Ch. 2, 2000–2005A3—General Process Identification of Providers and Suppliers; Initial Certification “Kits”; Designation; Enrollment; Initial Certifications; Approval/Denial • Ch. 2, 2020–2054—Hospitals <ul style="list-style-type: none"> – 2020—Definition and Citations – 2022—Hospitals Accredited by the JCAHO or AOA [Deemed Facilities] – 2024—Hospital Merger/Multiple Campus – 2026—Certification of Parts of Institutions as Hospitals (Hospitals Other Than Psychiatric) – 2030/-34—Temporary Waivers Applicable to Rural Hospitals – 2036–2040—Hospital Providers of Extended Care Services (“Swing Beds”) – 2042—Psychiatric Hospitals – 2044—Accredited Psychiatric Hospitals Not Deemed to Meet Special CoPs – 2048—Distinct Parts Psychiatric Hospital – 2050—Medical-Surgical Unit of Psychiatric Hospital 	<ul style="list-style-type: none"> • (12/07/2007) S&C 08-06—Revisions to State Operations Manual (SOM) Exhibits • (12/07/2007) S&C 08-05—Waiver of EMTALA Sanctions in Hospitals Located in Areas Covered by a Public Health Emergency • (11/21/07) S&C 08-04—Revisions to the Hospital Interpretive Guidelines for Infection Control • (04/27/07) S&C 07-20—EMTALA Issues Related to Emergency Transport Services • (04/26/07) S&C 07-19—Provision of Emergency Services - Important Requirements for Hospitals • (04/13/07) S&C 07-17—Revisions to the Hospital Interpretive Guidelines for Informed Consent • (09/14/07) S&C 07-37—Hospital and Laboratory Verbal Order Authentication Requirements Guidance • (01/26/07) S&C 07-13 (revised)—Publication of the Hospital CoPs: Requirements for H and P; Authentication of Verbal Orders; etc. • (07/13/07) S&C 07-28 (revised)—Requirement to Provide Medicare Beneficiaries Notice of Their Rights, Including Discharge Appeal • (06/22/07) S&C 07-23—EMTALA On-Call Requirements and Remote Consultation Utilizing

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		<ul style="list-style-type: none"> – 2052—Non-Participating Emergency Hospitals/Emergency Hospital Services – 2054—Certification of Religious Nonmedical Health Care Institutions (RNHCIs) • Ch. 2, 2700–2800—Survey Process General information on survey and certification process, not provider-specific; includes Summary of SA Certification Actions Performed After Survey, Objectives of RO Certification Review, and RO Assignment of Provider and Supplier Identification Numbers • Appendix A—Survey Protocol, Regulations, and Interpretive Guidelines for Hospitals Includes Survey Modules for Psychiatric Hospitals and Units, Rehabilitation Hospitals and Inpatient Rehabilitation Units, and Hospital Swing-Bed Survey Module • Appendix AA—Psychiatric Hospitals: Interpretive Guidelines and Survey Protocol, Regulations and Interpretive Guidelines • Appendix Q—Guidelines for Determining Immediate Jeopardy • Appendix V—Responsibilities of Medicare Participating Hospitals in Emergency Cases • Exhibit 63—List of Documents in Certification Packet 	<p>Telecommunications Media</p> <ul style="list-style-type: none"> • (07/22/07) S&C 07-24—Utilization Review Condition of Participation for Hospitals • (01/12/07) S&C 07-11—Use of Alcohol-based Skin Preparations in Anesthetizing Locations • (07/13/06) S&C 06-21—Revisions to Special Responsibilities of Hospitals under EMTALA • (09/29/06) S&C 06-31—Hospital Death Reporting Requirements Related to Behavior Management Restraint and Seclusion • (09/29/06) S&C 06-32—Revisions to Special Responsibilities of Hospitals under EMTALA • (8/18/05) S&C 05-42—Hospitals—Revision to Interpretive Guidelines for CMS Hospital Conditions of Participation 42 CFR §§482.12, 482.13, 482.27 and 482.28 • (8/18/05) S&C 05-40—Eligibility for Conversion to Critical Access Hospitals • (6/9/05) S&C 05-35—Hospitals—Suspension of Processing New Provider Enrollment Applications (CMS-855A) for Specialty Hospitals • (6/9/05) S&C 05-33—Multiple Providers—Adoption of a New Fire Safety Amendment for the Use of Alcohol Based Hand Rubs (ABHRs) • (5/12/05) S&C 05-28—Renewal of Deeming Authority for Hospitals Accredited by the AOA, and Home Health Agencies Accredited by the JCAHO and the Community Health Accreditation Program (CHAP) • (4/22/05) S&C 05-26—Interaction of the Emergency Medical Treatment and Labor Act (EMTALA) and the Born-Alive Infants Protection Act of 2002 • (11/12/04) S&C 05-04—CMS Requirements for Hospital Medical Staff Privileging

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			<ul style="list-style-type: none"> • (5/13/04) S&C 04-33—Life Safety Code (LSC) and State Performance Standards • (5/13/04) S&C 04-31—Status of Form CMS-1514 • (5/13/04) S&C 04-29—Life Safety Code (LSC) Surveyor Reference Materials • (3/11/04) S&C 04-23—Procedures in the Event of a Fire in a Medicare- or Medicaid-Certified Health Care Facility
<p>Critical Access Hospitals (CAHs)</p> <p><i>(Note: Also see listing for Hospital Providers of Extended Care Services—Swing Beds)</i></p>	<ul style="list-style-type: none"> • 42 CFR 485.601–485.645 • 42 CFR 488 • 42 CFR 489.24 • 42 CFR 489.3 <i>(Immediate jeopardy defined)</i> 	<ul style="list-style-type: none"> • Ch. 2, 2000–2005A3—General Process Identification of Providers and Suppliers; Initial Certification “Kits”; Designation; Enrollment; Initial Certifications; Approval/Denial • Ch. 2, 2254–2262 CAH Citations; Requirements for CAHs; SA and RO Procedures for CAH Approval; Anti-Dumping Requirements; Advance Directive Requirements; Processing CAH Swing-Bed Applications; Survey/Post-Survey Procedures for Swing-Bed Approval; RO Approval Procedures for Swing-bed Approval • Ch. 2, 2700–2800—Survey Process General information on survey and certification process, not provider-specific; includes Summary of SA Certification Actions Performed After Survey, Objectives of RO Certification Review, and RO Assignment of Provider and Supplier Identification Numbers • Appendix Q—Guidelines for Determining Immediate Jeopardy • Appendix W—Survey Protocol, Regulations, and Interpretive Guidelines for Critical Access Hospitals 	<ul style="list-style-type: none"> • (12/07/2007) S&C 08-06—Revisions to State Operations Manual (SOM) Exhibits • (09/07/07) S&C 07-35—CAHs: Distance from Other Providers and Relocation of CAHs with a Necessary Provider Designation • (07/13/07) S&C 07-28 (revised)—Requirement to Provide Medicare Beneficiaries Notice of Their Rights, Including Discharge Appeal • (07/13/2007) S&C 07-27—Emergency Medical Screening in Critical Access Hospitals • (06/22/07) S&C 07-23—EMTALA On-Call Requirements and Remote Consultation Utilizing Telecommunications Media • (01/12/07) S&C 07-11—Use of Alcohol-based Skin Preparations in Anesthetizing Locations • (11/14/05) S&C 06-04—Location and Relocation of CAHs and Relocation of Necessary Provider CAHs • (8/18/05) S&C 05-40—Eligibility for Conversion to CAH • (6/09/05) S&C 05-32—CAH Requirement for Doctor of Medicine/Doctor of Osteopathy (MD/DO) Review of Medical Records for Mid-Level Practitioners • (9/29/04) S&C 04-48—Implementation of CAH Distinct Part Units (DPUs) for Psychiatric and Rehabilitation Services

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		and Swing Beds in CAHs • Exhibit 63—List of Documents in Certification Packet	• (12/11/03) S&C 04-14—Implementation of CAH Bed Size Increase • (5/08/03) S&C 03-21—Adoption of New Fire Safety Requirements for RNHCIs, ASCs, Hospice, PACE, Hospitals, Long-Term Care, ICFs/MR, and CAHs • (4/10/03) S&C 03-17—Personnel Provisions of the CAH Emergency Services Requirement for Frontier Areas and Remote Locations
<p>Hospitals and Hospital Units Excluded from Prospective Payment System (PPS) (Includes PPS-Excluded Psychiatric Hospitals, Rehabilitation Hospitals, Children’s Hospitals, Long-Term Hospitals, Hospitals within Hospitals, and Psychiatric and Rehabilitation Units within Hospitals)</p>	<ul style="list-style-type: none"> • 42 CFR 412.20–30 • 42 CFR 488 • 42 CFR 489.3 <i>(Immediate jeopardy defined)</i> 	<ul style="list-style-type: none"> • Ch. 2, 2700–2800—Survey Process General information on survey and certification process, not provider-specific; includes Summary of SA Certification Actions Performed After Survey, Objectives of RO Certification Review, and RO Assignment of Provider and Supplier Identification Numbers—see Special Numbering for Units of PPS-excluded Hospitals, 2779C • Ch. 3, 3100–3112.3 Annual Self-Attestation of Hospitals and Hospital Units Excluded from PPS; General Information on PPS Exclusion; Criteria for PPS-Excluded Hospitals; Criteria for Psychiatric and Rehabilitation Units within Hospitals; SA First-Time Verification and Re-Verification Procedures for Hospitals and Units; RO Procedures for Exclusion from PPS Hospitals and Units • Appendix A Sections specifically addressing PPS-excluded hospitals and units include: Psychiatric Unit Survey Module; Rehabilitation Hospital Survey Module; Inpatient Rehabilitation Unit Survey Module 	<p><i>[No recent letters identified]</i></p>

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		<ul style="list-style-type: none"> • Appendix AA—Psychiatric Hospitals • Appendix Q—Guidelines for Determining Immediate Jeopardy • Exhibit 63—List of Documents in Certification Packet 	
<p>Hospital Providers of Extended Care Services—Swing Beds (Includes Short-Term and Long-Term Swing Bed Hospitals, and Critical Access Hospitals and Rehabilitation Hospitals with Swing Beds)</p>	<ul style="list-style-type: none"> • 42 CFR 482.66 (<i>Hospital</i>) • 42 CFR 485.645 (<i>Critical Access Hospital</i>) • 42 CFR 488 • 42 CFR 489.3 (<i>Immediate jeopardy defined</i>) 	<ul style="list-style-type: none"> • Ch. 2, 2036–2040—Hospitals with Swing Beds Definition, Authority, and Provider Requirements; Requirements Assessed Prior to Survey for Swing Bed Approval; Survey and Post-survey Procedures; RO Approval Procedures • Ch. 2, 2259–2262 Critical Access Hospitals (CAHs) with Swing Beds—Procedures for Processing CAH Swing-Bed Applications; Survey and Post-Survey Procedures for Swing-Bed CAHs; RO Approval Procedures • Ch. 2, 2700–2800—Survey Process General information on survey and certification process, not provider-specific; includes Summary of SA Certification Actions Performed After Survey, Objectives of RO Certification Review, and RO Assignment of Provider and Supplier Identification Numbers—see Special Numbering for Hospitals with SNF Swing-Bed Designation, 2779C • Appendix A—Section on Hospital Swing-Bed Survey Module • Appendix Q—Guidelines for Determining Immediate Jeopardy • Appendix T—Swing Beds in Hospitals • Appendix W—CAHs/Swing Beds in 	<ul style="list-style-type: none"> • (12/07/2007) S&C 08-06—Revisions to State Operations Manual (SOM) Exhibits • (1/13/05) S&C-05-14—Electronic Signature Guidance—Clarification • (12/16/04) S&C-05-09—Clarification of Nursing Home Reporting Requirements for Alleged Violations of Mistreatment, Neglect, and Abuse, Including Injuries of Unknown Source, and Misappropriation of Resident Property • (11/12/04) S&C-05-08—Clarification of Survey Agency Responsibilities in Obtaining Information for Civil Rights Clearances for Initial Certification and Changes of Ownership (CHOW) • (8/12/04) S&C 04-41—Corridor Width & Corridor Mounted Computer Touch Screens in Health Care Facilities—Clarification Effective Immediately • (8/12/04) S&C 04-40—Resident Assessment Instrument (RAI) Training Program • (8/12/04) S&C 04-38—Additional Language Required in Initial Letter to Nursing Homes • (7/8/04) S&C 04-37—Addendum I to S&C Letter 04-24 on the Care for Residents of LTC Facilities • (7/8/04) S&C-04-35—Physicians’ Rubber Stamp Signature • (5/13/04) S&C-04-29—Life Safety Code (LSC) Surveyor Reference Materials • (5/13/04) S&C-04-27—Opening of New CMS

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		CAHs • Exhibit 63—List of Documents in Certification Packet	Web Site Resource for Long Term Care (LTC) Surveyors and Providers • (4/8/04) S&C-04-25—Upcoming Criminal Background Checks Pilot Project • (3/11/04) S&C 04-23—Procedures in the Event of a Fire in a Medicare- or Medicaid-Certified Health Care Facility
Religious Nonmedical Health Care Institutions (RNHCIs) <i>(Christian Science handled only by Boston RO)</i>	• 42 CFR 403.720 • 42 CFR 488	• Ch. 2, 2054—Certification of Religious Nonmedical Health Care Institutions (RNHCIs) • Appendix U—Responsibilities of Medicare Participating Religious Nonmedical Healthcare Institutions • Exhibit 63—List of Documents in Certification Packet	<i>[No recent letters identified]</i>
Other Non-LTC Providers			
Hospices	• 42 CFR 418.1–418.100 • 42 CFR 488 • 42 CFR 489.2 • 42 CFR 489.3	• Ch. 2, 2000–2005A3—General Process Identification of Providers and Suppliers; Initial Certification “Kits”; Designation; Enrollment; Initial Certifications; Approval/Denial • Ch. 2, 2080–2087 Hospice Citations and Description; Termination of Services; Multiple Locations; Election of Hospice Benefit by Resident of SNF, NF, ICF/MR, or Non-Certified Facility; Hospice Regulations and Non-Medicare Patients; Hospice In-patient Services Furnished Directly or Furnished Under Arrangements; Operation Across State Lines; Hospice Home Visits; Compliance with Advance Directives • Ch. 2, 2700–2800—Survey Process General information on survey and	• (09/14/06) S&C 06-28—Impact of Nursing Shortage on Hospice Care • (10/14/04) S&C 05-02—Impact of Nursing Shortage on Hospice Care • (7/08/04) S&C 04-35—Physician’s Rubber Stamp Signature • (2/12/04) S&C 04-21— Impact of Section 946 of the MMA on the Hospice Core Services Requirement • (5/10/02) S&C 02-29—Promising Practices for Implementing the Medicare Hospice Benefit for Nursing Home (NH) Resident Letter To Chris Cody Regarding Hospice Benefit For Nursing Home Residents • (5/03/01) S&C 01-18—Response to Questions from the National Hospice and Palliative Care Organization (NHPCO) • (4/24/01) S&C 01-13—Hospice Questions and

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Provider/Supplier Types	Code of Federal Regulations (CFR)	CMS State Operations Manual (SOM)	CMS Survey & Certification (S&C) Letters
		certification process, not provider-specific; includes Summary of SA Certification Actions Performed After Survey, Objectives of RO Certification Review, and RO Assignment of Provider and Supplier Identification Numbers <ul style="list-style-type: none"> • Appendix M—Guidance to Surveyors—Hospice • Exhibit 63—List of Documents in Certification Packet 	Answers
Community Mental Health Centers (CMHCs)	<ul style="list-style-type: none"> • 42 CFR 410.2 • 42 CFR 410.2, 410.43, 410.110 • 42 CFR 424 • 42 CFR 488 • 42 CFR 489.2(c) (2) • 42 CFR 489.3 	<ul style="list-style-type: none"> • Ch. 2, 2000–2005A3—General Process Identification of Providers and Suppliers; Initial Certification “Kits”; Designation; Enrollment; Initial Certifications; Approval/Denial • Ch. 2, 2250–2252 <ul style="list-style-type: none"> –2050—Definition and Citations—CMHC Citations and Description—General and Special Requirements; Partial Hospitalization program; Partial Hospitalization Services provided by CMHCs or Others Under Arrangements with the CMHC; Definitions of Core Services; Threshold and Service Requirements; Revisions to Core Service Screening Requirements as a Result of the Passage of BIPA – 2252—Certification Process—Request to Participate; Processing CMHC Requests; Onsite Visit; Facility Alleges It Is Provider-Based; Facility Requests Alternate Site to be Approved; RO Approval/Denial of CMHC Request for Medicare Approval; Changes of Ownership; Voluntary and Involuntary Termination 	<i>[No recent letters identified]</i>

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Provider/Supplier Types	Code of Federal Regulations (CFR)	CMS State Operations Manual (SOM)	CMS Survey & Certification (S&C) Letters
<p>Home Health Agencies (HHAs)</p>	<ul style="list-style-type: none"> • 42 CFR 484.1–484.55 • 42 CFR 488 • 42 CFR 489.2(b)(3), 489.3, 489.12, 489.13 	<ul style="list-style-type: none"> • Ch. 2, 2000–2005A3—General Process Identification of Providers and Suppliers; Initial Certification “Kits”; Designation; Enrollment; Initial Certifications; Approval/Denial • Ch. 2, 2008B—Initial Surveys of HHAs • Ch. 2, 2180–2202.19 HHAs—Citations and Description; Organization of HHA; Separate Entities; Operation of HHAs across State Lines; Surveying HHAs (Frequency, Process, Survey Tasks); Outcome and Assessment Information Set (OASIS) Requirements • Ch. 2, 2700–2800—Survey Process General information on survey and certification process, not provider-specific; includes Summary of SA Certification Actions Performed After Survey, Objectives of RO Certification Review, and RO Assignment of Provider and Supplier Identification Numbers • Appendix B—Guidance to Surveyors: Home Health Agencies • Exhibit 63—List of Documents in Certification Packet 	<ul style="list-style-type: none"> • (12/07/2007) S&C 08-06—Revisions to State Operations Manual (SOM) Exhibits • (05/01/06) S&C 06-14—Approval of Deeming Authority of the Accreditation Commission for Healthcare (ACHC) for HHAs • (5/12/05) S&C 05-28—Renewal of Deeming Authority for Hospitals Accredited by the American Osteopathic Association (AOA), and Home Health Agencies Accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Community Health Accreditation Program (CHAP) • (3/10/05) S&C 05-22—Nursing Homes and Home Health Agencies—Updated Facility Computer Specifications • (11/12/04) S&C 05-07—Home Health Agency (HHA) Drop Sites • (11/12/04) S&C 05-06—Application of the Home Health Agency (HHA) Conditions of Participation (CoPs) to Patients Receiving Chore Services Exclusively • (9/9/04) S&C 04-45—Home Health Agencies (HHAs): Clarification of Timing Requirements For Conducting The Comprehensive Assessment On Pediatric And Maternity Patients As Well As Those Patients Receiving Personal Care Services Only • (4/08/04) S&C 04-26—Clarification of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003 for Non-Medicare/Non-Medicaid Patients in Home Health Agencies (HHAs) • (9/11/03) S&C 03-33—Correction Policy for Home Health Agency (HHA) Administrative Data on the Home Health Compare Web Site • (2/13/03) S&C 03-13—Home Health Survey Protocol Enhancements

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Provider/Supplier Types	Code of Federal Regulations (CFR)	CMS State Operations Manual (SOM)	CMS Survey & Certification (S&C) Letters
<p>Providers of Outpatient Physical Therapy or Outpatient Speech Pathology (OPT/OSP) Services</p> <p>(Includes Rehabilitation Agencies, Clinics, and Public Health Agencies that provide OTP/OSP services)</p>	<ul style="list-style-type: none"> • 42 CFR 485 Subpart H • 42 CFR 488 • 42 CFR 489.2(b)(4), 489.2(c)(1), 489.3, 489.12, 489.13 	<ul style="list-style-type: none"> • Ch. 2, 2290–2306 OPT/OSP Citations and Types of Providers; Exceptions to CoPs; SA Verification of Services Provided; Site of Service Provision; SA Annual Report to RO; SA Survey Providers Offering OPT Only • Ch. 2, 2700–2800—Survey Process General information on survey and certification process, not provider-specific; includes Summary of SA Certification Actions Performed After Survey, Objectives of RO Certification Review, and RO Assignment of Provider and Supplier Identification Numbers • Appendix E—OTP/OSP Services—Interpretive Guidelines • Exhibit 63—List of Documents in Certification Packet 	<ul style="list-style-type: none"> • (12/07/2007) S&C 08-06—Revisions to State Operations Manual (SOM) Exhibits • (12/21/06) S&C 07-08—Forms CMS-1856 and 1893E for Occupational Therapy Services • (07/27/06) S&C 06-23—Clarification of 42 CFR Section 485.711(c) Standard: Emergency Care • (9/22/05) S&C 05-45—Updates to the SOM for OPT Services and Comprehensive Outpatient Rehabilitation Facilities (CORFs) • (6/22/05) S&C 05-36—Assigning Provider Identification Numbers to Extension locations to OPT and OSP Service Providers • (3/11/04) S&C 04-23—Procedures in the Event of a Fire in a Medicare- or Medicaid-Certified Health Care Facility
<p>Comprehensive Outpatient Rehabilitation Facilities (CORFs)</p>	<ul style="list-style-type: none"> • 42 CFR 410.100–410.105 • 42 CFR 485.50–485.74, 485.701–485.729 • 42 CFR 488 • 42 CFR 489.2(b)(5) • 42 CFR 489.12–489.13 	<ul style="list-style-type: none"> • Ch. 2, 2000–2005A3—General Process Identification of Providers and Suppliers; Initial Certification “Kits”; Designation; Enrollment; Initial Certifications; Approval/Denial • Ch. 2, 2360–2366 CORF Citations and Description; Scope and Site of Services; CORF’s Relationship with Other Providers/Suppliers; Conversion of OTP/OSP to CORF • Ch. 2, 2700–2800—Survey Process General information on survey and certification process, not provider-specific; includes Summary of SA Certification Actions Performed After Survey, Objectives of RO Certification Review, and RO Assignment of Provider and Supplier 	<ul style="list-style-type: none"> • (9/22/05) S&C 05-45—Updates to the SOM for Outpatient Rehabilitation Therapy Services (OPTs) and Comprehensive Outpatient Rehabilitation Facilities (CORFs)

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Provider/Supplier Types	Code of Federal Regulations (CFR)	CMS State Operations Manual (SOM)	CMS Survey & Certification (S&C) Letters
		Identification Numbers <ul style="list-style-type: none"> • Appendix K—Comprehensive Outpatient Rehabilitation Facilities • Exhibit 63—List of Documents in Certification Packet 	
Psychiatric Residential Treatment Facilities (PRTF) <i>(Note: PRTFs are Title XIX/Medicaid-only providers.)</i>	<ul style="list-style-type: none"> • 42 CFR 431.610(b) • 42 CFR 440.40(b)(1) • 42 CFR 441 Subparts B and D • 42 CFR 488 	<ul style="list-style-type: none"> • Ch. 1, 1000B—Medicaid Provisions (General) • Ch. 2, 2779B—Numbering System for Medicaid Providers 	<ul style="list-style-type: none"> • (02/16/07) S&C 07-15—Psychiatric Residential Treatment Facilities (PRTF) Clarification • (7/14/05) S&C 05-37—Responsible State Agency for Psychiatric Residential Treatment Facility (PRTF) Surveys • (2/12/04) S&C 04-20—Resource Materials for Death Reporting in Psychiatric Residential Treatment Facilities (PRTFs); List of PRTFs by State within each Region • (12/11/03) S&C 04-13—Validation, Complaint, and Reporting Requirements: Use of Restraint and Seclusion in Psychiatric Residential Treatment Facilities Providing Inpatient Psychiatric Services to Individuals Under Age 21 (42 CFR 483 Subpart G) • (6/1/01) S&C 01-19—Reporting Requirements: Use of Restraint and Seclusion in Psychiatric Treatment Facilities Providing Inpatient Psychiatric Services to Individuals Under Age 21
Suppliers			
Ambulatory Surgical Centers (ASCs)	<ul style="list-style-type: none"> • 42 CFR 416 • 42 CFR 488.1 	<ul style="list-style-type: none"> • Ch. 2, 2210—ASC Citations and Description • Ch. 2, 2472—Life Safety Code Surveys and Waivers • Ch. 2, 2700–2800—Survey Process General information on survey and certification process, not provider-specific; includes Summary of SA Certification Actions Performed After Survey, Objectives of RO Certification Review, and RO 	<ul style="list-style-type: none"> • (05/04/07) S&C 07-21—Generators in Ambulatory Surgical Centers (ASCs) • (01/12/07) S&C 07-11—Use of Alcohol-based Skin Preparations in Anesthetizing Locations • (6/17/03) S&C 03-22—Clarification of CMS Payment Policies Regarding Ambulatory Surgical Centers/Independent Diagnostic Testing Facilities (ASCs/IDTFs) Conducting Business From the Same Location • (5/08/03) S&C 03-21—Adoption of New Fire

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Provider/Supplier Types	Code of Federal Regulations (CFR)	CMS State Operations Manual (SOM)	CMS Survey & Certification (S&C) Letters
		Assignment of Provider and Supplier Identification Numbers <ul style="list-style-type: none"> Appendix L—Ambulatory Surgical Services Interpretive Guidelines Exhibit 63—List of Documents in Certification Packet 	Safety Requirement for Religious Nonmedical Health Care Institutions (i.e., ASCs, Hospices, etc.) <ul style="list-style-type: none"> (2/19/02) S&C 021—Clarification of CMS Policies Regarding Ambulatory Surgical Centers
Portable X-Ray Services	<ul style="list-style-type: none"> 42 CFR 486 Subparts A and C 42 CFR 488 	<ul style="list-style-type: none"> Ch. 2, 2420–2424 Portable X-Ray Services Citations; Location of Service; Suppliers Using Improperly Labeled or Post-1974 Equipment Ch. 2, 2700–2800—Survey Process General information on survey and certification process, not provider-specific; includes Summary of SA Certification Actions Performed After Survey, Objectives of RO Certification Review, and RO Assignment of Provider and Supplier Identification Numbers Appendix D—Guidance to Surveyors—Portable X-ray Services Exhibit 63—List of Documents in Certification Packet 	[No recent letters identified]
End Stage Renal Disease (ESRD) Facilities (Includes hospital-based facilities such as hospital-owned/operated satellite facilities and Special Purpose Renal Dialysis facilities, as well as Independent Renal Disease Treatment Centers and Independent Special Purpose Renal Dialysis facilities)	<ul style="list-style-type: none"> 42 CFR 405 Subpart U 42 CFR 413 Subpart H 42 CFR 488 	<ul style="list-style-type: none"> Ch. 2, 2270–2287 ESRD Citations; Types of ESRD Facilities; Application Requirements; Survey Procedures; Additional Conditions Assessed by RO; RO Facility Classification; VA Hospital Participation in ESRD Program; Change of Ownership of Hospital-Located Renal Dialysis Facilities; Sanctions for Failure to Participate in Network Activities; Continuous Ambulatory Peritoneal Disease Coverage (CAPD) and Continuous Cycling Peritoneal Dialysis (CCPD); Classification 	<ul style="list-style-type: none"> (12/07/2007) S&C 08-06—Revisions to State Operations Manual (SOM) Exhibits (08/24/2007) S&C 07-34—Guidance for New Home Hemodialysis Water Treatment Device (7/8/04) S&C 04-24—Addendum I to S&C Letter 4-24 on the care for Residents of Long-Term Care (LTC) Facilities Who Receive ESRD Services (7/8/04) S&C 04-36—Corrections to Appendix H of the State Operations Manual (SOM) Web Version (3/19/04) S&C 04-24—Clarification of Certification Requirements and Coordination of

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Provider/Supplier Types	Code of Federal Regulations (CFR)	CMS State Operations Manual (SOM)	CMS Survey & Certification (S&C) Letters
		of Hospital-Based or Independent ESRD Facilities <ul style="list-style-type: none"> • Ch. 2, 2700–2800—Survey Process General information on survey and certification process, not provider-specific; includes Summary of SA Certification Actions Performed After Survey, Objectives of RO Certification Review, and RO Assignment of Provider and Supplier Identification Numbers—see ESRD Identification Numbers, 2279J • Appendix H—ESRD Facilities (Surveyor and Interpretive Guidelines) • Exhibit 63—List of Documents in Certification Packet 	Care for Residents of Long-Term Care (LTC) Facilities Who Receive ESRD Services <ul style="list-style-type: none"> • (3/11/04) S&C 04-23—Procedures in the Event of a Fire in a Medicare- or Medicaid-Certified Health Care Facility • (8/14/03) S&C 03-32—Pilot Program for Surveyor Technical Assistant for Renal Disease (STAR) • (5/08/03) S&C 03-20—Medicare Identification Number Assignment for End Stage Renal Dialysis (ESRD) Facilities • (9/12/02) S&C 02-43—CDC Revised Recommendations for Single-Use Intravenous Medication Vials in ESRD Facilities & Tunis Letter • (8/08/02) S&C 02-39—Nursing Home That Has No Arrangement to Provide Dialysis To Its Residents
Organ Procurement Organizations (OPOs)	<ul style="list-style-type: none"> • 42 CFR 486.304 • 42 CFR 486.306 • 42 CFR 486.310–486.325 • 42 CFR 488 	<ul style="list-style-type: none"> • Ch. 2, 2810–2819 OPO Citations and Definitions; OPO Application Process—RO Responsibilities; OPO Initial Designation Requirements; Designation Procedures; Redesignation; OPOs Operating in a Noncontiguous U.S. State; Interim Designations; Opening Service Area for Competition; Unserved Service Area; Changes in Ownership or Service Area • Exhibit 63—List of Documents in Certification Packet 	<ul style="list-style-type: none"> • (12/07/2007) S&C 08-06—Revisions to State Operations Manual (SOM) Exhibits
Rural Health Clinics (RHCs) (Freestanding and provider-based)	<ul style="list-style-type: none"> • 42 CFR 405.2400–405.2417 • 42 CFR 488.2 	<ul style="list-style-type: none"> • Ch. 2, 2000–2005A3—General Process Identification of Providers and Suppliers; Initial Certification “Kits”; Designation; Enrollment; Initial Certifications; 	<ul style="list-style-type: none"> • (12/07/06) S&C 07-06—Hours of Operation for Rural Health Clinics (RHC) • (8/12/04) S&C 04-42—Status of the December 24, 2003 Final Rule: Rural Health Clinics

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Provider/Supplier Types	Code of Federal Regulations (CFR)	CMS State Operations Manual (SOM)	CMS Survey & Certification (S&C) Letters
	<ul style="list-style-type: none"> • 42 CFR 491.1–491.11 	<p>Approval/Denial</p> <ul style="list-style-type: none"> • Ch. 2, 2240–2249 RHC Citations and Description; Conditions to be Assessed Prior to Scheduling Survey; Preparing for Survey; Clinic’s Request to Provide Visiting Nurse Services; Clinic’s request for Waiver of Staffing Requirements; RO Notification of RHC Approval • Ch. 2, 2700–2800—Survey Process General information on survey and certification process, not provider-specific; includes Summary of SA Certification Actions Performed After Survey, Objectives of RO Certification Review, and RO Assignment of Provider and Supplier Identification Numbers • Appendix G—Guidance to Surveyors: Rural Health Clinics • Exhibit 63—List of Documents in Certification Packet 	<ul style="list-style-type: none"> • (10/9/03) S&C 04-02—Use of mapping to determine rural eligibility for RHCs • (6/13/02) S&C 02-36—Privacy of Medical Records in RHCs
<p>Federally Qualified Health Centers (FQHCs)</p>	<ul style="list-style-type: none"> • 42 CFR 405.240, 405.2430–405.2472 • 42 CFR 488.2 • 42 CFR 489.13(a)(2) • 42 CFR 491.1–491.11 	<ul style="list-style-type: none"> • Ch. 2, 2000–2005A3—General Process Identification of Providers and Suppliers; Initial Certification “Kits”; Designation; Enrollment; Initial Certifications; Approval/Denial • Ch. 2, 2700–2800—Survey Process General information on survey and certification process, not provider-specific; includes Summary of SA Certification Actions Performed After Survey, Objectives of RO Certification Review, and RO Assignment of Provider and Supplier Identification Numbers 	<p><i>[No recent letters identified]</i></p>

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Provider/Supplier Types	Code of Federal Regulations (CFR)	CMS State Operations Manual (SOM)	CMS Survey & Certification (S&C) Letters
		<ul style="list-style-type: none"> • Ch. 2, 2825–2826 FQHC Citations and Description; RO Approval Process for FQHCs • Exhibit 63—List of Documents in Certification Packet 	
<p>Clinical Laboratory Improvement Amendments of 1988 (CLIA) Laboratories</p>	<ul style="list-style-type: none"> • 42 CFR 493 • 42 CFR 488.1 	<ul style="list-style-type: none"> • Ch. 2, 2000–2005A3—General Process Identification of Providers and Suppliers; Initial Certification “Kits”; Designation; Enrollment; Initial Certifications; Approval/Denial • Ch. 6—Special Procedures, Laboratories <ul style="list-style-type: none"> – 6000–6139—Program Background and Actions Related to Certification, including Application and Certificate Process; CLIA Certificate Status Changes; Laboratory Location; Assignment of CLIA Identification Numbers; CLIA Information in OSCAR; CLIA Database System; RO Role; SA Role; Mobile Labs and Multiple Sites; Transfusion Services; Proficiency Testing (PT); Enrollment Information: The Survey Process; Survey Responsibilities; Completing the Survey Report (Form CMS-1557); Certification Actions Performed After Survey; Statement of Deficiencies and PoC (Form CMS-2567); Evaluation of Compliance; and Complaints – 6150–6184—Sample Validation Surveys of Accredited Laboratories – 6200–6224—Sample Validation of CLIA-Exempt Laboratories 	<ul style="list-style-type: none"> • (08/24/07) S&C 07-33—Continuation and Revision of the Components of the CLIA Educational Period Regarding QC • (08/24/07) S&C 07-32—Clarification and Standardization of CLIA Complaint Closeouts to Complainants • (08/24/07) S&C 07-31—New CLIA Loss of Accreditation (LoA) Procedures • (01/12/07) S&C 07-12—New and Revised CLIA Policies and Procedures • (12/07/06) S&C 07-04—SA Responsibilities for 2007 Regarding Cytology PT) under CLIA and Additional Program Information • (11/17/06) S&C 07-02—CLIA Additional Topics Concerning Proficiency Testing Policies • (09/14/06) S&C 06-27—Doctors of Optometry serving as Directors and/or Technical Consultants Under CLIA • (01/23/06) S&C 06-07—SA Responsibilities for 2006 Regarding Gynecologic Cytology (PT) under CLIA - Update • (9/22/05) S&C 05-44—Doctors of Optometry and/or Ophthalmology serving as Laboratory Director under the CLIA • (7/14/05) S&C 05-39—Extension of the CLIA Educational Period Regarding the Final CLIA Regulation (CMS-2226-F) (Refer to S&C 03-30 and S&C 04-16)

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Provider/Supplier Types	Code of Federal Regulations (CFR)	CMS State Operations Manual (SOM)	CMS Survey & Certification (S&C) Letters
		<ul style="list-style-type: none"> – 6226–6228—Validation Surveys Performed Simultaneously with Inspections – 6230–6240—Other Activities, e.g., CLIA State Agency Performance Review (SAPR), Federal Monitoring Survey (FMS) of Laboratories, etc. • Appendix C—Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services • Exhibit 63—List of Documents in Certification Packet 	<ul style="list-style-type: none"> • (12/16/04) S&C 05-11—SA Responsibilities in Enforcing the Gynecologic Cytology Proficiency Testing (PT) Requirements under the CLIA • (8/12/04) S&C 04-39—CLIA State Agency Performance Review (SAPR)—Fiscal Year 2004 (FY2004) • (1/08/04) S&C 04-16—CLIA Policy and Data Reporting Guidance for First Survey Cycle Following the Effective Date of CMS-2226-F • (11/13/03) S&C 04-05—Guidance On Test Systems Categorized as Either Waived or Moderate Complexity Under the CLIA • (8/14/03) S&C 03-30—CLIA Policy Letters for First Survey Cycle Following the Effective Date of CMS-2226-F • (5/08/03) S&C 03-19—Policy for Interim Period Between the Effective Date of CMS-2226-F and Publication of Surveyor Guidelines

[**Note:** See also Section II of this Quick Reference—*Enforcement and Other Program Activities*—beginning on the next page.]

SECTION II: ENFORCEMENT and OTHER PROGRAM ACTIVITIES			
Type of Action	Code of Federal Regulations (CFR)	CMS State Operations Manual (SOM)	CMS Survey & Certification (S&C) Letters
Initial Denial of Participation	<ul style="list-style-type: none"> • 42 CFR 489.12 • 42 CFR 489.13 	<ul style="list-style-type: none"> • Ch. 2, 2005A3—Initial Certifications—Denial • Ch. 2, 2734—SA Evaluation of Compliance (see 2734B—Certifying Noncompliance) • Ch. 3, 3001—Initial Denials of Medicare Provider/Supplier Requests for Program Participation • Ch. 7, 7300C—Initial Survey and Certification Responsibility (for SNFs/NFs; see also 7203B for Initial Certification Surveys) 	<i>[No recent letters identified]</i>
<p>Enforcement and Involuntary Termination: Long-Term Care Providers—Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs)</p> <p><i>(Covers Enforcement Process, Remedies, Involuntary Termination Procedures, Appeals, and Readmission)</i></p>	<ul style="list-style-type: none"> • 42 CFR 488.400–488.456 	<ul style="list-style-type: none"> • Ch. 2, 2000–2012—Identification of Providers and Suppliers and Related Pre-Survey Activities • Ch. 2, 2470–2490—Life Safety Code (LSC) • Ch. 3, 3005C-2—Decision to Terminate or Deny Payment for Medicaid Facilities—Medicare-Medicaid SNFs/NFs • Ch. 3, 3005D—Cause for Termination • Ch. 7—Survey and Enforcement Process for SNFs and NFs: <ul style="list-style-type: none"> – 7300—Certification of Compliance and Non-Compliance – 7301—Action When Facility is Not in Substantial Compliance – 7303—Appeal of Certification of Noncompliance – 7304–7320—Certification-Related Terms; Notice Requirements; Timing of Civil Monetary Penalties; Immediate 	<ul style="list-style-type: none"> • (11/02/07) S&C 08-02—National Special Focus Facility Program Improvements for Nursing Facilities, Notice Requirements • (10/20/05) S&C 06-01—Nursing Homes: Citations of Past Noncompliance—Revised Guidelines • (12/16/04) S&C 05-13—Improving Enforcement via the Special Focus Facility Program for Nursing Homes • (12/16/04) S&C 05-12—Response to Referrals from Public Entities Alleging Noncompliance with Federal Nursing Home Requirements • (12/16/04) S&C 05-10—Federal Requirements for the Informal Dispute Resolution (IDR) Process for Nursing Homes • (06/12/03) S&C 03-25—Clarification of Issues Related to Informal Dispute Resolution • (03/28/02) S&C 02-20—Review of Time Frames for Reporting Abuse; Reporting Abuse to Law Enforcement; Displaying Complaint Telephone Numbers; and Clarification on Defining and Citing Abuse—ACTION

SECTION II: ENFORCEMENT and OTHER PROGRAM ACTIVITIES			
Type of Action	Code of Federal Regulations (CFR)	CMS State Operations Manual (SOM)	CMS Survey & Certification (S&C) Letters
		<p>Jeopardy—Enforcement Actions; No Immediate Jeopardy; Response to Plan of Correction; Procedures for Certifying Compliance; Action When There Is Sub-Standard Quality of Care;</p> <ul style="list-style-type: none"> – 7321—Readmission After Termination – 7400–7410—Enforcement Process (Enforcement Remedies and Selection of Remedies; Life Safety Code Enforcement Guidelines) – 7500–7752—Remedies—Directed Plan of Correction; Directed In-Service Training; State Monitoring; Denial of Payment; Civil Monetary Penalties; Temporary Management; Transfer of Residents – 7556—Termination Procedures – 7600—Continuation of Payments During Correction Period – 7800–7809—Program Management – 7900–7907—Disclosure • Ch. 3, 3050–3058—Reconsideration, Hearings, and Appeals • Appendix Q—Determining Immediate Jeopardy 	
<p>Enforcement and Involuntary Termination: Non-Long-term Care Providers and Suppliers</p> <p>(Includes psychiatric hospitals and OPOs; excludes ICF/MRs)</p> <p><i>(Covers Enforcement Process, Involuntary Termination Procedures, Appeals, and Readmission)</i></p>	<ul style="list-style-type: none"> • 42 CFR 405.2180, 42 CFR 405.2182 (ESRD) • 42 CFR 405.2404, (RHC) • 42 CFR 405.2442 (FQHC) • 42 CFR 416.35 (ASC) • 42 CFR 489.52–489.57 	<ul style="list-style-type: none"> • Ch. 3, 3000–3049—Adverse Actions <ul style="list-style-type: none"> – 3000–3005—Adverse Actions—General Information; Initial Denials of Provider/Supplier Requests for Program Participation; Basis for Terminating Provider Participation—Citations, Discussion – 3010–3012—Termination Procedures, Immediate Jeopardy or Noncompliance with CoPs/Conditions for Coverage <ul style="list-style-type: none"> o 30012.1—Termination of Psychiatric 	<ul style="list-style-type: none"> • (04/22/05) S&C 05-26—Interaction of the EMTALA and the Born-Alive Infants Protection Act of 2002

SECTION II: ENFORCEMENT and OTHER PROGRAM ACTIVITIES			
Type of Action	Code of Federal Regulations (CFR)	CMS State Operations Manual (SOM)	CMS Survey & Certification (S&C) Letters
		<ul style="list-style-type: none"> Hospitals Based on CMS Mental Health Surveyor’s Survey <ul style="list-style-type: none"> o 3012.2—Termination of Organ Procurement Organizations (OPOs) – 3014—RO Termination Action based on Onsite Federal Survey – 3018—Termination—SA Documentation Requirements – 3022—Notice of Termination (Medicare) – 3024—RO Termination Processing Sequence – 3026–3028—Significance of Documentary Evidence in Determining Noncompliance; Documentation Guide, Termination for Non-Compliance – 3030–3044—Additional topics on Involuntary Terminations • Ch. 3, 3050–3058—Reconsideration, Hearings, and Appeals • Ch. 2, 2016A–2016G—Readmission to Medicare/Medicaid After Involuntary Termination—Reasonable Assurance • Appendix Q—Determining Immediate Jeopardy 	
<p>Enforcement and Involuntary Termination: Intermediate Care Facilities for Mentally Retarded (ICFs/MR)</p> <p><i>(Covers “Look Behind” Termination, Principal and Alternative Sanctions, Enforcement Action Processing Procedures, Appeals, and Readmission)</i></p>	<ul style="list-style-type: none"> • 42 CFR 442.117–442.119 	<ul style="list-style-type: none"> • Ch. 3—Adverse Actions <ul style="list-style-type: none"> – 3005C-1—Decision to Terminate or Deny Payment for Medicaid Facilities/ ICFs/MR – 3005D—Cause for Termination – 3005E—Termination of Title XIX-only NFs and ICFs/MR – 3005G—“Look-Behind” Authority – 3006—Denial of Payments in Lieu of Termination of ICFs/MR; Alternative Sanctions in Non-Immediate Jeopardy 	<i>[No recent letters identified]</i>

SECTION II: ENFORCEMENT and OTHER PROGRAM ACTIVITIES			
Type of Action	Code of Federal Regulations (CFR)	CMS State Operations Manual (SOM)	CMS Survey & Certification (S&C) Letters
		<p>Situations; Directed Plan of Correction (DPoC); Directed In-Service Training; State Monitoring; Criteria for Review of State Plans for Approval/Disapproval of Alternative Sanctions</p> <ul style="list-style-type: none"> – 3007—Nonrenewal or Automatic Cancellation of Time-Limited Agreements for ICFs/MR – 3008—Services After Termination – 3040–3042—Terminating Medicaid ICF/MR Eligibility based on “Look-Behind” Determination – 3060—Appeals of Adverse Actions • Ch. 2, 2016F—Readmission of ICFs/MR After Termination • Appendix Q—Determining Immediate Jeopardy 	
<p>Enforcement and Sanctions: CLIA Laboratories</p> <p><i>(Covers Enforcement Options, Principal/Alternative Sanctions, Enforcement Action Processing Procedures, Appeals, and Readmission)</i></p>	<ul style="list-style-type: none"> • 42 CFR 493.561–493.575, 493.1800–493.1846 	<ul style="list-style-type: none"> • Ch. 6, 6250–6316—Laboratories, Adverse Actions <ul style="list-style-type: none"> – 6250–6252—Purpose/Basis for Enforcement; Definitions/Terms – 6254–6260—Denial of Form CMS-116; Voluntary Withdrawals from CLIA Program; Voluntary Withdrawal of Certification to Test; Requests to Change Certificate Type – 6262–6280—CLIA Conditions Not Met—Enforcement Options and Principal and Alternative Sanctions; Failure to Furnish Notification of Changes; Failure to Meet Proficiency Testing Requirements; Sanctions (Principal and Alternative—detailed) – 6282–6299—Procedures for Processing Immediate Jeopardy/No Immediate Jeopardy Enforcement Actions; 	<p><i>[No recent letters identified]</i></p>

SECTION II: ENFORCEMENT and OTHER PROGRAM ACTIVITIES			
Type of Action	Code of Federal Regulations (CFR)	CMS State Operations Manual (SOM)	CMS Survey & Certification (S&C) Letters
		Deficiencies/Timely Corrections; Duration and Lifting of Alternative Sanctions; RO Responsibilities during Adverse Action Process – 6300–6316—Appeals Procedures; Reconsideration; Administrative Hearings; Readmission to CLIA Program	
Sample Validation Surveys: Accredited (Deemed) Non-Long-Term Care Providers and Suppliers	<ul style="list-style-type: none"> • 42 CFR 488.7 • 42 CFR 489.52–489.57 	<ul style="list-style-type: none"> • Chapter 3, 3240–3257A—Validation Surveys of Accredited Providers and Suppliers <ul style="list-style-type: none"> – 3240–3248—Validation Surveys— Citations, General Description; Objective of Validation Surveys; Setting Up/Preparing for Validation Survey, Authorization for Release of Hospital Accreditation Survey – 3250–3252—SA Actions – 3254—RO Actions Following Sample Validation Survey (Provider/Supplier in Compliance or Not in Compliance [Immediate Jeopardy or No Immediate Jeopardy]; Plans of Correction; Termination; After Correction of Deficiencies – 3256–3257—Documents to be Forwarded to Accrediting Organizations (RO); Reinstatement to Accrediting Organization Jurisdiction • Appendix Q—Determining Immediate Jeopardy • Exhibit 63—List of Documents in Certification Packet <i>[see listing for Accredited Hospital Complaint/Validation]</i> 	<ul style="list-style-type: none"> • (05/12/05) S&C 05-28—Renewal of deeming authority for hospitals accredited by the American Osteopathic Association (AOA), and home health agencies accredited by the JCAHO and the Community Health Accreditation Program (CHAP) • (01/13/05) S&C 05-15—Renewal of the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) deeming authority for ASCs

SECTION II: ENFORCEMENT and OTHER PROGRAM ACTIVITIES			
Type of Action	Code of Federal Regulations (CFR)	CMS State Operations Manual (SOM)	CMS Survey & Certification (S&C) Letters
Complaints/Reported Incidents	<ul style="list-style-type: none"> • 42 CFR 405.2180–.2182 • 42 CFR 488.400–.456, 488.7 • 42 CFR 489.3, 489.52–.57 	<ul style="list-style-type: none"> • Chapter 5—Complaint Procedures <ul style="list-style-type: none"> – 5000–5080—Complaints Against all Medicare/Medicaid Certified Providers/Suppliers (Management of Complaints and Incidents; Intake Process; RO responsibility; Aspen Complaints/Incident Tracking System (ACTS); Priority Assignment; Priority Definitions; State Monitoring Visits; Investigation Findings and Reports – 5100–5170—Complaints Against Deemed Providers/Suppliers – 5200–5240—Complaints Against Non-Deemed Providers/Suppliers Excluding Nursing Homes (SNFs/NFs) – 5300–5390—Investigating Complaints in Nursing Homes – 5400–5480—Investigations of Alleged EMTALA (“Dumping”) Violations – 5500–5590—Complaints Involving Labs (Unaccredited, CLIA-Exempt, and Accredited/CLIA Labs) • Appendix Q—Determining Immediate Jeopardy • Exhibit 63—List of Documents in Certification Packet <i>[see listings under General Complaint and Accredited Hospital Complaint/Validation]</i> 	<ul style="list-style-type: none"> • (09/14/06) S&C 06-25—Final Timeliness Guidelines to Support the Entry of Data into ACO and ASPEN • (03/22/06) S&C 06-12—State Operations Manual (SOM) Chapter 5, Complaints • (6/09/05) S&C 05-31—Promising Practices to Support the Intake of Nursing Home Complaints • (4/22/05) S&C 05-26—Interaction of the EMTALA and the Born-Alive Infants Protection Act of 2002 • (11/13/03) S&C 04-09—Guidelines to Support National Implementation of the ACTS
Change of Ownership (CHOW)	<ul style="list-style-type: none"> • 42 CFR 489.18 	<ul style="list-style-type: none"> • Ch. 2, 2005E—Changes of Ownership • Ch. 3, 3200—Action Based on Changes in Provider Organization, Services, or Action of Other Approving Agencies • Ch. 3, 3210—CHOW of Providers and Suppliers; Determining Ownership; SA 	<ul style="list-style-type: none"> • (11/12/04) S&C 05-08—Clarification of Survey Agency Responsibilities in Obtaining Information for Civil Rights Clearance for Initial Certifications and Changes of Ownership (CHOWs)

SECTION II: ENFORCEMENT and OTHER PROGRAM ACTIVITIES			
Type of Action	Code of Federal Regulations (CFR)	CMS State Operations Manual (SOM)	CMS Survey & Certification (S&C) Letters
		<p>Actions to Be Taken; Certification of Accredited Providers/Suppliers Which Change Ownership; CHOW Situations and Analysis—General Rules; RO Role in CHOW Determination; RO Procedures</p> <ul style="list-style-type: none"> • Exhibit 63—List of Documents in Certification Packet <i>[see listings under CHOW]</i> 	
Voluntary Terminations	<ul style="list-style-type: none"> • 42 CFR 489.52 • 42 CFR 489.55 • 42 CFR 489.57 	<ul style="list-style-type: none"> • Ch. 2, 2005F—Voluntary Terminations • Ch. 2, 2017—Readmission Following Voluntary Termination of Program Participation • Ch. 3, 3046–3049A—Voluntary Terminations (General; Decision by Provider/Supplier to remain in Medicare Program; Notice to Public; Effective Date of Voluntary Termination); Notice to Intermediary or Carrier—Voluntary Termination; Completing Certification and Transmittal Form (Form CMS-1539), Voluntary Terminations and Close of Business • Exhibits 188 and 189—Notification: Voluntary Termination of Provider Agreement Approved; Notification: Approval of Voluntary Termination of a Supplier • Exhibits 190 and 191—Notification to a Provider that Has Ceased/Is Ceasing Operations; Notification to a Supplier that Has Ceased/Is Ceasing Operations 	<i>[No recent letters identified]</i>