Revision History

Revision	Effective Date	Author	Description of Change
1.0.0	05/21/2014	Jasmine Powell	Although this course has previously occurred, this is the first offering to be recorded under the CMS version control policy. This documents the baseline version for purposes of document control. Released for the class offering beginning August 18-22, 2014.

Field Resource Guide

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SURVEY PROCEDURES AND INTERPRETIVE GUIDELINES FOR INTERMEDIATE CARE FACILITIES FOR INDIVIDUALS WITH INTELLECTUAL DISABILITIES

APPENDIX J

SURVEY PROCEDURES FOR INTERMEDIATE CARE FACILITIES FOR INDIVIDUALS WITH INTELLECTUAL DISABILITIES (ICFs/IID)

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INTERPRETIVE GUIDELINES FOR INTERMEDIATE CARE FACILITIES FOR INDIVIDUALS WITH INTELLECTUAL DISABILITIES

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SURVEY PROCEDURES
INTERMEDIATE CARE FACILITIES FOR INDIVIDUALS WITH INTELLECTUAL DISABILITIES

I. INTRODUCTION

This revised ICF/IID survey protocol is to assist surveyors to focus attention on the outcomes of individualized active treatment services. The Health Care Financing Administration (HCFA) intends the revised survey process to be less resource intensive for providers who consistently demonstrate compliance with the regulations. The survey process is based on the October 3, 1988 regulation and is applicable to all ICFs/IID, regardless of size.

In 1988, when the current ICF/IID regulation was implemented, it was viewed as a great step forward in promoting a focus on the actual outcomes experienced by consumers, rather than on the policies, procedures and paperwork of the facility. Since that time there has been an evolution on thinking in both the field of developmental disabilities (DD) and in the field of quality assurance (QA).

The field of DD is increasingly emphasizing supporting individuals in their own homes and communities, rather than placing people in facilities. In addition services in virtually all States are placing increased emphasis on person-centered planning and person-centered services that focus on the preferences, goals and aspirations of each individual and on supporting them in reaching their personal goals. The field of QA is placing increased emphasis on outcomes related to choice, control, relationships, community inclusion, and satisfaction with life, as well as satisfaction with services and supports. Many QA systems also include organizational self-assessment and continuous quality improvement components. These trends have contributed to the perception by providers and advocates that the ICF/IID regulation and oversight process is too prescriptive and cumbersome, and should be altered to reflect newer values of quality enhancement and continuous quality improvement.

This revised survey protocol gives facilities broader latitude to develop the processes by which it implements active treatment services. While the facility practice must comply with the requirements of 42 CFR 483, Subpart I, the survey is to center on the fundamental requirements that produce outcomes for individuals. When those outcomes occur, review of additional supporting requirements of process and structure is not indicated.

A survey which focuses on observations of staff/consumer interaction and on interviews with consumers regarding their participation and choice of services is sufficiently informative to determine the outcomes of active treatment. In the presence of problems, a more in-depth review of how the process unfolded for a particular individual(s) occurs.

A facility may receive reimbursement <u>only</u> for the cost of care of individuals classified as eligible for the ICF/IID level of care who are receiving active treatment. Determine <u>facility</u> compliance with Conditions of Participation and with standards in the context of <u>individual</u> experiences within the facility. When performing certification surveys to assess facility compliance, assess whether individuals are receiving needed active treatment services.

II. PRINCIPAL FOCUS OF SURVEYS

The principal focus of the survey is on the "outcome" of the facility's implementation of ICF/IID active treatment services. Direct your principal attention to what actually happens to individuals: whether the facility provides needed services and interventions; whether the facility insures

individuals are free from abuse, mistreatment, or neglect; whether individuals, families and guardians participate in identifying and selecting services; whether the facility promotes greater independence, choice, integration and productivity; how competently and effectively the staff interact with individuals; and whether all health needs are being met.

Use observation and interview as the primary methods of information gathering. Conduct record reviews after completion of observations and interviews to confirm specific issues. Verify that the facility develops interventions and supports that address the individuals' needs, and provides required individual protections and health services. Do not conduct in-depth reviews of assessments, progress notes or historical data unless outcomes fail to occur for individuals.

III. SURVEY PROCESS

The survey process is divided into three stages. They are the fundamental, extended and full survey. **(Note: These stages do not apply to the Life Safety Code survey. Every certification and annual re-certification requires a complete Life Safety Code survey (see instructions in Appendix I)).**

A. Fundamental Survey.--A fundamental survey is conducted to determine the quality of services and supports received by individuals, as measured by outcomes for individuals and essential components of a system which must be present for the outcomes of active treatment to occur. Certain requirements are designated as fundamental and are reviewed first. The remaining requirements (that are not designated as fundamental) are supporting structures or processes that the facility must implement. A decision that a provider is in compliance with the fundamental requirements indicates an outcome-reviewed compliance with the non-fundamental requirements and associated conditions of participation. Focus initial attention on the fundamental requirements of the conditions of participation for:

42 CFR 483.420 Client Protections

Fundamental requirements:

483.420(a)(2) - (7)	W124 - W130
483.420(a)(9)	W133
483.420(a)(11) - (12)	W136 - W137
483.420(c)(1) - (6)	W143 - W148
483.420(d)(2) - (4)	W153 - W157

42 CFR 483.440 Active Treatment Services

Fundamental requirements:

483.440(a)(1) - (2)	W196 - W197
483.440(c)(2)	W209
483.440(c)(4)	W227
483.440(c)(6)(i)	W240
483.440(c)(6)(111)	W242
483.440(c)(6)(vi)	W247
483.440(d)(1)	W249
483.440(f)(1)	W255 - W257
483.440(f)(3)(i) - (ii)	W262 - W263

In addition include:

483.410(d)(3)	W120
483.430(d)(2)	W186
483.470(g)(2)	W436
483.470(i)(4)	W448 - W449

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42 CFR 483.450 Client Behavior and Facility Practices

Fundamental requirements:

483.450(b)(2)	W285
483.450(b)(3)	W286 - W288
483.450(c)(1)	W291
483.450(c)(3)	W293
483.450(d)(4)	W301 - W302
483.450(e)(3)	W313
483.450(e)(4)(i)	W314

42 CFR 483.460 Health Care Services

Fundamental requirements:

483.460(a)(3)	W322
483.460(c)	W331
483.460(c)(3)(v)	W338
483.460(g)(2)	W356
483.460(k)(2)	W369
483.460(k)(4)	W371

All fundamental requirements must be reviewed in every annual recertification survey. When observations and interviews are complete, review the individuals' records, as needed, to verify observation and interview findings. If indicated, verify that individual health needs are met and protections are in place. When the fundamental requirements are "met", the facility meets the Conditions of Participation.

When fundamental requirements are "not met", review the condition-level compliance principles found in the interpretive guidelines for W122, W195, W266, and W318. Determine whether deficiencies at the fundamental requirements, when viewed as a whole, lead you to believe that one or more of the "not met" compliance principles is present. If this is the case, conduct an extended survey, as instructed below. When the "met" compliance principles are present, the facility is assumed to be in compliance with all conditions of participation. This is the end of the fundamental survey. The survey agency would prepare a Form CMS-2567, Statement of Deficiencies, and report any standard-level deficiencies based on the findings from the fundamental survey.

B. Extended Survey.--An extended survey is conducted when standard-level deficiencies are found during the fundamental survey and the survey team has determined or suspects that one or more Conditions of Participation examined during the fundamental survey (42 CFR 483.420, 42 CFR 483.440, 42 CFR 483.450, and 42 CFR 483.460) are "not met." The team would need to gather additional information in order to identify the structural and process requirements that are "not met" and to support their condition-level compliance decision. The team reviews all of the requirements within the Condition(s) for which compliance is in doubt. Using the condition-level compliance principles in the interpretive guidelines as a guide, determine if the facility complies with the relevant Condition(s) of Participation.

When the survey team determines that the facility is in compliance with the relevant Conditions of Participation, conclude the survey and prepare a CMS-2567 for facility practices not in compliance with standards. When the facility is not in compliance with one or more Conditions of Participation, prepare a CMS-2567 describing the deficient facility practices which are not in compliance with the Conditions of Participation of either 42 CFR 483.420, 42 CFR 483.440, 42 CFR 483.450, or 42 CFR 483.460. Base any required adverse action on these findings. Review of additional requirements under other

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Conditions of Participation is at the option of the survey agency based on the criteria under paragraph "C" of this section.

NOTE: Neither the fundamental or the extended survey process preclude the survey agency from review of any standard, if evidence of non-compliant facility practice is suspected during any survey.

C. Full Survey.--A full survey is conducted at an initial survey and at the discretion of the survey agency, based on the survey agency's identification of concerns related to the provider's capacity to furnish adequate services. This decision may be based on criteria, including but not limited to, the following:

- o A condition-level deficiency on the previous year's recertification survey,
- o The existence of a time-limited agreement of less than twelve months due to programmatic deficiencies, or
- o Evidence related to diminished capacity to provide services based on other sources, such as complaints, inspection of care findings or State licensure deficiencies that are relevant to Federal requirements.

The team reviews all the requirements in all Conditions of Participation to determine if the facility maintains the process and structure necessary to achieve the required outcomes. Based on the information collected, determine whether facility practice is in compliance with all Conditions of Participation.

IV. COMPONENTS OF ACTIVE TREATMENT

The definition of "active treatment in intermediate care facilities for individuals with intellectual disabilities" in 42 CFR 435.1009 refers to treatment that meets the requirements specified in the standard for active treatment 42 CFR 483.440(a). The components of the active treatment process are:

A. Comprehensive Functional Assessment (42 CFR 483.440(c)(3)).--The individual's interdisciplinary team must produce accurate, comprehensive functional assessment data, within 30 days after admission, that identify all of the individual's:

- o Specific developmental strengths, including individual preferences;
- o Specific functional and adaptive social skills the individual needs to acquire;
- o Presenting disabilities, and when possible their causes; and
- o Need for services without regard to their availability.

B. Individual Program Plan (IPP) (42 CFR 483.440(c)).--The interdisciplinary team must prepare an IPP which includes opportunities for individual choice and self-management and identifies: the discrete, measurable, criteria-based objectives the individual is to achieve; and the specific individualized program of specialized and generic strategies, supports, and techniques to be employed. The IPP must be directed toward the acquisition of the behaviors necessary for the individual to function with as much self-determination and independence as possible, and the prevention or deceleration of regression or loss of current optimal functional status.

C. Program Implementation (42 CFR 483.440(d)).--Each individual must receive a continuous active treatment program consisting of needed interventions and services in sufficient intensity and frequency to support the achievement of IPP objectives.

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D. Program Documentation (42 CFR 483.440(e)).--Accurate, systematic, behaviorally stated data about the individual's performance toward meeting the criteria stated in IPP objectives serves as the basis for necessary change and revision to the program.

E. Program Monitoring and Change (42 CFR 483.440(f)).--At least annually, the comprehensive functional assessment of each individual is reviewed by the interdisciplinary team for its relevancy and updated, as needed. The IPP is revised, as appropriate.

V. TASK 1 - SAMPLE SELECTION

A. Purpose of the Sample.--The purpose of drawing a sample of individuals from the facility is to reflect a proportionate representation of individuals by the four functional levels (mild, moderate, severe, and profound mental retardation) as defined by the American Association on Mental Deficiency, Classification in Mental Retardation (eighth edition, 1983).

The sampling process is not designed to produce a "statistically valid" sample. Apply the method with flexibility based upon the prevailing developmental strengths and needs presented by the individuals served by the facility. A "statistically valid" sample would not accommodate this need.

While the individuals in the sample are targeted for observation and interview, conduct each program audit of the individual within the context of each of the environments in which the individual lives, works, and spends major leisure time. Although you focus on the individual, the behavior and interactions of all other individuals and staff within those environments also contribute to the total context and conditions for active treatment. Therefore, other individuals will be included in the overall sample.

As the sample is built, additional information about the facility's services and special individual needs may emerge. If you find that a disproportionate number of disabilities or needs are present within the facility's population add to or replace originally selected individuals of the same functional level in the program audit sample to ensure that the appropriate care and services are reviewed. Staff interview for individual characteristics (see the back of Form CMS-3070G) may help identify areas of individual need that should be reflected in the sample.

For example, if you discover a significant percentage of individuals are nonambulatory, and this characteristic has not been represented in the sample, add additional individuals. Likewise, if while observing Individual A (a member of the sample), you note that Individual B (who was not targeted for the sample) engages in a particular problematic behavior for which staff do not appear to provide appropriate intervention, add Individual B to the sample in order to probe further if needs are addressed. You are free by this methodology to add to the sample on an as needed basis.

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B. Sample Size.--Calculate the size of the sample by the following guidance:

Number of Individuals residing in the Facility	Number of Individuals in the Sample	Number of Interviews with Individual/Family
4 - 8	50 percent	50 percent of sample
9 - 16	4	4
17 - 50	8	5
51 - 100	10	5
101 - 500	10 percent	50 percent of sample (max.: 15)
Over 500	50	15

C. Sample Selection.--Do not allow the facility staff to select the sample.

1. Facilities Serving 100 or Fewer Individuals.--Draw a sample that evenly distributes the individuals among buildings and functioning levels. Usually, this can be done by asking the staff to provide a full list of the individuals with their building locatons and functional levels and you choosing the names.

2. Facilities with over 100 individuals.--

o Request a listing of all individuals by overall functional (cognitive and adaptive) level (i.e., mild, moderate, severe, profound) and building location.

o Determine the number of individuals to draw based upon the total individuals from Section III B.

o Determine the percentage occurrence of each functional level in the overall population (e.g., 12 percent mild; 24 percent moderate; 63 percent severe).

o Determine the number of individuals to draw in each functional category (for example, if the sample size is 50, and 12 percent of the individuals have mild mental retardation, then multiply 50 by .12 = 6, and draw 6 individuals who have mild mental retardation into the sample).

o Draw the sample for each functional category. (Assume there are 60 with mild mental retardation, and 6 are to be sampled. Divide 60 by 6 = 10, and draw every tenth individual.) The interval of selection varies with each functional category because there will be a different percentage occurrence at each. Thus, assuming there are 16 individuals with severe mental retardation and 4 are to be sampled, draw every fourth name from the list of individuals with severe mental retardation.

o Locate each selected individual's living unit on a map of the facility building(s) to see if too many are concentrated in too few buildings. To provide a comprehensive look at the facility, drop some individuals and add others in other buildings for a better distribution. Each individual replacing an originally selected individual must be of the same functional level.

3. Alternate Sampling Procedure.--In the rare situation in which the facility is unable to produce the necessary data on which to draw the sample, draw a random sample, to the maximum extent possible. Supplement it as described in Section VA.

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Mental retardation, as defined by the American Association on Mental Retardation (AAMR) in Mental Retardation: Definition, Classification and Systems of Supports (ninth edition, 1992), is no longer classified in four functional levels (mild, moderate, severe, and profound.) Most facilities have not yet adopted the 1992 classification system; however, when the facility does use the 1992 classification system and information regarding the four functional levels is not available, revise the sampling procedure. Follow the instructions in A and B above but, instead of using the four functional levels referenced in AAMR's Classification System of 1983, use the four levels of intensity of supports (intermittent, limited, extensive, and pervasive) on Dimension I for Self-Care from the new classification system. Although not equivalent to the 1993 classifications, this method should provide a sample of individuals within the facility who represent a variety of functional abilities.

D. Program Audit Approach.--To maximize the advantage of an interdisciplinary survey team, the team leader assigns each member an equitable number of individuals on whom to focus. For each individual, assess all applicable fundamental requirements of the ICF/IID Conditions of Participation based on the individual's need for that particular service. Each member of the team shares salient data about findings relative to his or her assigned individuals. Consult with one another, on a regular basis during the survey, to maximize sharing of knowledge and competencies.

E. Sampling on Follow-up Survey.--The purpose of the follow-up survey is to verify correction of deficiencies previously cited on the CMS-2567. It is NOT necessary to do a full review of all services being received, only those areas in which deficiencies were previously cited. Sample selection on the follow-up survey is, therefore, dependent on the nature of the deficiencies for which follow-up must be done.

If the last survey found multiple standard-level deficiencies that are not limited to a specific area or issue, follow the procedure described in paragraphs A through D above to select a new sample and use the same sample size specified in paragraph B. This procedure may result in inclusion of some individuals from the previous sample, however, approximately 50% of the sample on the follow-up survey should be individuals who were not previously reviewed in order to assure systemic correction of the identified deficiencies. This can be accomplished by beginning the interval of selection at a different point on the list of individuals residing at the facility. The maximum sample size on a follow-up survey is 30.

When Conditions of Participation have been found not met in the annual survey and the types of deficiencies are limited to a specific need or service area, then the follow-up sample may be drawn from the specific universe of individuals who have that specific need. To select the sample, start with the total number of individuals affected by the specific need, then choose the sample size. The sample universe will be the total number of individuals who have that specific need. For example, if the facility has 20 individuals receiving medications to manage behavior, the sample size would be 8, in accordance with paragraph B.

VI. TASK 2 -REVIEW OF FACILITY SYSTEMS TO PREVENT ABUSE, NEGLECT AND MISTREATMENT AND TO RESOLVE COMPLAINTS

During the entrance conference, determine how the facility resolves individual complaints and allegations of abuse, mistreatment and neglect. While no specific system is required, 42 CFR 483.420(d)(4) does require that the results of all investigations are reported to the administrator and are reported in

accordance with State law. The facility, therefore, should have a reproducible mechanism to assure its responsiveness to concerns of individuals and their families. That system must assure prompt detection, reporting, investigation and resolution of complaints and of allegations and occurrences of abuse, mistreatment and neglect and injuries from unknown sources.

Review the facility's system (e.g., accident and injury logs and reports) for any evidence that suggests that individuals are being abused or are vulnerable to abuse and injury. Data that is derived from these reports are important in the event that you find an immediate and serious threat to an individual's health and safety. If you discern any patterns that suggest abuse, follow up on the status and condition of those individuals. Also review investigations completed and those in process to determine that the facility protects individuals from abuse, mistreatment and neglect while the allegation is under investigation. If the State law or regulation requires the facility to report such allegation to other agencies, determine that this occurs.

Conducting this review early in the survey process facilitates any necessary follow-up during later observations, interviews or record reviews of individuals. Use the Interpretive Guidelines and Additional Data Probes at 42 CFR 483.420(a)(5) or W127 for further guidance. If you believe serious and immediate threat to individual's health and safety exists, consult Appendix Q.

VII. TASK 3 - INDIVIDUAL OBSERVATIONS

Upon completion of Task 2, surveyors are to conduct observations of the individuals selected for the sample. DO NOT:

- Conduct a detailed review of individual's records;
- Conduct an inspection tour of the facility's environment; or
- Request facility staff to keep people home from scheduled activities, such as work or day programs.

A. Purpose.--Determine if the necessary relationship between the individual's needs and preferences, and what staff know and do with individuals, in both formal and informal settings throughout the day and evening, is made.

As a result of any observation, the surveyor should be able to determine whether:

- Competent interaction occurs between staff and the individual(s);
- Individuals are given the opportunity to exercise choice and function with as much self-determination and independence as possible; and
- Staff provide the needed supports and interventions to increase skills or prevent loss of functioning.

The primary purpose of the visit to the out-of-home program is to determine whether the individual is receiving services that promote growth and independence and how the residence assures consistent delivery of services. Generally the out-of-home program and residence should be using the same interventions, communication methods, and behavior shaping strategies. If not, determine the justification for the difference in services. For example, if the day program is using physical restraints as an intervention and the home is not, determine the justification for the restraints.

B. Survey Conduct.--Be present when individuals are present. If individuals are in a program other than in the residence, go to that location. Observe each person in the sample in the home environment and in the day

program. Observations across the entire survey (e.g., early morning, afternoon and evening observations) are absolutely essential. One method to conduct observations over this time span is to alter the work day of the survey team members. For example, some members might work from 6:30 a.m. to 3:00 p.m., while others work from 1:00 p.m. to 9:30 p.m.

Schedule your time to observe special training programs that are critical to the individuals' development. Use your observations to determine if individual training is carried out consistently at all appropriate times throughout the day. Observations of meal times, individuals' communication with staff and others, behavior shaping interventions, and routine activities should reflect a consistent pattern of interaction with the individual and demonstrate the staff's knowledge of the individual. Take steps to validate any discrepancies noted. Additional observations within similar situations, locations or activities may be necessary to identify a systemic deficient practice as opposed to a one time occurrence.

Show respect for the individuals' home and their privacy. As a courtesy, alway request permission before entering a bedroom. Do not observe activities in which individuals are undressed unless that observation is essential to your assessment of facility compliance and the information cannot be obtained from other reliable sources. Most information about routine hygiene activities during which individuals are undressed can be obtained through interview of individuals or staff. As a general policy, it is preferable to ask permission to make these types of observations from the individual, or from the staff person who is present if the individual cannot communicate. An individual's request not to be observed while undressed should be honored, when possible. The surveyor does have authority, however, to access information that is essential to determining compliance without asking permission. This authority may need to be exercised in regard to an individual who is undressed, for example, in order to observe for bruises or other signs of injury when it is suspected that the individual is being abused. These observations should be conducted in private, with as little of the body exposed as possible, and with a staff person present. Consent from staff or guardians is not required in order to access information or make observations.

For individuals who are working in competitive employment sites, ask the individual's permission to visit that site. If the individual is unable to communicate, discuss with the staff the advisability of visiting the competitive site. The intent is that the individual is not identified as different from other workers at the site. If the individual works in a restaurant, for example, you may be able to visit as a "customer" to observe the work environment. If an interview with a job supervisor or support person is indicated, attempt to conduct this interview in a private or inconspicuous area. Upon arrival, introduce yourself to the individual and to the staff and explain the purpose of your visit.

C. Observation Procedure.--Initially the surveyor should note the general impressions of the area. Note things such as:

1. General Impressions.--
   - o How are individuals dressed?
   - o What activities are taking place?
   - o What materials and supplies are present?
   - o Is the environment pleasant and conducive to learning? (e.g., odors, noise, furniture, and adequate bathroom facilities)
   - o How many staff are present? How many individuals?
   - o What types of adaptive equipment or assistive devices are used?

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2. Specific Activities and Interactions.--After noting the general setting, the surveyor should begin to focus on the specific activities and interactions. For example:

o Are individuals involved and participating in the activity? Are the activities active or passive? Does the activity appear to have a purpose? Are staff able to explain how the activity is promoting greater independence for each of the individuals present?

o Are there supplies and materials used to assist the individuals? Do individuals use the materials? Do they seem appropriate for the task or activity? Are they appropriate for the individuals?

o What interaction is occurring between staff and individuals? Do the interactions give evidence of respect, dignity? Do staff recognize efforts made by the individuals and provide positive reinforcement?

o Is the number of staff present sufficient for the number of individuals based on the individual needs or the type of activity?

o Are individuals encouraged to make their own choices and decisions? Are they encouraged to complete tasks with as much independence as possible? Are staff doing the activity for the person, or is the person encouraged to do things for him or herself?

o Are any maladaptive behaviors exhibited? How do staff respond?

o Are any individuals ignored or isolated from the activity? If so, what is the reason or justification for this?

3. Individuals in Sample.--The third step of the observation process focuses on the individual(s) in the sample. The surveyor should specifically note:

o What is the appearance of the individual? Is the individual dressed neatly? Does the person appear clean and is his/her hair combed?

o Does the individual exhibit any apparent physical or medical needs? Is the individual over or under weight, edentulous, continent? Does the individual have contractures, vision or hearing impairments?

o What adaptive devices/assistive devices are used? Does the individual use a hearing aid, glasses, plate guard , etc.? Does the device(s) appear to be used correctly?

o How does the individual move about in the environment? Does the individual use a walker, ambulate, move his own wheelchair, etc.?

o How does the person communicate? Does the person talk, use sign or a communication board, make facial expressions or behavioral responses? Do others appear to understand the person's communications?

o What is the person's level of social skill or behavior toward others? What types of interactions occur and with whom? Does the individual exhibit any maladaptive behaviors?

o What are the individual's observed skills relative to the activity or task observed? For example, if observed during dining, does the individual eat without assistance? What utensils

are used? Are applicable skills developed or encouraged during the activity, such as passing food, pace of eating, social conversations? Is the individual receiving any special diet?

o What level of assistance is provided by staff? What types of assistance are used - verbal prompts, gestures, hand over hand?

o Are there any individual needs that are not being addressed? Are staff aware of the observed needs? Is there a reason it is not being addressed?

4. Areas for Further Observation.--The surveyor will then identify areas to which to pay attention during other observations. Those areas may include any supports, interventions or skills that would be expected to occur consistently across settings or any apparent needs, concerns or discrepancies noted during the observation. For example, if the surveyor notes that the individual uses sign language for communication, do all staff working with the individual understand and use sign with him/her? Or if an individual is observed to have good gross motor skills, do staff feed the person or perform other tasks for him/her that your observation indicates the person could possibly do independently? Focus interviews and record review based on concerns, issues, inconsistencies and needs noted from these observation(s).

D. Documentation.--Record your observations. The optional individual observation worksheet (CMS-3070I (10/95)) may be used. If your behavior or presence disrupts the activity being observed, wait five minutes before recording the observation.

VIII. TASK 4 - REQUIRED INTERVIEWS WITH INDIVIDUALS AND/OR FAMILY/ADVOCATE, AND DIRECT CARE STAFF

A. Purpose.--Individuals living in the facility, their families/guardians and advocates, and direct care staff are important sources of information about the receipt of active treatment on a daily basis. Interviews are conducted for two purposes: to determine how the individual perceives the services delivered by the facility, and to clarify information gathered during observations. Only interviews with the individuals, their family members/guardians, advocates, and direct care staff count toward the total number of required interviews (as reflected in the sample chart shown in Section 5B - Sample Size).

B. Interview Procedure.--Start with the individual in the sample and the people most closely associated with the individual's daily program implementation. Use the following hierarchy of sources, to the maximum extent possible, in the order shown:

- Individual;
- Families, legal guardian, or advocate;
- Direct care staff;
- Qualified Intellectual Disabilities Professional (QIDP) and/or professional staff; and
- Managers, administrators, or department heads

Determine from your observations and from the staff how the individual communicates with others. Also determine from the staff the extent of involvement of family members, guardians or advocates with the individuals in the sample. Based on this information, select the individuals from the sample with whom you will conduct more in-depth interviews. Select those individuals who will be able to communicate at least some basic information or those who have actively involved family members, guardians or advocates. Do not exclude from interviews individuals who use alternate means of communication, such as communication boards, sign language, and gestures. Most individuals are able to communicate in some manner. At a minimum conduct the number of in-depth interviews specified in Section V, Task 1B.

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Attempt to obtain the required number of interviews first from individuals and then from family members, guardians or advocates. In the absence of individuals who are able to communicate and active significant others, interview the direct care staff person who works most closely with the individual in order to obtain the required number of in-depth interviews.

The questions and communication method will vary from person to person. For individuals who use a specialized communication method, attempt to begin the interview on a one to one basis. If you find you are unable to communicate with the individual, ask someone familiar with the person to assist you (e.g., a family member or a staff person.) For this individual, pay close attention to how the staff communicates with him or her. If the person uses sign language or a communication board, do staff understand and interact with the individual using the same method? If the person uses gestures, do staff take time to determine his or her needs?

Family members, guardians or advocates may be interviewed at the facility, at a location convenient to both the surveyor and the interviewee, or by telephone. All interviews should be conducted in private locations and scheduled at mutually agreed upon times in order to minimize disruptions to individual, family, or staff activities.

C. Content of In-depth Interviews.--Determine what the facility does to provide individualized services and supports; and how individuals and families participate in service planning and in making choices about matters important to them. Are individuals treated with respect and dignity? Does the facility attempt to help the person set and attain individual goals? Are there consistent opportunities for making choices? When a choice is not an option, how is the individual assisted to understand? For example, if a planned activity is to go to a restaurant for dinner, who chooses the restaurant? Staff or the individuals living in the facility? If one group of people does not want to go, how is this choice accommodated? Is the accommodation based on individual choice, staff convenience, or a reasonable justification if a choice is not an option?

See section D for suggested interview questions. Unless designated to be directed to a certain person, questions are relevant to whomever is being interviewed (individual, family member, advocate or staff person.) Modify the wording of the questions based on the person being interviewed (individual, family member, or staff) and on the communication skills of that individual. For example, you may discover that the person responds better to questions that can be answered "yes" or "no" than to open-ended questions. Be sensitive to signs that the individual is tiring or becoming uncomfortable and either end the interview or continue it at a later time if this occurs. It is not necessary to ask every question in the guide, but do try to ask at least one question from each topic area.

D. Suggested Interview Questions.--If you have not met the person before, begin the interview by explaining who you are and what your role is. To put the person at ease you may want to begin with some general conversation, e.g., about the weather or a special event coming up. At the end of the interview, if you think you may need to discuss or confirm personal information with staff or family, ask the person if it is OK to share that information.

1. Questions Related to Choice and Community Participation (W136, W147, W247):
   - What sorts of things do you like to do for fun?
   - Do you go out to activities or events in the community (like shopping, movies or church)?
   - How often do you do this?
   - How do you get there?

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- Who chooses where you go?
- Do you go to visit family members or take vacations?
- Is there something you would like to do more often?

2. Questions Related to Personal Finances and Possessions (W126, W137):

- Do you earn money on your job (at your day program)?
- What do you like to buy with your money?
- Do you have enough money to buy the things you want or need?
- Does someone help you with spending or saving your money?
- When you go to the store, do you pay for items or does a staff person pay for them?
- Do you have enough clothes and shoes?
- Do you always have enough deodorant and toothpaste, etc.?
- What do you do if you need to buy something?

3. Questions Related to Personal Relationships and Privacy (W129-W130, W133, W143 -W148):

- Do you have family or friends who visit you?
- Does your family write to you or telephone you?
- Does someone help you read their letters/ call them on the phone?
- If you feel like being alone or spending private time with a friend or family where do you go?
- Do staff knock on your door before they come into the room?

For family member/advocate:

- How do you learn about things like the services your family member receives, an illness or a change in medication?
- Are there any restrictions on when you visit your family member or where you can go within the home?

4. Questions Related to Individual's and Family's Participation in the IPP Process (W209, W247):

- Do you go to (team) meetings with the staff where they talk about the services you get?
- Does your family/advocate come to these meetings?
- Were you asked if the date and time of the meeting were OK with you?
- What would you like to learn to do for yourself?
- Do the staff ask you what you want?
- Who chooses what you do?
- Does the staff listen to you and make changes based on what you want?

For staff:

- How do you communicate with this individual?
- What does (s)he like and dislike? How do you know that?

5. Questions Related to Service Delivery (W242, W249, W436):

- What help do you need from staff to dress, eat, bathe, etc?

- Do you get any special therapy (e.g., speech or physical therapy)?
- What new things are you learning to do?
- What chores do you help with around the house?
- Who helps you when you do not know how to do something?
- What special equipment do you use?

6. Questions Related to Individual's Rights and Protections: W124-W125, W127, W153-W157, W127-W128, W263:

- Who do you tell if you do not like something, or something is wrong?
- Are there rules that everyone who lives here must follow?
- What sorts of things are you allowed to do or not do?
- How does the staff treat you?
- Are staff loud?
- Does staff yell, swear or hit?
- Do you ever do things you are not supposed to do? What happens then?
- Were you ever asked to give consent for any treatments or services?
- Were you told the benefits, risks and alternatives?

7. Questions Related to Health Status (W322, W356):

- How often do you see a doctor? A dentist?
- Do you have any health problems?
- Do you take any medicines? Do you know what they are for?

8. Wrap-up Questions:

- Is there anything you especially like about living here? Anything you especially dislike?
- Is there anything else you think I should know about what it is like to live here?

E. Interviews to Clarify Observations.--In the absence of finding appropriate interaction between staff and individuals during observations, it may be necessary to judge whether or not staff are knowledgeable about individual objectives and techniques for implementation of programs. If possible, interview staff following the interval in which the individual was observed with the particular staff member. (For example, if you have just observed Individual A engaging in stereotypical behaviors, ask: "Can you tell me what, if anything, you do when he rocks back and forth?") Ask questions that elicit information about how staff learn what to do with individuals across the spectrum of support and programming activities they are expected to perform. Ask professional staff questions to see if they know how to implement programs for an individual other than their professional discipline (e.g., how to carry through with a behavior program in the midst of communications training).

Ascertain whether the staff are competent to carry out the individual's choices and skill development activity. Is there evidence that programs are in fact being carried out throughout the individual's waking hours? Are interventions revised based on changes in the individual's progress toward goals? If staff cannot demonstrate the skills necessary to implement the individual's programs and choices, if interventions are not being carried out consistently, or if revisions to interventions do not occur, you have findings that active treatment is not being delivered.

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E. Documentation.--Record each interview you conduct with individuals, staff, consultants, off-site day program staff, legal guardians, etc., in your personal notes or on the optional observation worksheet (CMS-3070I). Include the following information in your notes for each interview:

- Date and time of interview;
- Job title and assignment at the ICF/IID;
- Relationship to the individual or reason for the interview; and
- Summary of the information obtained.

IX. TASK 5 - DRUG PASS OBSERVATION

Observe the preparation and administration of medications to individuals. With this approach, there is no doubt that the errors detected, if any, are errors in drug administration, not documentation. Follow the procedure in the interpretive guidelines at W369 for conducting the drug pass observation. Notes on observations of the drug pass may be recorded on Form HCFA-677 (LTC Medication Pass Worksheet) or in the surveyor's personal notes. The purpose of the review is to direct the facility's attention to assuring an error free drug distribution system and away from the paper processes that often do not represent actual errors in medication administration. For the purposes of this task, a "small" facility is one which houses 16 or fewer residents.

X. TASK 6 - VISIT TO EACH AREA OF FACILITY SERVING CERTIFIED INDIVIDUALS

A. Purpose.--By the end of the survey, visit each area of the facility serving certified individuals in order to:

- Ensure that all areas of the facility (including those which are not represented by individuals in the sample) are providing services in the manner required by the regulations.
- Assess generally the physical safety of the environment.
- Assess that individual rights are proactively asserted and protected.

B. Protocol.--After individuals in the sample have been assigned to team members, review the facility's map or building layout. Assign members to visit each remaining residential and on-campus day program site prior to completing the survey. Insure that each area of the facility that is utilized by individuals has been visited. This visit may be done with or without facility staff accompanying you, as you prefer, and subject to their availability. Record your observations in your notes.

Converse with individuals, family members/significant others (if present), and staff. Ask open-ended questions in order to confirm observations, obtain additional information, or corroborate information, e.g., accidents, odors, apparent inappropriate dress, adequacy and appropriateness of training activities. Observe staff interactions with other staff members as well as with individuals for insight into matters such as individual rights and staff responsibilities.

XI. TASK 7 - RECORD REVIEW OF INDIVIDUALS IN THE SAMPLE

A. Introduction.--Do not spend an excessive amount of time looking at fine details in the record review of the selected sample. The purposes are to:

- Verify the applicable information obtained from your observations and interviews;
- Review revisions that have been made to the objectives; and
- Verify that needed health and safety supports are in place.

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Do not review in detail the written training programs that are developed for each individual unless you discover serious differences between the record and your observations and interviews. Review those parts of the record most relevant to your purposes as described below.

B. The Individual Program Plan (IPP).--Identify the developmental, behavioral, and health objectives the facility has committed itself to accomplish during the current IPP period. Identify what, if any, behavioral strategies (e.g., behavior modification programs, use of psychotropics) are being used with individuals in your sample. Determine what, if any, health or other problems might interfere with participation in program services.

C. Program Monitoring and Change.--Skim the most recent interdisciplinary team review notes to identify what revisions were made to the IPP. Determine whether revisions were based on objective measures of the individual's progress, regression, or lack of progress toward his/her objectives.

D. Health and Safety Supports.--Verify, either through the interdisciplinary team review notes or through the most recent nursing notes, that the individual has received follow-up services for any health or dental needs identified in the IPP and check the person's current drug regimen. For individuals with whom restrictive or intrusive techniques are used, verify that the necessary consents and approvals have been obtained.

If this information is consistent with your observations and interviews, conclude the record review. If discrepancies are found, conduct further observations or interviews as needed to verify your findings.

XII. TASK 8 -TEAM ASSESSMENT OF COMPLIANCE AND FORMATION OF THE REPORT OF ICF/IID DEFICIENCIES

A. General.--The Survey Report Form (CMS-3070H) is composed during the pre-exit conference and contains the negative findings that contribute to a determination that an ICF/IID requirement is "not met." Meet as a team, in a pre-exit conference, to discuss the findings and make conclusions about the deficiencies, subject to additional information provided by facility officials. Review the summaries/conclusions from each task and decide whether further information and/or documentation is necessary. Ask the facility for additional information or clarification about particular findings, if necessary. Consider information provided by the facility. If the facility maintains that a practice in question is acceptable, request reference material or sources that support the facility's position.

B. Team Assessment of Compliance.--During the pre-exit conference, the survey team reviews each survey tag number reviewed during either the fundamental, extended or full survey, and comes to a consensus as to whether or not the facility complies with each requirement. The team reviews all data collected. For each standard determined to be not met, record salient findings on the CMS-3070H. With the exception of the Life Safety Code Survey, compliance decisions are not made by individual surveyors when more than one surveyor has conducted the survey.

C. Analysis.--Analyze your findings relative to each requirement reviewed during either the fundamental, extended or full survey for the degree of severity, frequency of occurrence and impact on delivery of active treatment or quality of life. The threshold at which the frequency of occurrences amounts to a deficiency varies. One occurrence directly related to a life-threatening or fatal outcome can be cited as a deficiency. On the other hand,

a few sporadic occurrences may have so slight an impact on delivery of active treatment or quality of life that they do not warrant a deficiency citation.

The interpretive guidelines contain two types of guidance designed to assist the survey team in analyzing their findings and making consistent compliance decisions:

1. Facility Practice Statements.--The purpose of facility practice statements is to clarify the information that is relevant to specific requirements, and to increase the survey focus on outcomes for individuals. Facility practice statements are provided for those requirements which experience has shown, are difficult to interpret. The practice statements are not necessarily all inclusive, but rather represent the practices most commonly associated with compliance for specific requirements. Each facility practice statement relates directly to the language of the requirement to which it applies. Positive outcomes identified by the practice statements should be observed in operation in the facility during the survey. When the team's negative findings indicate that a practice is not present, a citation of the requirement may be appropriate, depending upon the frequency and the severity of those findings. Use the practice statements during the pre-exit conference to assist the team in analyzing negative findings and determining the appropriate requirement at which to cite negative findings. When stated in the negative, facility practice statements may form the basis for a citation on the CMS-2567.

2. Condition Level Compliance Principles.--The purpose of the compliance principles is to assist in consistent decision-making about facility compliance at the Condition of Participation level. The primary focus of those decisions is placed on the outcomes to the individuals and their actual experiences of daily life. At each Condition of Participation, the guidelines contain compliance principles which identify those outcomes that must be present in order for the Condition to be found "met," and those outcomes that indicate the Condition is "not met." The compliance principles are based on the requirements which fall under the Condition. This guidance is NOT to replace professional surveyor judgement. It is possible that the surveyor may encounter a situation which is not covered by the compliance principles, however, such instances are expected to be rare. In the event the survey team makes a determination that the Condition is "not met," and the situation causing that determination is not identified in one of the "not met" compliance principles, notify CMS's Central Office in writing within 10 days after the completion of the survey for purposes of review, possible dissemination to other surveyors, and to ensure consistency within the survey process.

Some of the compliance principles for the Conditions of governing body, facility staffing and physical environment reference other Conditions. Governing body, facility staffing and physical environment tend to address organizational processes which support the provision of active treatment, protection of rights and adequate health and dietary services. Therefore, the governing body, facility staffing and physical environment Conditions are usually "met" unless it is first determined that there are serious deficiencies in services or protections which fall under one or more of the other areas.

After the survey team reviews its positive and negative findings for the requirements within a particular Condition of Participation and determines which of those requirements are deficient, examine the findings for that Condition as a whole. When analysis of these findings leads the team to conclude that each of the "met" compliance principles for that Condition is present, then the facility is in compliance with that Condition. When analysis

of the standard level deficiencies viewed as a whole, leads the team to conclude that one or more of the "not met" compliance principles for that Condition is present for one or more individuals or situations, consider the frequency and the severity of the negative finding(s) in relation to the applicable "not met" compliance principle(s) in order to determine whether Condition level noncompliance is warranted.

D. Composing the Report of ICF/IID Deficiencies (CMS-3070H/(10/95)).--
During the pre-exit conference, the survey team records on the CMS-3070H those requirements that are determined to be deficient and the findings which support that determination. Write the deficiency statement in terms specific enough to allow a reasonably knowledgeable person to understand the aspect(s) of the requirement(s) that is (are) not met. Do not delve into the facility's policies and procedures to determine or speculate on its root cause, or sift through various alternatives to prescribe an acceptable remedy. Indicate on the CMS-3070H the data prefix tag, followed by a summary of the deficient facility practice(s). Briefly identify the supporting findings for each deficiency (i.e., transfer to the CMS-3070H the identifier numbers of all individuals to whom the deficient practice applies.) It is not necessary to write a full description of the findings on the CMS-3070H since they will be described in more detail on the completed Statement of Deficiencies (CMS-2567). It is necessary to complete the CMS-3070H for each survey because the CMS-3070H is the only document in which the survey team's recommendations for deficiencies are recorded (which may be changed later on the final CMS-2567 as a result of supervisory review) and because not all individual examples may be used on the CMS-2567. Instructions for the CMS-3070H are found on page J-18.6.

Alternatively, when the survey team enters its findings directly into a computerized system such as Automated Survey Processing Environment during the pre-exit conference, the statement of deficiencies (CMS-2567) that is generated onsite at the facility may be substituted for the CMS-3070H. The CMS-2567 generated onsite then must contain the information required for the CMS-3070H and must be clearly marked "DRAFT - SUBJECT TO STATE AGENCY REVIEW" on each page.

XIII - ADDITIONAL SURVEY REPORT DOCUMENTATION (FOR THE FILE)

Upon the completion of each survey, the team leader completes the following additional documentation. This information remains at the survey agency with the CMS-3070G-H (10/95) in the official file:

A. Summary Listing of all ICF/IID Individuals Comprising the Survey Sample (include any additional individuals added to the sample).--At a minimum, identify:

- The name or Medicaid number of each individual chosen to be part of the sample;

- Any individual identifier codes used as a reference to protect the individual's confidentiality; and

- The reason for including the individual in the sample (e.g., "Random Program Audit," "Discharge," "New Admission," "Death," "Abuse Investigation", "Drugs to Control Behavior"). This listing serves as a future reference to any individual identifiers recorded in surveyors' notes, the CMS-3070G-I, and the CMS-2567.

B. Description of the Representative Sample Selection.--At a minimum, identify, at the time of the survey:

- How the sample was selected;

o What was the percentage occurrence of each functional level of mental retardation in the facility's overall population;

o The distribution of the individuals in the sample across the facility's living units;

o The number of people in the sample;

o The number, if any, of individuals substituted in the sample, and the reason; and

o Any other characteristic of individuals served that was specifically introduced into the sampling process and the reason.

C. Summary of Individual Observations.--Include all individual observation worksheets (CMS-3070I) and any surveyor notes containing information regarding observations. These notes should include the dates, locations, and starting and ending times for each observation.

D. Summary of Interviews.--Include all surveyor notes containing information obtained during interviews with individuals, families, guardians, direct care staff, QIDPs, professional staff or consultants, administrators and managers, and others. These notes should identify the person interviewed by name or position, and date and time of interview.

E. Drug Pass Worksheets (CMS-677) or Surveyor Notes of the Drug Pass Observation

F. Other Relevant Facility Data.--Include other salient data used in support of the survey findings with the CMS-3070G-H (10/95) (e.g., photographs, affidavits). The survey agency's documentation of the justification for the decision to conduct a full survey must be maintained in the survey agency's file.

XIV. COMPLETING THE REVISED CMS-3070-G-I (10/95) ICF/IID SURVEY REPORT FORM (SRF)

Part 1 (3070G): This is the cover sheet for the ICF/IID SRF which summarizes data relative to: facility characteristics; description of the individual population served; special needs represented by that population; and essential characteristics of the survey conducted. Portions of this information are entered into the Onsite Survey and Certification Automated Reporting (OSCAR) System and used to review trends about the ICF/IID program nationwide.

General Instructions:

1. Complete all portions of Part 1 onsite, preferably during the first day of the survey. Work with the facility to complete the form according to these instructions and to ensure accurate information is obtained prior to leaving the facility.
2. If a number is requested (e.g., No. of beds, No. of individuals), and the answer is NONE or ZERO, enter a "O" in the space provided.

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3. If a box is provided to "check one" of the answers provided, enter a check mark.
4. Abbreviations used: "CEO" means Chief Executive Officer; "QIDP" means Qualified Intellectual Disabilities Professional; "ID" means intellectual disability; "No." means number.
5. Regulatory references on the form refer to regulations found in the Code of Federal Regulations, and refer to regulations applicable to ICFs/IID.
6. Review all portions for accuracy prior to leaving the facility.

Specific instructions:

Blocks 1-10, 13-14: Enter identifying data, as requested.

Block 11: Enter the dates of the first and last days of the survey (even if there is a break in survey days).

Block 12: Enter the number describing the ownership/control type in the box marked "W6." If "other" best describes the facility, specify the other type on the space provided.

Blocks 15 (A-M): (Col. 1): Enter the No. of disciplines that best describe your team's composition. If a surveyor has multiple areas of expertise (e.g., a nurse surveyor who is also a dietitian), include each discipline of expertise. (Col. 2) Enter the No. of disciplines represented on the team which also qualified as a QIDP (as per 42 CFR 483.430(a)(1)(2)(i)-(iii) and 42 CFR 483.430(b)(5) of the ICF/IID Conditions of Participation.

Blocks 15 (N-O): Enter the number, as requested.

Blocks 16 (A-B): A "Yes" indicates that the CEO directs not only the activities of the ICF/IID, but also those of another residential services program (e.g., another ICF/IID; another Medicare/Medicaid Provider that serves individuals with intellectual disabilities regardless of funding source). A "No" indicates that the CEO of the ICF/IID does not direct the activity of another residential services program for persons with ID. If "Yes" was indicated for 16A, identify the name, address and CEO of the larger organization or agency in 16B (could be the same
information for this ICF/IID in Block 7.) Enter the total bed capacity of all residential services for which the CEO is directly responsible (including the ICF/IID bed capacity) in "W14". Do not include beds for which the CEO is indirectly responsible. (For example, in some States the CEO of a State-operated institution is also indirectly responsible for all beds in a region, including those operated by private providers within that region. Do not include beds directly operated by another agency or organization for the purposes of

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W14.) Enter the total No. of individuals residing in the beds (including ICF/IID individuals) in "W15."

Block 16C: Enter the No. as requested.

Block 16 D: A "Yes" indicates that this ICF/IID (i.e., the beds under this provider number) is the only house or apartment at the address stated in Block 2 and is located in close proximity to other houses or apartments occupied by people who are not disabled. A "No" indicates that there is other bed capacity to provide residential services to persons with disabilities at the address stated in Block 2 or that this ICF/IID is surrounded by other buildings or residential units serving people with disabilities.

Block 16 E: Enter the No., as requested.

Block 16 F: Enter the total No. of discrete units. If the ICF/IID encompasses several bldgs, count the total No. of discrete living units within all buildings.

Block 16 G: List the ages of the youngest individual in W20 and oldest in W21.

Block 16 H: Each day's program site included in this number should be located off the grounds or campus of the ICF/IID. Any individual going to this program should be scheduled to attend regularly (at least 3 hrs.a day, 2-5 days a wk.). If the day program provides 2 or more programs at the same address, for purposes of this item, consider it one site.

Blocks 17 (A-D): Enter the full time equivalents (FTEs) for each category listed. For 17A, include only staff who provide direct care services to individuals at their living units. Include direct care supervisors only if they are also responsible to provide direct care as part of their duties. (See 42 CFR 483.430(d).) For 17D, include all personnel, including the No. of direct care and licensed nursing personnel, as well as professional and support staff employed by the facility. To determine FTEs: add the total No. of hrs. worked the week prior to the survey, by all employees identified in each category of 17 (A-D); divide this No. by the No. of hrs. in the standard work week. Express FTEs to the nearest quarter decimal (i.e., ".00", ".25", ".50", and ".75").

Block 18 A: Enter the No. of individuals in the total sample (i.e., the representative sample and any other individuals added to the sample for other reasons.)

Block 18 B: Enter the No. of sites visited in which observations of individuals in the sample were completed.

Blocks 20 (A-L): INDIVIDUAL CHARACTERISTICS: The last date of the survey is the date by which age is determined. The term "Total" No. refers to the No. of ICF/IID individuals fitting the

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characteristic listed who are currently living in the facility.

20 A (1): Enter the total No. of individuals within each age group regardless of sex.

Blocks 20 A (2): Enter the No. of individuals by sex and the total. The total should equal the No. entered in 20 (A)(1), Total (W33).

Blocks 20 (B-C): Enter the total No. of individuals by each characteristic requested; and the total. Count individuals with more than one disability in every applicable column. Use the following definitions:
Autism is a diagnosis whereby the individual exhibits extreme forms of self-injurious, repetitive, aggressive, or withdrawal behaviors; extremely inadequate social relationships; or extreme language disturbances.

Cerebral Palsy is a diagnosed condition whereby gross and fine movements and speech clarity of the individual may be impaired but performance of activities of daily living is functional; or, the individual is unable to perform adequately activities of daily living such as walking, using hands, or using speech for communication.

Mental retardation levels (mild, moderate, severe, and profound) are described in the American Association on Mental Deficiency's Manual on Classification in Mental Retardation (1983 edition).

Nonambulatory means unable to walk independently.

Mobile nonambulatory means unable to walk independently, but able to move from place to place with the use of such devices as walkers, crutches, wheelchairs, and wheeled platforms.

Nonmobile means unable to move from place to place.

Epilepsy means a neurological disorder characterized by seizures of motor and sensory movements.

Hard of Hearing means able to hear speech, including with amplification.

Deaf means unable to hear speech, even with amplification.

Impaired vision means able to see objects, with correction.

Blind means unable to see objects.

Blocks 20 (D-K): Enter the total No. of ICF/IID individuals who have the following care needs or characteristics: Medical Care Plan (i.e., requires 24 hour licensed nursing care as defined at
42 CFR 483.450(a)(2)); Drugs to Control Behavior (42 CFR 483.450(b)(1)(iv)(C); Restraints
(42 CFR 483.450(b)(1)(iv)(B);Time-out rooms (42 CFR

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483.450(b)(1)(iv)(A); Application of Painful or Noxious Stimuli (42 CFR 483.450(b)(1)(iv)(D); Attend Off-Campus Day Programs; Court Ordered Admissions; and the No. Over Age 18 with a Legally Appointed Guardian.

Block 20 L:

If the facility or you believe that a particular individual or program characteristic that describes the population has not been requested on this form, identify it, programs provided, etc., in the space provided. Enter the total Nos. of individuals having this characteristic.

Part 2 (3070-H):

REPORT OF DEFICIENCIES
Use this part in conjunction with the regulation text and interpretive guidelines. Include basic information on non-compliance. Complete the report during the pre-exit conference for all surveys. Record all deficiencies found during the survey. Sign it, certifying that all other facility requirements not documented as deficiencies, are in compliance.

Evaluate each discrete requirement identified by a tag number in the ICF/IID Interpretive Guidelines. For each identified deficiency:
o In the first column, identify the data tag number;
o In the second column, write the standard number. If it is a Condition of Participation, enter "CoP" below the standard number.
o Identify the deficient facility practice, findings and evidence in the "Comments" column.
o Draw horizontal lines to separate identified tag numbers.
o Use as many sheets as needed.
o Each surveyor must sign the appropriate certifying statement on the last page of Part 2.

Part 3 (3070-I):

INDIVIDUAL OBSERVATION WORKSHEET
Part 3 of the SRF is an optional worksheet that may be used to record and structure observations so that individual data relative to compliance with the statutory active treatment requirement are available for analysis and retrieval. This is completed for each observation as follows:

Heading: Enter requested names, locations, codes, times and dates. Enter "individual codes" only if individuals in the sample are present.

Column 1 - Time: Enter the time of discrete observations or consecutive time intervals.

Column 2 - Observation: Include the information specified in Section V-B of this Appendix for each observation (e.g., number of individuals; number of staff; activity in progress).

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SURVEY PROCEDURES
INTERMEDIATE CARE FACILITIES FOR INDIVIDUALS WITH INTELLECTUAL DISABILITIES

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	§440.150 Intermediate care facility services, other than in institutions for mental diseases.	
W100	(c)"Intermediate care facility services" may include services in an institution for the mentally retarded (hereafter referred to as intermediate care facilities for individuals with intellectual disabilities) or persons with related conditions if- - (1) The primary purpose of the institution is to provide health or rehabilitative services for individuals with intellectual disabilities or persons with related conditions; (2) The institution meets the standards in Subpart E of Part 442 of this Chapter; and (3) The intellectually disabled recipient for whom payment is requested is receiving active treatment as specified in §483.440.	§440.150(c) FACILITY PRACTICES: The facility is in compliance with the Condition of Participation at W195, i.e., individuals are in need of and receiving active treatment. §440.150(c) GUIDELINES: The statutory and regulatory use of the word "institution" includes settings that serve four or more people with intellectual disabilities and/or related conditions. See §435.1009 for definition of "persons with related conditions." The presence or absence of an individual requiring a medical care plan, as defined at W320, is not salient in the determination of whether a facility is eligible to participate in the ICF/IID program.
*	W101 is reassigned to §483.410(e). Section 442.251, the standard which requires that facilities meet the requirement for a State license, is redesignated to §483.410(e) and W101 is reassigned as well to afford a sense of continuity.	

INTERPRETIVE GUIDELINES - INTERMEDIATE CARE FACILITIES FOR INDIVIDUALS WITH INTELLECTUAL DISABILITIES

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W102	§483.410 Condition of participation: Governing body and management.	§483.410 COMPLIANCE PRINCIPLES: The Condition of Participation of Governing Body is met when each of the other Conditions of Participation are also met. The Condition of Participation of Governing Body is not met when: o One or more of the other 7 Conditions of Participation have first been determined to be not met, and the governing body has failed to take action that identifies and resolves systemic problems of a serious and recurrent nature; or o The facility has been denied any license or approval required by Federal, State or local law by the authority having jurisdiction for that law.
	(a) Standard: Governing body.	
W103	The facility must identify an individual or individuals to constitute the governing body of the facility.	
	The governing body must- -	
W104	(1) Exercise general policy, budget, and operating direction over the facility;	§483.410(a)(1) FACILITY PRACTICES: The governing body provides, monitors, and revises, as necessary, policies and operating directions which ensure the necessary staffing, training resources, equipment and environment to provide individuals with active treatment and to provide for their health and safety. §483.410(a)(1) GUIDELINES: The responsibility for direction includes areas such as health, safety, sanitation, maintenance and repair, and utilization and management of staff, especially when problems in these areas are of a serious or recurrent nature. Condition level deficiencies (other than the Governing Body Condition) or repeat, pervasive patterns of deficiencies at the Standard level may be an indication that the governing body is not providing sufficient operating direction over the facility. When a pattern of serious or repeated deficiencies is identified during the survey, interview the administrator or review the minutes of governing body meetings, if available, to determine whether or not the governing body has identified and addressed the problem. Staff who have been trained, but are not implementing programs or are inappropriately deployed (e.g., there are enough staff but they are assigned to duties like record keeping which prevents them from delivering needed services), may indicate a failure of the governing body to adequately direct the staff's activities.

INTERPRETIVE GUIDELINES - INTERMEDIATE CARE FACILITIES FOR INDIVIDUALS WITH INTELLECTUAL DISABILITIES

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W105	(2) Set the qualifications (in addition to those already set by State law, if any) for the administrator of the facility; and	
W106	(3) Appoint the administrator of the facility.	
	(b) Standard: Compliance with Federal, State and local laws.	
	The facility must be in compliance with all applicable provisions of Federal, State and local laws, regulations and codes pertaining to	§483.410(b) FACILITY PRACTICES: The facility has received no adverse action(s) by the Federal, State or local authority having jurisdiction in these areas. The facility is in compliance with W101, W105, W153, W156, W170, W265, W328, W345, W370 and W374. §483.410(b) GUIDELINES: Licenses, permits, and approvals of the facility must be available to you upon request. Current reports of inspections by State and/or local health authorities are on file, and notations are made of action taken by the facility to correct deficiencies. Some State or local laws are more stringent or prescriptive than the Federal Medicaid requirement on the same issue. Failure of the facility to meet a Federal (i.e., non-Medicare or Medicaid), State or local law may be cited only when the authority having jurisdiction (AHJ) has both made a determination of non-compliance and has taken a final adverse action. An adverse action is defined as any procedure that goes beyond the approval of a plan of correction, such as a civil money penalty, ban on admissions, denial of payment, or loss of license, and is not under appeal by the provider. The AHJ is the public official(s) having authority to make a determination of noncompliance, and is responsible for signing correspondence notifying the facility of the adverse action. If the you believe you have identified a situation indicating the provider may not be in compliance with a Federal, State or local law, refer that information to the AHJ for follow-up action. If a final adverse action results, then the facility could be found to not meet §483.410(b).
W107	o health,	
W108	o safety, and	
W109	o sanitation.	

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	Standard: Client records.	
W110	(1) The facility must develop and maintain a recordkeeping system that includes a separate record for each client and	
W111	that documents the client's health care, active treatment, social information, and protection of the client's rights.	§483.410(c)(1) GUIDELINES: The structure and content of the individual's record must be an accurate, functional representation of the actual experience of the individual in the facility. This should be identified through interviews with staff and, when possible, with individuals being served, as well as through observations. The regulations do not specify that all information about an individual be located in the individual program plan (IPP) document, only that information explicitly identified in the regulations. The regulations do not prescribe the manner, form or where in the individual's record this information is to be recorded.
W112	(2) The facility must keep confidential all information contained in the clients' records, regardless of the form or storage method of the records.	§483.410(c)(2) FACILITY PRACTICES: The facility has in place sufficient safeguards to ensure that access to all information regarding individuals is limited to those individuals designated by law, regulation, policy, or duly authorized consent as having a need to know. No unauthorized access or dissemination has occurred. §483.410(c)(2) GUIDELINES: "Keep confidential" means safeguarding the content of information including 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, and consistent with the advocate's right of access, as required in the Developmental Disabilities Act. Facility 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 the individual. Confidentiality applies to both central records and information kept at dispersed locations. If there is information considered too confidential to place in the record used by all staff (e.g., identification of the family's financial assets, sensitive medical data), it may be retained in a secure place in the facility (e.g., social worker's locked desk). A notation must be made in the record of the location of confidential information (e.g., "Family information is available from the social worker"). The sharing of individual specific information with members of the "specially constituted committee" required by §483.450(f)(3), who are not affiliated with the agency, does not violate an individual's right to have information about him or

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		her kept confidential. The committee needs to know relevant information to function properly. The facility is allowed the flexibility to work out arrangements with its members to maintain confidentiality.
W113	(3) The facility must develop and implement policies and procedures governing the release of any client information, including consents necessary from the client, or parents (if the client is a minor) or legal guardian.	§483.410(c)(3) FACILITY PRACTICES: The facility has developed the required policies and procedures and follows them. Release of any personally identifiable information does not occur unless appropriate consent(s) is obtained prior to the release. §483.410(c)(3) GUIDELINES: Although one facet of the requirement is that the facility must decide how this is to be accomplished (i.e., policies and procedures), the surveyor's primary focus should be on the second part of the requirement, i.e., the facility's implementation or "outcome" that consent is obtained prior to the release of any individual information (e.g., records, photographs, interviews, or other means of exposure to public view or identification). The following guidance is provided to assist in determining whether informed consent for release of information is adequate: 1. Was the confidential information to be released specifically identified? 2. Was the person or agency to whom the information was to be released identified to the consenting party? 3. Was the consent time-limited (i.e., include the date the consent was given, and the date which the specific consent would be invalid)? 4. Was the person giving consent legally able to give consent? Information regarding an individual's HIV status may not be released without specific consent and may not be in the record if that consent has not been given. Staff are expected to use universal precautions when dealing with all individuals, therefore, it is unnecessary to routinely share information about HIV status with all staff. Under some conditions, knowledge may be shared with those directly involved in the care of infected persons. Surveyors should be familiar with State law requirements.
W114	(4) Any individual who makes an entry in a client's record must make it legibly, date it, and sign it.	§483.410(c)(4) GUIDELINES: In cases in which facilities have created the option for an individual's record to be maintained by computer, rather than hard copy, electronic signatures are acceptable. Given the large number of entries that are made in individual's records, this requirement is cited only when a systemic problem is identified.

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W115	(5) The facility must provide a legend to explain any symbol or abbreviation used in a client's record.	
W116	(6) The facility must provide each identified residential living unit with appropriate aspects of each client's record.	§483.410(c)(6) FACILITY PRACTICES: The staff of the residential living unit has, and can access, all information which is relevant to implementing individual program plans, appropriate care of, interaction with, and provision of services for the individual. §483.410(c)(6) GUIDELINES: "Appropriate" means those parts of each individual's record most likely (or known) to be needed by the residential staff to carry out the individual's active treatment program in the unit, to alert staff to health risks and other aspects of medical treatment, to support the psychosocial needs of the individual, and anything else necessary to the staff's ability to work on behalf of the individual.
	(d) Standard: Services provided under agreements with outside sources.	
W117	(1) If a service required under this subpart is not provided directly, the facility must have a written agreement with an outside program, resource, or service to furnish the necessary service, including emergency and other health care.	§483.110(d)(1) GUIDELINES: Federal statute (P.L. 94-142) requires all school-aged children to receive a free and appropriate school education. Therefore, a written agreement between ICFs/IID and public schools is not necessary.
	(2) The agreement must- -	
W118	(i) Contain the responsibilities, functions, objectives, and other terms agreed to by both parties; and	
W119	(ii) Provide that the facility is responsible for assuring that the outside services meet the standards for quality of services contained in this subpart.	

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		§483.410(d)(2)(ii) GUIDELINES: Outside providers of day services would not have to meet certain requirements relating to physical environment under §§483.470 (a)-(g), (j), and (k) unless that source also provides living quarters for ICF/IID individuals. Outside sources must, of course, meet any applicable State and local requirements. The facility's responsibility includes assuring that any restrictive techniques proposed for use by outside service providers are used only when warranted and with the required safeguards and approvals.
W120	(3) The facility must assure that outside services meet the needs of each client.	§483.410(d)(3) FACILITY PRACTICES: Outside service providers meet the needs of each individual as identified by the interdisciplinary team. Programs and services are coordinated/integrated and consistent with those provided by the facility. §483.410(d)(3) GUIDELINES: "Assure" means that the facility's staff actively participate with staff in outside programs in the assessment process and in development of objectives and intervention strategies. For example, if a public school is implementing a manual communication system with an individual, the direct care staff in the individual's living unit should have instructions to implement the program in the residential environment. Likewise, if the facility is implementing a behavior management program for the individual, it should be shared with and implemented as needed by the outside program. This communication is often difficult, but nevertheless essential to the provision of active treatment. §483.410(d)(3) PROBES: Is there evidence of shared communication, program planning and implementation, and problem solving? Is there a relationship among the objectives, data, techniques, etc., within the programs or services delivered? Does the facility periodically observe services that are provided by the outside resource?
W121	(4) If living quarters are not provided in a facility owned by the ICF/IID, the ICF/IID remains directly responsible for the standards relating to physical environment that are specified in §483.470(a) through (g), (j) and (k).	§483.410(d)(4) GUIDELINES: Even though the facility's premises may be rented from a landlord, the facility must ensure that the requirements for physical environment are met, either through arrangement with the landlord or through the facility's own services.

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	(e) Standard: Licensure.	
W101	The facility must be licensed under applicable State and local law.	§483.410(e) FACILITY PRACTICES: The facility has a current, valid State license when required under State law.

INTERPRETIVE GUIDELINES - INTERMEDIATE CARE FACILITIES FOR INDIVIDUALS WITH INTELLECTUAL DISABILITIES

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W122	§483.420 Condition of participation: Client protections.	§483.420 COMPLIANCE PRINCIPLES: The Condition of Participation of Client Protections is met when: o Individuals are free from abuse and neglect; o Individuals are free from unnecessary drugs and restraints; and o Individual freedoms are promoted (e.g., individuals have choice and opportunities in their money management, community involvement, interpersonal relationships, daily routines, etc.). The Condition of Participation of Client Protections is not met when: o Individuals have been abused, neglected or otherwise mistreated and the facility has not taken steps to protect individuals and prevent reoccurrence; o Individuals are subjected to the use of drugs or restraints without justification; or o Individual freedoms are denied or restricted without justification (e.g., systemic lack of privacy, of freedom of access to the community or to other individuals, in use of personal possessions and money, etc.). §483.420 GUIDELINES: A citation of W127 or W150, which require that individuals are not subjected to verbal, sexual, or psychological abuse or punishment, is sufficient justification that the facility has failed to comply with the most fundamental of protections and, therefore, does not comply with this Condition of Participation.
	(a) Standard: Protection of clients' rights.	§483.420(a) GUIDELINES "Ensure" means that the facility actively asserts the individual's rights and does not wait for him or her to claim a right. This obligation exists even when the individual is less than fully competent and requires that the facility is actively engaged in activities which result in the pro-active assertion of the individual's rights, e.g., guardianship, advocacy, training programs, use of specially constituted committee, etc.
	The facility must ensure the rights of all clients. Therefore, the facility must- -	
W123	(1) Inform each client, parent (if the client is a minor), or legal guardian, of the client's rights and the rules of the facility;	§483.420(a)(1) FACILITY PRACTICES: Individuals and their representatives, if applicable, are aware of the individual's rights and the rules of the facility. Information has been provided to the individual and their representatives, if applicable, in terms and language they understand. Individuals who are unable to understand their rights have family members, legal guardians or advocates who are involved in protection of their rights. §483.420(a)(1) GUIDELINES: The obligation to inform requires that the facility present information in a manner and form which can be understood, e.g., use of print materials, specialized programs to inform individuals who are deaf or blind, use of interpreters, etc.

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		§483.420(a)(1) PROBES: How does the facility determine if an individual can or cannot understand his/her rights? How does the facility inform staff, individuals, parents and/or guardians , or non-English speaking individuals of rights (e.g., use of printed materials, specialized programs to inform deaf and/or blind individuals, informal conferences)? To what extent has the question of advocacy been raised if individuals do not have family members? If individuals have family members who do not wish to have contact made with them? If the individual does not want the family to participate in decision making? What manner of assistance is provided once a decision is made that an individual has a need for advocacy, guardianship, or protective services?
W124	(2) Inform each client, parent (if the client is a minor), or legal guardian, of the client's medical condition, developmental and behavioral status, attendant risks of treatment, and of the right to refuse treatment;	§483.420(a)(2) FACILITY PRACTICES: Individuals and their representatives, if applicable, are aware of the individual's medical condition and treatment, therapies, services and other treatment or prescribed approaches being received, the reason for their use, as well as any risks involved in those treatments or approaches. Individuals and their representatives, if applicable, understand the alternatives to proposed treatments, that they can refuse treatment, and the possible consequences/ alternatives to such refusal of treatment. §483.420(a)(2) GUIDELINES: The term "attendant risks of treatment" refers to all treatment, including medical treatment. An individual who refuses a particular treatment (e.g., a behavior control, seizure control medication or a particular intervention strategy) must be offered information about acceptable alternatives to the treatment being refused, if acceptable alternatives are available. The individual's preference about alternatives should be elicited and considered in deciding on the course of treatment. If the individual also refuses the alternative treatment, or if no alternative exists to the treatment refused, the facility must consider the effect this refusal may have on other individuals, the individual himself or herself and the facility, and if it can continue to treat the individual consistent with these regulations. Thus, every effort must be made to assist the individual to understand and cooperate in the legitimate exercise of the IPP. An individual being considered for participation in experimental research must be fully informed of the nature of the experiment (e.g., medication, treatment) and understand the possible consequences of participating or not participating. The individual's written consent must be received prior to participation. For an individual who is a minor or who has been adjudicated as incompetent, the written informed consent of parents of the minor or the legal guardian is required. The determination as to whether the individual was sufficiently "informed" is based on

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		the following: 1. Was the individual aware of the proposed program or treatment, the procedures to be followed, and the identification of the person who will perform the treatment activity? 2. Was the individual aware of the intended outcome or benefits of the proposed program or treatment? 3. Was the individual aware of the possible risks, including side effects and attendant discomfort of the proposed program or treatment, and the steps to be taken to minimize risk? 4. Was the individual aware of the ramifications if he or she decided not to participate, and of the alternatives to the proposed activity, particularly alternatives offering less risk or adverse effects? 5. Did the individual participate voluntarily? Did the individual have the opportunity to have questions about the activity answered? 6. Was the information about the activity presented in language that could be readily understood by the individual? Additionally, for experimental, invasive or potentially harmful treatment, activities or procedures for which written informed consent is recommended, if not otherwise required by State or Federal law: 1. Was the consent time-limited (i.e., include the date the consent was signed and the date it becomes invalid)? 2. Did the individual realize that consent to participate could be withdrawn at any time without risk of punitive action? 3. Was the person who gave consent the legally appropriate party to do so for the individual? §483.420(a)(2) PROBES: How does the facility inform the individual/parent/guardian of the individual's condition, and of other significant events (e.g., through written correspondence, phone calls, informal conferences, in native language, in a timely manner)? Is there correspondence in the record informing the appropriate guardian of the individual's condition? Is there evidence of informed consent when needed? Are alternative treatment procedures made available for those who refuse specific treatment? What kinds of treatments do individuals refuse (if any)? Why? How does the facility respond to refusals? How does the facility ensure that the concept of informed consent has been taught to individuals, including the ramifications of refusal of treatment? Is there evidence that appropriate people are informed of benefits and risks of treatments, including psychoactive drugs?

INTERPRETIVE GUIDELINES - INTERMEDIATE CARE FACILITIES FOR INDIVIDUALS WITH INTELLECTUAL DISABILITIES

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		What does the facility do when individuals show consistent patterns of refusal of treatments or programs?
W125	(3) Allow and encourage individual clients to exercise their rights as clients of the facility, and as citizens of the United States, including the right to file complaints, and the right to due process.	§483.420(a)(3) FACILITY PRACTICES: Individuals are taught and encouraged to claim and exercise their rights. A personal advocate or legally sanctioned surrogate decision-maker has been identified, when appropriate, and is encouraged to assist/support the individual in exercising these rights. Individuals and their representatives, if applicable, are aware of how to file a complaint and are free from reprisal when they do so. Individuals have the opportunity to register to vote and are taught skills to assist them in exercising this right. §483.420(a)(3) GUIDELINES: The facility must ensure protection of the individual from any form of reprisal or intimidation as a result of a complaint or grievance reported by an individual. As long as there are no decisions or circumstances which require action by a legally- appointed surrogate, a spokesperson or advocate could assist the individual in exercising his or her rights as a citizen of the United States and as a person residing in the facility. Some examples might include assisting the individual to express his/her needs, wants and interests, to utilize community resources or to file a complaint. A spokesperson might also express opinions regarding situations in which consent by the beneficiary, parent of a minor, or legal guardian is required in order to bring to the attention of the facility potential concerns or problems. The extent to which any person can act on behalf of another individual who has been assessed as needing a guardian, however, is entirely dependent upon the needs of the individual client and upon the laws and regulations of the State in which that individual resides. The facility and surveyor must be familiar with the laws and regulations of the State in which the facility is located. It is inappropriate for the facility to unofficially delegate the individual's rights to others (e.g., parents, family, advocacy groups, etc.) To the extent that the individual is able to make decisions for himself or herself, it is inappropriate to delegate the person's rights to others. Individuals who need guardianship or advocacy, and do not have this need addressed, are not prepared to exercise their rights as citizens of the United States. The facility's failure to ensure guardianship or advocacy for those who need it should be cited. Further deficiencies may also be cited under W123, W124, W143, and W263, depending upon the survey findings.

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		§483.420(a)(3) PROBES: How are individuals prepared to exercise their rights? Are provisions made for all individuals to assert their rights including those with mobility, sensory and communication impairments? Can staff explain individual rights and how they facilitate individual exercise of rights? Do individuals use advocacy systems? Are there established individual grievance procedures? Are advocates given access to the individual and his/her records, as appropriate, consistent with the Developmental Disabilities Assistance and Bill of Rights Act, as amended? Are rights that are modified or limited specific, general, or blanket? Are they reviewed to ensure continued appropriateness to the individual? What ways show that individuals assert their rights (e.g., do they vote, self-advocate, participate in self-governance council, participate in citizenship training, participate in community political activities)? What type of complaints do individuals report (if any) and how well does the facility respond? When interviewing individuals, do they describe situations which demonstrate the exercising of their rights? On what basis does the facility accept, or not accept, an individual's informed choice? In what manner is due process ensured? How does the team fit into this process?
W126	(4) Allow individual clients to manage their financial affairs and teach them to do so to the extent of their capabilities;	§483.420(a)(4) FACILITY PRACTICES: Individuals receive instruction (either as part of a formal program or a more general, informal series of activities) on handling their money which is geared to the individual's functional level. Individuals have opportunities to hold and manage their own money to the maximum extent of their capabilities. §483.420(a)(4) GUIDELINES: Since the use of money is a right, determine if the facility demonstrated, based on objective data, that the individual was unable to be taught how to use money before the decision was made to restrict that right.

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		§483.420(a)(4) PROBES: How many individuals does the facility report manage their own funds? Through interview and observation of staff and individuals served, are there individuals who are able to manage their own money with assistance, if needed? Are individuals allowed to spend funds as they choose? Are there spending opportunities? Do they have cash? Does staff, in fact, make financial decisions for use of individual funds which the facility reports are managed by the individual? Do staff work closely with particular individuals to participate in decisions about spending their money? For those individuals who manage their financial affairs, are they knowledgeable of their income source and amount? What evidence is manifest by individuals that they know what to do with personal finances? To what extent do individuals know how to conduct bank transactions? How are individuals paid? Cash? Check? Vouchers? Tokens?
W127	(5) Ensure that clients are not subjected to physical, verbal, sexual or psychological abuse or punishment;	§483.420(a)(5) FACILITY PRACTICES: No patterns, isolated incidents, unexplained functional regression, or other evidence of physical, verbal, sexual or psychological abuse or punishment posing a serious and immediate threat to individuals are present, are likely to occur, or have occurred without corrective action. The following situations constitute evidence of abuse: 1. Individuals are involved in serious incidents (e.g., injuries, elopements) caused by one or more of the following: o Insufficient or incompetent supervision, regardless of the location of the incident; o Program structure not meeting individual needs; o Failure to intervene when indicated (i.e., neglect); o Active treatment strategies that have proven to be ineffective and have not been revised to meet individual needs; o Placement in an unsafe environment; o Monitoring systems that are absent or are inadequate to prevent such incidents; or o Placement with aggressive/assaultive individuals in the absence of adequate supervision. 2. Individuals are found with serious injuries of unknown origin that are suspicious based on the nature or circumstances of the injury, and on the functional or medical status of the individual.

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		3. Individuals are found with suspicious injuries of unknown origin and have been provided care and supervision by a person who has a confirmed history of abuse. 4. Individuals are subject to punitive techniques in the absence of positive teaching strategies or in the absence of their effectiveness. 5. Individuals suffer death/deterioration due to lack of medical attention and oversight. 6. There is observed abuse and the facility takes no action to correct the situation and protect the individual. §483.420(a)(5) GUIDELINES: The facility is responsible to organize itself in such a manner that it proactively assures individuals are free from serious and immediate threat to their physical and psychological health and safety. Citing of this requirement indicates that there is a high probability that abuse to individuals could occur at any time, or already has occurred and may well occur again, if the individuals are not effectively protected from the serious physical or psychological harm or injury, or if the threat is not removed. A citation of this requirement, therefore, must result in a determination of Condition level non-compliance due to immediate and serious threat. Cross reference W122 for additional guidance. "Threat," as used in this guideline, is any condition/situation which could cause or result in severe, temporary or permanent injury or harm to the mental or physical condition of individuals, or in their death. "Abuse" refers to the ill-treatment, violation, revilement, malignment, exploitation and/or otherwise disregard of an individual, whether purposeful, or due to carelessness, inattentiveness, or omission of the perpetrator. "Physical abuse" refers to any physical motion or action, (e.g., hitting, slapping, punching, kicking, pinching, etc.) by which bodily harm or trauma occurs. It includes use of corporal punishment as well as the use of any restrictive, intrusive procedure to control inappropriate behavior for purposes of punishment. Observe individuals to see if they are bruised, cut, burned (cigarettes, etc.). "Verbal abuse" refers to any use of oral, written or gestured language by which abuse occurs. This includes pejorative and derogatory terms to describe persons with disabilities. "Psychological abuse" includes, but is not limited to, humiliation, harassment, and threats of punishment or deprivation, sexual coercion, intimidation, whereby individuals suffer psychological harm or trauma. Individuals must not be subjected to abuse by anyone (including, but not limited to, facility staff, consultants or volunteers, staff of other agencies serving the individual, family members or legal guardians, friends, other individuals, or themselves).

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		Since many individuals residing in ICFs/IID are unable to communicate feelings of fear, humiliation, etc., the assumption must be made that any actions that would usually be viewed as psychologically or verbally abusive by a member of the general public, is also viewed as abusive by the individual residing in the ICF/IID, regardless of that individual's perceived ability to comprehend the nature of the incident. The facility must take whatever action is necessary to protect the individuals residing there. For example, if a facility is forced by court order or arbitration rulings to retain or reinstate an employee believed to be abusive, the facility may need to take other measures (such as assigning the employee to an area where there is no contact with beneficiaries, providing increased supervision and additional training for the employee, appealing the arbitration or court decision or pursuing formal criminal charges) in order to ensure beneficiary safety. SURVEY PROCEDURE: Use the following procedures in the order shown: o Review incident/accident reports or logs for at least a 3-6 month period and for all three shifts. o Review recent hospitalizations or transfers to the facility infirmary as a result of an individual incident or accident. o Note any failure of the facility to provide protective supervision, especially after knowing an individual has in the past been injured as a result of omissions in supervision. (For example, usually after 3 incidents of injury, within a short time-frame, one begins to think about the repetitive nature of the incidents. However, if even one very serious incident resulting in medical intervention has occurred, review it to assure that the facility has taken effective, corrective action.) o After identifying those individuals repeatedly being injured, go to the living unit or wherever the injuries are reoccurring and observe the level of supervision provided. o There are going to be unexplained injuries, given the nature of the population served. However, as a surveyor, you are examining what the facility has done to reduce the probability of further injury. o Observe individuals to determine if there is a pattern of individuals appearing fearful, suspicious, timid, shaking when approached, avoiding eye contact, overly obedient, etc. o Other factors to evaluate include: the needs of the individuals served, the degree of program structure available in the environment, the effectiveness of active treatment strategies, and whether or not the frequency or intensity of injuries is abnormally high or low, etc. These conditions may indicate the potential for a

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		threat which requires indepth investigation and evaluation. §483.420(a)(5) PROBES: Are there patterns of staff conduct which may be punitive, abusive, retributive, counterproductive or a substitute for programming towards self-control? Is there a systematic pattern of incident reports which suggest or allege abuse? How is the facility organized to prevent abuse (i.e., investigative systems, abuse management, analysis of incident and injury patterns, individual/parent/guardian ombudsman systems)? Cross-reference W150 for more probes.
W128	(6) Ensure that clients are free from unnecessary drugs and physical restraints and are provided active treatment to reduce dependency on drugs and physical restraints;	§483.420(a)(6) FACILITY PRACTICES: The use of all drugs and physical restraints is based on individual need and the presenting problem cannot be addressed by other means. An active treatment program which includes mechanisms to reduce dependency on drugs and restraints is in effect, and is based on the needs of the individual. The use of a drug or restraint is discontinued if it is not effective. Drugs are not used at levels which are toxic or otherwise result in deterioration of the individual. §483.420(a)(6) GUIDELINES: The chronic use of restraints may indicate one or more of the following: the individual's developmental and/or behavioral needs are not being met and the appropriateness of placement should be questioned; staff behavior may be prompting behaviors in individuals which result in the chronic use of physical restraints and drugs to control behavior; staff may have inadequate training and/or experience to provide active treatment and employ preventive measures that reduce the levels of behaviors judged to require physical restraints and drugs to control behavior; and restraints may be applied to behaviors which are, in fact, not threatening to the health and welfare of the individual or other individuals and staff. §483.420(a)(6) PROBES: Is there evidence of substitutions of one form of restrictive procedures for another, e.g., as drug usage is reduced, is there widespread increase in the use of time-out and restraint procedures and vice versa? Does the active treatment plan address drug use, physical restraint and/or time-out modification?

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		Are individuals receiving any drugs for which there are no substantiated uses or active monitoring to support their use? How long is use of a psychoactive drug allowed to continue without improvement to the individual? What criteria must be satisified before a psychiatric consultation is requested? Cross reference W295 and W311 for more probes.
W129	(7) Provide each client with the opportunity for personal privacy and	§483.420(a)(7) FACILITY PRACTICES: Individuals have time to be alone, when appropriate, and to have privacy for personal interactions/activities. §483.420(a)(7) GUIDELINES: The facility must have a method of arranging for privacy of visits between individuals with significant relationships, if they do not both reside at the facility. §483.420(a)(7) PROBES: Do individuals actually seek out and utilize opportunities for privacy? Do individuals actually have places to go to be alone and are they allowed to do so? For example, are individuals allowed to go to their room alone? Allowed to go to a quiet private area, or do staff routinely "herd" individuals preventing opportunities for privacy? Are these rights afforded to less-disabled individuals only? Are individuals taught "private area" behavior and responsibilities? What do you see staff do when individuals are not mindful of their or other's privacy? To what extent are individuals talked about in the presence of other individuals?
W130	ensure privacy during treatment and care of personal needs;	§483.420(a)(7) FACILITY PRACTICES: Individuals have privacy during personal hygiene activities (e.g., toileting, bathing, dressing) and during medical/nursing treatments that require exposure of one's body. §483.420(a)(7) GUIDELINES: The facility must examine and treat individuals in a manner that maintains the privacy of their bodies. Only employees directly involved in the treatment are present when treatments are given. Some method or mechanism which ensures privacy (such as a closed door, a drawn curtain or systematically implemented training for an individual to use their own methods) must be employed to shield the individual from passers-by. People not involved in the care of the individual should not be present without their consent while they are being examined or treated. If an individual requires assistance during toileting, bathing, and other personal hygiene activities, staff should assist, giving utmost attention to the individual's

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		need for privacy. There is no prohibition, however, on staff to work with individuals of the opposite sex. Exercise special attention to ensure that your behavior, during onsite observations in the individual's home, does not violate an individual's right to privacy during treatment and care of personal needs. §483.420(a)(7) PROBES: To what extent have accommodations been made so that individuals with physical disabilities, who otherwise would be independent, can perform basic personal hygiene activities without staff present? How does staff preserve personal privacy of individuals when visitors are present?
W131	(8) Ensure that clients are not compelled to perform services for the facility and	§483.420(a)(8) FACILITY PRACTICES: The individual is not required or expected to do chores or work for the facility, other than appropriate care of one's own personal space or shared responsibility for common areas. §483.420(a)(8) GUIDELINES: "Work," as used in the regulation, means any directed activity, or series of related activities which results in benefit to the economy of the facility or in a contribution to its maintenance, or in the production of a salable product. In deciding whether a particular activity constitutes "work" as defined above, the key determinant is if an individual was unavailable to perform the particular activity or function, would the facility be required to hire additional full or part-time staff (or pay overtime to existing staff) in order to properly maintain the facility or to provide necessary care services to individuals, in order to carry out its assigned mission? Individuals are not to be used to provide a source of labor for a facility against their will or in opposition to the objectives of the IPP. Seriously question any situation in which an individual is observed or reported to be "volunteering" to do real work that benefits the facility, or its maintenance without compensation. Interview such individuals to determine if they have given informed consent to such practices and understand that by providing employable services they are able to be compensated. This does not preclude an individual from helping out a friend or being kind to others. Self-care activities related to the care of one's own person are not considered "work" for purposes of compensation. Regular participation in the domiciliary activities of maintaining one's own immediate household or residential living unit which can lead to the individual's greater functional ability to perform independent household tasks is also not considered "work" for the facility. Shared duties are common and appropriate. Included in, but not limited to, these domiciliary tasks are: o Meal planning, food purchasing, food preparation, table setting, serving,
W132	ensure that clients who do work for the facility are compensated for their efforts at prevailing wages and commensurate with their abilities;	

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		dishwashing, etc.; o Household cleaning, laundry; o Clothes repair; o Light yard and house maintenance (painting, simple carpentry, etc.); and o General household shopping, including clothing. In general, participation in any household task which promotes greater independent functioning (and which the individual has not yet learned) is permitted as long as tasks are included in the IPP in written behavioral and measurable terms. This participation must be supervised, and indices of performance should be available. No task may be performed for the convenience of staff (e.g., supervising individuals, running personal errands) or which has no relationship to the individual's IPP. As individuals become widely competent and independent in household tasks, they must not be used in those capacities and represented as "in training" and serious consideration should be given to the individual's potential for even less restrictive residential environments. (See also §483.440(a)(2) and (b)(1).) However, it is acceptable for individuals to engage in household tasks which are in common with other individuals, all sharing the total household tasks commonly shared in nuclear family units. The test in this regard is: o The expectation is that tasks are the general responsibility of the individual, and that the duties rotate to the maximum extent possible; and/or o The individual can assume control in performing the responsibility given (e.g., John has until Thursday at 8 p.m. to clean the living and dining rooms), thereby adding to the development of internal controls and assumption of responsibility by individuals. Work performed by the individual which no other individual is required or expected to do, or is not a regular part of running the household, must be compensated. "Compensated" means the receipt of money or other forms of negotiable compensation for work (including work performed in an occupational training program) which is available to the individual, to be used at his or her discretion in determining the benefits to be derived therefrom. "Prevailing wage" refers to the wage paid to non-disabled workers in nearby industry or the surrounding community for essentially the same type, quality and quantity of work or work requiring comparable skills. A working individual must be paid at least the prevailing minimum wage except when an appropriate certificate has been obtained by the facility in accordance with current regulations and guidelines issued under the Fair Labor Standards Act, as amended. Any individual performing work, as defined above, must be compensated in direct proportion to his or her productivity as measured in work equivalents of a regular

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		employee's output. For example, if an individual's productivity for a particular work activity or function is determined to be 30% of normal output for an average non-disabled worker, and the prevailing wage is $4.00 an hour, then the individual should be compensated in money at a rate of one dollar and twenty cents per hour (.30 x $4.00 = $1.20). If a piece rate can be determined for a particular job, an individual is paid based on the number of pieces he or she produces. An individual's pay is not dependent on the production of other individuals when he or she works in a group. When the individual's active treatment program includes assignment to occupational or vocational training or work, specific work objectives of anticipated progress should be included in the IPP along with reasons for the assignments. If the training of individuals on particular occupational activities or functions involves "real work" to be accomplished for the facility, the individuals must be compensated based on ability. For example, if in the process of work training activities involved with learning to clean a floor, the floor for a particular building is cleaned and does not require further janitorial cleanup, then the individual must be compensated for this activity. §483.420(a)(8) PROBES: Are individuals assigned to bathe, toilet or feed other individuals? Is each individual who provides work for the facility allowed to refuse to work for the facility? Are there individual payment records? If an individual makes less than the prevailing wage, can that person's individual production or performance record be retrieved? If time studies were conducted, did the facility measure the same skills as performed by persons who are not disabled? Are household tasks assigned and changed equitably? Do individuals have reasonable responsibilities, to the extent possible, for keeping their own private areas of living unit clean and neat? Are individuals coerced to work for staff in order to gain privileges? Are individuals trained to perform services for the facility for reinforcers or tokens rather than pay? Do individuals work the same job everyday without pay?
W133	(9) Ensure clients the opportunity to communicate, associate and meet privately with individuals of their choice,	§483.420(a)(9) GUIDELINES: Space must be provided for individuals to receive visitors in reasonable comfort and privacy.

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		§483.420(a)(9) PROBES: Does the facility provide individuals with the opportunity to form individual relationships with others including opportunities to experience personal relationships both within and outside the facility? What pattern of freedom of movement do you see at the facility? Do most individuals move freely? Few? On what basis is freedom of movement restricted? Is this dealt with programmatically in the individual program plan for each individual? How often is this restriction re-evaluated?
W134	and to send and receive unopened mail;	§483.420(a)(9) GUIDELINES: Assistance must be provided to individuals who require help in reading or sending mail. Refer to W145. §483.420(a)(9) PROBES: How do individuals send and receive mail? Do staff assist individuals who are unable to open and read mail themselves? Is writing assistance provided?
W135	(10) Ensure that clients have access to telephones with privacy for incoming and outgoing local and long distance calls except as contraindicated by factors identified within their individual program plans;	
W136	(11) Ensure clients the opportunity to participate in social, religious, and community group activities;	§483.420(a)(11) FACILITY PRACTICES: Individuals are involved in various types of activities in the community (e.g., going to parks, movies, restaurants, church, community meetings and events) based on their interests and choices. Individuals are taught the skills and are provided with appropriate levels of support, commensurate with functional levels, for community participation. §483.420(a)(11) GUIDELINES: Outdoor and out of home activities are planned for all individuals on a regular basis. §483.420(a)(11) PROBES: Are all activities agency-centered or sponsored? Are religious preferences known and honored?

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		What is the level of individual participation (relevant to level of individual functioning): o Fully independent? o Staff assisted/individual participation? o Total staff assistance? Are the individuals allowed to participate independently in activities commensurate with their level of functioning and interest? What is the facility's system to facilitate an individual's participation? What does the facility do to draw out non-participating individuals to the point that the individual makes his/her own active choice to participate or not? Does the facility arrange for individuals to participate in community integrated activities individually or in small groups (3 or less) at least part of the time? Does the facility arrange age and interest appropriate outside activities for individuals with the community (e.g., recreation centers, churches, social clubs)?
W137	(12) Ensure that clients have the right to retain and use appropriate personal possessions and clothing, and	§483.420(a)(12) FACILITY PRACTICES: Individuals have personal possessions and clothing which meet their needs, interests and choices. Individuals have free access to their own possessions and clothing. Individuals, who are unable to access and use personal possessions and clothing appropriately, are involved in programs to learn the necessary skills to do so. §483.420(a)(12) GUIDELINES: All individual possessions regardless of their apparent value to others must be treated with respect, for what they are and for what they may represent to the individual. The facility should encourage individuals to use or display possessions of his or her choice in a culturally normative manner. Appropriate personal possessions includes personal care and hygiene items. Individuals should not be without personal possessions because of the behavior of others with whom they live. If a method for identifying personal effects is used, it should be inconspicuous and in a manner that will assist the individual to identify them. "Appropriate" clothing means a supply of clothing that is sufficient, in good repair, accounts for a variety of occasions and seasons, and appropriate to age, size, gender, and level of activity. Modification or adaptation of clothing fasteners should be considered based on the needs of an individual with a physical disability to be independent. As appropriate, each individual's active treatment program maximizes opportunities for choice and self-direction with regard to choosing and shopping for clothing which

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		enhances his or her appearance, and selecting daily clothing in accordance with age, sex and cultural norms. Individuals are permitted to keep personal clothing and possessions for their use while in the facility. Determine how the facility both ensures the safety of personal possessions while at the same time providing individual access to them when the individual chooses. Individuals are provided the opportunity, encouraged, and trained to use age-appropriate materials. The term "age-appropriate" refers to anything that reinforces recognition of the individual as a person of a certain chronological age. The facility's environment must be furnished with materials and activities that will enhance opportunities for growth. Determine whether the failure of an individual to achieve functional, adaptive skills, or to have opportunities to make informed choices, or to achieve any positive outcomes is a result of the constant use of materials or participation in activities that are age-inappropriate. §483.420(a)(12) PROBES: Are individuals dressed in their own clean, neat and attractive clothing? Is it of the correct size and in good condition? Is clothing appropriate for the weather and type of activity? To what extent is there a pattern of slacks that are too long or too short? Are cords and pins used to keep pants up instead of belts? To what extent does the facility provide items of lesser quality or provide only one type of a particular item? Is there clothing for a variety of activities (e.g., clothing for church, casual social functions, sport events)? Do colors, styles, and designs match and conform with community standards? Are individuals assisted in clothes selection, room decoration and other forms of self-expression? Are individuals satisfied with the access to and choice of the kinds and numbers of personal possessions they have? How frequently during the course of the day do you observe individuals using their personal possessions? Are individuals' personal decorative possessions displayed? Are individual possessions protected?

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		To what extent is there a pattern of individual loss, due to theft or destruction by others? What does the facility do to prevent loss? Is it successful?
W138	ensure that each client is dressed in his or her own clothing each day; and	§483.420(a)(12) PROBES: To what extent are items of clothing such as pajamas, underwear, and socks, considered "stock" items as opposed to belonging to individuals?
W139	(13) Permit a husband and wife who both reside in the facility to share a room.	
	(b) Standard: Client finances.	
	(1) The facility must establish and maintain a system that--	
W140	(i) Assures a full and complete accounting of clients' personal funds entrusted to the facility on behalf of clients; and	§483.420(b)(1)(i) GUIDELINES: A "full and complete accounting for personal funds" does not need to document accounting for incidental expenses or "pocket money," funds a capable individual handles without assistance, funds dispensed to an individual under a program to train the individual in money management, and funds that are not entrusted to the facility (e.g., funds paid directly to the individual's representative payee).
W141	(ii) Precludes any commingling of client funds with facility funds or with the funds of any person other than another client.	§483.420(b)(1)(ii) GUIDELINES: Although prudent to do so, there is no Federal requirement to maintain individuals' personal funds in financial institutions in interest bearing accounts, or in accounts separate from other individual accounts. However, if the facility elects to pool individuals' funds in an interest bearing account, including common trust accounts, it is expected to know the interest separately accrued by each individual, as part of its required accounting of funds. Interest accumulated to an individual's account belongs to the individual, not the facility.
W142	(2) The client's financial record must be available on request to the client, parents (if the client is a minor) or legal guardian.	§483.420(b)(2) GUIDELINES: Parents or other family members should not have automatic access to the financial records of adult individuals. It is not necessary that a facility be required to furnish an annual financial statement to the individual or the individual's family, since the facility is already required to make the financial record available at any time upon request. The individual, in turn, is free to choose to make his or her financial record available to anyone else.
	(c) Standard: Communication with clients, parents, and guardians.	
	The facility must- -	

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W143	(1) Promote participation of parents (if the client is a minor) and legal guardians in the process of providing active treatment to a client unless their participation is unobtainable or inappropriate;	§483.420(c)(1) GUIDELINES: "Unobtainable," as used in this standard, means that the facility has made a bonafide effort to seek parental or guardian participation in the process, even though the effort may ultimately be unsuccessful (for example, the parent may be impossible to locate or may prove unwilling or unable to participate). "Inappropriate" as used in this standard means that the parent or legal guardian's behavior is so disruptive or uncooperative that others cannot effectively participate; the individual does not wish his or her parent to participate, and the individual is competent to make this decision; or there is strong evidence that the parent or guardian is not acting on the individual's behalf or in the individual's best interest. In the case of the latter, determine what the facility has done to bring effective resolution to the problem. §483.420(c)(1) PROBES: Are families contacted for involvement in planning services/treatments for individuals? On a routine basis, what kinds of activities, information, and problems get communicated? How does the facility develop and maintain active family/guardian participation? Does the facility respond to the wishes of non-adjudicated adult individuals who do not wish their family's involvement? Does information in the individual record correlate with information provided families? Are parents and guardians allowed to talk to direct care and service providers? What is the facility's basis for denying participation by the parents or guardians? Is there a pattern to the denials or to the reasons stated? How does the facility explain the meaning of "active treatment" to parents and guardians? To what extent are families informed of how to reinforce training and/or the maintenance of skills while individuals are with them? What efforts has the facility made to accommodate scheduling problems for interdisciplinary team or other meetings of families?
W144	(2) Answer communications from clients' families and friends promptly and appropriately;	§483.420(c)(2) GUIDELINES: Where possible, randomly select a family or guardian to validate the quality, nature and frequency of the communications between the facility and families or guardians (but only with their consent). There is no requirement that each contact with family and

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		friends be documented. §483.420(c)(2) PROBES: How does the facility communicate with families and friends of those served? Is there a pattern of lag time between contact and response which suggest responses are not timely?
W145	(3) Promote visits by individuals with a relationship to the client (such as family, close friends, legal guardians and advocates) at any reasonable hour, without prior notice, consistent with the right of that client's and other clients' privacy, unless the interdisciplinary team determines that the visit would not be appropriate;	§483.420(c)(3) GUIDELINES: Any limitations of visitors are recorded by the interdisciplinary team with reason and time limits given. Decisions to restrict a visitor must be reviewed and re-evaluated each time the IPP is reviewed or at the individual's request. If you find broad restrictions, review general facility access policies. The facility should have arrangements available to provide privacy for families and others when visiting with individuals. §483.420(c)(3) PROBES: Is there a systematic pattern of unreasonable restrictions on visitors in terms of when they can come, where they can go on the facility's property and to whom they can speak?
W146	(4) Promote visits by parents or guardians to any area of the facility that provides direct client care services to the client, consistent with the right of that client's and other clients' privacy;	§483.420(c)(4) PROBES: Is there a pattern to the types of restricted locations? Is there evidence such as "no admittance" signs or policies against visitors in any of these areas?
W147	(5) Promote frequent and informal leaves from the facility for visits, trips, or vacations; and	§483.420(c)(5) GUIDELINES: It is not acceptable for a facility to sponsor or allow individuals to take a particular type of trip that is contraindicated. For example, in the situation of an individual subject to abuse by a parent, the facility obviously is not required to permit such a trip. However, as with any right that may need to be modified or limited, the individual should be provided with the least restrictive and most appropriate alternative available. §483.420(c)(5) PROBES: What is the frequency of these outings? What types of outings? Are outings age-appropriate? How does the facility provide choice in outings? Can individuals choose not to participate?

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W148	(6) Notify promptly the client's parents or guardian of any significant incidents, or changes in the client's condition including, but not limited to, serious illness, accident, death, abuse, or unauthorized absence.	§483.420(c)(6) GUIDELINES: "Significant" incidents or changes in the individual's condition refers to any type of occurrence or event, that is perceived to have some level of importance to the individual, family or guardian. Examples include, but are not limited to, allegations of mistreatment, psychological trauma experienced by the individual, loss or change of a program service or staff person, entry or placement in new programs or agencies, day-to-day events on which family members express interest to be informed, etc. §483.420(c)(6) PROBES: Are family members/guardians informed of incidents/alleged abuse? Are telephone numbers and addresses for parents and guardians kept and periodically updated? What is the time frame for notification?
	(d) Standard: Staff treatment of clients.	
W149	(1) The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect or abuse of the client.	§483.420(d)(1) FACILITY PRACTICES: The facility, through implementation of its policies, has set up a structure which protects individuals from mistreatment, neglect and abuse. §483.420(d)(1) GUIDELINES: "Mistreatment" as used in this standard, includes behavior or facility practices that result in any type of individual exploitation such as financial, sexual, or criminal. "Neglect" means failure to provide goods or services necessary to avoid physical or psychological harm. See W127 for definitions related to "abuse." §483.420(d)(1) PROBES: Refer to W186 because there is often a relationship between the adequacy of facility staffing and staff treatment of individuals. Is there a pattern among incidents of alleged abuse, accidents, behavior programs, psychoactive drug use, staff training, and adequacy of staffing levels that may suggest possible mistreatment, neglect or abuse of individuals? How does the facility monitor staff treatment of individuals to ensure that the requirements are not being violated?
W150	(i) Staff of the facility must not use physical, verbal, sexual or psychological abuse or punishment.	§483.420(d)(1)(i) GUIDELINES: See W127, Facility Practices, as related specifically to staff of the facility.

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		A citation of this requirement indicates that abuse to an individual by staff of the facility is highly likely to occur or has already occurred and may well occur again if the individual is not effectively protected. A citation of this requirement, therefore, must result in Condition-level non-compliance due to immediate and serious threat. Cross reference W122 and W127. §483.420(d)(1)(i) PROBES: Can staff define what constitutes abuse and punishment? Are programs or policies "masks" for punitive, abusive controls? How does the facility actively promote respect for individuals? How do staff members set acceptable behavioral limits for individuals? Does group punishment occur? Does demeaning, belittling or degrading punishment occur? Do staff speak loudly, harshly? In negative, punishing terms? With threats, coercion? Cross-reference W127 for definitions and additional probes.
W151	(ii) Staff must not punish a client by withholding food or hydration that contributes to a nutritionally adequate diet.	§483.420(d)(1)(ii) GUIDELINES: Cross-reference W465.
W152	(iii) The facility must prohibit the employment of individuals with a conviction or prior employment history of child or client abuse, neglect or mistreatment.	§483.420(d)(1)(iii) FACILITY PRACTICES: No one hired after October 3, 1988, has had a conviction or a prior employment history of child or client abuse, neglect or mistreatment of which the facility was aware based on pre-employment screening. No one with a conviction or substantiated allegation of child or client abuse, neglect or mistreatment occurring outside the jurisdiction of the ICF/IID after October 3, 1988, regardless of employment date, is employed by the facility. §483.420(d)(1)(iii) GUIDELINES: This regulation applies to the hiring of new employees on or after 10/3/88. The facility is required to screen potential employees for a prior employment history of child or client abuse, neglect or mistreatment, as well as for any conviction based on those offenses. The abuse, neglect or mistreatment must be directed toward a child or an individual who is a client (resident, patient) in order for the prohibition of employment to apply.

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		This requirement also applies to acts of abuse, neglect or mistreatment committed by a current ICF/IID employee outside the jurisdiction of the ICF/IID (e.g., in the community or in another health care facility). A substantiated allegation of abuse, neglect or mistreatment which occurred after October 3, 1988 (regardless of the date of the person's employment in the ICF/IID), and which resulted in the termination of that person's employment from another health care facility, becomes a part of the person's employment history and the ICF/IID is prohibited from continuing to employ the individual. For example, an individual who abused a resident in a nursing facility and as a result, is barred from employment in the nursing home setting would also be prohibited from employment in the ICF/IID. While facilities are not required to periodically screen existing employees, if the facility becomes aware that such action has been taken against an employee, the facility is required to prohibit continued employment. This is also true of any conviction in a court of law for child or client (resident, patient) abuse, neglect or mistreatment. Therefore, conviction for abusing one's own child is also a reason employment would be prohibited. The definition of "mistreatment" under the guideline at W153 includes financial exploitation. Therefore, if an employee was convicted or had a prior employment history of theft of an individual's funds, that would also be a reason employment would be prohibited. Access other information, as appropriate, including information contained in "closed" records, in order to adequately evaluate compliance. §483.420(d)(1)(iii) PROBES: How does the facility screen employees for previous convictions? Who are the facility's new hires? Has the facility implemented its system in such a fashion to ensure that W152 has been achieved?
W153	(2) The facility must ensure that all allegations of mistreatment, neglect or abuse, as well as injuries of unknown source, are reported immediately to the administrator or to other officials in accordance with State law through established procedures.	§483.420(d)(2) GUIDELINES: The facility is responsible for reporting any injuries of unknown origin and any allegations of mistreatment to an individual residing in the facility regardless of who is the perpetrator (e.g., facility staff, parents, legal guardians, volunteer staff from outside agencies serving the individual, neighbors, or other individuals, etc.). §483.420(d)(2) PROBES: How many alleged violations have been reported this year? Last year? What mechanisms are in place to ensure prompt detection, reporting, and appropriate follow-up?
W154	(3) The facility must have evidence that all alleged	§483.420(d)(3) GUIDELINES: The facility is responsible for investigating all injuries of unknown origin and

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	violations are thoroughly investigated and	allegations of mistreatment, neglect or abuse. The particular mechanisms developed by a facility for investigation are at its discretion, provided that alleged violations of individual rights are thoroughly investigated and appropriate actions are taken. Review reports of investigations to determine that necessary information relevant to the incident was obtained and considered. §483.420(d)(3) PROBES: After you review reports of investigation, do you identify a pattern to the depth, thoroughness, conclusions and actions taken that suggest: o Comprehensive and responsive investigations? o Well conducted but negated or altered reports? o Shallow or routinized investigations?
W155	must prevent further potential abuse while the investigation is in progress.	
W156	(4) The results of all investigations must be reported to the administrator or designated representative or to other officials in accordance with State law within five working days of the incident and,	§483.420((d)(4) GUIDELINES: Some States require that allegations of abuse must be reported to the police. CMS cannot regulate the activities of the police. However, if the police take longer than five working days for their investigation, the facility is still required to complete an internal investigation report of findings within the five day timeframe. "Working days" means Monday through Friday, excluding State and Federal holidays. §483.420(d)(4) PROBES: If a report of known or suspected abuse or neglect involves the acts or omissions of the administrator, how has the provider arranged for an unbiased review of the allegation (such as, an authority outside of the facility investigating the report and, if necessary, taking appropriate corrective action)?
W157	if the alleged violation is verified, appropriate corrective action must be taken.	§483.420(d)(4) FACILITY PRACTICES: The seriousness of the violation is considered by the facility to determine appropriate corrective action. When the intentional action or inaction of a staff person has resulted in abuse, neglect or mistreatment which was a serious and immediate threat to the individual's health and safety, the staff person's employment is terminated. The corrective action taken by the facility is reasonably likely to assure that the abuse, neglect, mistreatment or injury will not occur again. §483.420(d)(4) GUIDELINES: This requirement refers to corrective action taken based upon findings of investigations of incidents which have occurred within the jurisdiction of the facility. It requires that the seriousness of infractions be weighed in the determination of what action is necessary by the facility to correct the situation appropriately. In cases of abuse, neglect or mistreatment by staff, where extenuating circumstances exist and dependent on the nature of the infraction, a remedy that is consistent with appropriate progressive disciplinary measures may be acceptable. When the intentional action or inaction of a staff person has resulted in abuse, neglect or

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		mistreatment which poses a serious and immediate threat to individuals' health and safety, termination of employment is the only acceptable corrective action. Appropriate corrective action is also required for findings of abuse, neglect or mistreatment by other individuals residing in the facility, staff of outside agencies, parents or any other person, and for injuries to individuals resulting from controllable environmental factors. Appropriate corrective action is defined as that action which is reasonably likely to prevent the abuse, neglect, mistreatment or injury from recurring. When an employee appeals a finding of abuse by the facility, whether through arbitration or in a court of law, the decision of the arbitrator or the court of law is then considered the final finding. If the arbitrator found that the charges lacked substance, the allegation would be considered unsubstantiated. The facility, however, is still required to ensure that individuals residing in the facility are not subjected to physical, verbal, sexual or psychological abuse or punishment by W127. An arbitrator may find that the allegation of abuse is substantiated, but impose a lesser penalty than that which was sought by the facility. For example, the facility may seek termination of employment as the appropriate corrective action but the arbitrator determines that a 10 day suspension is more appropriate. The facts of the situation will have to be evaluated by the surveyor and a judgement made regarding appropriateness. Therefore, while the facility is permitted by the regulation to exercise judgement regarding appropriate corrective action, the surveyor must also exercise judgement and may determine that the corrective action is NOT reasonably likely to prevent the abuse from recurring. §483.420(d)(4) PROBES: After investigations have been completed, how many alleged violations culminated in progressive discipline actions? Staff discharges? As a result of the facility's investigations, is there a pattern of reduction of allegations?

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W158	§483.430 Condition of participation: Facility staffing.	§483.430 COMPLIANCE PRINCIPLES: The Condition of Participation of Facility Staffing is met when: o The Condition of Participation of Active Treatment is met (i.e., there are sufficient numbers of competent, trained staff to provide active treatment.); and o The Condition of Participation of Client Protections is met (i.e., there are sufficient numbers of competent, trained staff to protect individuals' health and safety.). The Condition of Participation of Facility Staffing is not met when: o The Condition of Participation of Active Treatment has first been determined to be not met and the lack of active treatment has resulted from insufficient numbers of staff or lack of trained, knowledgeable staff to design and carry out individual's programs; or o The Condition of Participation of Client Protections has first been determined to be not met and the lack of client protection has resulted from insufficient numbers of competent, trained staff to protect the health and safety of individuals.
	(a) Standard: Qualified intellectual disabilities professional.	
W159	Each client's active treatment program must be integrated, coordinated and monitored by a qualified intellectual disabilities professional	§483.430(a) FACILITY PRACTICES: There is an assigned qualified intellectual disabilities professional (QIDP). There are sufficient numbers of QIDPs to accomplish the job. The QIDP observes individuals, reviews data and progress, and revises programs based on individual need and performance. The QIDP ensures consistency among external and internal programs and disciplines. The QIDP ensures service design and delivery which provides each individual with an appropriate active treatment program. The QIDP ensures that any discrepancies or conflicts between programmatic, medical, dietary, and vocational aspects of the individual's assessment and program are resolved. The QIDP ensures a follow-up to recommendations for services, equipment or programs. The QIDP ensures that adequate environmental supports and assistive devices are present to promote independence. §483.430(a) GUIDELINES: View the person serving in the QIDP role as pivotal to the adequacy of the program the

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		individual receives, since it is this role that is intended to ensure that the individual receives those services and interventions necessary by competent persons capable of delivering them. The paramount importance of having persons competent to judge and supervise active treatment issues cannot be overstated. An individual's IPP may be coordinated and monitored by more than one QIDP or by other staff persons who perform the QIDP duties. There must, however, be one QIDP who is assigned primary responsibility and accountability for the individual's IPP and the QIDP function. The regulations do not specify if the person designated as QIDP must do the duties of a QIDP exclusively, or is allowed to perform other professional staff duties in addition. The facility has the flexibility to allocate staff resources in whatever manner it believes is necessary as long as it ensures that the QIDP function is performed effectively for each individual. The test of whether the number of QIDPs is adequate rests with the ability of the facility to provide the services described in §483.430(a) in an effective manner. The number will vary depending on such factors as the number of individuals the facility serves, the complexity of needs manifested by these individuals, the number, qualifications and competencies of additional professional staff members, and whether or not other duties are assigned to the QIDP function. §483.430(a) PROBES: Are the QIDP functions actually being carried out, or is paperwork simply reviewed? Are timely modifications of unsuccessful programs or development of programs for unaddressed, but significant needs made or ensured by the QIDP function? Are program areas visited and are performance and problems of individuals discussed? Does the plan flow from only the original diagnosis/assessment? Does it take into consideration interim progress on plans and activities? Does the QIDP make recommendations and requests on behalf of individuals? How does the facility respond?
	who--	
W160	(1) Has at least one year of experience working directly nith individuals with intellectual disabilities or other developmental disabilities; and	§483.430(a)(1) GUIDELINES "Experience" means providing professional services, either paid or volunteer, in a setting that serves individuals with intellectual disabilities. The experience working directly with individuals with intellectual disabilities or other developmental disabilities can be obtained prior to or after obtaining the qualifying degree or credentials. Experience as a State or Federal surveyor of ICFs/IID does NOT qualify an individual as a QIDP.

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	(2) Is one of the following:	
W161	(i) A doctor of medicine [or] osteopathy.	
W162	(ii) A registered nurse.	
W163	(iii) An individual who holds at least a bachelor's degree in a professional category specified in paragraph (b)(5) of this section.	
	(b) Standard: Professional program services.	
W164	(1) Each client must receive the professional program services needed to implement the active treatment program defined by each client's individual program plan.	§483.430(b)(1) FACILITY PRACTICES: Individuals receive professional services when the comprehensive functional assessment or the active treatment program defined by the IPP requires the knowledge, skills and expertise of someone specially trained in a given discipline in order to be effectively implemented. In the presence of a functional deficit, there is input by the relevant professional discipline(s) in order to assess the individual and develop a relevant active treatment program. §483.430(b)(1) GUIDELINES: For an active treatment program to be responsive to the individual's unique needs, there must be a foundation of competent professional knowledge that can be drawn upon in the implementation of the interdisciplinary team process. Individuals with developmental deficits will require initial, temporary, or ongoing services from professional staff, knowledgeable about contemporary care practices associated with these areas. A special mention needs to be made that individuals should not be provided with services that are not needed (e.g., if an individual is basically healthy and not on medication, then the individual should not be provided extensive health and health-related services). The needs identified in the initial comprehensive functional assessment, as required in §483.440(c)(3)(v), should guide the team in deciding if a particular professional's further involvement is necessary and, if so, to what extent professional involvement must continue on a direct or indirect basis. Since such needed professional expertise may fall within the purview of multiple professional disciplines, based on overlapping training and experience, determine if the facility's delivery of professional services is adequate by the extent to which individuals' needs are aggressively and competently addressed. Some examples in which professional expertise may overlap include:

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		o Physical development and health - nurse (routine medical or nursing care needs that do not interfere with participation in other programs); physician, physician assistant, nurse practitioner (acute major medical intervention, or the treatment of chronic medical needs which will be dependent upon an individual's success or failure in other treatment programs). o Nutritional status - nurse (routine nutritional needs that do not affect participation in other programs); nutritionist or dietitian (chronic health problems related to nutritional deficiencies, modified or special diets). o Sensorimotor development: physical educators, adaptive physical educators, recreation therapists, (routine motor needs involving varying degrees of physical fitness or dexterity); special educators or other visual impairment specialists (specialized mobility training and orientation needs); occupational therapist, physical therapist, physiatrist (specialized fine and gross motor needs caused by muscular, neuromuscular, or physical limitations, and which may require the therapeutic use of adaptive equipment or adapted augmentative communication devices to increase functional independence); dietitians to increase specialized fine and gross motor skills in eating. o Affective (emotional) development: special educators, social workers, psychologists, psychiatrists, mental health counselors, rehabilitation counselors, behavior therapists, behavior management specialists. o Speech and language (communication) development: speech-language pathologists, special educators for people who are deaf or hearing impaired. o Auditory functioning: audiologists (basic or comprehensive audiologic assessment and use of amplification equipment); speech-language pathologists (like audiologists, may perform aural rehabilitation); special educators for individuals who are hearing impaired. o Cognitive development: teacher (if required by law, i.e., school aged children, or if pursuit of GED is indicated), psychologist, speech-language pathologist. o Vocational development: vocational educators, occupational educators, occupational therapists, vocational rehabilitation counselors, or other work specialists (if development of specific vocational skills or work placement is indicated). o Social Development: teachers, professional recreation staff, social workers, psychologists (specialized training needs for social skill development). o Adaptive behaviors or independent living skills. Special educators, occupational therapists.
	Professional program staff must work	
W165	directly with clients	§483.430(b)(1) FACILITY PRACTICES: Individuals receive interventions or services directly from professional staff when required by individual needs, program design, implementation, or monitoring.
W166	and with paraprofessional, nonprofessional and other professional program staff who work with clients.	§483.430(b)(1) FACILITY PRACTICES: When required by individual need, program design, implementation, or monitoring, professional staff work directly with paraprofessional, nonprofessional and other professional program staff to assure that these individuals have the skills

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		necessary to carry out the needed interventions. §483.430(b)(1) GUIDELINES: There are some individuals in ICFs/IID who can often have their needs effectively met without having direct contact with professional staff on a daily basis. The intent of the requirement is not to require that professionals work directly with individuals on a daily basis, but only as often as an individual's needs indicate that professional contact is necessary. The amount and degree of direct care that professionals must provide will depend on the needs of the individual and the ability of other staff to train and direct individuals on a day-to-day basis.
W167	(2) The facility must have available enough qualified professional staff to carry out and monitor the various professional interventions in accordance with the stated goals and objectives of every individual program plan.	§483.430(b)(2) FACILITY PRACTICES: Each individual receives professional interventions as needed and specified in the IPP, in sufficient quantity to assure correct implementation. §483.430(b)(2) GUIDELINES: If there is sufficient evidence that para- and non-professional staff demonstrate the needed competencies to carry through with intervention strategies, you may be satisfied there is sufficient professional staff to carry out the active treatment program. However, if the professional's expertise is not demonstrable at the para- and non-professional staff level, question both the numbers of professional staff and the effectiveness of the transdisciplinary training of para- and non-professional staff. §483.430(b)(2) PROBES: Are these services available when they are most beneficial for the individual? Are these people available to staff on other shifts? Weekend staff? Are professional staff available to monitor the implementation of individual programs if necessary?
W168	(3) Professional program staff must participate as members of the interdisciplinary team in relevant aspects of the active treatment process.	§483.430(b)(3) FACILITY PRACTICES: When necessary to develop, implement or monitor an individual's active treatment program, appropriate professional staff participate as interdisciplinary team (IDT) members. §483.430(b)(3) GUIDELINES: "Participate" means providing input through whatever means is necessary to ensure that the individual's IPP is responsive to the individual's needs. The purpose of the interdisciplinary team process is to provide team members with the opportunity to review and discuss information and recommendations relevant to the individual's needs, and to reach decisions as a team, rather than individually, on how best to address those needs. Therefore, determine whether or not there is a pattern of active treatment based on professional participation in the process. Without a negative outcome to demonstrate that professional involvement in any aspect7

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		of the active treatment process (e.g., comprehensive functional assessment, IPP development, program implementation, etc.) was insufficient or inaccurate, the facility is allowed the flexibility to use its resources in a manner that works in behalf of the client, in accordance with the regulations.
W169	(4) Professional program staff must participate in on-going staff development and training in both formal and informal settings with other professional, paraprofessional, and nonprofessional staff members.	§483.430(b)(4) FACILITY PRACTICES: Professional staff receive training in their own discipline to assure adequate delivery of services and to be aware of developments in their field. Professional staff receive training in other disciplines to the extent necessary to meet the needs of each individual. Professional staff provide training to others. §483.430(b)(4) GUIDELINES: "Participate" means both seeking out self-training and provision of training to others.
W170	(5) Professional program staff must be licensed, certified, or registered, as applicable, to provide professional services by the State in which he or she practices.	§483.430(b)(5) PROBES: How does the facility verify that its professionals meet State licensing requirements?
	Those professional program staff who do not fall under the jurisdiction of State licensure, certification, or registration requirements, specified in §483.410(b), must meet the following qualifications:	
W171	(i) To be designated as an occupational therapist, an individual must be eligible for certification as an occupational therapist by the American Occupational Therapy Association or another comparable body.	§483.430(b)(5)(i)-(ix) GUIDELINES: The introductory phrase "to be designated as- - -" means that a provider is allowed to represent him or herself as a professional provider in that discipline, only if the provider meets State licensing requirements, or if the particular discipline does not fall under State licensure requirements, the provider meets the qualifications specified in §§483.430(b)(5)(i)-(ix). A person who is not qualified, for example, as a social worker, may not be referred to as a social worker per se. Nevertheless, such a person may be able to provide social services in an ICF/IID if there is no conflict with State law, and as long as the individuals' needs are met.

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W172	(ii) To be designated as an occupational therapy assistant, an individual must be eligible forcertification as a certified occupational therapy assistant by the American Occupational Therapy Association or another comparable body.	
W173	(iii) To be designated as a physical therapist, an individual must be eligible for certification as a physical therapist by the American Physical Therapy Association or another comparable body.	
W174	(iv) To be designated as a physical therapy assistant, an individual must be eligible for registration by the American Physical Therapy Association or be a graduate of a two year college-level program approved by the American Physical Therapy Association or another comparable body.	
W175	(v) To be designated as a psychologist, an individual must have at least a master's degree in psychology from an accredited school.	
	(vi) To be designated as a social worker, an individual must- -	

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W176	(A) Hold a graduate degree from a school of social work accredited or approved by the Council on Social Work Education or another comparable body; or (B) Hold a Bachelor of Social Work degree from a college or university accredited or approved by the Council on Social Work Education or another comparable body.	
	(vii) To be designated as a speech-language pathologist or audiologist, an individual must- -	
W177	(A) Be eligible for a Certificate of Clinical Competence in Speech-Language Pathology or Audiology granted by the American Speech-Language-Hearing Association or another comparable body; or (B) Meet the educational requirements for certification and be in the process of accumulating the supervised experience required for certification.	
W178	(viii) To be designated as a professional recreation staff member an individual must have a bachelor's degree in recreation or in a specialty area such as art, dance, music or physical education.	
W179	(ix) To be designated as a professional dietitian, an individual must be eligible for registration by the American Dietetics Association.	§483.430(b)(5)(ix) GUIDELINES: The Commission on Dietetic Accreditation of the American Dietetic Association is the organization to whom the American Dietetic Association delegates this responsibility.

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W180	(x) To be designated as a human services professional an individual must have at least a bachelor's degree in a human services field (including, but not limited to: sociology, special education, rehabilitation counseling, and psychology).	§483.430(b)(5)(x) GUIDELINES: The intent for including a "human services professional" category is to expand the number and types of persons who could qualify as QIDPs, while still maintaining acceptable professional standards. "Human services field" includes all the professional disciplines stipulated in §§483.430(a)(3)(i)(ii) and §§483.430(b)(5)(i)-(ix), as well as any related academic disciplines associated with the study of: human behavior (e.g., psychology, sociology, speech communication, gerontology etc.), human skill development (e.g., education, counseling, human development), humans and their cultural behavior (e.g., anthropology), or any other study of services related to basic human care needs (e.g., rehabilitation counseling), or the human condition (e.g., literature, the arts). An individual with a "bachelors degree in a human services field" means an individual who has received: at least a bachelor's degree from a college or university (master and doctorate degrees are also acceptable) and has received academic credit for a major or minor coursework concentration in a human services field, as defined above. Although a variety of degrees may satisfy the requirements, majors such as geology and chemical engineering are not acceptable. Taking into consideration a facility's needs, the types of training and coursework that a person has completed, and the intent of the regulation, the facility and you can exercise wide latitude of judgment to determine what constitutes an acceptable "human services" professional. Again, the key concern is the demonstrated competency to do the job.
W181	(xi) If the client's individual program plan is being successfully implemented by facility staff, professional program staff meeting the qualifications of paragraph (b)(5)(i) through (x) of this section are not required- - (A) Except for qualified intellectual disabilities professionals; (B) Except for the requirements of paragraph (b)(2) of this section concerning the facility's provision of enough qualified professional program staff; and (C) Unless otherwise specified by State licensure and certification requirements.	

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	(c) Standard: Facility staffing.	
W182	(1) The facility must not depend upon clients or volunteers to perform direct care services for the facility.	§483.430(c)(1) FACILITY PRACTICES: The facility has sufficient staff to provide needed care and services without the use of volunteers or enlisting the help of individuals residing in the facility. §483.430(c)(1) GUIDELINES: Volunteers may provide supplementary services. The facility may not rely on volunteers to fill required staff positions and perform direct care services. Examine closely the adequacy of staffing when individuals served are engaged in the care, training, treatment or supervision of other individuals, either as part of training, "volunteer work," or normal daily routines. (See W131-W132 for additional interpretation of productive work done as a "volunteer" or as part of the individual's active treatment program.) The test of adequacy is whether or not there is sufficient staff to accomplish the job in the absence of the individual's work. Work done as part of an active treatment training program requires that the staff are monitoring and teaching new skills as part of the IPP. §483.430(c)(1) PROBES: After observing client or volunteer activities done with individuals served, can you determine whether or not those same services should and could have been provided reasonably by the facility, in the absence of those clients or volunteers? Are individuals served assigned to bathe, toilet, feed or supervise other individuals served in the absence of hired staff?
W183	(2) There must be responsible direct care staff on duty and awake on a 24-hour basis, when clients are present, to take prompt, appropriate action in case of injury, illness, fire or other emergency, in each defined residential living unit housing- - (i) Clients for whom a physician has ordered a medical care plan; (ii) Clients who are aggressive, assaultive or security risks; (iii) More than 16 clients; or (iv) Fewer than 16 clients within a multi-unit building.	§483.430(c)(2) FACILITY PRACTICES: Staff are awake and providing needed care and services for the types of individual living arrangements specified. Staff know how to handle emergency situations for the types of individual living arrangements specified. §483.430(c)(2) GUIDELINES: The test of adequacy about "awake" staffing is how well the facility has organized itself to detect and react to potential emergencies, such as fire, injuries, health emergencies described in the medical care plan (e.g., aspiration, cardiac or respiratory failure, uncontrolled seizures) and behavioral crises described in the IPP. §483.420(c)(2) PROBES: Are there incidences of aggression, assault, or individuals leaving the building at night, without immediate detection?

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W184	(3) There must be a responsible direct care staff person on duty on a 24 hour basis (when clients are present) to respond to injuries and symptoms of illness, and to handle emergencies, in each defined residential living unit housing- - (i) Clients for whom a physician has not ordered a medical care plan; (ii) Clients who are not aggressive, assaultive or security risks; and (iii) Sixteen or fewer clients.	§483.430(c)(3) FACILITY PRACTICES: Staff are available and know how to respond to individual needs and emergencies at all times. §483.430(c)(3) GUIDELINES: The intent of the regulation is that at all times a staff person is in a position to help if individual needs arise. For purposes of this provision, "on duty" staff need not be awake during normal bedtime hours. Facilities sending some or all of the individuals to out of home or off grounds active treatment programs for a majority of the day need not provide a full complement of direct care staff in the residence during their absence. However, a minimum of one staff person must be on duty, if even one individual is present.
W185	(4) The facility must provide sufficient support staff so thatdirect care staff are not required to perform support services to the extent that these duties interfere with the exercise of their primary direct client care duties.	§483.430(c)(4) FACILITY PRACTICES: Direct care staff are not diverted from their primary direct care duties to performsupport functions (e.g., making beds, cooking, cleaning, etc.) when individual needs and programming require their presence and involvement. §483.430(c)(4) GUIDELINES: "Support staff" include all personnel hired by the facility that are not either direct care staff or professional staff. For example, support staff include, but are not limited to, secretaries, clerks, housekeepers, maintenance and laundry personnel. Direct care staff should be utilized at their highest level of competence, but they may assume other roles as long as their ability to exercise their primary direct care duties is not diluted. For example, direct care staff may serve as aides in a training program during the hours individuals are away from the living unit. §483.430(c)(4) PROBES: Is there observational or other evidence to suggest that individuals are being neglected (e.g., demonstrate need for toileting, changing, active treatment interventions) while staff do laundry, housekeeping, cooking or serving household tasks?
	(d) Standard: Direct care residential living unit staff.	
W186	(1) The facility must provide sufficient direct care staff to manage and supervise clients in accordance with their individual program plans.	§483.430(d)(1) FACILITY PRACTICES: There are sufficient numbers of direct care staff over and above minimum ratios to meet individual's needs and to implement the active treatment program as defined in the IPP. There are sufficient numbers of direct care staff to provide needed care and services

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		so that individuals do not injure themselves, others, or destroy property. Special staffing needs identified by the IPP (e.g., 1:1s) are provided. There are adequate numbers of direct care staff to supervise individuals during periods of time when other direct care staff are unavailable, e.g., breaks, meals, meetings, training, etc. §483.430(d)(1) GUIDELINES: "Sufficient" direct care staff means the number of staff, over and above the ratios specified in §483.430(d)(3), necessary to implement active treatment, as dictated by the individual's active treatment needs. Do not look at numbers alone. The facility is responsible for organizing and evaluating its individual appointments, programming schedules, activities, materials, equipment, grouping assignments and available staff in such a way that maximizes benefit to the individual. During the course of the onsite survey, you should be able to observe behavioral evidence of such organization. Evaluate this data in light of the success or failure observed relevant to providing active treatment, and come to a judgment about the adequacy of the facility's staffing.
	(2) Direct care staff are defined as the present on-duty staff calculated over all shifts in a 24-hour period for each defined residential living unit.	§483.430(d)(2) GUIDELINES: "Direct care staff" are those personnel whose daily responsibility it is to manage, supervise and provide direct care to individuals in their residential living units. This staff could include professional staff (e.g., registered nurses, social workers) or other support staff, if their primary assigned daily shift function is to provide management, supervision and direct care of individuals' daily needs (e.g., bathing, dressing, feeding, toileting, recreation and reinforcement of active treatment objectives) in their living units. However, professional staff who simply work with individuals in a living unit on a periodic basis cannot be included. Also, supervisors of direct care staff can be counted only if they share in the actual work of the direct care of individuals. Supervisors whose principal assigned function is to supervise other staff cannot be included.

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W187	(3) Direct care staff must be provided by the facility in the following minimum ratios of direct care staff to clients: (i) For each defined residential living unit serving children under the age of 12, severely and profoundly retarded clients, clients with severe physical disabilities, or clients who are aggressive, assaultive, or security risks, or who manifest severely hyperactive or psychotic-like behavior, the staff to client ratio is 1 to 3.2; (ii) For each defined residential living unit serving moderately retarded clients, the staff to client ratio is 1 to 4; (iii) For each defined residental living unit serving clients who function within the range of mild retardation, the staff to client ratio is 1 to 6.4.	§483.430(d)(3) GUIDELINES: The minimum ratios in this standard indicate the minimum number of direct-care staff that must be present and on duty, 24 hours a day, 365 days a year, for each discrete living unit. It does not include anyone functioning as direct care staff. For example, to calculate the minimum number of living unit staff that must be present and on duty in a discrete living unit serving 16 individuals with multiple disabilities: divide the number of individuals "16", by the number corresponding to the regulation "3.2", the result equals "5". Therefore, the facility must determine how many staff it must hire to ensure that at least 5 staff will be able to be present and on duty during the 24 hour period in which those individuals are present. Using the living unit described above, "calculated over all shifts in a 24-hour period" means that there are present and on duty every day of the year: one direct care staff for each eight individuals on the first shift (1:8), one direct care staff for each eight individuals on the second shift (1:8), and one direct care staff for each 16 individuals on the third shift (1:16). Therefore, there are five (5) direct care staff present and on duty for each twenty-four hour day, for 16 individuals. The same calculations are made for the other ratios, whichever applies. Determine if absences of staff for breaks and meals results in a pattern of prolonged periods in which present and on-duty staff do not meet the ratios.
W188	(4) When there are no clients present in the living unit, a responsible staff member must be available by telephone.	
	(e) Standard: Staff training program.	
W189	(1) The facility must provide each employee with initial and continuing training that enables the employee to perform his or her duties effectively, efficiently, and competently.	§483.430(e)(1) FACILITY PRACTICES: Staff have received training, both upon hiring and on an ongoing basis, which results in the competencies needed to do their job. §483.430(e)(1) PROBES: Is there an observed systemic lack of appropriate interactions and interventions with individuals? Does interview of staff and review of inservice records confirm little or no training activities? Does new staff receive orientation to the facility and the individuals with whom they are to work?

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	(2) For employees who work with clients, training must focus on skills and competencies directed toward clients'	§483.430(e)(2) GUIDELINES: View inservice training as a dynamic growth process. It is predicated on the view that all levels of staff can share competencies which enable the individual to benefit from the consistent, wide-spread application of the interventions required by the individual's particular needs. In the final analysis, the adequacy of the inservice training program is measured in the demonstrated competencies of all levels of staff relevant to the individual's unique needs as well as in terms of the "affective" characteristics of the caregivers and the personal quality of their relationships with the individuals. Observe the staff's knowledge by observing the outcomes of good transdisciplinary staff development (i.e., in the principles of active treatment) in such recommended competencies as: o Respect, dignity, and positive regard for individuals (e.g., how staff refers to individuals, refer to W150); o Use of behavioral principles in training interactions between staff and individuals; o Use of developmental programming principles and techniques, e.g., functional training techniques, task analysis, and effective data keeping procedures; o Use of accurate procedures regarding abuse detection and prevention, restraints, medications, individual safety, emergencies, etc.; o Use of adaptive mobility and augmentative communication devices and systems to help individuals achieve independence in basic self-help skills; and o Use of positive behavior intervention programming. §483.430(e)(2) PROBES: Does the staff training program reflect the basic needs of the individuals served within the program? Does observation of staff interactions with individuals reveal that staff know how to alter their own behaviors to match needs and learning style of individuals served?
W190	developmental,	§483.430(e)(2) FACILITY PRACTICES: Staff are observed to demonstrate cross-cutting skills which are appropriate when training and interacting with any individual with developmental disabilities (e.g., shaping, breaking tasks into small steps, providing positive reinforcement, providing informal opportunities to practice skills, using appropriate materials, etc.).
W191	behavioral,	§483.430(e)(2) FACILITY PRACTICES: Staff are observed to demonstrate cross-cutting skills and interactions which are effective in addressing inappropriate behavior and in supporting appropriate behavior for any individual (e.g., teaching and reinforcing positive, adaptive or incompatible behaviors, diffusion strategies, environmental manipulation, differential reinforcement of other behaviors (DRO), differential reinforcement of incompatable behaviors (DRI), physical management techniques, etc.).

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W192	and health needs.	§483.430(E)(2) FACILITY PRACTICES: Staff display the knowledge and competence to address the health and emergency medical needs of the individuals residing in the facility.
W193	(3) Staff must be able to demonstrate the skills and techniques necessary to administer interventions to manage the inappropriate behavior of clients.	§483.430(e)(3) FACILITY PRACTICES: Staff have the knowledge to correctly and consistently implement the intervention techniques specified in the behavior plans of individuals with whom they are working. §483.430(e)(3) GUIDELINES: Observe staff interactions with individuals to see if the specific interventions, techniques and strategies to change inappropriate behavior outlined in the sampled individual's program plans are correctly implemented. In the absence of implementation, investigate further to determine if there was a justifiable reason for not implementing an intervention (e.g., the plan was revised, the specific situation demanded a different approach, the conditions for use of a particular technique were not present, etc.) When staff are unable to demonstrate how to correctly implement an intervention, or are unable to explain when and how the intervention is to be implemented, inadequate training is evident.
W194	(4) Staff must be able to demonstrate the skills and techniques necessary to implement the individual program plans for each client for whom they are responsible.	§483.430(e)(4) FACILITY PRACTICES: Staff have the knowledge to correctly and consistently implement the specific IPPs of the individuals with whom they are working. §483.430(e)(4) GUIDELINES: Observe whether or not staff are competent and knowledgeable about the needs, programs and progress of each sampled individual with whom they are assigned to work. Staff should be able to demonstrate in practice the results of training for the individuals for whom they are responsible. See guidelines at §483.430(e)(3).

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W195	§483.440 Condition of participation: Active treatment services.	§483.440 COMPLIANCE PRINCIPLES: The Condition of Participation of Active Treatment Services is met when: o Individuals have developed increased skills and independence in functional life areas (e.g., communication, socialization, toileting, bathing, household tasks, use of community, etc.); o In the presence of degenerative or other limiting conditions, individuals' functioning is maintained to the maximum extent possible; o Individuals receive continuous, competent training, supervision and support which promotes skills and independence; and o Individuals need continuous, competent training, supervision and support in order to function on a daily basis. The Condition of Participation of Active Treatment Services is not met when: o Individuals functional abilities have decreased or have not improved and the facility has failed to identify barriers and implement a plan to minimize or overcome barriers; o Individuals are not involved in activities which address their individualized priority needs; o Individuals do not have opportunities to practice new or existing skills and to make choices in their daily routines; or o Individuals are able to function independently without continuous training, supervision and support by the staff.
	(a) Standard: Active treatment.	
W196	(1) Each client must receive a continuous active treatment program, which includes aggressive, consistent implementation of a program of specialized and generic training, treatment, health services and related services described in this subpart, that is directed toward-- (i) The acquisition of the behaviors necessary for the client to function with as much self determination and independence as possible; and (ii) The prevention or deceleration of regression or loss of current optimal functional status.	§483.440(a)(1) FACILITY PRACTICES: When viewed as a whole, the active treatment program is pervasive, systematic and sufficient in scope to assure that individuals are appropriately served. The major elements of the active treatment process are present and functioning in a consistent, cohesive manner including: o Each individual's needs and strengths have been accurately assessed and relevant input has been obtained from team members; o Each individual's IPP is based on assessed needs and strengths and addresses major life areas essential to increasing independence and ensuring rights; o Identified priority needs are addressed formally and through activities which are relevant and responsive to individual need, interest and choice; o Active treatment is consistently implemented in all relevant settings both formally and informally as the need arises or opportunities present themselves; o Each individual receives aggressive and consistent training, treatment, and services by trained staff in accordance with their needs and the IPP; o New skills and appropriate behaviors are encouraged and reinforced; o Each individual has the adaptive equipment and assistive technology necessary for him/her to function with increased independence; o Individual's routines and environments are organized to facilitate acquisition of skills, appropriate behavior, greater independence and choice;

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		o Each individual's performance is accurately measured and programs are modified based on data and major life changes; and o Individuals with degenerative conditions receive training, treatment and services designed to maintain skills and functioning and to prevent further regression to the extent possible. §483.440(a)(1) GUIDELINES "Continuous" is defined to mean the competent interaction of staff with individuals served at all times, whenever the need arises or opportunities present, in both formal and informal settings. Verify that active treatment is identifiable during formal and informal interactions between staff and individuals served. The performance of the individual should reflect the success, if any, of interventions being applied or the need to alter the intervention procedures. The ICF/IID ensures that each individual receives active treatment daily regardless of whether or not an outside resource(s) is used for programming (e.g., public school, day habilitation center, senior day services program, sheltered workshop, supported employment). Those "active" interventions necessary to prevent or decelerate regression are considered to be part of the overall active treatment program. For example, if the application of a specific stimulation technique to the area of the mouth of an individual with severe physical and medical disabilities, decelerates the individual's rate of reliance on tube feedings, and helps the individual retain ability to take food by mouth, then this intervention is considered to be a component of active treatment for the individual. Active treatment for elderly individuals may increasingly need to focus on interventions and activities which promote physical wellness and fitness, socialization and tasks that stress maintaining coordination skills and reducing the rate of loss of skills that accompanies the physical aspects of the aging process. Attending a senior center may be a justifiable part of an active treatment program for an elderly person. Active treatment is the sum total of the major components of the active treatment process or loop which make up the requirements under this Condition of Participation (i.e., assessment, individual program planning, implementation, program documentation, program monitoring and change). It defines the primary nature of the services which must be provided by a facility (and received by its clients) in order to make it eligible under the law to be "certified" as an ICF/IID. Active treatment results in the positive outcomes identified by the Condition-level compliance principles. Surveyors must examine and evaluate all negative findings related to active treatment, and if determined to be significant, those findings should be cited at the salient tag numbers related to each of the components of the active treatment process. When review of

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		those deficiencies leads to the conclusion that active treatment is not being received, then this standard and the explicit statutory requirement for active treatment at '1905(d)(2) of the Social Security Act are not met. A determination of noncompliance with this requirement, therefore, must also result in a determination of noncompliance at the Condition of Participation level for Active Treatment Services and at §440.150(c), tag number W100. Although the active treatment process must be identifiable in documentation, it must be observable in daily practice. Determine how the ICF/IID accomplishes (or fails to accomplish) an environment of competence that enables active treatment to occur. SURVEY PROCEDURE: Record each observation done of individuals served by the facility. The optional Client Observation Worksheet (CMS-3070-I) is the mechanism by which answers to identified data probes may be recorded. The worksheet is applicable to any observation, regardless of whether or not the individual is part of the representative random sample. See Task 3, pages J-7-8, for instructions for completing observations. §483.440(a)(1) PROBES: How does the facility address the active treatment needs of individuals along their full life span? As you conduct each observation, determine: o Is the activity scheduled or planned? o Are materials present to implement the activity? o Are they used? o Are all individuals present involved or engaged in the activity? o Are the activity and materials age-appropriate, adaptive and functional? o Are new skills and behaviors being taught or reinforced? o Are all individuals reinforced and prompted frequently? o Are all staff verbally and physically involved? o Are there sufficient staff for the activity? o Are interactions characterized by a "mentor/friend" tone? Does the activity relate directly to specific objectives and needs? Do staff demonstrate the skills necessary to train or reinforce training on the IPP objectives? o Are individuals observed to engage in aggression, self-injurious behavior or self-stimulatory behavior (e.g., finger flicking)? If so, do staff intervene as per the IPP?
W197	(2) Active treatment does not include services to maintain generally independent clients who are able to function with little supervision or in the absence of a continuous active treatment program.	§483.440(a)(2) FACILITY PRACTICES: As a practice, the facility does not serve individuals who, to a large extent, are able to care for their own basic needs, require minimal supervision and do not require the structure, support and resources of a comprehensive service program on an ongoing basis.

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		§483.440(a)(2) GUIDELINES: The regulations define the target population eligible for the ICF/IID benefit, by defining the services that are required for a facility to provide in order for it to qualify as an ICF/IID and receive Federal Financial Participation (FFP). At the front end, one of the "required services" is training in basic fundamental skills. The type of skills described in W242, by their very nature, target a population who have significant deficits in growth and development. The presence of any group of individuals (court-ordered or not), could call into question the overall nature of the services provided by the ICF/IID. Individuals displaying some or all of the characteristics described in the Interpretive Guideline at '483.440(b)(1), do not "need active treatment services" or ICF/IID level of care, and are not appropriately placed. Agencies which provide residential services to individuals with intellectual disabilities do not qualify automatically for participation in Medicaid as ICFs/IID. Although the facility may be providing services to meet the needs of these types of individuals, the services provided by the facility do not meet the regulatory definition of "active treatment." Furthermore, if the primary purpose of the facility is no longer to provide services to individuals with intellectual disabilities or related conditions who are in need of active treatment, then the facility does not meet the statutory equirement at '1905(d) of the Social Security Act and the regulatory definition of an ICF/IID, and therefore cannot be certified. A determination of noncompliance with this requirement, therefore, must result in a determination of noncompliance at the Condition of Participation level and at §440.150(c). Conversely, if the overall facility meets the definition of an ICF/IID, the law does tolerate the presence of a few individuals for whom payment cannot be claimed. If an entity must serve both people who are generally independent and people who are in need of active treatment, then the entity may need to consider establishing a distinct part ICF/IID to serve those individuals who are in need of active treatment. Negative findings about active treatment with regard to generally independent clients may be in conflict with level of care determinations made by State inspection of care (IOC) teams. Bring these negative active treatment findings to the attention of the IOC agency within the State for appropriate disposition of Medicaid ICF/IID certification. (See also W198, if the negative findings involve newly admitted individuals.) There are some individuals who need the help of an ICF/IID to continue to function independently because they have learned to depend upon the programmatic structure it provides. The fact that they are not yet independent, even though they can be, makes it appropriate for them to receive active treatment services directed at achieving needed and possible independence.
	(b) Standard: Admissions, transfers, and discharge.	

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W198	(1) Clients who are admitted by the facility must be in need of and receiving active treatment services.	§483.440(b)(1) FACILITY PRACTICES: The facility has determined that each individual admitted into the ICF/IID benefit program since October 3, 1988, is in need of a program of active treatment. Each individual needing active treatment receives it from the time of their admission to the facility. §483.440(b)(1) GUIDELINES: Individuals with the following characteristics do not necessarily require a continuous active treatment program in order to function or to achieve optimal independence. Review closely to what extent the ICF/IID serves individuals, who in the aggregate: o Are independent without aggressive and consistent training; o Are usually able to apply skills learned in training situations to other settings and environments; o Are generally able to take care of most of their personal care needs, make known to others their basic needs and wants, and understand simple commands; o Are capable of working at a competitive wage level without support, and to some extent, are able to engage appropriately in social interactions; o Are engaged in productive work within the facility which is done at an acceptable level of independence (i.e., not done as part of a training program to teach the individual new skills); o Are able usually, to conduct themselves appropriately when allowed to have time away from the facility's premises; and o Do not require the range of professional services or interventions in order to make progress. Based on the order of a court, the ICF/IID may be required to admit individuals who do not need active treatment. Although CMS has no jurisdiction to prevent the courts from ordering the placements of such individuals into institutions certified as ICFs/IID, the individuals, by definition, would be ineligible to be classified by Medicaid for the ICF/IID benefit. To the extent that the placement of these court-ordered individuals does not interfere with the ability of the ICF/IID to provide active treatment for its individuals, the facility's overall certification is not affected.
W199	(2) Admission decisions must be based on a preliminary evaluation of the client that is conducted or updated by the facility or by outside sources.	§483.440(b)(2) FACILITY PRACTICES: A preliminary evaluation to determine the need for active treatment is conducted, obtained or updated. The information from the preliminary evaluation is used by the facility to make an admission decision. §483.440(b)(2) GUIDELINES: No admission should be regarded as permanent. Readmission of an individual to the ICF/IID falls under the same requirements as initial admission.

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		In the absence of State regulations designating the person(s) authorized to approve admission (e.g., State or Regional Admissions Committees), the decision to admit an individual to the ICF/IID is based on the findings of an interdisciplinary team, including a QIDP. Occasionally, emergency admissions of individuals may occur without benefit of a preliminary evaluation having been conducted prior to admission. For purposes of '483.440(b)(2) and consistent with '456.370(a), this requirement will be considered as "met" at such time that an evaluation is conducted which supports the need for an individual's placement in the ICF/IID. Refer to W210.
W200	(3) A preliminary evaluation must contain background information as well as currently valid assessments of functional developmental, behavioral, social, health and nutritional status to determine if the facility can provide for the client's needs and if the client is likely to benefit from placement in the facility.	§483.440(b)(3) FACILITY PRACTICES: Information in the preliminary evaluation accurately describes the individual. The preliminary evaluation contains specific information that identifies the individual's needs and whether or not the facility has the ability to respond to those needs in a manner which is likely to benefit the individual. §483.440(b)(3) GUIDELINES: The facility must decide, based on objective data, whether or not needs can be met. In some cases, the facility may be required to meet the "reasonable accommodation" requirement of the Americans with Disabilities Act. Failure to admit individuals merely because they have a particular medical condition may constitute a civil rights violation. All such instances should be reported to the Office of Civil Rights for investigation.
	(4) If a client is to be either transferred or discharged, the facility must- -	
W201	(i) Have documentation in the client's record that the client was transferred or discharged for good cause; and	§483.440(b)(4)(i) FACILITY PRACTICES: Transfer or discharge occurs only when the facility cannot meet the individual's needs, the individual no longer requires an active treatment program in an ICF/IID setting, the individual/guardian chooses to reside elsewhere, or when a determination is made that another level of service or living situation, either internal or external, would be more beneficial, or for any other "good cause," as defined below. §483.440(b)(4)(i) GUIDELINES: "Transfer" means the temporary movement of an individual between facilities, the temporary movement from the ICF/IID to a psychiatric or medical hospital for medical reasons, the permanent movement of an individual between living units of the same facility, or the permanent movement of an entire facility (including individuals served, staff and records) to a new location. "Discharge" means the permanent movement of an individual to another facility or setting which operates independently from the ICF/IID. Moving an individual for "good cause" means for any reason that is in the best interest of the individual.

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		§483.440(b)(4)(i) PROBES: Can you identify a pattern of transfer or discharge that occurs suddenly and that cannot be accounted for on an emergency basis? What are the facility's criteria for emergency transfer or discharge and what are the procedures? Do parents/family members/friends/advocates/guardians participate with the individual in the transfer/discharge decision-making process? Does the reason for transfer/discharge given by the individual and/or family correspond with what is reported in the record?
W202	(ii) Provide a reasonable time to prepare the client and his or her parents or guardian for the transfer or discharge (except in emergencies).	§483.440(b)(4)(ii) FACILITY PRACTICES: The individual and the family or guardian are involved in planning for movement. The individual and the family or guardian receive the services necessary to assist in preparing for movement, unless an emergency situation prevents that involvement. §483.440(b)(4)(ii) GUIDELINES: The family and the individual should be involved in any decision to move an individual, since this decision generally, should be part of a team process that includes the individual or guardian. If an individual has an advocate, the advocate should participate in the decision-making process. §483.440(b)(4)(ii) PROBES: What do individuals who are being considered for transfer/discharge (and/or parents, etc.) report about their participation in the process (if any)? Does the IPP reflect objectives preparing the individual for transfer or community placement? How are individual and family views recognized by facility staff? How do they deal with them?
	(5) At the time of the discharge, the facility must- -	
W203	(i) Develop a final summary of the client's developmental, behavioral, social, health and nutritional status	§483.440(b)(5)(i) FACILITY PRACTICES: A final summary is developed. The final summary accurately describes the individual, including his/her strengths, needs, required services, social relationships and preferences.

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W204	and, with the consent of the client, parents (if the client is a minor) or legal guardian, provide a copy to authorized persons and agencies; and	§483.440(b)(5)(i) FACILITY PRACTICES: The final summary is released only with the consent of the legally appropriate party.
W205	(ii) Provide a post-discharge plan of care that will assist the client to adjust to the new living environment.	§483.440(b)(5)(ii) FACILITY PRACTICES: Information in the post-discharge plan is sufficient to allow the receiving facility to provide the services and supports needed by the individual in order to adjust to the new placement. The facility supports and assists the individual in this transfer. §483.440(b)(5)(ii) GUIDELINES: The discharge plan required by 42 CFR 456.380 and the "post-discharge plan of care are the same. The regulations require only one discharge plan which meets the requirements.
	(c) Standard: Individual program plan.	
W206	(1) Each client must have an individual program plan developed by an interdisciplinary team that represents the professions, disciplines or service areas that are relevant to- - (i) Identifying the client's needs, as described by the comprehensive functional assessments required in paragraph (c)(3) of this section; and (ii) Designing programs that meet the client's needs.	§483.440(c)(1) FACILITY PRACTICES: The individual's interdisciplinary team is composed of those individuals (professionals, paraprofessionals and non-professionals) who possess the knowledge, skills and expertise necessary to accurately identify the comprehensive array of the individual's needs and design a program which is responsive to those needs. §483.440(c)(1) GUIDELINES: There is no "correct" number of individuals who comprise the interdisciplinary team. The regulation also does not specify the professional disciplines which make up the interdisciplinary team. Based upon outcomes, assess whether the expertise available to the team was appropriate to meet the needs of the individual. The facility must make every effort to coordinate the IEP or program plan from an outside day program with the IPP process. This may result in a single IEP/IPP document, but there is no requirement for the IPP to be one document. The "collective" IPP must contain the information required under the regulations, and observation should confirm integration of the IPP across the various settings. Negative answers to the following probes may indicate a lack of input from appropriate team members. Evaluate findings for systemic lack of input by a particular team member, lack of communication among team members, or lack of team effort and cooperation.

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		§483.440(c)(1) PROBES: Do the plans from individual to individual have a predictable sameness about them? Does the plan flow from only original diagnosis/assessment? Does it take into consideration interim progress or emergent needs? Does the team create an integrated plan or is the plan a "stapling together" of individual pieces with little or no discussion as to how pieces relate/impact on each other? Are conflicts seen among various pieces of the plan? Refer to W120. When prepackaged programs are used, are needed individual adaptations tailored to the needs, and functional skills of an individual?
W207	(2) Appropriate facility staff must participate in interdisciplinary team meetings.	§483.440(c)(2) GUIDELINES: Meetings should be scheduled and conducted to facilitate the participation of all members of the team, but especially the individual, unless he or she is clearly unable or unwilling, the individual's parents (except in the case of a competent adult who does not desire them to do so) or the individual's guardian or legal representative. The ICF/IID is expected to pursue aggressively the attendance of all relevant participants at the team meeting, (e.g., a conference call with a consultant during deliberations meets this requirement). Question routine "unscheduled" absences by individuals, guardians and particular disciplines or consultants, and determine the impact on effectiveness and responsiveness of the IPP to meet the individual's needs. §483.440(c)(2) PROBES: Does the facility have a working means of gathering all needed data for IPP sessions? Are the views of staff not present at the team meeting incorporated in the plan? Are individuals/parents/guardians provided with information prior to a meeting which will be used at the meeting to make decisions? Does the scheduling of the program planning meeting take into account the schedules of day programs and the availability of family? If unable to attend, does someone review the results of meetings, and act on areas of question, dispute? If individuals served do not attend IPP meetings, what reasons do staff give to explain their absence? How does staff prepare individuals to participate in interdisciplinary team meetings? Does the facility respect individual wishes for additional representatives on the interdisciplinary team, such as friends or advocates?
W208	Participation by other agencies serving the client is encouraged.	
W209	Participation by the client, his or her parent (if the client is a minor), or the client's legal guardian is required unless the participation is unobtainable or inappropriate.	

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W210	(3) Within 30 days after admission, the interdisciplinary team must perform accurate assessments or reassessments as needed to supplement the preliminary evaluation conducted prior to admission.	§483.440(c)(3) FACILITY PRACTICES: For new admissions, the assessment is completed within 30 days of admission. New, revised or updated assessments accurately identify the functional abilities of the individual (whether or not that individual is a new admission). Observations and interviews confirm the accuracy of these assessments. §483.440(c)(3) GUIDELINES: "Accurate" assessments refer to assessment data that are current, relevant and valid, and that the skills, abilities, and training needs identified by the assessment correspond to the individual's actual status. Additionally, for assessment data to be accurate, the cultural background and experience of the individual must be reflected in the choice, administration and interpretation of the evaluation(s) used. A few examples of appropriate adaptations might be: specialized equipment, use of an interpreter, use of manual communication, tests designed to measure performance in the presence of visual disability, etc. The contents of assessments or the particular assessment which must be used are not specified. A nursing assessment, for example, would not need to reference all domains, or a psychiatric or psychological evaluation would not necessarily have to be based on a particular "tool". Similarly, the results of the comprehensive assessment are not required to be written into a narrative report(s). Verify that the tests, evaluations, etc. that comprise the comprehensive functional assessment, yield data that are accurate, reflect the current status and needs of the individual, and can serve as a functional basis for an IPP to be developed.
	The comprehensive functional assessment	
W211	must take into consideration the client's age (for example, child, young adult, elderly person) and the implications for active treatment at each stage, as applicable, and must- -	§483.440(c)(3) FACILITY PRACTICES: Assessments address areas and active treatment needs which are relevant to the person's chronological age. The individual is given opportunities to participate in age-appropriate activities to assess the person's functioning in those activities or settings. §483.440(c)(3) GUIDELINES: The active treatment assessment process should be sensitive to the behaviors of individuals throughout their life span. For example, infants and toddlers are expected to engage in more play-related, exploratory activities, adolescents are expected to engage in activities of increasingly greater responsibility in preparation for adulthood, adults are expected to support themselves or at least be engaged in training or education activities toward that end, and elderly citizens, are expected to choose whichever form of productive activity meets their needs and interests (employment, handiwork, pursuit of leisure, etc.) for as long as they are able.

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W212	(i) Identify the presenting problems and disabilities and where possible, their causes;	§483.440(c)(3)(i)--(iv) FACILITY PRACTICES: Diagnoses are present, when applicable. Diagnoses are based on relevant, objective and accurate data. Diagnoses are modified as accurate, relevant, and updated as medical or other professional information becomes available. §483.440(c)(3)(i) GUIDELINES: In the presence of a diagnoses (medical or otherwise), evaluation data must be available to support the determination.
W213	(ii) Identify the client's specific developmental strengths;	§483.440(c)(3)(ii) FACILITY PRACTICES: The individual's preferences, methods of coping/compensation, friendships and positive attributes are clearly described in functional terms in assessments. Identified strengths are current, complete and consistent with the individual's observed functional status.
W214	(iii) Identify the client's specific developmental and behavioral management needs;	§483.440(C)(3)(iii) FACILITY PRACTICES: The individual's needs, skill deficits, and functional limitations are clearly described in functional terms in the assessments. Identified needs are current, accurate, complete and reflect the individual's observed functional status. §483.440(C)(3)(ii-iii) GUIDELINES: The comprehensive functional assessment (CFA) may be a report synthesizing the results of salient assessments or a series of reports. If individual reports are utilized, the complete diagnostic work-up or problem list identified by others is not required to be repeated unless it is relevant to the particular assessment. Findings are recorded in terms that facilitate clear communication across disciplines. Diagnoses or imprecise terms and phrases (including, but not limited to, "grade level," "age level," "developmental level," "good attending skills," and "poor motor ability") in the absence of specific terms, are not acceptable. Assessment of the behavior assumed to be maladaptive should include analyses of the potential causes, such as lack of exposure to positive models and teaching strategies, lack of ability to communicate needs and desires, lack of success experiences, a history of punishing experiences, presence of a physiological condition, or other environmental or social conditions which may elicit or sustain the behavior. Specific "developmental" strengths and needs describe what the individual "can" and "cannot" do.

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		§483.440(c)(3)(i)--(iii) PROBES: Do assessments interpret the significance of the results in terms of the individuals' functional daily life needs or do they simply describe diagnoses, test performances or clinical impressions? Do assessments merely report scores or functioning age levels or in the absence of strengths/needs lists, are the skills necessary to support those determinations identified within the assessment? Do the strengths and needs identified by the facility correspond to what you see individuals do or not do during observations? Does the assessment reflect how the environment could be changed to support the person?
W215	(iv) Identify the client's needs for services without regard to the actual availability of the services needed; and	§483.440(c)(3)(iv) FACILITY PRACTICES: Identification of needed services is based on the comprehensive functional assessment. Recommendations are present to address areas of deficits. §483.440(c)(3)(iv) GUIDELINES: In the presence of significant developmental deficits, it is not acceptable for the comprehensive evaluation to identify that a particular professional therapy or treatment is not needed. To meet the requirement for "need for service," the assessment must identify the course of specific interventions recommended to meet the individual's needs in lieu of direct professional therapy or treatment. §483.440(c)(3)(iv) PROBES: Do assessments conclude whether or not "hands-on" therapy conducted by professionals is indicated, and if an individual problem still exists, does the assessment recommend how the team should deal with the problem? Is there a pattern of individual need areas not addressed in individuals' IPP objectives that correspond to the absence of those professional service areas at the facility?
	(v) Include	§483.440(c)(3)(v) FACILITY PRACTICES: Assessment of each area is present. Assessment of each area provides specific information about the person's ability to function in different environments, specific skills or lack of skills, and how function can be improved, either through training, environmental adaptations, or provision of adaptive, assistive, supportive, orthotic, or prosthetic equipment. §483.440(c)(3)(v) GUIDELINES: The facility must assess in developmental areas, but not by professional disciplines unless the functional assessment shows a need for a full professional evaluation. Findings relative to the domains required under '483.440(c)(3)(v) include, but are not

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		limited to:
W216	physical development and health,	1. Physical development and health. Physical development includes the individual's developmental history, results of the physical examination conducted by a licensed physician, physician assistant, or nurse practitioner, health assessment data (including a medication and immunization history), which may be compiled by a nurse, and skills normally associated with the monitoring and supervision of one's own health status, and administration and or scheduling of one's own medical treatments. When indicated by physical examination results, consultations by specialists are provided or obtained. The need for advance directives or do not resuscitate (DNR) orders may be assessed on a case-by-case basis, as part of this area by individuals qualified to do so.
W217	nutritional status,	2. Nutritional status. Nutritional status includes determination of appropriateness of diet, adequacy of total food intake, and the skills associated with eating, (including chewing, sucking and swallowing disorders), food service practices, and monitoring and supervision of one's own nutritional status.
W218	sensorimotor development,	3. Sensorimotor development: Sensory development includes the development of perceptual skills that are involved in observing the environment and making sense of it. Motor development includes those behaviors that primarily involve: muscular, neuromuscular, or physical skills and varying degrees of physical dexterity. Because sensory and motor development are intimately related, and because activities in these areas are functionally inseparable, attention to these two aspects of bodily activity is often combined in the concept of sensorimotor development. Assessment data identify the extent to which corrective, orthotic, prosthetic, or support devices would impact on functional status.
W219	affective development,	4. Affective (Emotional) development. Affective or emotional development includes the development of behaviors that relate to one's interests, attitudes, values, and emotional expressions.
W220	speech and language development	5. Speech and language (communication) development. Communication development refers to the development of both verbal and nonverbal and receptive and expressive communication skills. Assessment data identify the appropriate intervention strategy to be applied, and which, if any, augmentative or assistive devices will improve communication and functional status.
W221	and auditory functioning,	6. Auditory functioning. Auditory functioning refers to the extent to which a person can hear and to the maximum use of residual hearing if a hearing loss exists and whether or not the individual will benefit from the use of amplification, including a hearing aid or a program of amplification. An individual's treatment might need to include being desensitized to tolerate the use of a hearing aid or assistive listening device to prevent the device from being rejected or destroyed. Assessment may include teaching techniques for conducting the assessment or the use of electrophysiologic techniques.

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W222	cognitive development,	7. Cognitive development. Cognitive development refers to the development of those processes by which information received by the senses is stored, recovered, and used. It includes the development of the processes and abilities involved in memory, reasoning and problem solving.
W223	social development,	8. Social Development. Social development refers to the formation of those self-help, recreation and leisure, and interpersonal skills that enable an individual to establish and maintain appropriate roles and fulfilling relationships with others.
W224	adaptive behaviors or independent living skills necessary for the client to be able to function in the community,	9. Adaptive behaviors or independent living skills. Adaptive behavior refers to the effectiveness or degree with which individuals meet the standards of personal independence and social responsibility expected of their age and cultural group. Independent living skills include, but are not limited to, such things as meal preparation, doing laundry, bedmaking, and budgeting. Assessment may be performed by anyone trained to do so. Standardized tests are not required. Standardized adaptive behavior scales which identify all or predominantly all "developmental needs" are not sufficient enough to meet this requirement, but can serve as a basis for screening.
W225	and as applicable, vocational skills.	10. Vocational (prevocational) development, "as applicable". Vocational development refers to work interests, work skills, work attitudes, work-related behaviors, and present and future employment options. The determination of whether or not a vocational assessment is "applicable" is typically based on age (adolescents or adults more than likely require this type of assessment). §483.440(c)(3)(v) PROBES: For all domains, do assessments describe what individuals can and cannot do in terms of skills needed within the context of their daily lives? Is the assessment based on: o Actual performance of the individual against objectified criteria? o Reports by staff/parents/guardians? o Observed performance in a variety of settings? o Simple checklists? Are assessments individualized? Are assessments conducted in appropriate environments?
W226	(4) Within 30 days after admission, the interdisciplinary team must prepare for each client an individual program plan	

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W227	that states the specific objectives necessary to meet the client's needs, as identified by the comprehensive assessment required by paragraph (c)(3) of this section,	§483.440(c)(4) FACILITY PRACTICES: The IPP contains a list of specific objectives based on needs identified in the CFA. There is a clear link between the specific objectives and the functional assessment data and recommendations. Objectives are developed for those needs that are observed to most likely impact on the individual's ability to function in daily life. §483.440(c)(4) GUIDELINES: The presence of a comprehensive list of behaviorally stated needs is acceptable for this portion of the requirement. "Comprehensive" means that objectives are stated for the needs identified in each domain included in the comprehensive functional assessment. Objectives may address services to be provided, learning/treatment needs, adaptive equipment, etc. "483.440(c)(4)(i)-(v) regulate requirements for current IPP training objectives (as opposed to staff, service, or long term objectives). Validate that the needs identified by the team are appropriate for the individual based upon review of the comprehensive functional assessment data, observations, and interviews with the individual and staff. §483.440(c)(4) PROBES: Is there a predominant pattern of staff-oriented objectives rather than learner-oriented objectives? Is there repetition and predictability of programming across individuals?
W228	and the planned sequence for dealing with those objectives.	§483.440(c)(4) FACILITY PRACTICES: The objectives identified in W227 are arranged in a sequence identifying the logical order in which they will be addressed. Objectives are organized in a sequence relevant to the individual's long term development. §483.440(c)(4) GUIDELINES: To organize objectives into a planned sequence the ICF/IID must consider the outcomes it projects for the individual in the long term. For example, if the long term objective is for the individual to travel independently in the community, the planned sequence may involve training the individual to recognize traffic signs, cross a street safely, and to obtain help when needed if lost or an emergency arises. Interview staff to discover the purpose to be achieved upon completion of the objective. For example, does staff know why an individual is taught to stack rings?
	These objectives must- -	

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W229	(i) Be stated separately, in terms of a single behavioral outcome;	§483.440(c)(4)(i) FACILITY PRACTICES: Each objective clearly states one expected learning result. §483.440(c)(4)(i) GUIDELINES: "Single" behavioral outcome means that for each discrete behavior that the team intends the individual to learn a separate objective is assigned. (For example, "Mary will bake a cake and clean the oven" are two separate behaviors and, therefore, should be stated in two separate objectives.) Performance of a series of separate behaviors could constitute a single behavioral outcome when appropriate for the individual. For example, completing a hygiene routine of face washing, toothbrushing and haircombing is one behavioral outcome when the individual is able to perform each of those skills, but needs to learn to complete the entire routine each morning.
W230	(ii) Be assigned projected completion dates;	§483.440(c)(4)(ii) FACILITY PRACTICES: Completion dates are based on the individual's rate of learning. Completion dates are assigned to each objective on which the individual is currently working. Completion dates are individualized (i.e., not all the same for all clients and all objectives). §483.440(c)(4)(ii) GUIDELINES: The "projected date of completion" for an IPP objective is not the same as a "review" date. For each objective assigned priority, the team should assign a projected date (month and year) by which it believes the individual will have learned the new skill, based on all of the assessment data. This date triggers the team to evaluate continuously whether or not the individual's progress or learning curve is sufficient to warrant a revision to the training program. There is no requirement to identify an implementation date for each objective in the plan.
W231	(iii) Be expressed in behavioral terms that provide measurable indices of performance;	§483.440(c)(4)(iii) FACILITY PRACTICES: The learning outcome is stated in a manner which enables all staff working with the individual to consistently identify the target behavior and to clearly identify when it is being displayed. The objective is stated in a manner which permits it to be quantifiably measured. §483.440(c)(4)(iii) GUIDELINES: "Behavioral" terms include only those behaviors which are "individual" rather than "staff" oriented and those that any person would agree can be seen or heard. Determine if all staff who work with the individual can define the exact same outcome on which to measure the individual's performance. "Measurable indices of performance" are the quantifiable criteria to use in determining successful achievement of the objective. Criteria include various measurements of intensity and duration. For example, "M. will walk ten feet, with her tripod walker, for 5 consecutive days."

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W232	(iv) Be organized to reflect a developmental progression appropriate to the individual; and	§483.440(c)(4)(iv) FACILITY PRACTICES: Objectives and criteria for success are based on the individual's current or baseline functional abilities. Objectives are designed to allow the individual to experience success in achieving those objectives. Objectives are individualized to take into consideration the individual's abilities and disabilities. Objectives are organized to begin with the next logical step, given the individual's current functioning, and move toward more complex behavior. §483.440(c)(4)(iv) GUIDELINES: To organize an objective in an appropriate progression, the ICF/IID must consider the person's current functional abilities and project what steps, methods and strategies are likely to be effective in achieving the objective. Baseline data are one means of establishing an appropriate starting point for an objective. Objectives must be adapted based upon the person's functional abilities. For example, if the objective is to learn to put on shoes independently and the person does not have the manual dexterity to tie shoe laces, then the objective could include the use of slip-on shoes or shoes with velcro closures in order to facilitate the person learning this skill. §483.440(c)(4)(iv) PROBES: Are chosen objectives the most direct means for resolving identified needs? Do programs and strategies have a relationship to needs identified and objectives chosen?
W233	(v) Be assigned priorities.	§483.440(c)(4)(v) FACILITY PRACTICES: The IDT identifies which objectives are the most important to work on now. Skills and behaviors which significantly impact upon the individual's day-to-day functioning are worked on first. §483.440(c)(4)(v) GUIDELINES After all the training objectives have been established as required by W227, the IPP identifies those objectives which the team considers to be most important, or which need to be implemented before others can be accomplished, and then assigns them priority. Some examples of assigning priority include, but are not limited to, rank ordering (most important to least important), assignment of "priority" or "non-priority", etc. §483.440(c)(4)(v) PROBES: Is there a pattern of most individuals' objectives having the same "prioritization" assignment (e.g., do most individuals have a number one objective as handwashing or

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		does the facility select a specific number of objectives of equal importance)? Are objectives and priorities based on each individual's needs?
	(5) Each written training program designed to implement the objectives in the individual program plan must specify:	§483.440(c)(5) GUIDELINES: The written training program refers only to those objectives to which the team has assigned priority status for formal implementation.
W234	(i) The methods to be used;	§483.440(c)(5)(i) FACILITY PRACTICES: The training program provides clear directions to any staff person working with the individual on how to implement the teaching strategies.
W235	(ii) The schedule for use of the method;	§483.440(c)(5)(ii) FACILITY PRACTICES: The training program provides clear directions to any staff person working with the individual about when the strategies are to be implemented.
W236	(iii) The person responsible for the program;	§483.440(c)(5)(iii) FACILITY PRACTICES: The person who will monitor the program and ensure it is being implemented appropriately, is clearly identified on the written training program. §483.440(c)(5)(iii) GUIDELINES: This may or may not be the same person who implements the program. There is no requirement to identify who implements the program.
W237	(iv) The type of data and frequency of data collection necessary to be able to assess progress toward the desired objectives;	§483.440(c)(5)(iv) FACILITY PRACTICES: The training program provides clear directions to any staff person working with the individual about the type of data to record, and the frequency which data is to be recorded. The data collection system is directly related to the outcome stated in the objective. §483.440(c)(5)(iv) GUIDELINES: The facility must determine the type of data necessary to judge an individual's progress on an objective, and describe that data collection method in the written training program. The facility determines what data to collect, but the system chosen must yield accurate measurement of the criteria stated in the individual's IPP objectives. For example, if the criteria in the individual's IPP objective specified some behavior to be measured by "accuracy," or "successes out of opportunities," then it would not be acceptable for the prescribed data collection method to record "level of prompt." Methods of data collection on IPP training programs should be based on the total (including direct care) facility's staff analysis and observations of an individual's behavior. Examples of a few data collection systems include, but are not limited to,

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		level of prompt, successful trials completed out of opportunities given, frequency counts, frequency sampling, etc. The facility should collect data with enough frequency and enough content that it can measure appropriately the individual's performance toward the targeted IPP objective.
W238	(v) The inappropriate client behavior(s), if applicable; and	§483.440(c)(5)(v) FACILITY PRACTICES: Any behaviors which would interfere with the individual's ability to function in, or benefit from the training program are identified.
W239	(vi) Provision for the appropriate expression of behavior and the replacement of inappropriate behavior, if applicable, with behavior that is adaptive or appropriate.	§483.440(c)(5)(vi) FACILITY PRACTICES: The training program provides specific information as to how to elicit or strengthen appropriate behavior and what behaviors to teach, reinforce or encourage which would reduce or replace the inappropriate behavior. Replacement behaviors are functionally related to the targeted behavior.
	(6) The individual program plan must also:	
W240	(i) Describe relevant interventions to support the individual toward independence.	§483.440(c)(6)(i) FACILITY PRACTICES: The IPP provides specific information to any staff person working with the individual about what services and supports they are to provide to assist the individual in functioning at a more independent level.
W241	(ii) Identify the location where program strategy information (which must be accessible to any person responsible for implementation) can be found.	§483.440(c)(6)(ii) FACILITY PRACTICES: Staff know where to find information about the programs to be implemented.
W242	(iii) Include, for those clients who lack them, training in personal skills essential for privacy and independence (including, but not limited to, toilet training, personal hygiene, dental hygiene, self-feeding, bathing, dressing, grooming, and communication of basic needs), until it has been demonstrated that the client is developmentally incapable of acquiring them.	§483.440(c)(6)(iii) FACILITY PRACTICES: All individuals who lack the skills listed have training programs designed to meet their needs. These programs are consistently implemented in both formal and informal settings. There is documentation of consistent, appropriate attempts to teach individuals these skills, or specific evidence as to a medical condition which would preclude acquisition, prior to determination of developmental incapability. Appropriate materials, adaptations and modifications to equipment and the environment are available in order to promote and support individual training programs. §483.440(c)(6)(iii) GUIDELINES: The receipt of training targeted toward amelioration of these most basic skill deficit

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		areas is a critical component of the active treatment program needed by individuals who are eligible for the ICF/IID benefit, and therefore, is a required ICF/IID service. Some ADL skills overlap with each other (e.g., personal hygiene, oral hygiene, grooming and bathing). It is acceptable for the interdisciplinary team to set priorities within these overlapping skills. It must be clear, however, that the facility has organized its services to emphasize training in these areas. This will be seen not only in the IPP, but also in the competent interaction of staff with individuals, in both formal and informal settings. This basic skill training defines the nature of ICF/IID services. To the extent that individuals demonstrate that they increasingly do not need the types of services described in this requirement, and increasingly correspond to the characteristics of clients described at W197 such that the "overall" nature of the facility services would not be required to provide the type of emphasis described at W242, question the appropriateness of the individual's placement in an ICF/IID and/or the certification of the facility as an ICF/IID (see W197 and W198). "Training" as used in this regulation means: o Aggressive implementation of a systematic program of formal and informal techniques (competent interactions); o Continuously targeted toward the individual achieving the measurable behavioral level of skill competency specified in IPP objectives; o Conducted in all applicable settings; and o Conducted by all personnel involved with the client. "Developmental incapability" is a decision to be made by the interdisciplinary team based on its assessment of the individual's developmental strengths and needs. For example, there is ample evidence that even individuals with the most severe physical and mental disabilities can be toilet trained. Recognition is given to the fact that some individuals, however, have insufficient sensory and neuromuscular control ever to be totally independent in toileting skills. For most of this group, there are intermediate steps which can be achieved, including toilet scheduling, in which the individual is able to be trained to a schedule of elimination with needed assistance from staff. The intent of the toileting part of this regulation is met if there is evidence that the individual has been provided an aggressive, well organized, and well executed toilet training program in the past and that the team determines the individual's "developmental incapability." §483.440(c)(6)(iii) PROBES: Is evidence of "developmental incapability" based on individual performance, medical evidence, historical efforts at training; or is it based on "opinions" of staff (in the absence of performance data)? Does the activity prepare individuals to function more independently or does it merely train the individual to adapt to his/her particular facility (e.g., large institutional living)? Do staff direct their activities toward the acquisition of individuals to learn increasingly complex skills or do staff accept that individuals will not or cannot grow and change?

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	(iv) Identify mechanical supports, if needed, to achieve proper body position, balance, or alignment. The plan must specify	§483.440(c)(6)(iv) GUIDELINES: Mechanical devices used to support an individual's proper body position or alignment may be essential to prevent contractures and deformities, but the staff should be sensitive to the fact that mechanical supports may restrict movement and the individual should not be in the supports all the time or as a substitute for programs or therapy which may reduce the dependency on the support. Some supports allow movement and provide opportunity for more increased functioning. Some examples of devices used as mechanical supports include splints, wedges, bolsters, lap trays, etc. Wheelchairs are not generally used to position or align the body and would not alone constitute a mechanical support. However, adaptations to wheelchairs which do position or align the body would have to be specified according to this requirement. Adaptations to a wheelchair which facilitate correct body alignment by inhibiting reflexive, involuntary motor activity are also mechanical supports.
W243	the reason for each support,	
W244	the situations in which each is to be applied,	
W245	and a schedule for the use of each support.	
W246	(v) Provide that clients who have multiple disabling conditions spend a major portion of each waking day out of bed and outside the bedroom area, moving about by various methods and devices whenever possible.	§483.440(c)(6)(v) FACILITY PRACTICES: Individuals with sensory or physical difficulties have the same opportunities to move around in their environments as individuals who do not have those difficulties. v483.440(c)(6)(v) GUIDELINES: With the exception of those individuals who are acutely ill (such as those who are hospitalized or incapacitated by a short term illness), all individuals should be out of bed and outside their bedroom area as long as possible each day, and in proper body alignment at all times. This is a necessity in order to prevent regression, contractures, and deformities and to provide sensory stimulation. Question patterns of bed rest "orders" or "scheduled" bed rest as a routine part of an individual's program. A nap period of an hour, for example, is not "bed rest." However, if the ICF/IID, as a general pattern of scheduling, expects an individual to be one-two hours in bed in the morning, one-two hours in bed in the afternoon, and an 8:00 p.m. bedtime in the evening, for example, then the practice becomes "bed rest," and the intent of the regulation will more than likely not be met. Question seriously large amounts of time during which a resident is confined to bed. §483.440(c)(6)(v) PROBES: For those for whom out-of-bed activity is a threat to their health and safety, look for: o Individuals and staff engaged in activities to increase sensory stimulation; and o Equipment designed to promote increasing the individual's sensory stimulation. Is equipment available to provide access to community activities? Are mobility devices available and used as needed by individuals?

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W247	(vi) Include opportunities for client choice and self-management.	§483.440(c)(6)(vi) FACILITY PRACTICES: Individuals are provided opportunities for choice, encouraged and taught to make choices, and to exercise control over themselves and their environment. §483.440(c)(6)(vi) GUIDELINES: Due to the basic underlying importance "choice" plays in the quality of one's life, the ICF/IID should maximize daily activities for its individuals in such a way that varying degrees of decision-making can be practiced as skills are acquired. Examples of some activities leading toward responsibility for one's own self-management include, but are not limited to, choosing housing or roommates, choosing clothing to purchase or wear, choosing what to eat, making and keeping appointments, and choosing from an array of appropriate activities. Interview staff to determine how attitudes and activities of the team and consultants facilitate or impede individual choice. Choices can be made by all individuals. The type of choices the person makes may vary from very simple to more complex, depending upon individual abilities. Look at choices in the context of the individuals served by the facility.
W248	(7) A copy of each client's individual plan must be made available to all relevant staff, including staff of other agencies who work with the client, and to the client, parents (if the client is a minor) or legal guardian.	§483.440(c)(7) FACILITY PRACTICES: The individual or legal representative, as well as the facility staff, and staff from outside agencies have, or can access, a copy of the plan.
	(d) Standard: Program implementation.	
W249	(1) As soon as the interdisciplinary team has formulated a client's individual program plan, each client must receive a continuous active treatment program consisting of needed interventions and services in sufficient number and frequency to support the achievement of the objectives identified in the individual program plan.	§483.440(d)(1) FACILITY PRACTICES: Each individual is receiving training and services consistent with the current IPP. Staff use the adaptive equipment, assistive devices, environmental supports, materials, supplies, etc., specified in each individual's IPP to accomplish stated objectives. A consistent approach is being implemented in all environments. The pattern of interactions observed supports the active treatment program (e.g., informal opportunities to reinforce learning or appropriate skill development are taken, needs are addressed as they present themselves). The active treatment program is not delayed or suspended while waiting for the written IPP document. Activities support the accomplishment of the IPP objectives.

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		An individual's persistent refusal to participate in active treatment is being addressed by the IDT. §483.440(d)(1) GUIDELINES: For an individual newly admitted to the ICF/IID, the time period between admission and the 30 day interdisciplinary team meeting should be primarily for purposes of assisting the individual to become adjusted and acclimated to his or her new living environment and completing the functional assessment. During this time period the facility should also be providing those services and activities determined during the pre-admission assessment as essential to the individual's daily functioning. In order to be able to produce the comprehensive assessment, the facility must evaluate the individual's status in as many naturally occurring, functional environments as possible. It must be clear that the active treatment program received by the individual is internally consistent and not simply a series of disconnected formal intervention applications within certain scheduled intervals. The criteria of what constitutes a "sufficient number and frequency of interventions" are based on the individual's assessment and the progress the individual makes toward achieving IPP objectives. Whether "structure" must be imposed by staff or whether the individual can direct his or her own activities for a period of time (without direct staff observation) is based on the individual's ability to engage in constructive, age-appropriate, adaptive behavior (without engaging in maladaptive behavior to self or others). Be certain that an individual's time in the home or living unit is maximized toward the further development and refinement (including self-initiation) of appropriate skills, including, but not limited to, leisure and recreation. For the active treatment process to be effective, the overall pattern of interaction between staff and individuals must be accountable to the comprehensive functional assessment and the IPP process. During the overall observation of individuals, you should be able to track that: the individual's comprehensive assessment identified the specific developmental need or strength justifying the activity, technique or interaction; in the case of a "need," the team projected a measurable objective or target to address it; and the technique, interaction, or activity which is observed, produced the desired target, produced a close approximation of the target, or was modified based on the individual's response. §483.440(d)(1) PROBES: Does the activity schedule and the content of the activities relate directly to the strengths, needs and objectives in the IPP for each individual or are the activities/content "make work," generalized, non-developmental time fillers? Can staff describe how activities relate to strengths, needs and IPP objectives?

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		Are active treatment activities integrated into a "normal daily rhythm"? Are individuals observed performing scheduled active treatment activities? Are there sufficient and appropriate staff to implement IPPs? Is training on priority objectives implemented at discrete time intervals exclusively, or is training implemented as the individual's needs emerge during the course of the day, as well? Is there a consistent discernible pattern of evidence that staff implement, practice, reinforce, and otherwise carry out strategies to achieve individual objectives? At any point in time are IPP interventions observable during staff and individual interactions, in formal and informal settings alike, throughout the individual's living experience? Does the classroom, therapy or activity environment lend itself to the learning experience or are distractions, noise levels, or other individual behaviors obstacles to individual learning?
W250	(2) The facility must develop an active treatment schedule that outlines the current active treatment program and that is readily available for review by relevant staff.	§483.440(d)(2) FACILITY PRACTICES: The schedule is individualized and consistent with the individual's objectives. The schedule is known to staff working with the individual. Staff know where to locate a schedule when they need it. The active treatment schedule allows flexibility and is adjusted to the needs and preferences of the individual, as necessary. The active treatment schedule reflects normal daily rhythms. §483.440(d)(2) GUIDELINES: The active treatment schedule directs the intensity of the daily work of the staff and the individuals in implementation of the IPP in both informal and formal training activities. To the extent possible, the schedule provides a range of options, rather than a fixed regimen. Individuals should have opportunities to choose activities and to engage in them as independently and freely as possible. Staff routines and schedules should be supportive of this goal and result in the presence of reasonable choices by individuals. Investigate any pattern of staff action or scheduling which results routinely in all or the majority of individuals engaging in the same activity or routine at the same time. For example, everyone is out of bed, awake and dressed before staff on the third shift go home, or everyone goes to bed before the third shift arrives.

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		The active treatment schedule is not required to be posted. While the facility should have the individual's schedule from the day program, there is no requirement that this schedule and the residential schedule be merged into one document.
W251	(3) Except for those facets of the individual program plan that must be implemented only by licensed personnel, each client's individual program plan must be implemented by all staff who work with the client, including professional, paraprofessional and nonprofessional staff.	§483.440(d)(3) FACILITY PRACTICES: All staff working with the individual implement all aspects of the active treatment program unless such implementation is restricted to licensed personnel. Each discipline works together to provide a uniform, consistent approach to implementation of the IPP across disciplines. §483.440(d)(3) GUIDELINES: The facility is responsible for ensuring that during staff time spent with individuals, the staff member is able to provide needed interventions or reinforce acquired skills in accordance with the IPP. This is one of the ways the ICF/IID implements continuous active treatment. "All" staff includes direct care staff. The activities of the ICF/IID are coordinated with other habilitative and training activities in which the individual may participate outside of the ICF/IID, and vice versa. §483.440(d)(3) PROBES: Do staff assigned to work with the individual encourage him or her to perform activities of daily living with maximum independence? Is development and reinforcement of these skills implemented regularly? Is there evidence that each discipline working with the individual integrates, as appropriate, other disciplines' objectives and techniques? (For example, does direct care staff implement manual communications systems? Does the O.T. implement behavior management programs, if needed by the individual, during O.T. training sessions?) Are informal daily activities designed to promote choice, self-management, skill enhancement or reinforcement?
	(e) Standard: Program documentation.	
W252	(1) Data relative to accomplishment of the criteria specified in client individual program plan objectives must be documented in measurable terms.	§483.440(e)(1) FACILITY PRACTICES: Data are collected in the form and frequency required by the plan. Data are accurate, i.e., reflective of actual individual performance. §483.440(e)(1) GUIDELINES: Data collection is evidence of individual performance and should not be taken

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		constantly as evidence for surveyors that "treatments" occurred. "Data" are defined to be performance information collected and reported in numerical or quantifiable form on training objectives assigned priority in the IPP. Data are those performance measurements recorded at the time the treatment, procedure, intervention or interaction occurs with the individual. They should be located in a place accessible to staff who conduct training. §483.440(e)(1) PROBES: Do the data collected on an individual basis vary according to the nature of the task, or are data collected the same way for all individuals on all tasks? Do the data collected yield information relevant to making program decisions? Are the data collected on objectives implemented outside the agency also reviewed and analyzed to justify change in the objectives? Is there a correlation between recorded data and observed individual performance?
	(2) The facility must document significant events that	§483.440(e)(2) GUIDELINES: See also '483.410(c) Client Records.
W253	are related to the client's individual program plan and assessments and	§483.440(e)(2) FACILITY PRACTICES: Changes in the individual's functional status, health condition, accomplishments, activities or needs which affect the CFA and IPP are documented. §483.440(e)(2) PROBES: Is there a discernable pattern indicating that the facility routinely fails to detect the need to change individual programs? Does the facility record unusual episodes and other incidents that suggest the staff needs to respond with a changing program or other special attention?
W254	that contribute to an overall understanding of the client's ongoing level and quality of functioning.	§483.440(e)(2) FACILITY PRACTICES: Any occurrence(s) inside or outside the facility which provides information about the individual's interactions, responses, progress, or problems beyond the specific parameters of the IPP, are documented.
	(f) Standard: Program monitoring and change.	

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	(1) The individual program plan must be reviewed at least by the qualified intellectual disabilities professional and revised as necessary, including, but not limited to situations in which the client- -	§483.440(f)(1)(i)-(iv) FACILITY PRACTICES: The QIDP ensures the program has been modified or changed in response to the individual's specific accomplishments, need for new programs, or difficulties in acquiring or maintaining skills. §483.440(f)(1)(i)--(iv) GUIDELINES: The interval within which IPP reviews are conducted is determined by the facility. However, the facility's review system must be sufficiently responsive to ensure that the IPP is reviewed whenever the conditions specified in "483.440(f)(1)(i-iv) occur. Information relevant to IPP changes should be recorded as changes occur. §483.440(f)(1)(i)--(iv) PROBES: Is the QIDP actually monitoring individual programs, or does the QIDP simply review paperwork? See also W159. Are timely modifications of unsuccessful programs or development of programs for unaddressed, but significant needs made or ensured by the QIDP? Does the QIDP routinely visit program areas and discuss performance and problems of individuals? Is there evidence that collected data are systematically recorded, analyzed, and used to make changes in programs? Can the QIDP describe the programs implemented with individuals for whom they are responsible or do they need to go to the record for this information?
W255	(i) Has successfully completed an objective or objectives identified in the individual program plan;	
W256	(ii) Is regressing or losing skills already gained;	
W257	(iii) Is failing to progress toward identified objectives after reasonable efforts have been made or;	
W258	(iv) Is being considered for training towards new objectives.	
	(2) At least annually,	§483.440(f)(2) GUIDELINES: For the "annual" review to meet the requirement, it must be completed by at least the 365th day after the last review. The ICF/IID may be required to conduct reviews at more frequent intervals by other, more stringent regulations (e.g., 90 day reviews required by §456.480(6)(c), State regulation, etc.). The facility's failure to comply with these other, more stringent regulations would NOT be cited under this requirement. Refer cases of suspected non-compliance to the authority having jurisdiction for the regulations in question.
W259	the comprehensive functional assessment of each client must be reviewed by the interdisciplinary team for relevancy and updated as needed;	§483.440(f)(2) FACILITY PRACTICES: The comprehensive functional assessment (CFA) is reviewed at least within the required timeframe. The review of the CFA occurs sooner than annually when indicated by the needs of the individual. The CFA reflects changes in the individual since the last assessment.

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		The CFA incorporates information about individual's progress, regression, etc. §483.440(f)(2) GUIDELINES: The review of the CFA applies to all evaluations conducted for an individual, unless otherwise specified in the regulation (e.g., annual physical examination). It is not required that each assessment be completely redone each year. It is required that at least annually the assessment(s) be updated when changes occur so as to accurately reflect the individual's current status. Systematic behaviorally stated data become part of the comprehensive functional evaluation of the individual.
W260	and the individual program plan must be revised, as appropriate, repeating the process set forth in paragraph (c) of this section.	§483.440(f)(2) FACILITY PRACTICES: The IPP reflects and responds to functional changes which have occurred since the last IPP. §483.440(f)(2) GUIDELINES: Look for IPPs that are unchanged from one year to the next, for priority skills and behaviors that are deferred or ignored for one reason or the other, and for informal, vague, and programmatically worthless statements in the review (such as "John did better this year--he wasn't as upset most of the time like he used to be). If the ICF/IID has not been providing the individual with a systematic, behaviorally-oriented active treatment program during the year, the review will be incapable of making systematic, behaviorally-oriented statements about progress and change. If you find problem behaviors which do not decrease significantly, relatively frequent usage of restraint or other intrusive restrictive procedures, a "plateauing" (e.g., reaches partial desired performance, but does not improve over time and staff does not reassess) of skills development, or any other signs of "sameness" year after year, questions should be raised about the extent to which the ICF/IID is providing active treatment, the adequacy of IPPs, staff training, etc., particularly, if many individuals' annual reviews reveal these characteristics. §483.440(f)(2) PROBES: Does the annual review result in actual changes in the individual's programs, or is it a "rubber stamp" duplication of the prior year's plan? Does the facility respond routinely to the need for change in an individual's program or does an individual's program tend to be changed only once a year or on a time periodic basis (e.g., every quarter or six months)? Is there a logical relationship among goals and objectives from year to year or are objectives established in a fragmented, unrelated pattern from year to year? Can the reason for changes, deletions, or additions to IPP objectives be identified?

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W261	(3) The facility must designate and use a specially constituted committee or committees consisting of members of facility staff, parents, legal guardians, clients (as appropriate), qualified persons who have either experience or training in contemporary practices to change inappropriate client behavior, and persons with no ownership or controlling interest in the facility to--	'§483.440(f)(3) FACILITY PRACTICES The facility has a specially constituted committee. The committee is used to accomplish the requirements of W262, W263 and W264. The committee has the required membership and those members participate regularly in the functioning of the committee. §483.440(f)(3) GUIDELINES: Depending on its size, complexity and available resources, the ICF/IID may establish one multi-purpose committee to serve it for all advisory functions, or it may establish separate single-purpose committees. The facility's human rights committee may be shared among other agencies or the ICF/IID may utilize a human rights committee established by another governing body, e.g., a county or a statewide group, as long as all pertinent regulatory requirements are met. The regulation does not specify the professional credentials of the "qualified persons who have either experience or training in contemporary practices to change inappropriate client behavior". There is no requirement that any specific disciplines, such as nurse, physician or pharmacist be members of the committee. The intent of including "persons with no ownership or controlling interest" on the committee is to assure that, in addition to having no financial interest in the facility, at least one member is an impartial outsider in that he/she would not have an "interest" represented by any other of the required members or the facility itself. Staff and consultants employed by the facility or at another facility under the same governing body cannot fulfill this role. Although occasional absences from committee meetings are understandable, patterns of absence by the required membership of the committee is not acceptable. At least a quorum of committee members must review, approve and monitor the programs which involve risk to client rights and protections. Depending upon the size of the facility and the number of individuals who need intrusive or restrictive techniques as a part of active treatment programs, more than one specially constituted committee may be needed to effectively meet the intent of the regulation. The facility is responsible to organize itself in a manner which permits the timely review of proposed programs.
W262	(i) Review, approve, and monitor individual programs designed to manage inappropriate behavior and other programs that, in the opinion of the committee, involve risks to client protection and rights;	§483.440(f)(3)(i) FACILITY PRACTICES: Any programs which incorporate restrictive techniques (e.g., restraints, medication to manage behavior, restrictions on community access, etc.) have been reviewed and approved by the committee prior to implementation. The committee periodically monitors restrictive programs to determine if the restriction of rights or risk to protections remains justified.

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		§483.440(f)(3)(i) GUIDELINES: Each individual program developed to decrease inappropriate behavior and which involves potential risk to rights and protections must be reviewed and approved by the committee prior to the program's implementation. Some examples of programs requiring review include, but are not limited to, programs incorporating usage of restraints, aversive conditioning, any medication used to modify behavior, contingent denial of any right or "earning" of a right as part of a behavior shaping strategy, and behavioral consequences involving issues of client dignity. There is no requirement for the committee to function as a peer review for technical or clinical adequacy of plans submitted for approval. The purpose is to assure that each individual's rights are protected through use of a group of outside individuals who are not invested in the maintenance of facility practices. The committee reviews the context by which each program is recommended, and then evaluates whether the program's level of intrusiveness is warranted. The committee should consider factors such as whether less intrusive methods have been attempted and whether the severity of behavior outweighs the risks of the proposed program. The committee need not reapprove a program when revisions are made, as long as those revisions are in accordance with the approved plan. For example, if the physician changes the dosage of a medication in accordance with the drug treatment component of the active treatment plan to which the legally authorized person has given consent and which has already been approved by the committee, then there is no need for the committee or the legally authorized person to reapprove the plan. (See also W263.) Generally, this would also apply if the medication was changed to another within the same therapeutic class or family. Reapproval would be needed, however, if the reason for the change was the individual's strong untoward response to the original medication. Due to the differences in side effects and potential adverse response between drugs of a different class, reapproval would also be required if the new medication was from a different therapeutic class or family of drugs. §483.440(f)(3)(i) PROBES: Does the committee generally approve whatever staff recommends without substantive review? Does the committee require that less restrictive means be demonstrated to be ineffective? What is the length of time from program submission to committee review? Do you discern a pattern of committee involvement in the ongoing monitoring of approved programs? Does the committee seek changes, if indicated? If staff assigned to the committee(s) are also members of the particular individual's interdisciplinary team, does that staff member abstain from approving formally the individual's program?

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W263	(ii) Insure that these programs are conducted only with the written informed consent of the client, parents (if the client is a minor) or legal guardian; and	§483.440(f)(3)(ii) FACILITY PRACTICES: Written consent is present prior to implementation of any restrictive program. Consent is given by the legally appropriate party. The consent is for the program which incorporates the use of a restrictive technique, rather than the restrictive technique alone. The consent is informed, i.e., the person giving consent is aware of the risks, benefits, alternatives, right to refuse and consequences. §483.440(f)(3)(ii) GUIDELINES: Informed consent consists of permission by the legally responsible party after having been informed of the specific issue, treatment or procedure; the individual's specific status with regard to the issue, treatment or procedure; the attendant risks and benefits; alternative forms of treatment; the right to refuse treatment and the consequences of that refusal. Informed consent implies that the person who is to give consent is competent to evaluate the decision requiring consent. For children up to the age of 18 the parent (natural guardian) or legally appointed guardian must give consent for him or her. At the age of 18, however, children become adults and are assumed to be competent unless otherwise determined by a court. For individuals who are minors or who are clearly incompetent, but have no appointed legal guardian, informed consent for use of restrictive programs, practices or procedures must be obtained from the legal guardian, parent or someone or some agency designated by the State, in accordance with State law, to act as the representative of the individual's interests. Become familiar with the statutes of the State in which the ICF/IID is located to determine who or what mechanism is designated to give informed consent in such circumstances. Verify whether or not consent was obtained in accordance with law. Additionally, under these circumstances, the facility is required to identify those individuals, and expected to advocate for them by demonstrating continuing efforts to obtain timely adjudication of the individual's legal status. The committee must ensure that the informed and voluntary consent of the individual, parent of a minor, legal guardian, or the person or organization designated by the State is obtained prior to each of the following circumstances: the involvement of the individual in research activities, or implementation of programs or practices that could abridge or involve risks to individual protections or rights. Informed consent should be specific, separate ("blanket" consents are not allowed), and in writing. In case of unplanned events requiring immediate action, verbal consent may be obtained, however, it should be authenticated in writing as soon as reasonably possible.

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W264	(iii) Review, monitor and make suggestions to the facility about its practices and programs as	§483.440(f)(3)(iii) FACILITY PRACTICES: The committee has been made aware of and reviewed facility programs and practices which may affect the rights of individuals.
	they relate to drug usage, physical restraints, time-out rooms, application of painful or noxious stimuli, control of inappropriate behavior, protection of client rights and funds, and any other areas that the committee believes need to be addressed.	Committee recommendations have been addressed by the facility. The committee has established and uses a mechanism for monitoring individuals' rights issues. §483.440(f)(3)(iii) GUIDELINES: The function of the committee is not limited to the review, approval and monitoring of restrictive behavior management practices. Examples of individual rights issues that might be reviewed by the committee, in addition to behavior management, include, but are not limited to, research proposals involving individuals, abuse, neglect and mistreatment of individuals, allegations dealing with theft of an individual's personal property or funds, damage to an individual's goods or denial of other individual rights, individual grievances, visitation procedures, guardianship/advocacy issues, rights training programs, confidentiality issues, advance directives/DNR orders, etc.
W265	(4) The provisions of paragraph (f)(3) of this section may be modified only if, in the judgment of the State survey agency, Court decrees, State law or regulations provide for equivalent client protection and consultation.	

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W266	§483.450 Condition of participation: Client behavior and facility practices.	§483.450 COMPLIANCE PRINCIPLES: The Condition of Participation of Client Behavior and Facility Practices is met when: o Individual programs and activities regularly include use of positive techniques, teaching strategies, and supports. Efforts are made to reduce and eliminate use of restrictive techniques with positive results; o Staff teach and reinforce appropriate behaviors, such as communication skills, social skills, independence and choice-making skills, coping skills, and leisure skills which serve as functional substitutes for inappropriate behaviors; and o Restrictive techniques are used only when warranted by the severity of the behavior, and result in desired behavioral outcomes. The Condition of Participation of Client Behavior and Facility Practices is not met when: o Restrictive, intrusive techniques are used to manage or control behavior in lieu of positive teaching strategies; o Individuals are physically or psychologically injured or harmed as a result of the use of the restrictive interventions and the facility has failed to adequately monitor the use of the intervention; or o Restrictive interventions are used when they are not warranted or without first attempting less restrictive/more positive measures.
	(a) Standard: Facility practices--Conduct toward clients.	
W267	(1) The facility must develop and implement written policies and procedures for the management of conduct between staff and clients.	§483.450(a)(1) FACILITY PRACTICES: Observed practices regarding the behavior and interactions of staff and individuals served demonstrate proactive assertion of the individual's right to learn to exercise his or her rights. §483.450(a)(1) GUIDELINES: "Conduct between staff and clients" refers to the language, actions, discipline, rules, order, and other types of interactions exchanged between staff and individuals or imposed upon individuals by staff during an individual's daily experiences and which affect the quality of an individual's life. While the regulation requires the development of written policies and procedures, the primary survey emphasis should be placed on the latter aspect of the regulation, i.e., implementation of those policies and procedures. Observations of interactions between staff and individuals should confirm that, to the maximum extent possible, individuals are provided with opportunities for growth and self-determination. Individual's dignity is respected by staff and their behavior is within the context of any rules of conduct which have been established.
	These policies and procedures must- -	

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W268	(i) Promote the growth, development and independence of the client;	§483.450(a)(1)(I) FACILITY PRACTICES: Staff are observed engaged in activities which promote the individual's growth, development and independence. Individual program plans and data support the fact that from the time of admission, individuals are learning new adaptive and functional skills while becoming more independent. There are consistent positive interactions between individuals and staff. Staff teach and encourage individuals to interact with each other in a socially acceptable manner. Opportunities to teach and reinforce skill acquisition are utilized. Staff identify and remove impediments in the learning environment. Staff encourage individuals to complete tasks with as much independence as possible. Staff encourage individuals to take risks while providing reasonable safeguards to prevent injury.
W269	(ii) Address the extent to which client choice will be accommodated in daily decision-making, emphasizing self-determination and self-management, to the extent possible;	§483.450(a)(1)(I) FACILITY PRACTICES: Staff actively engage in practices which provide individuals with opportunities for choice, decision-making and self-management, promote participation in these opportunities and provide necessary supports as the individual becomes more independent. Appropriate and purposeful activities and materials known to be preferred by the individual are available. Alternatives are available for individuals who do not choose to participate in a planned activity. Individual's preferences and choices play a key role in daily decision-making.
W270	(iii) Specify client conduct to be allowed or not allowed; and	§483.450(a)(1)(iii) FACILITY PRACTICES: Individuals know the benefits and consequences of their conduct or behavior. Staff are aware of what is or is not permissible and the positive or negative consequences which may be utilized. Staff behavior is consistent with this policy. §483.450(a)(1)(iii) GUIDELINES: "Client conduct" refers to any behavior, choice, action, or activity in which an individual may choose to engage alone or with others.

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		The policy or "house rules" include(s), for example: allowable individual conduct (e.g., swearing or cursing, freedom of choice in religion, consumption of alcohol, smoking, sexual relations), reasonable locations where this conduct may or may not occur, and parameters for decision-making when an individual's choice conflicts with the group's choice (e.g., consensus, voting, taking turns, negotiation of differences). "House rules" on the other hand, may not authorize staff or other individuals served to use a "laundry list" of discipline techniques to control an individual's inappropriate behavior, without regard to individualized need. If it is determined that staff must use a technique or intervention, then its use must be incorporated into an individual program plan that meets all applicable requirements specified in §483.450(b)-(e). Refer to W5123.
W271	(iv) Be available to all staff, clients, parents of minor children, and legal guardians.	
W272	(2) To the extent possible, clients must participate in the formulation of these policies and procedures.	§483.450(a)(2) FACILITY PRACTICES: Input and participation of the individuals residing in the facility has been obtained in developing/revising the policies and procedures.
W273	(3) Clients must not discipline other clients, except as part of an organized system of self-government, as set forth in facility policy.	
	(b)Standard: Management of inappropriate client behavior.	
W274	(1) The facility must develop and implement written policies and procedures that govern the management of inappropriate client behavior.	§483.450(b)(1) FACILITY PRACTICES: Programs and practices used to manage behaviors are consistent with written policies and procedures. §483.450(b)(1) GUIDELINES: Use of items, procedures, or systems which are potentially stigmatizing to the individual or otherwise would represent a substantial departure from the behavior of comparable peers without disabilities, to control or prevent inappropriate behavior, falls under this requirement as well. (For example, requiring an individual to live in a locked residence and not providing the individual with a key, using a high crib with bedrails for an adult who gets out of bed at night and wanders or upsets other individuals, requiring an individual who strips off his clothes at inappropriate times to wear a jumpsuit turned backwards, or other odd usages of fashion.)
	These policies and procedures must be	
W275	consistent with the provisions of paragraph (a) of this section.	

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	These procedures must- -	
W276	(i) Specify all facility approved interventions to manage inappropriate client behavior;	§483.450(b)(1)(i) FACILITY PRACTICES: All positive as well as intrusive behavioral interventions approved for use in the facility are clearly stated in its policy.
W277	(ii) Designate these interventions on a hierarchy to be implemented, ranging from most positive or least intrusive, to least positive or most intrusive;	§483.450((b)(1)(ii) FACILITY PRACTICES: There is a clear progression in how techniques are implemented from the most positive, functionally appropriate approaches to most intrusive approaches authorized.
W278	(iii) Insure prior to the use of more restrictive techniques, that the client's record documents that programs incorporating the use of less intrusive or more positive techniques have been tried systematically and demonstrated to be ineffective; and	§483.450(b)(1)(iii) FACILITY PRACTICES: In emergency situations where an unanticipated behavior requires immediate protection of the individual or others, the technique chosen is the least restrictive clinically appropriate technique possible. Based on a functional analysis of the behavior and the data resulting from use of positive/less restrictive techniques, there is clinically sound, professionally accepted justification before the implementation of any more restrictive techniques. §483.450(b)(1)(iii) GUIDELINES: You should see clear evidence to justify the use of a more restrictive technique. This requirement does not take away the team's discretion to use technology which represents reasonable standards of good practice, but it does require that there be evidence that justifies any decision not to use a positive or less restrictive technique first. Based on extraordinary circumstances resulting in an emergency, a facility may need to use a more restrictive method of intervention to protect the individual and others from harm than is consistent with the hierarchy it has established. This regulation does not prohibit a facility from using good judgement in this situation. The surveyor should assess the use of emergency restrictive interventions to assure that the facility could not have reasonably anticipated the behavior, and verify that the team has reviewed the individual program plan for its adequate attention to the problem precipitating the emergency measure. The facility is not required to justify discontinuing the use of a more restrictive technique before initiating a less restrictive technique, since the intent of the regulation is to use the most positive, least intrusive technique possible. §483.450(b)(1)(iii) PROBES: Do individuals observed with behavior problems (e.g., aggression, withdrawal, stereotypical, self-abusive) have individually designed behavior programs? Does the "maladaptive" behavior ever occur as an "appropriate" response given the individual's circumstances?

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		How has the staff tried to determine what the individual is trying to accomplish or communicate by displaying the maladaptive behavior? How do they respond to the behavior and the need being communicated? Was the possibility addressed that the inappropriate behaviors might be an expression of a mental disorder? Was a medical and/or psychiatric consultation obtained, especially if a treatment program was unsuccessful for a reasonable length of time? Are there consistent positive reinforcement procedures used with individuals? What specific individual behaviors do staff report they are to reinforce or are observed to be reinforcing? Would environmental alterations alone reduce or eliminate the maladaptive behavior? Does the team consider attempting environmental changes before instituting a more restrictive program to control inappropriate behavior? Is there evidence of interventions to change the conditions which lead to inappropriate behavior?
	(iv) Address the following:	
W279	(A) The use of time-out rooms;	§483.450(b)(1)(iv) GUIDELINES: "Time-out rooms" is defined as the use of a room to implement a clinical procedure by which an individual is removed from positive reinforcement contingent upon the exhibition of a maladaptive behavior, until appropriate or adaptive behavior is exhibited. See also §483.450(c).
W280	(B) The use of physical restraints;	"Physical restraint" is defined as any manual method or physical or mechanical device that the individual cannot remove easily, and which restricts the free movement of, normal functioning of, or normal access to a portion or portions of an individual's body. Examples of manual methods include therapeutic or basket holds and prone or supine containment. Examples of mechanical devices include arm splints, posey mittens, helmets, and straight jackets. Excluded are physical guidance and prompting techniques of brief duration and mechanical supports as defined in §483.440(c)(6)(iv) GUIDELINES to position or support an individual. See also §483.450(d).
W281	(C) The use of drugs to manage inappropriate behavior;	"Drugs to manage inappropriate behavior" is defined as medications prescribed and administered for purposes of modifying the maladaptive behavior of an individual. See also §483.450(e).

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TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
W282	(D) The application of painful or noxious stimuli;	"Application of painful or noxious stimuli" is defined as a clinical procedure by which staff apply, contingent upon the exhibition of maladaptive behavior, startling, unpleasant, or painful stimuli, or stimuli that have a potentially noxious effect. The application of painful or noxious stimuli is used as a last resort and only when documentation shows that implementation of consistent positive reinforcement methods have failed and that to withhold the procedure would cause irreparable harm to the health of the individual or others. Discomfort to the individual should not extend beyond the point of application of the stimuli. There must be continuous monitoring while the procedure is in effect. The procedure must not result in physical or mental harm to the health and safety of the individual.
W283	(E) The staff members who may authorize the use of specified interventions;	
W284	(F) A mechanism for monitoring and controlling the use of interventions.	As interventions become more restrictive, the specificity with which they must be explained increases, as does the intensity of the control established by the facility. This includes other techniques having similar degrees of intrusiveness to those defined above, such as positive practice and overcorrection training of extended duration and satiation.
W285	(2) Interventions to manage inappropriate client behavior must be employed with sufficient safeguards and supervision to ensure that the safety, welfare and civil and human rights of clients are adequately protected.	§483.450((b)(2) FACILITY PRACTICES: Monitoring has insured that individual rights are protected. Monitoring which is appropriate to the type of intervention being used, is in place to assure that the individual does not suffer unfavorable effects from the intervention. §483.450(b)(2) PROBES: What mechanism does the facility use to ensure that approval does not extend longer than warranted? To what extent is the special review committee involved in monitoring? Do the procedures deny requisite human needs, such as sleep, shelter, bedding, or use of bathroom facilities? Are rights denied in the absence of the required consent and approvals? Are drugs used to manage inappropriate behavior monitored for unfavorable side effects?

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	(3) Techniques to manage inappropriate client behavior must never be used	
W286	for disciplinary purposes,	§483.450(b)(3) FACILITY PRACTICES: No technique, whether a part of a formal program or in informal situations, is used as retaliation or retribution. §483.450(b)(3) PROBES: How commonly are these techniques used? What types of problems are they used for? Do these techniques continue to be implemented and/or authorized regardless of individual success on individual program plan objectives? Are restraints, time-out rooms or drugs used for environmental deficiencies (e.g., lack of staff, program structure)?
W287	for the convenience of staff	§483.450(b)(3) FACILITY PRACTICES: No technique, whether a part of a formal program or in informal situations, is used to compensate for lack of staff presence or competency. §483.450(b)(3) PROBES: Are the behaviors listed as problematic occurring only in certain situations, such as in living areas and on weekends, possibly indicative of understaffing? Are the problematic behaviors occurring during day programs, possibly indicative of inappropriate placement? Is there a systematic pattern showing restrictive technique usage occurring more frequently in units where staffing is not optimal? Where there is frequent staff turnover? Is usage tied directly to a carefully approved behavior reduction program? Or, is it in practice, a means of locking individuals at the convenience of staff or in the absence of effective programming?
W288	or as a substitute for an active treatment program.	§483.450(b)(3) FACILITY PRACTICES: Any intervention used is tied to a specific active treatment program which addresses both the inappropriate behavior and mechanisms to teach, improve, support, or substitute appropriate behaviors. §483.450(b)(3) PROBES: Does the program to control inappropriate behavior actually address the problems identified, or is it, in fact, a behavior control/punishment program that does not result in desired behavior outcomes?

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W289	(4) The use of systematic interventions to manage inappropriate client behavior must be incorporated into the client's individual program plan, in accordance with §483.440(c)(4) and (5) of this subpart.	§483.450(b)(4) FACILITY PRACTICES: All behavior interventions/supports are part of the individual program plan. All interventions are written as rigorously as other individual program plan training objectives and, in addition, include the extra provisions required by tags W238 and W239. §483.450(b)(4) PROBES: Are behavior programs demonstrably implemented in formal and informal settings alike as per the individual program plan? Is there a complete description of the behavior occurring and evidence to show that as inappropriate behaviors diminish, desired, appropriate behaviors increase?? Does the facility change the program as individual behavior indicates? What specific appropriate behaviors are being taught, improved, supported or substituted for the maladaptive behavior?
W290	(5) Standing or as needed programs to control inappropriate behavior are not permitted.	§483.450(b)(5) FACILITY PRACTICES: All interventions addressing the control of inappropriate behaviors are justified by the functional assessment and the current level of behavior. §483.450(b)(5) GUIDELINES: Ongoing authorization for "programs" or "programmatic usages" of restrictive techniques, in the absence of evidence to justify such usage, constitutes a "standing" or "as needed program" to control inappropriate behavior, and are therefore not permitted. §483.450(b)(5) PROBES: Is there a pattern of restrictive techniques used in tandem (e.g., an individual is released from time-out but is then put in another type of restraining device)? Is there a long term pattern of usage without discernible gains in individual progress? Do individual records contain "approved" programs incorporating restrictive techniques, yet there is: o Only episodic frequency of the maladaptive behavior? o Relatively rare usage of the restrictive technique? o No previously tried and implemented positive strategies showing lack of success?
	(c) Standard: Time-out rooms.	

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W291	(1) A client may be placed in a room from which egress is prevented only if the following conditions are met: (i) The placement is a part of an approved systematic time-out program as required by paragraph (b) of this section. (Thus, emergency placement of a client into a time-out room is not allowed.) (ii) The client is under the direct constant visual supervision of designated staff. (iii) The door to the room is held shut by staff or by a mechanism requiring constant physical pressure from a staff member to keep the mechanism engaged.	§483.450(c)(1) GUIDELINES: The use of time-out rooms is effective only if the individual does not like to be removed from an activity or from people. Look for patterns of frequent, lengthy time-out usage which often indicates that the environment is not reinforcing to the individual (i.e., the activities in and of themselves are not engaging, and/or the scheduled activities are potentially engaging yet the schedule is not implemented). If the individual who is in a time-out room engages in self-abuse, becomes incontinent or shows other signs of illness, staff should immediately discontinue the procedure and intervene. Verify whether or not anyone standing or lying in any position, in any part of the time-out room can be seen. Key locks, latch locks, and doors that open inward without an inside doorknob are not devices or mechanisms which require constant physical pressure from a staff member to keep a door shut, and, therefore, are not permitted by the regulations. Pressure sensitive mechanisms must allow staff to enter the room at the moment the need arises. §483.450(c)(1) PROBES: What reasons cause individuals to be placed in time-out rooms most frequently? Is there a pattern of time-out usage? What is it? On the average, how long are individuals placed in "time-out rooms"? Is time-out room usage extended on a routine basis? Does the frequency of time-out room usage indicate that isolation is more reinforcing to the individual than the environment? Are there plans to move to less restrictive means of modifying the behavior? Is criterion clearly specified for use/discontinuance of time-out rooms? What do staff do with individuals after they leave time-out rooms? Is usage directly tied to a carefully approved behavior reduction program or is it in practice a means of locking individuals at the convenience of staff or in the absence of effective programming? How do staff monitor individuals in time-out rooms? What do staff do if an individual in a time-out room screams? Engages in self-abuse? Becomes incontinent? Shows signs of medical illness?
W292	(2) Placement of a client in a time-out room must not exceed one hour.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
W293	(3) Clients placed in time-out rooms must be protected from hazardous conditions including, but not limited to, presence of sharp corners and objects, uncovered light fixtures, unprotected electrical outlets.	§483.450(c)(3) GUIDELINES: A door that opens inward can potentially be held closed, either intentionally or inadvertently, by the individual in the room, thereby denying staff immediate access to the room.
W294	(4) A record of time-out activities must be kept.	§483.450(c)(4) FACILITY PRACTICES: The record accurately reflects planned (i.e., part of the individual program plan) and emergency usage and presents a picture of events prior to, during, and following the use of time-out. §483.450(c)(4) PROBES: Can staff show how long and frequently time-out has been used? Can staff describe what environmental variables contributed to each time-out usage?
	(d)Standard: Physical restraints.	
	(1) The facility may employ physical restraint only- -	
W295	(i) As an integral part of an individual program plan that is intended to lead to less restrictive means of managing and eliminating the behavior for which the restraint is applied;	§483.450(d)(1)(i) FACILITY PRACTICES: The use of physical restraint is specified within the individual program plan. Physical restraint is used only in response to a specific type and/or severity of behavior and only for the amount of time specified in the individual program plan. The plan is directed toward reduction of the use of restraints. §483.450(d)(1)(i) PROBES: What is the reason for the restraint? Does the individual program plan identify the type of restraint to be used? Does the severity of the behavior justify its usage? Does the facility consider factors other than the individual in determining causes for need for restraints (e.g., other individuals, staff, building noise, sufficiency of program structure)? Are there clear, performance-based linkages between use of restraints in practice and behavior programs that use restraints? Or are restraints used in ways and at times other than prescribed in the individual's program?

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W296	(ii) As an emergency measure, but only if absolutely necessary to protect client or others from injury; or	§483.450(d)(1)(ii) FACILITY PRACTICES: Emergency physical restraint for an unanticipated type or severity of behavior is used only to prevent injury to the individual or others. §483.450(d)(1)(ii) GUIDELINES: "Emergency measure" is defined as use of the least restrictive procedures and for the briefest time necessary to control severely aggressive or destructive behaviors that place the individual or others in imminent danger when those behaviors reasonably could not have been anticipated, and only as they are necessary within the context of positive behavioral programming. Examine closely how frequently "emergency measures" are employed. Repeated applications of such measures within short intervals of time, without subsequent incorporation into a written active treatment program, as required by §483.440(c), raises serious questions about the individual's receipt of active treatment and the individual's right to be free from unnecessary restraint. §483.450(d)(1)(ii) PROBES: Is there a systematic pattern of incidents being called "emergencies" in order to apply restraints without use of an approved program? Are repeated emergency applications of restraints followed up with development of systematic behavior management programs? Is use of an emergency application documented and reviewed by the QIDP or designee with appropriate follow-up?
W297	(iii) As a health-related protection prescribed by a physician, but only if absolutely necessary during the conduct of a specific medical or surgical procedure, or only if absolutely necessary for client protection during the time that a medical condition exists.	§483.450(d)(1)(iii) FACILITY PRACTICES: Physical restraint is employed for medical reasons only when no other option is available or when no other option has proven effective in achieving the needed result for a particular individual, based on input from the IDT. In the presence of a restraint intended to be a health-related protection, there is an active medical condition at the time the physical restraint is used. §483.450(d)(1)(iii) PROBES: What do staff do to prepare individuals for medical or dental examinations in order to reduce the need for physical or mechanical restraints? Have other options such as desensitization training, behavior shaping, intensive positive reinforcement, environmental changes, etc. been tried? Are individuals routinely restrained before medical or dental examinations?
	(2) Authorizations to use or extend restraints as an emergency measure must be:	§483.450(d)(2) GUIDELINES: The facility determines who may authorize use of emergency restraints.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
W298	(i) In effect no longer than 12 consecutive hours; and	§483.450(d)(2)(i) GUIDELINES: The specific 12-hour authorization and re-authorization to use or extend usage of physical restraints does not apply to restraints used as an integral part of the individual program plan or to those that qualify as a health-related protection, as defined in the regulation.
W299	(ii) Obtained as soon as the client is restrained or stable.	§483.450(d)(2)(ii) GUIDELINES: This refers to the reporting and retrospective authorization of the emergency measure when no prior use authorization could be obtained due to the seriousness and immediacy of the event.
W300	(3) The facility must not issue orders for restraint on a standing or as needed basis.	
W301	(4) A client placed in restraint must be checked at least every 30 minutes by staff trained in the use of restraints,	§483.450(d)(4) GUIDELINES: The frequency of monitoring will vary according to the type and design of the device and the psychological and physical well-being of the individual. For example, an individual in four-point restraints might require constant monitoring while someone in soft mittens may require less frequent monitoring. It is also true that for some individuals, constant visual supervision would serve to reinforce the inappropriate behavior and thereby reduce the clinical effectiveness of using the restraint. However, in no case may the 30 minute time limit be extended. "As quickly as possible" means as soon as the individual is calm or no longer a danger to self or others. §483.450(d)(4) PROBES: Is there a pattern that individuals are placed in restraints repeatedly for 2-hour consecutive applications during the entire restraint authorization period? Does the team decide whether constant or frequent monitoring is helpful or contraindicated for an individual? On what basis is this decision made? When staff apply restraints do they demonstrate proper usage per each individual's program? Is the use of restraints well documented to present a clear picture of the events prior to, during, and following its use? Is this information reviewed by the IDT and addressed?
W302	released from the restraint as quickly as possible, and	
W303	a record of these checks and usage must be kept.	
	(5) Restraints must be designed and used	§483.450(d)(5) PROBES: Is there documentation in an individual's record regarding contraindications, if any, to certain types of restraints? How will the individual's safety be ensured?

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		How do staff decide which type of restraint to use for a particular individual?
W304	so as not to cause physical injury to the client	
W305	and so as to cause the least possible discomfort.	
	(6) Opportunity for motion and exercise must be provided	483.450(D)(6) GUIDELINES: "Motion and exercise" includes an opportunity for liquid intake and toileting, if needed by the individual.
W306	for a period of not less than 10 minutes during each two hour period in which restraint is employed,	§483.450(d)(6) GUIDELINES: In the presence of a restraint being worn during sleeping hours, surveyors must determine whether it is truly the nature of the individual's behavior which warrants this significant level of intrusion, or whether it in fact is a substitute for lower staffing during night time hours. The "motion and exercise" requirement applies to all restraints which restrict the range of motion of a limb or joint. Therefore, for example, if a helmet is applied to protect a head wound during sleeping hours, and the individual's range of motion in the neck has not been affected, then this requirement does not apply. This requirement also does not apply to cases of medical restraints that are specifically ordered for the immobilization of bones and joints during the physical healing process involved with fractures, sprains, etc. (e.g., a broken bone immobilized by a cast or splint). However, if a physical restraint was applied to an extremity to prevent an individual from removing post-operative sutures, the restraint would be required to be released every two hours for a period of not less than 10 minutes. Even though usage of mechanical supports, defined at §483.440(c)(6)(vi), may confine the movement of an individual, W306 does not apply to such usage.
W307	and a record of such activity must be kept.	
	(7) Barred enclosures	§483.450(d)(7) PROBES: For what reason does staff use barred enclosures? How long do individuals remain in these devices? What other interventions have been tried? Are use of these enclosures incorporated into individually designed plans, aimed at elimination of the behavior causing the need?
W308	must not be more than three feet in height and	
W309	must not have tops.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(e) Standard: Drug usage.	
W310	(1) The facility must not use drugs in doses that interfere with the individual client's daily living activities.	§483.450(e)(1) FACILITY PRACTICES: Individuals who are receiving medications are alert and available for participation in daily living activities, unless a well-documented condition (e.g., significant seizure activity) warrants the use of medication in sedating quantities to adequately control that condition. §483.450(e)(1) GUIDELINES: §483.450(e)(1) applies to all medications, including medications prescribed to control inappropriate behavior. Overmedication occurs for many reasons. For medications prescribed to control maladaptive behavior, the most common reasons are: the individual's maladaptive behavior may not be responsive to drugs (e.g., if an individual has a non-drug-responsive form of self injury, then use of psychotropics may simply lead up to maximum drug doses without suppressing the behavior), drug therapy may be exacerbating the behavior (e.g., if a drug-induced side effect is mistaken for agitation, then the physician may mistakenly believe that the individual is undermedicated and increase the dose), presence of polypharmacy within the same drug class may result in a drug dose that would exceed the maximum daily limit for any one drug, the individual may be receiving too frequent injections which may result in significant drug accumulation over time, and the use of daily medication plus PRN or stat (one time) doses may result in greater than the recommended daily doses being prescribed (especially since intramuscular administration may be up to four times as potent). Overmedication may also occur as a result of the interaction between drugs, whether these drugs were prescribed for control of inappropriate behavior, or for a physical or medical condition. Administration of PRN or stat doses for periods greater than a few weeks may indicate that the individual's daily dose is sub-therapeutic, the problem will not respond to the prescribed drug or the drug is exacerbating the problem. In such instances, the surveyor should verify whether or not the drug regimen has been reassessed. §483.450(e)(1) PROBES: Are individuals who receive medications lethargic and inactive during the day? If so: o How long has the individual been on medication? o How long have the overt behaviors of lethargy and inactivity been noticed? o Have there been any attempts to taper the medication down? Is there evidence that the medication helps to facilitate the individual's participation in his/her individual program plan objectives?
	(2) Drugs used for control of inappropriate behavior must	

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W311	be approved by the interdisciplinary team and	§483.450(e)(2) FACILITY PRACTICES: The physician and other team members have discussed the risks and benefits of the medication to address the target behavior/symptoms, and has approved the use of the drug as being consistent with the active treatment program.
W312	be used only as an integral part of the client's individual program plan that is directed specifically towards the reduction of and eventual elimination of the behaviors for which the drugs are employed.	§483.450(e)(2) FACILITY PRACTICES: The individual program plan identifies the drug usage and how it may change in relation to progress or regression in the objective. The individual program plan contains specific criteria for any PRN usage. §483.450(e)(2) GUIDELINES: For drugs to be an effective therapeutic tool, they must be prescribed only to the extent that they are necessary for normal medical management of the individual. In an emergency, a physician may authorize the use of a drug to control an inappropriate behavior. However, orders for continued emergency drug usage cannot continue until the team gives approval and the drug's usage has been included in the plan. Psychotropic drug therapy may not be used outside of an active treatment program targeted to eliminate the specific behaviors which are thought to be drug responsive. Although only a physician can prescribe medication, the decision to use medication for control of behavior must be based on input from other team members. W329 and W330 address the physician's participation in the person's individual program plan as part of the interdisciplinary team. The interdisciplinary team involvement in this decision-making process is inextricably linked to an obligation to develop and implement effective non-drug interventions that address the targeted behavior. This obligation requires constant monitoring of the non-drug interventions to determine its efficacy, and to determine whether the judicious use of drug therapy may at times be appropriate. Individuals who receive psychoactive drugs for behaviors associated with a diagnosed mental disorder, require an active treatment program designed to reduce, ameliorate, compensate or eliminate the psychiatric symptoms. The psychiatric diagnosis must be based on a comprehensive psychiatric evaluation in which the evidence supports the conclusion of a psychiatric diagnosis as required by W212. The focus of active treatment, in this instance, would be on the mental health of the individual. Drugs from categories other than the principle drug classes that have behavior controlling properties (e.g., antipsychotic, antianxiety, and antidepressants) are sometimes used to control inappropriate behavior. Examples include the use of propranolol (Inderal), which is classified as an antihypertensive and antianginal drug, for self-injurious behavior, and carbamazepine (Tegretol), which is an anticonvulsant, for aggression. The regulation was written to encompass any drug when its use is for purposes of controlling inappropriate behavior. This requirement does not apply to drugs, such as propranolol, when they are used to treat medical conditions. However,

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		if their use (e.g. dose, duration, etc.) indicates that they are being used to control inappropriate behavior, the interdisciplinary team must be involved in the decision to use them, and they must be incorporated into the active treatment program plan. In order for an individual to receive dental or medical treatment, the physician may need to prescribe a sedative as part of the normal medical management for that individual. This situation, occurring rarely, would not require an active treatment program targeted toward elimination of the behavior. The decision to use sedation for medical appointments must be made on an individual basis, and with input from the interdisciplinary team. When the individual is regularly exhibiting behaviors that are interfering with the ability to receive routine medical and dental treatment, then use of the sedative is required to be incorporated into a specific active treatment program. §483.450(e)(2) PROBES: Is there documentation that alternative interventions have been considered and tried where appropriate? Is there a pattern of prescription of the same drug used for many individuals, regardless of the problem? Is the overall rate of psychotropic medication usage appropriate to the nature of the population served (e.g., in relation to case mix)? Is there evidence that the individual can be and is placed on psychotropic medications without a full review and the protection processes of these requirements? Is there an identifiable working mechanism to reduce or eliminate the need for psychotropic drug use on each affected individual? Are data collected so that the effect of drug usage can be assessed? Does the physician, psychologist, pharmacist, nurse, and other program and health staff work together to reduce psychotropic drug utilization? Are drug reduction plans actually implemented as indicated by reaching criteria in the behavior management programs?
W313	(3) Drugs used for control of inappropriate behavior must not be used until it can be justified that the harmful effects of the behavior clearly outweigh the potentially harmful effects of the drugs.	§483.450(e)(3) FACILITY PRACTICES: The risk(s) associated with the drug being used is consistent with the type and severity of the behavior/symptoms it is intended to affect.

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	(4) Drugs used for control of inappropriate behavior must be- -	
	(i) Monitored closely,	
W314	in conjunction with the physician and the drug regimen review requirement at §483.460(j),	§483.450(e)(4)(i) FACILITY PRACTICES: The physician and the pharmacist regularly review use of medication for its effectiveness in changing the targeted behavior/symptoms, untoward side effects, contraindications for continued use, and communicate this information to relevant staff.
W315	for desired responses and adverse consequences by facility staff; and	§483.450(e)(4)(i) FACILITY PRACTICES: Staff are aware of what response the drug is expected to achieve, what side effects to watch for, and communicate this information to the appropriate persons. §483.450(e)(4)(i) GUIDELINES: Unless the physician regularly evaluates the individual and meets with those who work most closely with the individual to review treatment progress, it will be difficult to assess whether the individual responded positively to the treatment. Since each drug has a specific profile of side effects, potential reactions should be looked for by direct examination and questioning. It is important that everyone who works with the individual be aware of the conclusion drawn from these drug reviews. In addition to monitoring at regular intervals, the individual should be assessed at the time the medication is changed, as well. Individuals receiving long term antipsychotic drug therapy should be examined regularly for motor restlessness, such as Parkinsonian symptoms or tardive dyskinesia. §483.450(e)(4)(i) PROBES: How does the physician monitor usage of drugs prescribed and is this monitoring and decision-making for drug usage a part of the team process or is it done in isolation by the medical staff? Is there sufficient time for the physician to review the individuals with the team? What do staff report about the medications the individual receives? Their purpose? Side effects? What would they do if side effects suddenly appeared (e.g., extrapyramidal side effects in a person on anti-psychotic drugs)? Is there evidence that the effects of the therapeutic intervention are being assessed and modified in light of the presence or absence of the desired response? In light of the emergence of side effects?
	(ii) Gradually withdrawn	

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W316	at least annually	§483.450(e)(4)(ii) FACILITY PRACTICES: A gradual withdrawal occurs annually or sooner if warranted by progress to the criteria for reduction established in the individual program plan, by the particular drug which is being used, or the specific condition for which the drug is being prescribed.
W317	in a carefully monitored program conducted in conjunction with the interdisciplinary team, unless clinical evidence justifies that this is contraindicated.	§483.450(e)(4)(ii) FACILITY PRACTICES: The IDT is aware of and involved in planning the drug reduction program and participates in its implementation and monitoring. Progress or regression of the individual is monitored and taken into consideration in determining the rate of withdrawal and whether to continue withdrawal. In the absence of an annual drug withdrawal program, there must be strong, objective clinical evidence (e.g., results of previous reduction, research-based justification, etc.) which supports that decision. Changes in the individual, his environment or program is taken into consideration in determining the validity of this evidence. §483.450(e)(4)(ii) GUIDELINES: Planned drug withdrawals must be carefully instituted. For example, usage of antipsychotic drug therapy may not only cause tardive dyskinesia but may mask the clinical manifestations of tardive dyskinesia during treatment. This requirement applies only to drugs prescribed to modify behavior; therefore, if Thorazine is prescribed to decrease aggressive behavior, the annual drug withdrawal requirement applies. However, if Phenobarbital is prescribed to prevent seizures, or Insulin is prescribed to control diabetes, then this requirement does not apply. In determining whether there is clinical contraindication to the annual drug withdrawal, the physician and interdisciplinary team should consider the individual's clinical history, diagnostic/behavioral status, previous reduction/discontinuation attempts, and current regimen effectiveness. The individual's current clinical status or the nature of a psychiatric illness may indicate that gradual withdrawal of the drug is unwise at this time. It is not acceptable, however, to preclude a gradual drug withdrawal for a person, including a person with a psychiatric impairment, merely because of the possibility that his or her behavior may be exacerbated. Data which shows a direct relationship between past attempts at withdrawal, and an increase in the targeted behavior or symptoms should be available to support the decision not to attempt a gradual withdrawal. This data should reflect the programmatic interventions utilized to respond to the behavior prior to determining that gradual withdrawal is contraindicated. The team should periodically re-evaluate the decision not to attempt a gradual withdrawal based on the individual's progress or other changes in clinical status.

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TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		§483.450(e)(4)(ii) PROBES: Are staff aware of possible withdrawal symptoms, and are plans developed to assist the individual through these periods of stress? Is drug therapy prescribed for an indefinite period of time?

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TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
W318	§483.460 Condition of participation: Health care services.	§483.460 COMPLIANCE PRINCIPLES: The Condition of Participation of Health Care Services is met when: o Individuals receive preventative services and prompt treatment for acute and chronic health conditions; and o Individuals' health is improved or maintained unless the deterioration is due to a documented clinical condition for which deterioration or lack of improvement is an accepted prognosis. The Condition of Participation of Health Care Services is not met when individuals do not receive adequate health care monitoring and services, including appropriate and timely follow-up, based upon their individualized need for service.
	(a) Standard: Physician services.	
W319	(1) The facility must ensure the availability of physician services 24 hours a day.	§483.460(a)(1) GUIDELINES: Procedures must be established that provide steps to be followed when the designated physician is not available. Staff should be aware of procedures for contacting physicians in the event of an emergency.
W320	(2) The physician must develop, in coordination with licensed nursing personnel, a medical care plan of treatment for a client if the physician determines that an individual client requires 24-hour licensed nursing care.	§483.460(a)(2) GUIDELINES: The use of a medical care plan is intended only for those who are so ill or so at medical risk that 24-hour licensed nursing care is essential. A medical care plan need not be developed unless the individual requires licensed nursing care around the clock. Thus, individuals with chronic, but stable health problems such as controlled epilepsy, diabetes, etc. do not require a medical care plan. It is not required that an individual have a health deficit and/or a medical care plan in order to receive ICF/IID services. The regulation is sufficiently flexible that the entire range of individuals, from those in good physical health to those who are very medically fragile, may be served. A medical care plan may be temporary, in that it may be established to address acute health problems and then discontinued when those problems are resolved.
W321	This plan must be integrated in the individual program plan.	§483.460(a)(2) FACILITY PRACTICES: The medical care plan is a part of the IPP and, therefore, known and available to the inter-disciplinary team (IDT) and all staff working with the individual. Training programs take into consideration medical needs/status.

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	(3) The facility must provide or obtain	
W322	preventive and general care	§483.460(a)(3) FACILITY PRACTICES: The individual receives the services indicated by his/her health status. There is follow-up to recommendations for referrals to specialists, specific examinations or evaluations, and treatments. §483.460(a)(3) GUIDELINES: Medical services are provided as necessary to maintain an optimum level of health for each individual and to prevent disability. Medical services include evaluation, diagnosis and treatment, as needed, by individuals. Medical services, including sources for laboratory, radiology, and other medical and remedial services available to the individual must be provided if not provided in-house. There must be a written agreement that specifies the responsibilities of the facility and outside provider. (See §483.410(a).) §483.460(a)(3) PROBES: Are referrals made to other specialists when appropriate? Are referrals followed up? Are women provided with gynecological services? Are individuals referred to neurologists, if they have poor seizure control over a long period of time? A noted toxicity of seizure medications? Are individuals with apparent mental illness (e.g., depression, psychosis, obsessive/compulsive disorder) referred to specialists for proper diagnosis and treatment?
	as well as annual physical examinations of each client that at a minimum include the following:	
W323	(i) Evaluation of vision and hearing;	§483.460(a)(3)(i) FACILITY PRACTICES: The individual receives a screening of vision and hearing at least annually. Observation, documentation, or interview indicates that any vision or hearing problems which are suspected by staff are reported and follow-up assessments done. Special studies are conducted in accordance with the timeframe recommended by the relevant specialist when more traditional approaches to evaluation cannot be conducted.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		§483.460(a)(3)(i) GUIDELINES: This standard is intended to be an annual screening so that individuals who need further indepth examination can be identified. If hearing screens are conducted annually by speech-language pathologists or audiologists the physical exam does not need to repeat this information. Information relevant to knowing if the individual can see or hear, and how well, is tantamount for designing an appropriate active treatment strategy responsive to need. If an individual's vision or hearing can only be assessed through examinations conducted by specialists (e.g., comprehensive ophthalmological examinations and evoked response audiometry (ERA)), these tests need not be conducted yearly, but rather upon specialist's recommendations. In such situations determine if yearly, the team evaluates the individual's vision and hearing response behaviors for change, and makes referrals, if necessary. §483.460(a)(3)(i) PROBES: Do assessments of vision and hearing include acuity measures, as well as physiological measures, as appropriate?
W324	(ii) Immunizations, using as a guide the recommendations of the Public Health Service Advisory Committee on Immunization Practices or of the Committee on the Control of Infectious Diseases of the American Academy of Pediatrics;	§483.460(a)(3)(ii) GUIDELINES: These immunization guides can be obtained from the American Academy of Pediatrics, Elk Grove, IL, telephone: (708) 228-5005, or from the Centers for Disease Control, Division of Immunization Center for Preventive Services, telephone: (404) 639-8215.
W325	(iii) Routine screening laboratory examinations as determined necessary by the physician,	§483.460(a)(3)(iii) GUIDELINES: This does not preclude screening tests available to the general public such as tests for urine sugar. §483.460(a)(3)(iii) PROBES: Has physician justification been provided when the physician determines that a standard laboratory test is not necessary for the individual?
W326	and special studies when needed;	

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W327	(iv) Tuberculosis control, appropriate to the facility's population, and in accordance with the recommendations of the American College of Chest Physicians or the section on diseases of the chest of the American Academy of Pediatrics, or both.	§483.460(a)(3)(iv) FACILITY PRACTICES: When one or more individuals display tuberculosis (TB) symptoms, as substantiated by positive lab/x-ray results, appropriate treatment and precautions are in place. §483.460(a)(3)(iv) GUIDELINES: These recommendations can be obtained from the American Academy of Pediatrics, Elk Grove Village, IL, telephone: (708) 228-5005, or the American College of Chest Physicians, Northbrook, IL, telephone: (708) 498-1400. The American College of Chest Physicians and the American Academy of Pediatrics endorse the recommendations of the Center for Disease Control and Prevention, Guidelines for Preventing the Transmission of Tuberculosis in Health Care Facilities, (most recent edition). The facility should have in place a system appropriate to its population for the identification, reporting, investigation, and control of TB in order to prevent its transmission within the facility. This system should include policies and procedures for screening new employees, new clients, and other people who interact on a consistent basis with individuals residing in the facility; for reporting positive TB test results to the appropriate State authorities; for the investigative procedures that would be put in place should an individual or staff person test positive for TB; and for the evaluation of the effectiveness of the entire system. There should be arrangements with outside service providers, when needed, to ensure that any individual who tests positive for TB will receive appropriate medical treatment. Also, the system should address the issue of any staff member who tests positive for TB. The Occupational Health and Safety Administration (OSHA) requirements regarding exposure control plans and activities may also apply.
W328	(4) To the extent permitted by State law, the facility may utilize physician assistants and nurse practitioners to provide physician services as described in this section.	
	(b) Standard: Physician participation in the individual program plan.	
	A physician must participate in- -	
W329	(1) The establishment of each newly admitted client's initial individual program plan as required by §456.380 of this chapter that specifies plan of care requirements for ICFs; and	§483.460(b)(1) GUIDELINES: During the admission process, which extends from the time the individual is admitted to the time the initial IPP is completed, a physician is required to ensure that an assessment of the individual's medical status is thoroughly considered and addressed by the team as it develops the IPP. The physician's input may be by means of written reports, evaluations, and recommendations. 42 CFR 456.380 requires that a physician must establish a written plan of care for each

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		applicant or recipient before admission to an ICF. This is done in conjunction with the interdisciplinary team. (See §483.440(c).) The written plan of care required by §456.380 and the IPP required by §483.440(c) may be the same document, which can fulfill both requirements.
W330	(2) If appropriate, physicians must participate in the review and update of an individual program plan as part of the interdisciplinary team process either in person or through written report to the interdisciplinary team.	§483.460(b)(2) FACILITY PRACTICES: Based on the needs and health status of the individual, the physician participates in the IPP review and update in such a way as to ensure accurate and appropriate consideration of the individual's health status and functioning in the plan's creation and implementation. §483.460(b)(2) GUIDELINES: The need for physician participation is determined by the medical needs of the individual. How the participation (whether through written report, telephone consultation, attendance at the meeting, etc.) is to be accomplished is left to the discretion of the facility.
	(c) Standard: Nursing services.	
W331	The facility must provide clients with nursing services in accordance with their needs.	§483.460(c) FACILITY PRACTICES: Individuals on a medical care plan receive 24-hour nursing service as indicated by that plan. Individuals not on a medical care plan receive services as indicated by the assessment, the IPP, and in accordance with any changes in health status.
	These services must include- -	
W332	(1) Participation as appropriate in the development, review, and update of an individual program plan as part of the interdisciplinary team process;	§483.460(c)(1) FACILITY PRACTICES: A licensed nurse participates as a member of the IDT in the IPP process for all individuals on a medical care plan and, if individual needs dictate, for other individuals as well. §483.460(c)(1) GUIDELINES: Unless the individual is on a medical care plan, this participation may be through a written report.
W333	(2) The development, with a physician, of a medical care plan of treatment for a client when the physician has determined that an individual client requires such a plan;	§483.460(c)(2) GUIDELINES: See also W416.

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	(3) For those clients certified as not needing a medical care plan, a review of their health status which must- -	
W334	(i) Be by a direct physical examination;	§483.460(c)(3)(i) GUIDELINES: A direct physical examination means a visual review of the body as well as examination of body systems that might be necessary. This includes observing for any clues (including visual, tactile, nonverbal gestures, grimaces, etc.) to detect if there is a potential for needed follow-up and monitoring. A paper review of the individual's medical record and health statistics is not a direct physical examination. If an individual is on a medical care plan, it is not necessary to perform the quarterly direct nursing physical examination. §483.460(c)(3)(i) PROBES: An example of a body system review is foot care, and appropriate questions to ask in assessing the status of foot care would be: o Is there evidence of abnormal swelling? o Is skin supple? o Are there signs of skin cracking or breaking? o Are ulcers present? o Is fungus present? o Are there signs of ingrown nails? o Are nails painful when pressed? o Is there dampness between toes?
W335	(ii) Be by a licensed nurse;	§483.460(c)(3)(ii) GUIDELINES: The term "licensed nurse" for purposes of this requirement means a registered nurse, a licensed practical nurse or a licensed vocational nurse. A facility is allowed to use a physician, in place of a licensed nurse, although this is certainly not required.
W336	(iii) Be on a quarterly or more frequent basis depending on client need;	§483.460(c)(3)(iii) GUIDELINES: "On a quarterly basis" means that the examination must be performed within the month in which the end of the quarter falls. If during the course of a year, there were three examinations conducted by a licensed nurse and one annual examination performed by a physician, each of which is performed within the month in which the end of the quarter or year falls, the intent of this requirement is met.
W337	(iv) Be recorded in the client's record; and	§483.460(c)(3)(iv) GUIDELINES: The record includes the date of the exam.
W338	(v) Result in any necessary action (including referral to a physician to address client health problems).	§483.460(c)(3)(v) FACILITY PRACTICES: The nurse makes appropriate referrals and communicates or addresses problems if the quarterly exam yields physical findings considered abnormal or atypical for the individual.

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		This communication results in timely changes in the individual's health care when needed. §483.460(c)(3)(v) GUIDELINES: Some physical findings discovered by the nurse while conducting the physical exam will not necessarily result in referral to the physician. This practice is acceptable if the nurse is acting within the scope of the Nurse Practice Act of the State in which he or she is licensed. §483.460(c)(3)(v) PROBES: What is the feedback mechanism to the physician? Is there a traceable relationship between facility staff and physicians that results in timely changes in individuals' health care?
W339	(4) Other nursing care as prescribed by the physician or as identified by client needs; and	§483.460(c)(4) FACILITY PRACTICES: Health and wellness are actively promoted, problems are attended to before they become serious, and steps are taken to prevent the recurrence of such problems while responding promptly to individual's needs. Nursing interventions are implemented as required by the IPP. §483.460(c)(4) GUIDELINES: This includes nursing care for individuals without a medical care plan. §483.460(c)(4) PROBES: Is skin integrity maintained and breakdown prevented? Are measures used to prevent skin breakdown (e.g., padding pressure points, use of emollients)?
	(5) Implementing with other members of the interdisciplinary team, appropriate protective and preventive health measures that include, but are not limited to- -	
W340	(i) Training clients and staff as needed in appropriate health and hygiene methods;	§483.460(c)(5)(i) FACILITY PRACTICES: Individuals and staff receive direct training in how to care for health needs/conditions, personal hygiene, health maintenance, and disease prevention. Individuals are trained in areas such as taking medicine, sexuality, family planning, prevention of sexually transmitted diseases, control of other infectious diseases, self-monitoring of health status and self-prevention of health problems, etc., when such training is relevant to the needs of the individuals.

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		§483.460(c)(5)(i) GUIDELINES: Facility staff need to know what the limits of their responsibilities are with medically involved individuals, and how to teach individuals on a continuing basis how to take care of minor accidents until further care can be provided.
W341	(ii) Control of communicable diseases and infections, including the instruction of other personnel in methods of infection control; and	
W342	(iii) Training direct care staff in detecting signs and symptoms of illness or dysfunction, first aid for accidents or illness, and basic skills required to meet the health needs of the clients.	§483.460(c)(5)(iii) FACILITY PRACTICES: Direct care staff receive training in skills relevant to the population of individuals served by the facility.
	(d) Standard: Nursing staff.	
W343	(1) Nurses providing services in the facility must have a current license to practice in the State.	
W344	(2) The facility must employ or arrange for licensed nursing services sufficient to care for clients' health needs including those clients with medical care plans.	§483.460(d)(2) FACILITY PRACTICES: The facility provides for nursing services based on the health needs and conditions of individuals residing there. Individual health care needs are being met in a timely manner by the available nursing staff. §483.460(d)(2) GUIDELINES: In evaluating whether or not there is sufficient licensed nursing staff, evaluate the need for licensed nursing care represented by the health characteristics of the individuals served (as described in physical exam results, IPPs, and medical care plans) in relation to the competency and qualifications represented by the staff who provide care (through the onsite survey). Make a judgment about the sufficiency of nursing staff to care for this particular population. §483.460(d)(2) SURVEY PROCEDURE: In most circumstances, when one or more individuals in the facility require a medical care plan (i.e., the medical risk of an individual is so potentially life threatening that the individual requires continuous licensed nursing care in order to ensure his or her health and safety,) then that individual's needs are such that licensed personnel must be present. In the presence of such a situation, validate that 24-hour on duty staffing patterns of licensed personnel are provided.

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W345	(3) The facility must utilize registered nurses as appropriate and required by State law to perform the health services specified in this section.	
W346	(4) If the facility utilizes only licensed practical or vocational nurses to provide health services, it must have a formal arrangement with a registered nurse to be available for verbal or onsite consultation to the licensed practical or vocational nurse.	
W347	(5) Non-licensed nursing personnel who work with clients under a medical care plan must do so under the supervision of licensed persons.	
	(e) Standard: Dental services	
W348	(1) The facility must provide or make arrangements for comprehensive diagnostic and treatment services for each client from qualified personnel, including licensed dentists and dental hygienists either through organized dental services in-house or through arrangement.	
W349	(2) If appropriate, dental professionals must participate, in the development, review and update of an individual program plan as part of the interdisciplinary process either in person or through written report to the interdisciplinary team.	§483.460(e)(2) FACILITY PRACTICES: Based on the needs of the individual, dental personnel participate in development and monitoring the IPP to ensure accurate and appropriate consideration of the individual's dental needs in the plan's design and implementation.

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W350	(3) The facility must provide education and training in the maintenance of oral health.	§483.460(e)(3) FACILITY PRACTICES: Training in the maintenance of oral hygiene is provided to individuals who require it, and to those who are responsible for carrying out such activities.
	(f) Standard: Comprehensive dental diagnostic services.	
	Comprehensive dental diagnostic services include	
W351	(1) A complete extraoral and intraoral examination, using all diagnostic aids necessary to properly evaluate the client's condition not later than one month after admission to the facility (unless the examination was completed within twelve months before admission);	§483.460(f)(1) GUIDELINES: A "month" is defined as the interval between the date of admission and close of business of the corresponding day in the following month.
	(2) Periodic examination and diagnosis performed	§483.460(f)(2) GUIDELINES: The requirement applies to all individuals (including those without teeth), and more frequently as dictated by the individual's needs.
W352	at least annually,	
W353	including radiographs when indicated and detection of manifestations of systemic disease; and	
W354	(3) A review of the results of examination and entry of the results in the client's dental record.	
	(g) Standard: Comprehensive dental treatment.	§483.460(g) GUIDELINES: Comprehensive dental treatment might include, but is not limited to:
	The facility must ensure comprehensive dental treatment services that include- -	1. Periodic examination and diagnosis, including radiographs, when indicated and detection of all manifestations of systemic disease; 2. Elimination of infection or life hazardous oral conditions, oral cancer, or cellulitis;

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		3. Treatment of injuries; 4. Restoration of decayed or fractured teeth; 5. Retention or recovery of space between teeth in children, when indicated; 6. Replacement of missing permanent teeth, when indicated; and 7. Appropriate pain control procedures for optimal care of the patient.
W355	(1) The availability for emergency dental treatment on a 24-hour-a-day basis by a licensed dentist; and	
W356	(2) Dental care needed for relief of pain and infections, restoration of teeth, and maintenance of dental health.	§483.460(g)(2) PROBES: Are individuals' dental needs neglected until there is pain or other emergency? Do examinations indicate that services were furnished, rather than notes indicating that the individual was "unable to be examined" or "as best as can be determined?"
	(h) Standard: Documentation of dental services.	
	(1) If the facility maintains an in-house dental service, the facility must	
W357	keep a permanent dental record for each client,	
W358	with a dental summary maintained in the client's living-unit.	§483.460(h)(1) GUIDELINES: A "dental summary" means a brief written report of each visit to the dentist and includes any care instructions to be followed-up by facility staff as a result of treatment.
	(2) If the facility does not maintain an in-house dental service, the facility must	
W359	obtain a dental summary of the results of dental visits	§483.460(h)(2) GUIDELINES: The dentist used by the facility must agree to release the records and final recommendations for future care when the individual is discharged or discontinues service with the dentist.
W360	and maintain the summary in the client's living unit.	

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	(i) Standard: Pharmacy services.	
W361	The facility must provide or make arrangements for the provision of routine and emergency drugs and biologicals to its clients. Drugs and biologicals may be obtained from community or contract pharmacists or the facility may maintain a licensed pharmacy.	483.460(i) GUIDELINES: Emphasis is placed on the provision of the service, and not on its method of delivery. Whether the facility utilizes the unit dose, individual prescription or a combination of these systems, or whether the facility has its own pharmacy or provides the service through arrangement with a community pharmacy, the emphasis is on the accuracy of the drug distribution system and the effectiveness of the drug therapy.
	(j) Standard: Drug regimen review.	
W362	(1) A pharmacist with input from the interdisciplinary team must review the drug regimen of each client at least quarterly.	483.460(j)(1) FACILITY PRACTICES: The IDT provides the pharmacist with relevant input for the drug regimen review (e.g., changes in behavior, new medication the person has begun taking, etc.). Reviews are performed as often as individual need dictates, but not less than quarterly. §483.460(j)(1) GUIDELINES: The pharmacist should review on a more frequent basis the drug regimen of individuals whose response indicates problems with drug therapy. Refer to the "Indicators for Surveyor Assessment of the Performance of Drug Regimen Reviews" as stated in Appendix N to the State Operations Manual (Pharmaceutical Service Requirements in Long Term Care Facilities) to evaluate the drug regimen review done by the pharmacist. §483.460(j)(l) PROBES: Does this review look at the individual's response to the drug?
W363	(2) The pharmacist must report any irregularities in clients' drug regimens to the prescribing physician and interdisciplinary team.	483.460(j)(2) FACILITY PRACTICES: The pharmacist identifies apparent irregularities and determines their significance. The pharmacist reports apparent irregularities which are significant to the physician and the IDT. The physician and IDT are aware of all irregularities in the individual's drug regimen. §483.460(j)(2) GUIDELINES: The physician and interdisciplinary team must consider the report of the pharmacist and determine whether to accept or reject the recommendations in the report. The pharmacist is not required to repeatedly report the same minor irregularities which have already been considered by the physician and the interdisciplinary team, but were rejected based upon the individual's specific condition.

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		§483.460(j)(2) SURVEY PROCEDURE: Review the drug regimen reviews of sampled individuals in order to determine if the pharmacist has appropriately reviewed the drug regimen on a quarterly basis. Refer to the "Indicators for Surveyor Assessment of the Performance of Drug Regimen Reviews" as stated in Part One of Appendix N (Pharmaceutical Service Requirements in Long Term Care Facilities). Appendix N lists many apparent drug irregularities that can occur. The following exceptions apply to the "List of Apparent Irregularities" on pages N-7 and N-8: 1. "Use of a listed anti-psychotic drug unless one of the following specific conditions exists..." At the present time we have not developed a list of conditions which limit the use of anti-psychotic drugs for individuals in ICFs/IID. 2. "Use of anti-psychotic drugs in the absence of gradual dose withdrawal attempted every six months..." In ICFs/IID, the requirement is that gradual reduction be attempted at least annually unless clinically contraindicated. See W316 & W317. 3. "The use of a p.r.n. [as needed] anti-psychotic drug more than five times..." Standing or as needed programs to control inappropriate behavior are not permitted under the ICF/IID regulations. A drug may be used in an emergency situation, but emergency drug usage can not continue until that usage has been approved by the interdisciplinary team and included in the active treatment program. See W290, W311 and W312.
W364	(3) The pharmacist must prepare a record of each client's drug regimen reviews and the facility must maintain that record.	
W365	(4) An individual medication administration record must be maintained for each client.	§483.460(j)(4) GUIDELINES: Each dose of medication, whether self-administered or not, shall be properly recorded in the individual's record. The intent of this requirement is to maintain a record of drugs administered.
W366	(5) As appropriate the pharmacist must participate in the development, implementation, and review of each client's individual program plan either in person or through written report to the interdisciplinary team.	§483.460(j)(5) FACILITY PRACTICES: For individuals who have complex drug therapy, are taking medications which may have serious side effects or interactions, or whose team requires medication information in order to design the IPP, the pharmacist participates in the IPP process in order to address these issues. §483.460(j)(5) GUIDELINES: This regulation does not exclude the pharmacist from the evaluation process, but the pharmacist can best determine how to expend his/her efforts most productively in service to individuals at the facility.

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	(k) Standard: Drug administration.	
W367	The facility must have an organized system for drug administration that identifies each drug up to the point of administration.	
	The system must assure that- -	
W368	(1) All drugs are administered in compliance with the physician's orders;	
W369	(2) All drugs, including those that are self-administered, are administered without error;	§483.460(k)(2) GUIDELINES: A medication "error" is a discrepancy between what the physician has ordered, and what you observe during the drug pass observation. The regulation does not allow for any medication errors. "Self administered" means administration of medications by the individual, independent of a staff person obtaining, selecting, and preparing the medications for the individual. This includes all usage forms (oral, injections and suppositories). The individual should be trained until he/she can perform this function without error. §483.460(k)(2) SURVEY PROCEDURE: Use the observation technique to determine medication errors. The observation technique involves observing the administration of drugs, recording what is observed, and reconciling the record of observation with the physician's orders to determine whether or not medication errors have occurred. Do not rely on paper review to determine medication errors. Detection of blank spaces on the medication administration record does not constitute the detection of actual medication errors. Paper review only identifies possible errors. Observation Technique Follow these steps to detect medication errors: 1. Identify the drug product. Determine what drugs, in what strength and dosage forms, etc., are being administered. There are two principle ways of doing this. In most cases, they are used in combination. o Identify the product by its size, shape and color. Many products have a distinctive size, shape or color. However, this technique can be problematic because not all products are distinctive.

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		o Identify the product by observing the label. When the punch card or unit dose system is used, you can usually observe the label and adequately identify the drug product. When the vial system is used, observing the label is sometimes difficult. Ask the person administering medications to identify the drug product. 2. Observe the administration of drugs. Record your observations in your notes. Follow the person administering medications and observe the individuals receiving drugs (e.g., actually swallowing oral dosage forms). Be as neutral and as unobtrusive as possible during this process. Watch 16 drug doses being administered to the individuals residing in the facility, or observe a 100% sample of the residents in the facility whichever is smaller. For example, in a four bed facility with each individual taking two morning doses, you would watch a 100% sample of the individuals since only eight doses would have been administered. In an eight bed facility with each individual taking four morning doses you would observe a sample of 16 doses being administered. In a large facility, a larger sample (40 to 50 doses) taken from different units in the facility should be observed to ensure that an adequate sample of the drug distribution system has been evaluated. It is usually preferable to watch the morning pass because more doses per individual are administered at that time; however, you may observe the pass at any time. Observe more than one staff member administering drugs, if possible. You may observe the drugs being administered in the individual's living quarters or in the day program if the day program is operated by the ICF/IID on its grounds (i.e., the day program is not a separately certified entity). If there are individuals at the facility who self-administer medications, attempt to observe the self-administration (see W373). Respect the individual's right to privacy by verbally asking the individual for permission to observe. Note every detail about drug administration in your notes. For example, "eye drops administered to both eyes" or "nurse took pulse" or "all drugs crushed and administered in applesauce." 3. Record, in your notes, the most current physician's orders for those individuals who were observed receiving medications. The latest recapitulation of drug orders is sufficient for determining whether a valid order exists, provided that the physician has signed the "recap." The signed "recap" and subsequent orders constitute a legal authorization to administer the drug. You should now have a complete record of what you observed, and what should have occurred according to the physician orders.

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		4. Reconcile your record of observation with the physician's orders. Compare your record of observation to the most current signed orders for drugs. o For each drug on your list: Was it administered according to the physician's orders? For example, in the correct strength, by the correct route? Was there a valid order for the drug? o For drugs not on your list: Are there orders for drugs that should have been administered, but were not? Such circumstances represent omitted doses, which is one of the most frequent types of errors. 5. Determine the number of errors by adding the errors for each individual. Before concluding that an error has occurred, discuss the apparent error with the person who administered the drug. There may be a logical explanation, such as a more recent physician order which you have not seen. 6. Timing errors: If a drug is ordered before meals (AC) and administered after meals (PC) or vice versa, always count this as an error. If the drug is administered more than 60 minutes later or earlier than its scheduled administration time, count this as an error ONLY IF THAT WRONG TIME ERROR CAN CAUSE THE INDIVIDUAL DISCOMFORT OR JEOPARDIZE THE RESIDENT'S HEALTH AND SAFETY. Counting a drug with a long half-life (beyond 24 hours) as a wrong time error when it is 15 minutes late is improper because there is no significant impact on the individual. To determine the scheduled administration time, examine the facility's policy relative to dosing schedules.
W370	(3) Unlicensed personnel are allowed to administer drugs only if State law permits;	§483.460(k)(3) GUIDELINES: "Unlicensed personnel" of the facility does not refer to the situation of individuals administering their own medication. Unlicensed personnel administer only those forms of medication which State law permits.
W371	(4) Clients are taught to administer their own medications if the interdisciplinary team determines that self-administration of medications is an appropriate objective, and if the physician does not specify otherwise;	§483.460(k)(4) FACILITY PRACTICES: Based on assessment results and IDT discussion, the individual is instructed in skills leading to self-administration of medication, when appropriate, based on the person's functional abilities. No individual is precluded from training based solely on diagnosis or level of functioning. §483.460(k)(4) PROBES: Is there a pattern of refusal to allow self-medication? How is the health and safety of individuals assured during training for self-medication?

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W372	(5) The client's physician is informed of the interdisciplinary team's decision that self-administration of medications is an objective for the client;	
W373	(6) No client self-administers medication until he or she demonstrates the competency to do so;	§483.460(k)(6) FACILITY PRACTICES: Individuals are supervised during self-administration training programs. Individuals who demonstrate and master self-administration at the level and frequency specified, administer independent of staff. §483.460(k)(6) GUIDELINES: Do not expect individuals served to be more knowledgeable than members of the general public in order to self-administer medication. There is no requirement for the individual to be able to state both the generic and brand names of the medication being taken, nor is it expected that the individual be able to list all potential side effects of the medication. The test of competency to self-administer is whether the individual can take the correct medication, in the correct dosage, at the correct time. §483.460(k)(6) PROBES: Is there a pattern that all individuals self-medicate whether they can demonstrate the skill or not?
W374	(7) Drugs used by clients while not under the direct care of the facility are packaged and labeled in accordance with State law;	§483.460(k)(7) GUIDELINES: When individuals go out of a facility for home visits, or to attend workshops or school, drugs they are taking must be packaged and labeled in accordance with State law by a responsible person approved to administer medications. Be aware whether or not there are applicable State laws which may allow packaging by someone other than the pharmacist. The test of adequacy of packaging and labeling is whether or not other persons administering medications are able to identify the individual's medication, method of administration, contraindications, if appropriate, and administration schedule.
	(8) Drug administration errors and adverse drug reactions are	
W375	recorded	
W376	and reported immediately to a physician.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(l) Standard: Drug storage and recordkeeping.	
	(1) The facility must store drugs under proper conditions of	
W377	sanitation,	
W378	temperature,	
W379	light,	
W380	humidity,	
W381	and security.	
W382	(2) The facility must keep all drugs and biologicals locked except when being prepared for administration.	
W383	Only authorized persons may have access to the keys to the drug storage area.	§483.460(l)(2) GUIDELINES: "Authorized persons" must be restricted to those who administer the drugs and nursing supervisors (if any). No other personnel should have access to these keys.
W384	Clients who have been trained to self administer drugs in accordance with §483.460(k)(4) may have access to keys to their individual drug supply.	§483.460(l)(2) GUIDELINES: Drugs that are self-administered do not have to be double locked. The purpose for the double locking is to limit access to scheduled drugs. Since the individual is generally the only one who has access to his/her drug supply (with perhaps the exception of a facility's Director of Nursing Services, who may have access to all of the facility's drug supplies), there is no need to further limit access.
W385	(3) The facility must maintain records of the receipt and disposition of all controlled drugs.	§483.460(l)(3) GUIDELINES: The facility may also use the medication administration record for purposes of documenting receipt and disposition of controlled drugs. By recording the amount received, a record of the receipt and disposition, can be realized.
W386	(4) The facility must, on a sample basis, periodically reconcile the receipt and disposition of all controlled drugs in schedules II through IV (drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. 801 et seq., as implemented by 21 CFR Part 308).	§483.460(l)(4) GUIDELINES: Reconciliation of receipt and disposition of controlled drugs need not be done on each shift. If periodic (e.g., weekly or monthly) reconciliations indicate losses, more frequent reconciliation (daily or by shift) may need to be performed to identify and stop losses.

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W387	(5) If the facility maintains a licensed pharmacy, the facility must comply with the regulations for controlled drugs.	
	(m) Standard: Drug labeling.	
	(1) Labeling of drugs and biologicals must- -	
W388	(i) Be based on currently accepted professional principles and practices; and	
W389	(ii) Include the appropriate accessory and cautionary instructions, as well as the expiration date, if applicable.	
	(2) The facility must remove from use- -	
W390	(i) Outdated drugs; and	
W391	(ii) Drug containers with worn, illegible, or missing labels.	
W392	(3) Drugs and biologicals packaged in containers designated for a particular client must be immediately removed from the client's current medication supply if discontinued by the physician.	§483.460(m)(3) GUIDELINES: If a physician discontinues a drug for a particular individual, that particular drug supply should be removed from its usual storage area. This precludes that drug from being administered to the individual in error.
	(n) Standard: Laboratory services.	§483.460(n) FACILITY PRACTICES: If the facility performs laboratory services, it has a current, valid certificate for the types of tests it is performing.
W393	(1) If a facility chooses to provide laboratory services, the laboratory must meet the requirements specified in part 493 of this chapter.	§483.460(n) GUIDELINES: A "laboratory service or test" is defined as any examination or analysis of materials derived from the human body for purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings.

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W394	(2) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of service in accordance with the requirements of part 493 of this chapter.	A facility performing any laboratory service or test must have applied to CMS, and received either a certificate of waiver or a certificate of registration. An application for a certificate of waiver may be made if the facility performs only those tests on the waiver list. Those tests are: o Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: - Bilirubin; - Glucose; - Hemoglobin; - Ketone; - Leukocytes; - Nitrite; - pH; - Protein; - Specific gravity; and - Urobilinogen. o Fecal Occult blood; o Ovulation tests - visual color comparison tests for human luteinizing hormone; o Urine pregnancy tests - visual color comparison tests; o Erythrocyte sedimentation rate (non-automated); o Hemoglobin - copper sulfate (non-automated); o Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; o Spun microhematocrit; and o Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout. If the facility performs tests, other than those on the waiver list, a certificate of registration is required. These certificates are required regardless of the frequency with which the laboratory services or tests are conducted. When no tests are performed, a certificate is not needed. Facilities only collecting specimens and not performing testing do not need a certificate. A not-for-profit or a State or local government organization may have one certificate covering all the facilities it operates (i.e., all the separately certified residences which fall under its governing body), if no more than a total of 15 types of waivered or moderately complex laboratory tests are used. §483.460(n) SURVEY PROCEDURE: If the facility performs any laboratory service or test (as defined above), ask to see a current valid certificate of waiver, or certificate of registration, whichever is applicable.

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		Some facilities may be exempt from the Clinical Laboratory Improvement Act (CLIA) by virtue of being licensed by a State with a CMS-approved laboratory licensure program. In this case, the surveyor should ask to see a current valid State laboratory license. Concerns regarding the application of these requirements should be directed to your State laboratory consultant or the CMS regional office.

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W406	§483.470 Condition of participation: Physical environment.	§483.470 COMPLIANCE PRINCIPLES: The Condition of Participation of Physical Environment is met when: o The environment promotes the health and safety, independence and learning of the individuals who reside there. The Condition of Participation of Physical Environment is not met when: o Environmental conditions interfere with learning and independence (e.g., lack of appropriate assistive devices, accessible bathrooms and closets, house or water temperatures, etc.) to such an extent that the Condition of Participation for Active Treatment is not met. o Individuals are at risk to health and safety due to environmental conditions. o Poor infection control practices are observed and there is a high rate of infections or communicable diseases among the individuals residing in the facility.
	(a) Standard: Client living environment.	
W407	(1) The facility must not house clients of grossly different ages, developmental levels, and social needs in close physical or social proximity unless the housing is planned to promote the growth and development of all those housed together.	§483.470(a)(1) FACILITY PRACTICES: The grouping of individuals in living units takes into consideration the needs, functional levels, ages, interests, social skills and abilities of all residents and does not endanger the health, safety or development of any individual. The living arrangement promotes independence and learning for all individuals who reside there. §483.470(a)(1) GUIDELINES: Individuals should live in the least restrictive grouping in keeping with their level of functioning. Prime consideration in the grouping of individuals is made according to social and intellectual development, friendship patterns, and commonality of interests. The use of "grossly different ages" is intended to ensure, for example, that very young children are not inappropriately housed together with much older individuals. Extreme differences may in some instances actually impede appropriate training and may pose a threat to the safety of younger, more vulnerable individuals.

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W408	(2) The facility must not segregate clients solely on the basis of their physical disabilities. It must integrate clients who have ambulation deficits or who are deaf, blind, or have seizure disorders, etc., with others of comparable social and intellectual development.	§483.470(a)(2) FACILITY PRACTICES: Individuals with and without physical disabilities are integrated in living environments which are designed to meet the needs of all participants. §483.470(a)(2) GUIDELINES: The surveyor should determine if the individuals' skill level, rather than the individuals' physical, sensory or medical disability, justifies the housing pattern.
	(b)Standard: Client bedrooms.	
	(1) Bedrooms must- -	
W409	(i) Be rooms that have at least one outside wall;	
W410	(ii) Be equipped with or located near toilet and bathing facilities;	
W411	(iii) Accommodate no more than four clients unless granted a variance under paragraph (b)(3) of this section;	
	(iv) measure	
W412	at least 60 square feet per client in multiple client bedrooms	
W413	and at least 80 square feet in single client bedrooms; and	
W414	(v) In all facilities initially certified, or in buildings constructed or with major renovations or conversions on or after October 3, 1988, have walls that extend from floor to ceiling.	§483.470(b)(l)(v) GUIDELINES: An "initially certified" facility includes any facility or portion thereof that is certified for participation in Medicaid after a period of non-participation (e.g., if its certification has been terminated or voluntarily withdrawn). Each of the three criteria specified below must exist in order for a facility to qualify as undergoing "major renovations or conversions": o Individuals must vacate the building during the period of renovation or construction;

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		o No Medicaid billing takes place during the period of renovation or construction; and o A resurvey of the building is required before individuals may return to live in the building. Facilities with buildings which were undergoing major renovations and were not reoccupied prior to October 3, 1988, are expected to meet the floor to ceiling wall requirements. This also applies to those facilities with buildings that had plans for renovation approved prior to October 3. There is no provision in the regulation for granting waivers of this requirement. In a facility certified prior to October 3, 1988, if the conditions which define "major renovation or conversion" are avoided during installation of walls to divide "open bay sleeping areas," it is allowable for the walls not to extend from floor to ceiling.
W415	(2) If a bedroom is below grade level, it must have a window that-- (i) Is usable as a second means of escape by client(s) occupying the room; and (ii) Is no more than 44 inches (measured to the window sill) above the floor unless the facility is surveyed under the Health Care Occupancy Chapter of the Life Safety Code, in which case the window must be no more than 36 inches (measured to the window sill) above the floor.	§483.470(b)(2) GUIDELINES: The intent of the regulation is to prohibit the housing of individuals in basements that are entirely below grade. Individuals may be housed on the lower level of housing (e.g., a bi-level house), provided the window height requirements are met.

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W416	(3) The survey agency may grant a variance from the limit of four clients per room only if a physician who is a member of the interdisciplinary team and who is a qualified intellectual disabilities professional-- (i) Certifies that each client to be placed in a bedroom housing more than four persons is so severely medically impaired as to require direct and continuous monitoring during sleeping hours; and (ii) Documents the reason why housing in a room of only four or fewer persons would not be medically feasible.	§483.470(b)(3) GUIDELINES The only acceptable reason for individuals to be housed in bedrooms serving more than four people is because the individual is in very fragile health and needs extensive life support services, such as posturing for clearing the airways, or monitoring for uncontrolled seizures. If more than four people are housed together in the same room, the number should remain small, and each individual placed in the grouping must have a high level of medical monitoring need. Most extensive life support services, by their very nature are able to be provided by licensed personnel alone, or only under the direct visual supervision of licensed personnel. The presence of a medical care plan is not required because all such life threatening possibilities are difficult to predict. However, the greatest majority of individuals who might qualify for this variance will be on a medical care plan. See §2140 for the documentation required for a medical variance. §483.470(b)(3) SURVEY PROCEDURE The absence of a medical care plan for individuals for whom a variance is requested constitutes a "flag", and will necessitate an investigation into the individual circumstances to ensure that the facility has not routinely "certified" individuals as requiring more supervision as a means of justifying the continued use of open wards or nominally partitioned wards. If the medical risk of an individual is so potentially life threatening that the individual requires continuous unobstructed surveillance during sleeping hours to ensure the health and safety of the individual, then the individual's needs indicate that licensed personnel should be present and 24-hour on-duty staffing patterns will be validated by the surveyor. (See also W344, W333, and W183.)
	(4) The facility must provide each client with--	
W417	(i) A separate bed of proper size and height for the convenience of the client;	§483.470(b)(4)(i) FACILITY PRACTICES Beds are adapted to meet individual needs (not for staff convenience). The individual's preference, chronological age, and physical and medical needs are the determining factors in bed size and height. §483.470(b)(4)(i) PROBES Is there a pattern of placing adults with physical disabilities in cribs?
W418	(ii) A clean, comfortable, mattress;	

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W419	(iii) Bedding appropriate to the weather and climate; and	§483.470(b)(4)(iii) GUIDELINES: A single bedspread may be used year round, if it is appropriate for all seasons.
W420	(iv) Functional furniture, appropriate to the clients needs,	§483.470(b)(4)(iv) FACILITY PRACTICES: Individuals with physical disabilities who live in the room are able to use the furniture. Individual preferences and program needs are considered in furniture selection.
W421	and individual closet space in the client's bedroom with clothes racks and shelves accessible to the client.	§483.470(b)(4)(iv) FACILITY PRACTICES: Closets have enough space for a reasonable amount of the current season's clothing. Individuals who use wheelchairs or have other physical challenges can reach the racks and shelves in their closets. §483.470(b)(4)(iv) GUIDELINES: "Furniture" is to be distinguished from "furnishings" (such as plants, pictures, etc.), which though encouraged as being an appropriate and desirable aspect of a normalized living environment, cannot serve as a substitute for appropriate individual furniture that can be used by the individual alone. The facility is permitted either to provide the individual with an individualized closet or with a designated area in a shared closet. The use of central clothing bins in a facility clothing room, in the absence of required individual closet space in the bedroom, is not an acceptable practice.
	(c) Standard: Storage space in bedrooms.	
	The facility must provide--	
W422	(1) Space for equipment for daily out-of-bed activity for all clients who are not yet mobile, except those who have a short-term illness or those few clients for whom out-of-bed activity is a threat to health and safety; and	§483.470(c)(1) FACILITY PRACTICES: There is sufficient space in the bedroom to permit use of wheelchairs, walkers and other adaptive equipment as indicated by the needs of those living in the room.
W423	(2) Suitable storage space, accessible to clients, for personal possessions, such as TVs, radios, prosthetic equipment and clothing.	§483.470(c)(2) FACILITY PRACTICES: There is enough storage space for a reasonable amount of personal possessions. Individuals who use wheelchairs or have other physical challenges can reach and use their own storage space.

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		In the presence of an individual's personal storage space being locked by staff, the individual's program plan documents the necessity for limited access to his/her own possessions and includes provisions to teach the individual the necessary responsible behaviors. §483.470(c)(2) GUIDELINES: For a storage space to be determined as "suitable," it must assure the safekeeping of the individual's possessions among other things being stored. Use of the term "accessible" does not require unrestricted access in situations where this is precluded by an active treatment program designed to eliminate inappropriate behavior, or in which the individual's interdisciplinary team determines that unrestricted access would endanger the individual or others. The surveyor should determine whether or not there is a pattern of restricted access not because of the behavior of the individual, but because of the behavior of others with whom the individual lives. This could also raise the question of inappropriate grouping of individuals due to different functioning abilities.
	(d) Standard: Client bathrooms. The facility must--	
W424	(1) Provide toilet and bathing facilities appropriate in number, size, and design to meet the needs of the clients;	§483.470(d)(1) FACILITY PRACTICES: Bathrooms and fixtures are adapted to accommodate individuals with physical challenges. There are enough bathrooms so that individuals do not have a prolonged wait to use them. §483.470(d)(1) GUIDELINES: "Bathing facilities appropriate in . . . design" must include provisions for a mirror and sink/toothbrushing area.
W425	(2) Provide for individual privacy in toilets, bathtubs, and showers; and	§483.470(d)(2) FACILITY PRACTICES: In a bathroom containing multiple toilets, showers or bathtubs, there are doors, curtains or some other means of protecting the individual from view when fully or partially unclothed. Individuals using bathrooms cannot be seen when passing by the door or window. §483.470(d)(2) GUIDELINES: Gang showers and open toilets are inappropriate to the quality of life, privacy, and personal dignity of the individuals served in the facility. Individual privacy does not preclude the assistance provided by facility staff, when necessitated by the individual's condition.

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W426	(3) In areas of the facility where clients who have not been trained to regulate water temperature are exposed to hot water, ensure that the temperature of the water does not exceed 110° Fahrenheit.	§483.470(d)(3) GUIDELINES: Individuals must be under the direct supervision of staff while being trained to operate hot water temperature controls. §483.470(d)(3) PROBES: If water is above 110 degrees F, do individuals demonstrate ability to self regulate water temperature? Is there a pattern of excluding individuals from the opportunity to learn how to regulate water temperature?
	(e) Standard: Heating and ventilation.	
	(1) Each client bedroom in the facility must have--	
W427	(i) At least one window to the outside; and	§483.470(e)(1)(i) GUIDELINES: Since a door serves primarily to provide egress rather than to perform the ventilation and aesthetic functions of an outside window, it may not be used for room ventilation in place of a window.
W428	(ii) Direct outside ventilation by means of windows, air conditioning, or mechanical ventilation.	§483.470(e)(1)(ii) PROBES: How is ventilation provided? How does the facility regulate room temperatures and ventilation? Is there proper ventilation in individual bathrooms and shower areas?
	(2) The facility must--	
W429	(i) Maintain the temperature and humidity within a normal comfort range by heating, air conditioning or other means; and	§483.470(e)(2)(i) FACILITY PRACTICES: Individuals report that the temperature is comfortable under most circumstances. In extremely hot or extremely cold weather, precautions are taken by the facility to protect the individuals, particularly those who are medically compromised, from ill effects of the temperature. §483.470(e)(2)(i) GUIDELINES: A "normal comfort range" in most instances is defined as not going below a temperature of 68° F or exceeding a temperature of 81 degrees F for facilities in most geographic areas of the country (primarily at the Northernmost latitudes) where that temperature is exceeded only during rare, brief episodes of unseasonably hot weather. §483.470(e)(2)(i) PROBES: How often do temperatures depart from normal comfort ranges?

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		What does the facility do to accommodate temperature to meet individual needs? Are temperature ranges responsive to age or other special conditions or needs of individuals? When equipment failures occur, does the facility attempt to have repairs made as soon as possible?
W430	(ii) Ensure that the heating apparatus does not constitute a burn or smoke hazard to clients.	
	(f) Standard: Floors.	
	The facility must have--	
W431	(1) Floors that have a resilient, nonabrasive, and slip-resistant surface.	§483.470(f)(1) GUIDELINES: "Slip-resistant" is to be distinguished from "slip-free." There is a presumption made that floors will ordinarily be dry, and when wet, appropriate precautions will be taken.
W432	(2) Nonabrasive carpeting, if the area used by clients is carpeted and serves clients who lie on the floor or ambulate with parts of their bodies, other than feet, touching the floor; and	
	(3) Exposed floor surfaces and floor coverings that	
W433	promote mobility in areas used by clients,	
W434	and promote maintenance of sanitary conditions.	
	(g) Standard: Space and equipment.	
	The facility must--	

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W435	(1) Provide sufficient space and equipment in dining, living, health services, recreation, and program areas (including adequately equipped and sound treated areas for hearing and other evaluations if they are conducted in the facility) to enable staff to provide clients with needed services as required by this subpart and as identified in each client's individual program plan.	§483.470(g)(1) FACILITY PRACTICES: Staff and individuals have the space, materials and equipment needed for the formal and informal active treatment program to be carried out. There is sufficient space to accommodate group activities, including groups with individuals who use wheelchairs. Recreational supplies and materials are available and reflect the interests, abilities and chronological age of the individuals. §483.470(g)(1) PROBES: Is there sufficient space and adaptive equipment so that individuals in wheelchairs can go outside regularly and participate in recreational events?
W436	(2) Furnish, maintain in good repair, and teach clients to use and to make informed choices about the use of dentures, eyeglasses, hearing and other communications aids, braces, and other devices identified by the interdisciplinary team as needed by the client.	§483.470(g)(2) FACILITY PRACTICES: Individuals in need of adaptive/assistive/supportive/prosthetic equipment specified by the IDT are observed to have them and are taught to use and care for this equipment to the extent of their capabilities. Individuals are observed using braces, mobility aids, positioning devices, and other adaptive equipment which meet their needs and increase functionality. Equipment is observed to be in good repair. §483.470(g)(2) GUIDELINES: The term "furnish" means that the facility is responsible for obtaining or purchasing these items and is responsible for making any necessary arrangements to enable the individual actually to receive them. However, if an item is available free of charge the facility would satisfy the requirement simply by making the necessary arrangements for the individual to receive them. Individuals' personal funds should not be used for these items since this is a covered service under the ICF/IID benefit. The term "maintain in good repair" means that the facility is responsible for ensuring that these items are kept in good working order. §483.470(g)(2) PROBES: What provisions are made for repairs of protheses and assistive technology devices? Are repairs timely? Are needed protheses and assistive technology devices in good repair and proper fit? Are loaners available during repair periods? How does the facility address the use of special devices with individuals who are resistive of their use?
W437	(3) Provide adequate clean linen and dirty linen storage areas.	§483.470(g)(3) FACILITY PRACTICES: Clean linen is separated from dirty linen.

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		Clean linen is stored in a manner which prevents contamination. Linen soiled with bodily fluids is stored in a manner which protects individuals from exposure to possible infectious sources. §483.470(g)(3) GUIDELINES: A bedroom hamper can be an acceptable dirty linen storage "area" if kept odor free, consistent with the infection control requirements at §483.470(1).
	(h) Standard: Emergency plan and procedures.	
W438	(1) The facility must develop and implement detailed written plans and procedures to meet all potential emergencies and disasters such as fire, severe weather, and missing clients.	§483.470(h)(1) FACILITY PRACTICES: Emergency plans exist. Emergency plans address those types of emergencies relevant to the facility, its geographic location and the needs of the individuals served. Staff follow emergency procedures both during drills and in real emergencies.
W439	(2) The facility must communicate, periodically review, make the plan available, and provide training to the staff.	§483.470(h)(2) FACILITY PRACTICES: Staff know where emergency plans and procedures are located. Staff report training in emergency procedures. Emergency plans have been updated if conditions affecting them have changed. §483.470(h)(2) GUIDELINES: "Periodic review" is a judgment made by the facility based on the circumstances of the facility. If the facility changes its physical plant or if changes external to the facility necessitates a review of the disaster plan, then the facility is responsible for carrying out the review.
	(i) Standard: Evacuation drills.	
	(1) The facility must hold evacuation drills	
W440	at least quarterly for each shift of personnel	§483.470(i)(1) FACILITY PRACTICES: Each shift has participated in an evacuation drill at least once in a 3-month period.
W441	and under varied conditions to--	§483.470(i)(1) FACILITY PRACTICES: Staff, and individuals who are being trained/assisted/supported to evacuate on their own, practice evacuating at different times of the day and night, from different rooms in the facility, using different escape routes and in various weather conditions.

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W442	(i) Ensure that all personnel on all shifts are trained to perform assigned tasks;	§483.470(i)(1)(i) FACILITY PRACTICES: All staff know what they are to do in an emergency.
W443	(ii) Ensure that all personnel on all shifts are familiar with the use of the facility's fire protection features; and	§483.470(i)(1)(ii) FACILITY PRACTICES: Staff know how to use fire extinguisher, alarms, and any other safety features in the facility.
W444	(iii) Evaluate the effectiveness of emergency and disaster plans and procedures.	§483.470(i)(1)(iii) FACILITY PRACTICES: The facility determines whether the plans and procedures are adequate.
	(2) The facility must--	
W445	(i) Actually evacuate clients during at least one drill each year on each shift;	§483.470(i)(2)(i) FACILITY PRACTICES: All individuals totally evacuate the building at least once per year per shift, regardless of the occupancy chapter under which the building falls. §483.470(i)(2)(i) GUIDELINES: All facilities, regardless of their size require actual evacuation. "Actually evacuate," as used in this standard, applies to all individuals. The drills are conducted not only to rehearse the individuals and staff for fire (see §483.470(i)(2)(v)), but for other disasters such as hurricanes, tornadoes, floods, etc. Such disasters would require the entire occupancy to be evacuated, and, therefore, the actual evacuation must be practiced, as required.
W446	(ii) Make special provisions for the evacuation of clients with physical disabilities;	§483.470(i)(2)(ii) FACILITY PRACTICES: Individuals with physical disabilities can be evacuated.
W447	(iii) File a report and evaluation on each evacuation drill;	§483.470(i)(2)(iii) PROBES: What problems and corrective actions do fire drill reports identify?
W448	(iv) Investigate all problems with evacuation drills, including accidents,	
W449	and take corrective action; and	§483.470(i)(1)(iii) FACILITY PRACTICES: When a problem is identified in evacuating, the facility takes steps which are reasonably likely to correct the problem.

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TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
W450	(v) During fire drills, clients may be evacuated to a safe area in facilities certified under the Health Care Occupancies Chapter of the Life Safety Code.	
W451	(3) Facilities must meet the requirements of paragraph (i)(1) and (2) of this section for any live-in and relief staff they utilize.	§483.470(i)(3) GUIDELINES: Since live-in staff and their relief personnel are generally the same staff who work with the individuals on a round-the-clock basis, they must conduct a minimum of 4 drills a year, each of which must occur at different times within the day (24-hour period) (i.e., morning, afternoon, and night (sleep time)), and generally when individuals are at different locations within the house. If the facility has large numbers of relief personnel, more drills may be needed to meet the intent of this requirement.
	(j) Standard: Fire protection.	§483.470(j) GUIDELINES: These standards are covered by the Life Safety Code (LSC) survey. The facility must meet the appropriate chapter of the Life Safety Code, 1985 edition. §483.470(j) SURVEY PROCEDURES: When surveying an ICF/IID for compliance with the LSC, it is first necessary to determine whether the facility will be surveyed under Health Care (HC) or Board and Care (BC) occupancy. o If individuals receive nursing services, or if the provider elects to use Health Care, the facility should be surveyed as a Health Care Facility under Chapter 12 or 13 of the LSC, as appropriate. o If individuals receive personal care and protective oversight but not chronic nursing services, the facility is to be surveyed under Board and Care and the following three steps should be followed: 1. Determine the size (16 or less = small; 17 or more = large); 2. Determine the Evacuation Difficulty (PROMPT, SLOW, or IMPRACTICAL) using Appendix F of the fire safety evaluation system for board and care facilities (FSES/BC); and 3. Survey the building using one of two methods: a. The prescriptive requirements of Chapter 21; or b. The FSES/BC, Appendix G. If the FSES/BC is used, validate the rating of individuals as part of the sampling process. If significant discrepancies are noted from what staff report and what evidence can be ascertained about individual behavior, conduct an indepth investigation into the ratings of all individuals in conjunction with the LSC surveyor.
	(1) General. (i) Except as specified in paragraph (j)(2) of this section, the facility must meet the applicable provisions of either the Health Care Occupancies Chapters or the Residential Board and Care Occupancies Chapter of the Life Safety Code (LSC) of the National Fire Protection Association, 1985 edition, which is incorporated by reference.	
	(ii) The State survey agency may apply a single chapter of the LSC to the entire facility or may apply different chapters to different buildings or parts of buildings as permitted by the LSC.	
	(iii) A facility that meets the LSC definition of a residential board and care occupancy and that has 16 or fewer beds, must have its evacuation capability evaluated in accordance with the Evacuation Difficulty Index of the LSC (Appendix F).	

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	(2) Exceptions (i): For facilities that meet the LSC definition of a health care occupancy:	
	(A) The State survey agency may waive, for a period it considers appropriate, specific provisions of the LSC if-- (1) The waiver would not adversely affect the health and safety of the clients; and (2) Rigid application of specific provisions would result in an unreasonable hardship for the facility.	
	(B) The State survey agency may apply the State's fire and safety code instead of the LSC if the Secretary finds that the State has a code imposed by State law that adequately protects a facility's clients. (C) Compliance on November 26, 1982 with the 1967 edition of the LSC or compliance on April 18, 1986 with the 1981 edition of the LSC, with or without waivers, is considered to be in compliance with this standard as long as the facility continues to remain in compliance with that edition of the Code.	
	(ii) for facilities that meet the LSC definition of a residential board and care occupancy and that have more than 16 beds, the State survey agency may apply the State's fire and safety code as specified in paragraph (j)(2)(B) of this section.	
	(k) Standard: Paint.	

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TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	The facility must--	
W452	(1) Use lead-free paint inside the facility; and	
W453	(2) Remove or cover interior paint or plaster containing lead so that it is not accessible to clients.	
	(1) Standard: Infection Control.	
W454	(1) The facility must provide a sanitary environment to avoid sources and transmission of infections.	§483.470(l)(1) FACILITY PRACTICES: Individuals do not have access to soiled diapers, linens, bandages or any other potentially infectious material. These materials are handled in a manner which prevents leakage from containers or exposure to the general environment. Bathroom fixtures and surfaces are free from bodily wastes. Kitchen counters are cleaned at appropriate times during food preparation.
W455	There must be an active program for the prevention, control, and investigation of infection and communicable diseases.	§483.470(l)(1) FACILITY PRACTICES: Staff are observed washing hands, when appropriate. Individuals are trained and encouraged to maintain good hygiene practices. Staff follow Center for Disease Control (CDC) guidelines for universal precautions. §483.470(1)(1) GUIDELINES: An "active program" includes such observable practices as: the direct care staff routinely washing their hands or changing gloves after working with an individual who has an infectious disease or working with each individual during mealtimes; the use of aseptic technique, when appropriate; an ongoing program of communicable disease control and investigation of infections; and an active training program that ensures the individuals served receive adequate prevention of transmission information and skills, according to needs. Procedures must be followed to prevent cross-contamination, including hand washing or changing gloves at mealtimes, after providing personal care to more than one individual, or when performing other tasks among individuals which provide the opportunity for cross-contamination to occur. Facilities for hand washing must exist and be available to staff. Toothbrushes and other personal hygiene items must be stored and used in such a manner to prevent cross-contamination.

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		Both the OSHA and the CDC have specific requirements regarding human immuno-deficiency virus (HIV), TB, and hepatitis precautions. These requirements should be incorporated into the facility's practices when relevant to the individuals residing in the facility. Concerns about OSHA violations should be referred to OSHA.
W456	(2) The facility must implement successful corrective action in affected problem areas.	§483.470(1)(2) PROBES: In instances of infection control problems are there patterns to suggest: o Staff are not practicing established techniques? o Problems are not being analyzed to result in corrective action? o There is aggressive resolution to problems identified that leads overall to a reduction in the number of infection control problems? Is there evidence of individuals contracting infections or communicable diseases that can be attributed to poor infection control practices?
W457	(3) The facility must maintain a record of incidents and corrective actions related to infections.	§483.470(l)(3) GUIDELINES: This regulation does not require the recording or tracking of specific groups of symptoms, if a record of incidents and corrective actions related to infections is maintained. This regulation does not address the form or location of this record or direct that it be separate from the documentation required by CFR 483.410(c)(1).
W458	(4) The facility must prohibit employees with symptoms or signs of a communicable disease from direct contact with clients and their food.	§483.470(l)(4) FACILITY PRACTICES: Staff who have an illness or communicable disease that can be transmitted through direct contact with individuals or indirectly through their food, are not observed working with either. §483.470(1)(4) GUIDELINES: The facility should use the Recommendations for Prevention of Communicable Disease Transmission in Health Care Settings (such as preventing HIV) issued by the Centers for Disease Control, Atlanta, Georgia 30333, as well as OSHA guidelines in these areas. A facility participating in the Medicaid program may not discriminate against individuals who are HIV-infected so long as these individuals do not (on a case-by-case basis) pose a substantial health and safety risk to others, or pose a performance problem, and are "otherwise qualified."

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TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
W459	§483.480 Condition of participation: Dietetic services.	§483.480 COMPLIANCE PRINCIPLES: The Condition of Participation of Dietary Services is met when: o The individuals maintain body weights and lab levels considered acceptable for their age, height, body type and clinical condition or are receiving services and supports to assist them to do so; and o Individuals participate in normalized dining experiences appropriate to their functional abilities (e.g., using knives, family style meals, going to restaurants, etc.) and are being taught skills to do so. The Condition of Participation of Dietary Services is not met when: o Individuals experience excessive weight loss or gain, abnormal lab levels, or deterioration in health as a result of an inadequate diet; or o Individuals do not receive training and supports which enable them to eat as independently and in as normalized manner as possible.
	(a) Standard: Food and nutrition services.	
W460	(1) Each client must receive a nourishing, well-balanced diet including modified and specially-prescribed diets.	§483.480(a)(1) FACILITY PRACTICES: Individuals are receiving adequate nutrition as indicated by: o Maintaining body weights considered to be acceptable for their age, height and body type; o Laboratory studies show values within normal ranges; o Medical problems are not related to the facility's failure to provide adequate nutrition; o Food allergies are recognized and the person does not receive foods to which (s)he is allergic; o Substitutions made for planned menu items are of similar nutritive value; and o Diets are changed in response to identified nutritional deficiencies. The individual's unmet nutritional needs are known to the facility and are being addressed. §483.480(a)(1) GUIDELINES: "Modified and specially-prescribed" diets are defined as diets that are altered in any way to enable the individual to eat (for example, food that is chopped, pureed, etc.) or diets that are intended to correct or prevent a nutritional deficiency or health problem. §483.480(a)(1) PROBES: Within the context of the characteristics of the individuals who reside in the facility, is there a pattern of excessive usage of "food allergy," weight gain and/or reduction diets which may indicate an unnecessary and non-normalizing emphasis on special diets? When food consistency modifications are necessary, is there evidence of periodic efforts to upgrade the food consistency for individuals?

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		Are weight reduction diets generally coordinated with plans for exercise? Is the diet order followed as prescribed? Are between meal snacks provided as needed? Are desired weight range goals maintained or supported with the calories and nutrients provided? What evidence is there to support that the diet is being implemented? How does the facility assure that menus are nutritionally adequate and varied? Is there clinical evidence that supports observation of compromised nutritional status: o Recent significant weight gain or loss? o Fever/infection? o Diarrhea? o Chronic disease? o Chewing and swallowing problems? o Chronic blood loss? o Teeth and gum diseases? o Excessive use of laxatives? o Abnormal laboratory values? Are the staff aware of and do they respond to any potential adverse food/drug interactions? Have individuals on long term anticonvulsant drug regimens (e.g., phenobarbital, phenytoin, primidone) been monitored for decreased serum levels of folic acid and vitamin D? Have therapeutic doses of affected nutrients been provided to decrease the likelihood of megaloblastic anemia and decreased bone density? If not, why? Have fiber and fluids been increased in the diet of individuals on anticonvulsants and tranquilizers to decrease likelihood of constipation? If not, why?
W461	(2) A qualified dietitian must be employed either full-time, part-time, or on a consultant basis at the facility's discretion.	
W462	(3) If a qualified dietitian is not employed full-time, the facility must designate a person to serve as the director of food services.	

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	(4) The client's interdisciplinary team, including a qualified dietitian and physician must prescribe	
W463	all modified and special diets	§483.480(a)(4) FACILITY PRACTICES: The IDT, including the dietician and physician, have reviewed the individual preferences and attitudes about food and his/her nutritional and health status as a basis for prescription of the individual's diet. §483.480(a)(4) PROBES: Is the dietitian involved in reviewing information about individuals and gathering additional information, such as laboratory reports and drugs prescribed, that might affect food intake? Have the modified and special diet orders been reviewed for their appropriateness and effectiveness? How has the individual's response to the diet been considered?
W464	including those used as a part of a program to manage inappropriate client behavior.	§483.480(a)(4) FACILITY PRACTICES: When a special diet is to be used as part of a behavior management program, it has been reviewed for appropriateness, taking the individual's response to the diet into account.
W465	(5) Foods proposed for use as a primary reinforcement of adaptive behavior are evaluated in light of the client's nutritional status and needs.	§483.480(a)(5) GUIDELINES: Since the main purpose of food is to support and maintain the health of an individual, it is important that the use of food as a behavior reinforcing device (primary reinforcement) not be abused. Foods are selected to provide essential nutrients. When these foods are routinely removed and denied during the meals, without comparable replacements, the individual is at risk of consuming a diet that is not adequate to meet nutritional needs, and in violation of §483.420(d)(1)(ii), which does not allow food contributing to a nutritionally adequate diet to be used as "punishment." Likewise, the addition of high caloric reinforcers must be coordinated into the total daily diet intake. §483.480(a)(5) PROBES: If food is withheld during a meal, is food of comparable nutritive value to the withheld menu item provided? Are the primary reinforcers used with individuals consistent with the diet intended for those individuals? Are the types of food used as primary reinforcers consistent with other IPP objectives or needs (e.g., if the individual is learning to use finger foods, are "finger food" types of reinforcers (like grapes) used?) Refer to W151.

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W466	(6) Unless otherwise specified by medical needs, the diet must be prepared at least in accordance with the latest edition of the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences, adjusted for age, sex, disability and activity.	§483.480(a)(6) GUIDELINES: For suggested guidelines write to: 1. U.S. Department of Agriculture Human Nutrition Information Services Washington, D.C. 20250 2. The National Dairy Council Rosemont, Illinois 60028-42334
	(b) Standard: Meal services.	
W467	(1) Each client must receive at least three meals daily,	§483.480(b)(1) GUIDELINES: It is the facility's responsibility to ensure that meals eaten regularly outside the facility are adequate (e.g., that an individual at a community program setting has an adequate lunch carried from the facility or is able to purchase lunch). There is a concern that individuals may consume only "junk" food instead of an adequate meal when outside the facility.
W468	at regular times comparable to normal mealtimes in the community	§483.480(b)(1) FACILITY PRACTICES: The scheduling of meals is flexible and not overly rigid. Mealtimes accommodate a variety of recreational activities (in and out of the facility) throughout the year, especially weekend and holiday activities. §483.480(B)(1) PROBES: Are mealtimes, including snack times, sufficiently flexible to allow the individual opportunities to participate in a variety of activities in and out of the facility? Are snacks consistent with the individual's intended diet? Are snacks routinely provided to all individuals?
	with--	
W469	(i) Not more than 14 hours between a substantial evening meal and breakfast of the following day,	§483.480(b)(l)(i) GUIDELINES: A "substantial evening meal" is defined as offering of three or more menu items at one time, one of which includes a high-quality protein such as meat, fish, eggs, or cheese. The meal represents no less than 20% of the day's total nutritional requirements.

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W470	except on weekends and holidays when a nourishing snack is provided at bedtime, 16 hours may lapse between a substantial evening meal and breakfast; and	§483.480(b)(1)(i) GUIDELINES: A "nourishing snack" is an offering of items, single or in combination, from the daily food guide.
W471	(ii) Not less than 10 hours between breakfast and the evening meal of the same day, except as provided under paragraph (b)(1)(i).	
	(2) Food must be served--	§483.480(b)(2)(i) FACILITY PRACTICES: Portions served, either by staff or by the individuals themselves, closely match designated serving sizes on menus. Slight variations are not significant enough or frequent enough to affect individual's health.
W472	(i) In appropriate quantity;	
W473	(ii) At appropriate temperature;	§483.480(b)(2)(ii) FACILITY PRACTICES: Hot and cold foods are served promptly, i.e., within 15 minutes of removal from temperature control devices. When situations arise which prevent food from being maintained at proper temperatures, or prevent food from being served promptly upon removal from temperature control devices, that food is not served to individuals residing in the facility. §483.480(b)(2)(ii) PROBES: Are hot foods held at not less than 140 degrees F. and served promptly (i.e., within 15 minutes of being removed from temperature control devices)? Are cold foods held and served at 45 degrees F.? Do you observe individuals eating within 15 minutes from the time of service (time the food was taken out of temperature control devices)? Is there a pattern of food-related illnesses, resulting from inappropriate temperature control?
W474	(iii) In a form consistent with the developmental level of the client; and	§483.480(b)(2)(iii) FACILITY PRACTICES: The individual receives food that is ground, chopped or pureed, based on individual need, and only to the extent required.

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		§483.480(b)(2)(iii) GUIDELINES: The term "form," as used in this requirement, refers to food consistency (i.e., pureed, chopped, ground, etc.) §483.480(b)(2)(iii) PROBES: On what basis does the facility decide to modify the texture of an individual's diet? Is there specific justification for a pureed diet? When food consistency modifications are necessary, is there evidence of periodic efforts to upgrade the food consistency for individuals? Are foods sufficiently moist for ease of chewing and swallowing? Is pureed food of a consistency that is appropriate for the individual's eating and swallowing ability and not in liquid ("watery") consistency? For individuals who have great physical difficulty in eating and swallowing, and must be fed: o Do staff use appropriate swallowing stimulation techniques? o Proper tongue thrust reduction techniques? o Do staff use proper food and liquid thickening agents to facilitate easier eating and swallowing? o Are pureed foods mixed with other foods and fed to individuals? Or do individuals get to enjoy the tastes of various foods separately fed to them? o Is the food positioned so that the individual is permitted to see his or her meal? o Is the individual positioned appropriately?
W475	(iv) With appropriate utensils.	§483.480(b)(3) FACILITY PRACTICES: Common serving utensils are in good condition, clean, and yield portion sizes appropriate to the individual's prescribed diet.
W476	(3) Food served to clients individually and uneaten must be discarded.	§483.480(b)(3) GUIDELINES: This standard does not apply to food served in family-style dishes, unless the length of time the food is on the table or other considerations (such as individuals fingering or drooling in the food) compromise the safety and nutritive value for reuse of the food. §483.480(d)(3) PROBES: Is food remaining on the individual's dishes saved or reused after the meal is completed?
	(c) Standard: Menus.	

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	(1) Menus must--	
W477	(i) Be prepared in advance;	§483.480(c)(1)(i) PROBES: Are menus available for those individuals who can read?
W478	(ii) Provide a variety of foods at each meal;	§483.480(c)(1)(II) PROBES: Do individuals participate in the selection of menu items, to the maximum extent possible? Are substitutions made within the same food group, i.e., meat for another source of protein? Vegetable for another item similar in nutritional value? Are individuals allowed to substitute menu items with their own choices (even though seemingly void in variety (e.g., an individual wishes to consume pizza 3 times per week, or on consecutive days) provided that the items contain the nutritive value comparable to the planned items on the menu? Do menus specify the "name" of the juice, vegetable, or starch (i.e., orange juice, green beans, rice)?
W479	(iii) Be different for the same days of each week and adjusted for seasonal changes; and	§483.480(c)(1)(iii) PROBES: Do menus reflect variety for the season of the year (e.g., fresh fruits in summer)?
W480	(iv) Include the average portion sizes for menu items.	§483.480(c)(1)(iv) PROBES: Is there evidence that sufficient food exists to yield the portion sizes indicated on the menu?
W481	(2) Menus for food actually served must be kept on file for 30 days.	§483.480(c)(2) PROBES: Are substitutions noted when intended menu items are not served?
	(d) Standard: Dining areas and service.	
	The facility must--	
W482	(1) Serve meals for all clients, including persons with ambulation deficits, in dining areas, unless otherwise specified by the interdisciplinary team or a physician;	§483.480(d)(1) FACILITY PRACTICES: If an individual does not eat in the dining area, the physician has documented the medical necessity for, and/or the IPP documents the plan to teach the individual the physical and/or other skills necessary for inclusion. Individuals are not precluded from eating in the dining room solely based on diagnosis or level of functioning. §483.480(d)(1) GUIDELINES: For purposes of this standard "dining areas" mean discrete eating areas located outside

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		of bedrooms, established, furnished, and equipped for the purpose of eating meals. For purposes of this standard, provision of meals in dining areas outside of the home (such as restaurants, food vendors, etc.) may also be included. To the maximum extent possible, individuals should be afforded the opportunity to eat routine meals (like breakfast and dinner) in dining areas that approximate those afforded to their peers without disabilities (e.g., dining areas that are a part of the living unit, rather than eating all meals in buildings exclusively established for eating purposes). §483.480(d)(1) PROBES: Is the dining room a pleasant environment in which to eat? Is there a pattern of individuals eating their meals in their bedrooms, or other non-eating areas? What is the rationale for prohibiting an individual from eating in a dining area? Has eating in a dining area ever been tried with the individual before? What happened? Are periodic attempts to get such individuals to eat in a dining area, continued?
W483	(2) Provide table service for all clients who can and will eat at a table, including clients in wheelchairs;	§483.480(d)(2) GUIDELINES: The intent of this regulation is to afford individuals the opportunity to participate in the social experience of dining with their companions. Observe whether or not facility staff model and reinforce appropriate communication and social behavior between dining companions seated at the same table. §483.480(d)(2) PROBES: Do individuals eat together with others at the same table? Are individuals in wheelchairs positioned correctly and included in dining groupings of their peers without physical disabilities? Or do all individuals in wheelchairs eat together or are they located around the edges of dining areas? Are individuals in wheelchairs lined-up to eat? Do individuals in wheelchairs routinely eat at table? or do they eat on their lap trays or hospital bed trays? On what basis does the facility determine if an individual in a wheelchair needs to eat the meal in the wheelchair rather than transferring to a regular chair?
W484	(3) Equip areas with tables, chairs, eating utensils, and dishes designed to meet the developmental needs of each client;	§483.480(d)(3) FACILITY PRACTICES: Individuals are provided with adapted furniture and equipment as identified by the IDT at each meal. Individuals use adaptive equipment or are being trained to use it when needed. §483.480(d)(3) GUIDELINES: Single service eating devices must be discarded after each use.

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		Determine if the following types of adaptive devices are made available when needed: 1. Double suction cups or other devices to anchor dishes on a table or tray for individuals with major coordination problems; 2. Rocking one-handed knife-fork or knife-spoon for an individual with the use of only one hand; 3. Built up or extended handles or silverware for those with problems of grasp or range of motion; 4. Plate guards or plates with raised rims to provide a surface against which the individual with a physical disability can push food onto a fork or a spoon; 5. Flexible drinking straws; 6. Spoon bent to a 90 degree angle at the bowl or a swivel spoon to assist an individual without normal wrist motions. 7. Any other adaptive device deemed by the team as needed by the individual to eat more independently. §483.480(d)(3) PROBES: Are condiments, napkins and appropriate eating utensils provided? Are individuals trained to use them? Is there a pattern of staff allowing individuals to use any piece of adapted equipment, regardless of the individual's need for that equipment? Is the height of the dining table sufficient so that an individual in a wheelchair can sit in the wheelchair at the table, if needed?
W485	(4) Supervise and staff dining rooms adequately	§483.480(d)(4) FACILITY PRACTICES: There are sufficient staff to implement eating programs for individuals who require them and to provide necessary supervision.
W486	to direct self-help dining procedures,	§483.480(d)(4) FACILITY PRACTICES: Staff monitor individuals who are able to dine independently in order to promote, support, reinforce and encourage individuals to eat in an appropriate and normalized manner (e.g., manners, social behaviors, etc.)
W487	to assure that each client receives enough food and	§483.480(d)(4) FACILITY PRACTICES: As indicated by the nutritional assessment and prescribed diet, individuals can access second helpings.

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		For individuals who have significant spillage or refuse foods, diets are adjusted as needed. Individuals have enough time to finish their full meal.
W488	to assure that each client eats in a manner consistent with his or her developmental level; and	§483.480(d)(4) FACILITY PRACTICES: Individuals are actively encouraged to feed themselves to the extent possible and in accordance with their assessed abilities. Individuals learn skills in accordance with their functional levels including: o Use of utensils; o Meal preparation; o Socialization during meals; o Family style dining; and o Ordering food in restaurants. Individuals' eating programs are implemented in accordance with their training objectives. §483.480(d)(4) GUIDELINES: To the maximum extent possible, staff should model appropriate mealtime behavior and conversation by sitting at the table with individuals, and, when possible, eating meals with individuals. Mastery of the social skills involved in eating in a variety of dining areas and settings is another step to the individual's independence beyond the health aspects of nutrition and the basic skills involved in eating independently. Achieving independence will further help the individual to live in less restrictive environments. Determine to what extent individuals are exposed to out-of-the-home dining environments available to the general public (e.g., restaurants, fast-food establishments, picnics, parties, cafeterias, etc.) Depending on the needs of the individuals and the available space it may be more effective for meals to be conducted in two different seatings or groupings. §483.480(d)(4) PROBES: Is the individual encouraged, permitted and reinforced for being as independent as possible during meals? Do staff demonstrate skills and techniques which promote socialization? Do facility staff enable individuals who are eating dependent, when appropriate, to move from tube-feeding, or blended, ground, pureed, etc., to the next level of food size, texture, or otherwise greater levels of independent eating? How does staff address the problem of individuals who consistently show a lack of interest in eating?

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		Is family style dining made available to individuals who are able to participate? Are individuals allowed to dine out at places like fast food restaurants, buffets, vendors at the park or beach? How do staff deal with individuals who exhibit maladaptive behavior during mealtime? Is it part of the individual's IPP? Are individuals rushed through their meals? Is there a pattern of eating programs not being implemented on short staffed days? short staffed meals? In the presence of staff? Is the food to be eaten, located at a distance and level from the individual, such that the individual can eat with maximum independence? Is the individual taught to use the most normal, least stigmatizing clothing protectors during mealtimes? Do individuals take turns participating in setting their own tables? Serving their own meals? Preparing meals? Shopping for and putting food away?
W489	(5) Ensure that each client eats in an upright position, unless otherwise specified by the interdisciplinary team or a physician.	§483.480(d)(5) FACILITY PRACTICES: Individuals are positioned appropriately for eating. If an individual eats in a reclining position, the physician documents the medical necessity for the position, and/or the IPP includes the program plan to teach the individual the physical skill necessary for eating upright. §483.480(d)(5) GUIDELINES: This applies to all individuals, including those fed by nasogastric tube or gastrostomy tube. The IPP should identify the most appropriate position for the individual to be positioned during mealtime, in relation to the placement of the food contents. §483.480(d)(5) PROBES: For individuals who have great physical difficulty in eating or swallowing and must be fed, is the individual positioned in the upright position appropriate to the individual's needs?

Field Resource Guide

Tab 2:
Appendix Q:
Immediate Jeopardy

State Operations Manual

Appendix Q - Guidelines for Determining Immediate Jeopardy - (Rev. 1, 05-21-04)

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PREAMBLE

Changes made to Appendix Q – Guidelines for Determining Immediate Jeopardy, reflect CMS' concern that crisis situations in which the health and safety of individuals are at risk, are accurately identified, thoroughly investigated and resolved as quickly as possible. In the interest of consistency, the new Guidelines standardize the definitions of Immediate Jeopardy, abuse and neglect across all certified Medicare/Medicaid entities (excluding CLIA), and describe the process surveyors use in making a determination of Immediate Jeopardy. The Guidelines provide a detailed analysis of the steps surveyors should follow to assist them in accurately identifying those circumstances which constitute Immediate Jeopardy: preparation, investigation, decision-making and implementation. "Triggers" alert surveyors that some circumstances may have the potential to be identified as Immediate Jeopardy situations and therefore require further investigation before any determination is made. A detailed review of three sample cases "walk" surveyors through the steps necessary to carefully analyze and accurately determine whether or not an Immediate Jeopardy situation exists. To provide further guidance to surveyors, Attachment B uses actual examples of situations in which Immediate Jeopardy has been cited.

In the interest of reducing or eliminating abuse and neglect to all beneficiaries, the Guidelines caution surveyors that when abuse or neglect has been identified, the circumstances must be thoroughly evaluated to determine if Immediate Jeopardy exists.

The Guidelines also clarify that actual harm, as well as the **potential** for harm, to one or to more than one individual may constitute Immediate Jeopardy.

I - Introduction

Immediate Jeopardy is interpreted as a crisis situation in which the health and safety of individual(s) are at risk (see SOM §3010). These guidelines are for use in determining if circumstances pose an Immediate Jeopardy to an individual's health and safety. These guidelines will assist Federal and State Survey and Certification personnel and Complaint Investigators in recognizing situations that may cause or permit Immediate Jeopardy.

These guidelines apply to all certified Medicare/Medicaid entities (excluding CLIA) and to all types of surveys and investigations: certifications, recertifications, revisits, and complaint investigations. In these guidelines, "entity" applies to all Medicare/Medicaid certified providers, suppliers, and facilities. "Surveyor" represents both surveyors and complaint investigators. "Team" represents either a single surveyor or multiple surveyors. The term "Immediate Jeopardy" replaces the terms "Immediate and Serious Threat" and "Serious and Immediate Threat" for all certified Medicare/Medicaid entities.

NOTE: The primary goals of these Immediate Jeopardy guidelines are to identify and to prevent serious injury, harm, impairment, or death.

II - Definitions

The following definitions apply to all certified Medicare/Medicaid entities:

Immediate Jeopardy - "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." (See 42 CFR Part 489.3.)

Abuse - "The willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain, or mental anguish." (See 42 CFR Part 488.301.)

Neglect - "Failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness." (See 42 CFR Part 488.301.)

III - Principles

The goal of the survey process is to ensure the provision of quality care to all individuals receiving care or services from a certified Medicare/Medicaid entity. The identification and removal of Immediate Jeopardy, either psychological or physical, are essential to prevent serious harm, injury, impairment, or death for individuals.

- Only **ONE INDIVIDUAL** needs to be at risk. Identification of Immediate Jeopardy for one individual will prevent risk to other individuals in similar situations.

- **Serious harm, injury, impairment, or death** does **NOT** have to occur before considering Immediate Jeopardy. The high potential for these outcomes to occur in the very near future also constitutes Immediate Jeopardy.

- Individuals must not be subjected to abuse by **anyone** including, but not limited to, entity staff, consultants or volunteers, family members or visitors.
- Serious harm can result from both abuse and neglect.
- Psychological harm is as serious as physical harm.
- When a surveyor has established through investigation that a cognitively impaired individual harmed an individual receiving care and services from the entity due to the entity's failure to provide care and services to avoid physical harm, mental anguish, or mental illness, this should be considered neglect.
- Any time a team cites abuse or neglect, it should consider Immediate.

Upon recognizing a situation that may constitute Immediate Jeopardy, the investigation process must proceed until it confirms or rules out Immediate. The serious harm, injury, impairment or death may have occurred in the past, may be occurring at present, or may be likely to occur in the very near future as a result of the jeopardy situation. After determining that the harm meets the definition of Immediate Jeopardy, consider the following points regarding entity compliance:

- The entity either created a situation or allowed a situation to continue which resulted in serious harm or a potential for serious harm, injury, impairment or death to individuals.
- The entity had an opportunity to implement corrective or preventive measures.

After recognizing Immediate Jeopardy and completing the investigation, the team will then choose the specific Federal regulation(s) to address the deficient practice. Although a specific Federal regulation may not be found for each situation, all Medicare/Medicaid entities have a responsibility to provide quality care. The principles of Immediate Jeopardy apply to all certified entities and need to be followed for all individuals receiving care and services in those entities. The team should determine which Federal regulation(s) to document the deficient practices(s).

NOTE: The key factor in the use of Immediate Jeopardy termination authority is, as the name implies, limited to **Immediate Jeopardy**. Immediate Jeopardy procedures must not be used to enforce compliance quickly on more routine deficiencies.

IV - Immediate Jeopardy Triggers

This guide lists issues with associated triggers. The issues include general statements of practices such as "Failure to protect from abuse." The guide includes situations that most likely create jeopardy to an individual's psychological and/or physical health and safety.

Triggers that will assist the surveyor in considering Immediate Jeopardy accompany each issue. Triggers describe situations that will cause the surveyor to consider if further investigation is needed to determine the presence of Immediate Jeopardy. The listed triggers do not automatically equal Immediate Jeopardy. The team must investigate and use professional judgment to determine if the situation has caused or is likely to cause serious harm, injury, impairment or death. These triggers are general examples and are not all-inclusive. Many triggers may apply to more than one issue. A trigger for an issue such as C, "Failure to Protect from Psychological Harm," could well be an example of A, "Failure to Prevent Abuse," or B, "Failure to Prevent Neglect." The team must rely on professional judgment and utilize the resources of the State survey agency, the Regional Office and/or, in the case of Medicaid-only facilities, the State Medicaid Agency to determine the presence of Immediate Jeopardy.

NOTE: **Harm** does **NOT** have to occur before considering Immediate Jeopardy. Consider both potential and actual harm when reviewing the triggers in the table.

Triggers	
Issue	**Triggers**
A Failure to protect from abuse.	1. Serious injuries such as head trauma or fractures; 2. Non-consensual sexual interactions; e.g., sexual harassment, sexual coercion or sexual assault; 3. Unexplained serious injuries that have not been investigated; 4. Staff striking or roughly handling an individual; 5. Staff yelling, swearing, gesturing or calling an individual derogatory names; 6. Bruises around the breast or genital area; or Suspicious injuries; e.g., black eyes, rope marks, cigarette burns, unexplained bruising.
B Failure to Prevent Neglect	1. Lack of timely assessment of individuals after injury; 2. Lack of supervision for individual with known special needs; 3. Failure to carry out doctor's orders; 4. Repeated occurrences such as falls which place the individual at risk of harm without intervention; 5. Access to chemical and physical hazards by individuals who are at risk; 6. Access to hot water of sufficient temperature to cause tissue injury; 7. Non-functioning call system without compensatory measures; 8. Unsupervised smoking by an individual with a known safety risk; 9. Lack of supervision of cognitively impaired individuals with known elopement risk; 10. Failure to adequately monitor individuals with known severe self-injurious behavior; 11. Failure to adequately monitor and intervene for serious medical/surgical conditions; 12. Use of chemical/physical restraints without adequate monitoring; 13. Lack of security to prevent abduction of infants; 14. Improper feeding/positioning of individual with known aspiration risk; or 15. Inadequate supervision to prevent physical altercations.
C Failure to protect from psychological harm	1. Application of chemical/physical restraints without clinical indications; 2. Presence of behaviors by staff such as threatening or demeaning, resulting in displays of fear, unwillingness to communicate, and recent or sudden changes in behavior by individuals; or 3. Lack of intervention to prevent individuals from creating an environment of fear.
D Failure to protect from undue adverse medication consequences and/or failure to provide medications as prescribed.	1. Administration of medication to an individual with a known history of allergic reaction to that medication; 2. Lack of monitoring and identification of potential serious drug interaction, side effects, and adverse reactions; 3. Administration of contraindicated medications; 4. Pattern of repeated medication errors without intervention; 5. Lack of diabetic monitoring resulting or likely to result in serious hypoglycemic or hyperglycemic reaction; or 6. Lack of timely and appropriate monitoring required for drug titration.

Triggers	
Issue	**Triggers**
E Failure to provide adequate nutrition and hydration to support and maintain health.	1. Food supply inadequate to meet the nutritional needs of the individual; 2. Failure to provide adequate nutrition and hydration resulting in malnutrition; e.g., severe weight loss, abnormal laboratory values; 3. Withholding nutrition and hydration without advance directive; or 4. Lack of potable water supply.
F Failure to protect from widespread nosocomial infections; e.g., failure to practice standard precautions, failure to maintain sterile techniques during invasive procedures and/or failure to identify and treat nosocomial infections	1. Pervasive improper handling of body fluids or substances from an individual with an infectious disease; 2. High number of infections or contagious diseases without appropriate reporting, intervention and care; 3. Pattern of ineffective infection control precautions; or 4. High number of nosocomial infections caused by cross contamination from staff and/or equipment/supplies.
G Failure to correctly identify individuals.	1. Blood products given to wrong individual; 2. Surgical procedure/treatment performed on wrong individual or wrong body part; 3. Administration of medication or treatments to wrong individual; or 4. Discharge of an infant to the wrong individual.
H Failure to safely administer blood products and safely monitor organ transplantation.	1. Wrong blood type transfused; 2. Improper storage of blood products; 3. High number of serious blood reactions; 4. Incorrect cross match and utilization of blood products or transplantation organs; or 5. Lack of monitoring for reactions during transfusions.
I Failure to provide safety from fire, smoke and environment hazards and/or failure to educate staff in handling emergency situations.	1. Nonfunctioning or lack of emergency equipment and/or power source; 2. Smoking in high risk areas; 3. Incidents such as electrical shock, fires; 4. Ungrounded/unsafe electrical equipment; 5. Widespread lack of knowledge of emergency procedures by staff; 6. Widespread infestation by insects/rodents; 7. Lack of functioning ventilation, heating or cooling system placing individuals at risk; 8. Use of non-approved space heaters, such as kerosene, electrical, in resident or patient areas; 9. Improper handling/disposal of hazardous materials, chemicals and waste; 10. Locking exit doors in a manner that does not comply with NFPA 101; 11. Obstructed hallways and exits preventing egress; 12. Lack of maintenance of fire or life safety systems; or 13. Unsafe dietary practices resulting in high potential for food borne illnesses.

Triggers	
Issue	**Triggers**
J Failure to provide initial medical screening, stabilization of emergency medical conditions and safe transfer for individuals and women in active labor seeking emergency treatment (Emergency Medical Treatment and Active Labor Act).	1. Individuals turned away from ER without medical screening exam; 2. Women with contractions not medically screened for status of labor; 3. Absence of ER and OB medical screening records; 4. Failure to stabilize emergency medical condition; or 5. Failure to appropriately transfer an individual with an unstabilized emergency medical condition.

Guidelines for Determining Immediate Jeopardy

V - Procedures

A - Preparation

The team should be familiar with the contents of Appendix Q. The guidelines should be foremost in the team's mind to decrease the potential for missing Immediate Jeopardy. The team should also be familiar with the recommended Key Components of an entity's systemic approach to prevent abuse and neglect. The seven Key Components include: screening, training, prevention, identification, investigation, protection, and reporting/response. (Refer to Attachment C.) Both Appendix Q and the Key Components apply to all certified Medicare/Medicaid entities.

B - Investigation

The investigation must be conducted in an impartial, objective manner to obtain accurate data sufficient to support a reasonable conclusion.

1. Observation is a key component of any investigation. All observations need to be thoroughly documented. Be specific in noting time, location and exact observations.

2. The interview notes must be clear and detailed. The documentation should include the full name of the person interviewed. The time and date of the interview should be documented. Any witnesses present should be indicated.

3. Record review is used to support observations and interviews. Obtain copies of relevant documentation supporting the Immediate Jeopardy as you investigate (e.g., nurses' notes, and investigation reports).

4. If the case involves a potential criminal action, the surveyor should be aware that any physical evidence must be preserved for law enforcement agencies.

5. Team Actions

    a. Notify the team leader immediately when an Immediate Jeopardy situation is suspected. The team leader will then coordinate the investigative efforts.

    b. Contact the State survey agency (SA) per the SA protocol.

    c. Gather information to address who, what, when, where and why, such as:

WHO: Who was involved in the Immediate Jeopardy situation: staff, individuals receiving care and services, and others?

Does the individual(s) at risk have special needs? Has this happened to other individuals? If yes, how many? Are there others to whom this is likely to occur? If so, how many and who? Which entity staff knew or should have known about the situation?

WHAT: What harm has occurred, is occurring, or most likely will occur?

How serious is the potential/actual harm? How did the situation occur? What was the sequence of events? What attempts did the entity make to assess, plan, correct, and re-evaluate regarding the potential/actual harm? What did the entity do to prevent any further occurrences of the same nature?

WHEN: When did the situation first occur?

How long has the situation existed? Has a similar occurrence happened before? Has the entity had an opportunity to correct the situation? Did the entity thoroughly investigate the event? Did you agree with the facility's conclusion after their investigation? Did the entity implement corrective measures to prevent any further similar situations? Did they follow up and evaluate the effectiveness of their measures?

WHERE: Where did the potential/actual harm occur? Is this an isolated incident or an entity wide problem?

WHY: Why did the potential/actual harm occur?

Was the Immediate Jeopardy preventable? Is there a system in place to prevent further occurrences? Is this a repeat deficient practice? Is there a pattern of similar deficient practices?

The team then needs to proceed to **validate** the gathered information with facility staff.

Following are two examples of teams gathering information during the investigation to answer the questions: who, what, when, where and why. Refer to C – Decision Making for the completion of the examples.

Example Case #1: The resident was admitted following a hospitalization for psychiatric care. The resident had a history of exiting behavior, impulsiveness and impaired cognition and judgment. Diagnoses included dementia with psychosis and delusion, psychomotor agitation, acute behavioral disturbances, and possible right cerebral vascular accident (CVA). Documented behavior of standing by the facility door waiting for someone to open the door and then sneaking out very fast was included in the chart.

TRIGGER: Lack of supervision of cognitively impaired individuals with known elopement risk.

Investigation:

WHO: Who is the resident? Is the resident cognitively impaired with poor decision-making skills? Is the resident's diagnosis pertinent in this case? Is the resident physically impaired? What is the resident's ambulatory status? Was the resident identified by the facility as a wanderer oblivious to physical and safety needs? Does the resident have a history of leaving the facility without informing the staff? Does the resident's care plan address wandering and risk for elopement? Does the resident wear a safety alarm device? Is there a history of elopement from this facility? How many residents were/are at risk for elopement?

WHAT: What happened? What was the resident's physical, mental, and emotional status prior to elopement? Was the resident injured? Did the facility seek outside medical treatment for the resident? If so, what did the reports from the ER physician's exam include regarding the resident's condition when examined?

WHEN: When was the resident last seen? When did the resident leave the facility? When did the facility take action? When was the resident found? Who found the resident? Was the potential for injury present? Was the outdoor temperature excessively hot or cold? Was it raining, snowing, or storming, etc.? If excessively cold temperatures were present, what was the wind chill factor? How was the resident dressed? What areas of the skin were exposed and for how long?

WHERE: Where did the resident reside? Was the resident on a special unit with extra elopement precautions? Where did this happen? How did the resident exit the facility? Describe the exact location of exit. Where is the facility located (urban or rural)? What hazards were present in the vicinity of the facility (railroad, high motor vehicle traffic, construction zones, farm fields, lakes, ponds, etc.)?

WHY: Why did this happen? Was the care plan followed? Were door alarms working properly? Were exit doors visible at all times? If so, by whom? What was the facility's plan to supervise the resident?

Was it followed? If so, why did it fail? What was the physician's version of the cause for harm? Were crucial medications involving therapeutic blood/serum levels involved in the elopement (i.e., insulin, psychotropic, antihypertensives, etc.)? What other contributing factors, such as diagnosis, should be considered?

Example Case #2: Confused, debilitated 75 year old female admitted as an inpatient to the hospital has orders to discontinue all nutrition and hydration support.

TRIGGER: Withholding nutrition and hydration without sufficient documentation of advance directives could be an Immediate Jeopardy situation.

Investigation:

WHO: Who wrote the order? Is this the patient's primary care physician? Who has the authority to make the medical care decisions? Does the patient have a living will? Does the patient have a durable power of attorney? Who has spoken with the person designated to make health care decisions for the patient; e.g., social worker, primary care physician, specialist, hospice nurse, or chaplain?

WHAT: What is the patient's diagnosis? Is documentation of a terminal disease process by the attending physician contained in the progress notes? What does the progress note contain about risks and benefits of discontinuation of hydration and nutrition? What alternative treatment options have been considered and discussed with the person responsible for making health care decisions for this patient? What events precipitated the decision to discontinue hydration and nutrition? What care and services have been planned during the absence of nutrition and hydration? What steps have been taken to ascertain the patient's wishes? What is State law regarding advance directives and end of life issues?

WHEN: When did the hospital obtain evidence of the patient's wishes regarding end of life treatment? When did the physician discuss end of life issues, diagnosis, prognosis and the patient's wishes with the person designated by the patient or by law to make health care decisions?

WHERE: If the patient has an advance directive, how easy/difficult is it to find in the chart to verify the patient's wishes? If the advance directive is not in the chart, does the chart indicate where the advance directive is kept? If the patient does not have an advance directive, where is the documentation in the chart to support the patient's wishes to discontinue nutrition and hydration at the end of life? Where is the documentation to support that the person making the health care decisions is fully informed of the risks and benefits and is making the decisions the patient would have made? If the patient does not have an advance directive, does the patient's chart reflect compliance with the State law and the legal representative's decision-making authority concerning withdrawal of hydration and nutrition? Has the person with decision-making authority been fully informed of all options, including home care, hospice and long term care placement?

WHY: If the physician wrote an order to discontinue nutrition and hydration, does the progress note contain documentation of the rationale? Is there clear documentation to support the decision?

C - Decision-Making

The information gathered is used to evaluate the provision of related care and services, occurrence frequency, and the likelihood of repetition. The team needs to have gathered and validated sufficient information to address the three components of Immediate Jeopardy (listed below) to begin the decision process.

Components of Immediate Jeopardy

1. **Harm**

   a. **Actual -** Was there an outcome of harm? Does the harm meet the definition of Immediate Jeopardy, e.g., has the provider's noncompliance caused serious injury, harm, impairment, or death to an individual?

   b. **Potential -** Is there a likelihood of potential harm? Does the potential harm meet the definition of Immediate Jeopardy; e.g., is the provider's noncompliance likely to cause serious injury, harm, impairment, or death to an individual?

2. **Immediacy** - Is the harm or potential harm likely to occur in the very near future to this individual or others in the entity, if immediate action is not taken? (Refer to the SOM §3010(B)(6) for timelines during normal termination.)

3. **Culpability**

   a. Did the entity know about the situation? If so when did the entity first become aware?

   b. Should the entity have known about the situation?

   c. Did the entity thoroughly investigate the circumstances?

   d. Did the entity implement corrective measures?

   e. Has the entity re-evaluated the measures to ensure the situation was corrected?

Note: The team must consider the entity's response to any harm or potential harm that meets the definition of Immediate Jeopardy. The stated lack of knowledge by the entity about a particular situation does not excuse an entity from knowing and preventing Immediate Jeopardy. The team should use knowledge and experience to determine if the circumstances could have been predicted. The Immediate Jeopardy investigation should proceed until the team has gathered enough information to evaluate any prior indications or warnings regarding the jeopardy situation and the entity's response. The crisis situations in which an entity did not have any prior indications or warnings, and could not have predicted a potential serious harm, are very rare.

Team Actions:

- Meet as a team;
- Follow Appendix Q;
- Share collected data;
- Identify the three components of Immediate Jeopardy;
- Decide if you have enough information to make a decision. If not, continue the investigation;
- Identify any inconsistencies or contradictions between interviews, observations and record reviews;
- Clarify any inconsistencies or contradictions;
- Determine the specific Federal regulation for the situation; and

- Consult with the SA, as necessary.

The following are examples of decision-making as the team analyzes the information obtained during the investigation. Example #1 and 2 are continuations from B-Investigation.

Example Case #1 (Continued): (Refer to B - Investigation) During the survey, the resident was observed to enter the code and exit the unit without assistance 5 times in 30 minutes and was brought back by nursing staff from the unit, nursing staff from other units and administrative staff. The front door to the facility had a broken alarm and did not latch properly and was easily accessible after exiting the locked unit. The facility was aware of the broken alarm and latch. The chart contained documentation that the facility was aware of the resident's ability to operate the door keypads for at least 60 days. The facility was located in an urban area on a busy street. A row of trees prevented anyone in the facility from viewing a resident exiting the property and crossing the street.

The record included documentation of the resident exiting the building successfully without notice. The documentation included only a brief description of the incident. After a search, the resident was located in an area emergency room being treated for a minor laceration of the lip. Police notified the facility that bystanders who had called 911 had found the resident lying down with blood on her face. The chart included subsequent reports of repeated frequent attempts to elope 25-40 times per shift, and the statement, "Patient requires 1:1, care not safe on this unit secondary to continuous exit seeking." A review of the facility investigations revealed that the facility had not completed any investigations for this resident.

Decision Making:

- Has actual harm occurred? Yes.
- Does the actual harm that occurred meet the definition of Immediate Jeopardy? No.
- Is there a likelihood of potential serious harm? Yes.
- Does the potential harm meet the definition of Immediate Jeopardy? Yes.
- Is the harm likely to recur in the very near future, if immediate action is not taken? Yes.
- Did the facility have knowledge of the situation? Yes. If so when did they first become aware? Before admission when notified of history.
- Did they thoroughly investigate the circumstances? No.
- Did they implement corrective measures? No.
- Does this meet the definition of Immediate Jeopardy? Yes.
- Which is the most appropriate tag to define the failed practice?

Outcome:

- The team identifies the most appropriate regulation that applies to the situation.
- The team proceeds with documentation of the Immediate Jeopardy deficient practice.
- The SA proceeds with the termination procedures per the SOM.
- Except in the case of Medicaid-only facilities, the RO proceeds with termination actions.

Example Case #2 (Continued): (Refer to B - Investigation) During the investigation, the surveyor finds that the chart does not include a copy of the patient's advance directive. The progress note does not contain any documentation of the patient ever stating a wish to have nutrition and hydration withdrawn at the end of life. The patient has a diagnosis of advance dementia with a documented history of refusal to eat in a long-term care facility. The patient had been admitted because of continued weight loss and dehydration related to the refusal to eat or drink. The patient has a daughter who actively participates in her mother's care, is identified as the legal representative, and is identified in the social service notes as the closest living family member. The primary care physician documented a discussion with the daughter concerning the patient's poor prognosis for meaningful recovery. While death is not imminent as a result of the dementia, death is the expected result at some unknown time in the future. The chart does not include any documentation that the daughter expressed a wish to have nutrition and hydration support withdrawn. The social worker was unable to confirm that the daughter had expressed a wish to have all support withdrawn. The social worker is uncertain why the nutrition and hydration were discontinued. When contacted, the daughter is unaware that support has been withdrawn and is very upset. The surveyor copies the order sheet, the progress notes and the social service notes. The surveyor clearly documents the interviews with the social worker and the daughter. There is a discrepancy between the written order for withdrawal of support and the daughter's and the social worker's knowledge of the situation. The surveyor decides to present the information to the team prior to contacting the physician.

Decision Making:

- Has actual harm occurred? No.
- Is there a likelihood of potential serious harm? Yes.
- Does the potential serious harm meet the definition of Immediate Jeopardy, e.g., serious injury, harm, impairment, or death? Yes.
- Is the potential serious harm likely to occur in the very near future, if immediate action is not taken? Yes.
- Did the facility have knowledge of the situation? Yes.
- If so, when did they first become aware? After the doctor's order was written?
- Did they thoroughly investigate the circumstances? No.
- Did they implement corrective measures? No.
- Does this meet the definition of Immediate Jeopardy? Yes.
- Which is the most appropriate tag to define the failed practice?

Outcome:

- The team identifies the most appropriate regulation that applies to the situation.
- The team proceeds with documentation of the Immediate Jeopardy deficient practice.
- The SA proceeds with the termination procedures per the SOM.
- The RO proceeds with termination actions.

Example Case #3: An outside intruder entered a resident's room by cutting through the screen. A resident with a diagnosis of advanced dementia was raped. The resident did not notify staff at the time of the incident. The intruder was not observed entering the facility by any facility staff. However, nightshift staff immediately called the police after noticing a stranger in the courtyard at the back of the facility. The police came and were unable to locate anyone. The police checked the grounds without incident and then encouraged the staff to check the locks on the doors and windows and obtain services to monitor the premises for increased security. The police indicated that no prior intruders had been reported in the neighborhood.

The facility immediately contacted a local security service and hired a security guard to monitor the outside grounds. The security guard arrived within 45 minutes and began patrolling the grounds. The facility staff checked all the doors and windows to ensure security. They checked on all of the residents and did not observe any problems. During morning rounds, the resident reported that someone had hurt her during the night. The staff noted that the screen had been damaged and immediately contacted the police and the SA. The police came and had the resident transported to the nearest emergency room for a rape assessment. The emergency room confirmed that the resident had been raped.

Decision-Making:

- Has actual harm occurred? Yes.
- Does the harm meet the definition of Immediate Jeopardy, e.g., serious injury, harm, impairment, or death to an individual? Yes.
- Is the harm likely to recur in the very near future, if immediate action is not taken? Yes.
- Did the entity have knowledge of the situation? Yes.
- If so when did they first become aware? In the morning when the resident reported she had been hurt.
- Did they thoroughly investigate the circumstances? Yes.
- Did they implement corrective measures? Yes.
- Does this meet the definition of Immediate Jeopardy? No. The facility reacted appropriately and followed the recommendations of the law enforcement experts to protect all residents. The harm to the resident had already occurred before the facility had any indications or warnings, and could not have been predicted or prevented.

Outcome:

- The team gathered sufficient data to reach the conclusion that the facility had no predictable way of knowing that residents were at risk for harm from an intruder.
- The team also gathered sufficient data to reach a decision that the facility reacted immediately to protect residents when they had knowledge of a potential risk.
- The team concludes that there was no failed practice.
- The team concludes their investigation of this complaint.

VI - Implementation

A - Team Actions

If the team reaches a consensus concerning the presence of Immediate Jeopardy, the team leader then contacts the SA per the protocol established by the SA. The SA review should be expedited. If the team is unable to follow the SA protocol for administrative consultation, actions to proceed with implementation of Immediate Jeopardy must continue. Decide if any other agencies need to be notified, e.g., Law Enforcement Agency, Nurses Aide Registration Board.

NOTE: Any criminal act needs to be reported to the local law enforcement agency. The entity should be encouraged to make the report, if needed. The surveyor should only assume this responsibility if the entity refuses.

B - SA Actions

Upon review of the findings, if the SA concurs with the team's consensus of Immediate Jeopardy, the SA will inform the RO for all Medicare and dually certified entities. For Medicaid-only facilities, the SA will notify the State Medicaid Agency. For Immediate Jeopardy in Medicaid-only facilities, contact the RO per the protocol established between the SA and the RO.

C - Team Action

Once the team has decided that Immediate Jeopardy exists, the team should notify the administration of the Immediate Jeopardy. A verbal notice should be given with the specific details, including the individuals at risk, before the survey team leaves the premises of the entity. **The entity should begin immediate removal of the risk to individuals, and immediately implement corrective measures to prevent repeat Jeopardy situations**. The team should encourage the entity to provide evidence of their implementation of corrective measures.

The notice describing the Immediate Jeopardy must be delivered to the entity no later than 2 days (refer to specific SOM reference) of the end of the survey. If official notification of **all** deficiencies, i.e., Form CMS-2567, was not given on the second day, a completed Form CMS-2567 must be sent to the entity on the tenth working day.

VII - Documentation

A - Skilled Nursing Facilities/Nursing Facilities (SNF/NF)

1 - Confirmation of Removal of Immediate Jeopardy

Only onsite confirmation of implementation of the facility's corrective actions justifies a determination that the Immediate Jeopardy has been removed.

2 - Immediate Jeopardy Removed, Deficient Practice Corrected

If the facility is able to remove the Immediate Jeopardy before the survey team leaves the facility and to correct associated deficient practices, cite the Immediate Jeopardy at the Immediate Jeopardy severity and scope (J, K or L). Document evidence of the facility's actions, including dates that indicate that the facility has removed the Immediate Jeopardy and corrected the deficient practice. The date of full correction will be shown on the Form CMS-2567B, a copy of which can be found at http://cms.hhs.gov/forms/cms2567b.pdf

3 - Immediate Jeopardy Removed, Deficient Practice Present

If the facility is able to employ immediate corrective measures that remove the Immediate Jeopardy, but an associated deficient practice still exists at a lesser severity and scope, cite the Immediate Jeopardy at the Immediate Jeopardy severity and scope. Include the documentation to support the remaining deficient practice. Document the level of harm and the identified residents in the Statement of Deficiencies. Attach the corrective measures submitted by the facility as an immediate plan of correction.

4 - Immediate Jeopardy Not Removed

If the facility is unable or unwilling to remove the Immediate Jeopardy before the end of the survey, inform the administration that the RO will be notified of the Immediate Jeopardy and termination procedures will be initiated. Use the appropriate SOM reference to define the end of the survey.

B - All Entities Not Noted Above

Immediate Jeopardy is always cited at the **Condition** level on the Form CMS-2567, a copy of which can be found at http://www.cms.hhs.gov/forms/cms2567.pdf.

1 - Confirmation of Removal of Immediate Jeopardy

Only onsite confirmation of implementation of the facility's corrective action justifies a determination that the Immediate Jeopardy has been removed.

2 - Immediate Jeopardy Removed, Deficient Practice Corrected

If the entity is able to remove the Immediate Jeopardy and correct associated deficient practices before the team exits, cite the Immediate Jeopardy at the Condition level on the Form CMS-2567. Corrective actions taken by the provider/supplier will be included in the Form CMS-2567 documentation. The date of full correction will be shown on the Form CMS-2567B.

3 - Immediate Jeopardy Removed, Deficient Practice Present at Condition Level

If the entity is able to employ immediate corrective measures that remove the Immediate Jeopardy, but an associated deficient practice still remains at the condition level for the same Condition of Participation, cite the Condition of Participation as not met and proceed with 90-day termination procedures. Include documentation of both the Immediate Jeopardy with subsequent removal, and the remaining deficient practice in this citation.

4 - Immediate Jeopardy Removed, Deficient Practice Present at Standard or Elemental Level

If the entity is able to employ immediate corrective measures, which remove the Immediate Jeopardy but an associated deficient practice still remains at the standard or elemental level, cite the Immediate Jeopardy at the Condition of Participation level on Form CMS-2567. Cite the remaining deficiency at the most appropriate standard or elemental tag. The date of removal of the Immediate Jeopardy will be shown on the Form CMS-2567B.

5 - Immediate Jeopardy Not Removed

If the entity is unable or unwilling to remove the Immediate Jeopardy before the team's exit, inform the administration that the RO will be notified of the Immediate Jeopardy situation and termination procedures will be initiated. In the case of a Medicaid-only facility, the State Medicaid Agency will be notified of the Immediate Jeopardy.

VIII - Enforcement

A - Termination for Title XIX-Only NFs, ICF/IID

Refer to SOM §3005 E for specific instructions.

B - Enforcement for SNF/NF

Refer to SOM §§7307-7309 for specific instructions.

C - Termination for all other Medicare Entities

Refer to SOM §3010.

IX - References

- SOM Appendices (Excluding Appendix C, CLIA)
- Principles of Documentation
- SOM §3005 E
- SOM §§3010-3012
- SOM §§7307-7309

Attachment A

The jeopardy situations that follow are actual citations that have been upheld.

IMMEDIATE JEOPARDY NOT REMOVED BEFORE EXIT

ICF/IID Failed Practice

Condition of Participation - The facility failed to assure medical services were provided to a client with an emergency medical condition.

Summary - At 4:30 a.m. on x/x/x, the nursing staff was notified that Client #1 had not slept during their shift and had three to four liquid stools that night. Nursing staff assessed the client, found his bed smeared with feces (color and consistency not described), his color slightly pale, abdomen slightly distended, and dried blood around his mouth. Assessed vital signs were blood pressure 100/60, heart rate 70 beats per minute, temperature 100.5 degrees Fahrenheit. His treatment consisted of Tylenol (given orally) at 5:10 a.m.

At approximately 5:45 a.m., Client #1 became unsteady while exiting the bathroom and was lowered to the floor with staff assistance. At 6:00 a.m., the client was described as, "skin cold, clammy - color pale." His blood pressure had dropped to 88/50, heart rate 85 beats per minute, oxygen saturation 93%. The client was placed on oxygen at 5 liters per minute and preparations were initiated to transfer the client to the infirmary.

At 6:25 a.m., Client #1 was still on the floor outside of the bathroom and the records indicated he was unresponsive. His blood pressure was 80/50, and his heart rate dropped to 67 beats per minute. The client tried to remove the nasal cannula that supplied him with oxygen and "insisted on sitting up." After sitting up, his skin was documented as decreased in color and "sallow." He had coffee ground drooling coming from both corners of his mouth.

At 6:40 a.m., the community emergency response number (911) was called. At 6:45 a.m., Client #1 was documented as being unresponsive with absent blood pressure, pulse, and respirations. Cardiopulmonary Resuscitation (CPR) was initiated. At 6:49 a.m., the community 911-response team arrived and took over CPR. The client expired at 7:00 a.m..

The Superintendent stated that staff were expected to use their own judgment as to when to access 911 emergency services. Review of facility Procedure #X revealed a lack of clear guidelines to facility staff on when to call for community 911 emergency response.

Issue - Failure to protect from neglect.

Trigger - Failure to adequately monitor and intervene for serious medical/surgical conditions.

Decision Making:

- Has actual harm occurred? Yes
- Does the harm meet the definition of Immediate Jeopardy, e.g., serious injury, harm, impairment, or death to an individual? Yes
- Is the harm likely to recur in the very near future, if no immediate action is taken? Yes
- Did the entity have knowledge of the situation? Yes If so, when did the entity first become aware? On the night shift.

- Did they thoroughly investigate the circumstances? No
- Did they implement corrective measures? No
- Does this meet the definition of Immediate Jeopardy? Yes
- Which is the most appropriate tag to define the failed practice? Cite the most appropriate tag at the Condition of Participation level for Immediate Jeopardy.

Outcome - The team cited the Condition of Participation, Health Care Services (Tag W318). The facility implemented a corrective action plan after receiving written notice. Onsite revisit confirmed correction.

IMMEDIATE JEOPARDY NOT REMOVED PRIOR TO EXIT

Home Health Agency Failed Practice

Condition of Participation - The agency failed to assure medications were provided to patients in accordance with physician's orders and the patient's plans of care.

Summary - Patient #1: The patient was admitted on x/x/x with a diagnosis of Insulin Dependent Diabetes Mellitus. Orders were: Humulin Insulin N 2 units and Regular (Reg) Insulin 3 units subcutaneously every morning and evening plus sliding scale Regular insulin coverage for blood sugar ranges of: 200-299=2 units Reg. Insulin, 300-399=4 units Reg. Insulin, 400+=6 units Reg. Insulin. The frequency of the sliding scale coverage was not included in the physician's orders, nor was the frequency of blood glucose testing. A subsequent physician's order for NPH 3u BID was transcribed as NPH 3 units every evening.

The Director of Professional Services made an assumption that the blood glucose testing and sliding scale insulin coverage was two times a day. Because of missing documentation, it was unclear when the patient actually received the correct dose of insulin. On 11 occasions, the patient's blood glucose levels were between 200-299 or 300-399. There was no documentation that the sliding scale was followed. On 6 occasions, the patient's blood glucose levels were below 200 and regular insulin was giving contrary to the sliding scale. On x/x/x, the patient's blood glucose was 431 and 4 units of regular insulin were given, rather than 6 units per the sliding scale.

Patient #2 - The patient had a diagnosis of Insulin Dependent Diabetes Mellitus and orders for routine insulin coverage BID. The plan of care included teaching the patient's caregiver diabetes management. There were no orders for blood glucose testing in the plan of care. The nurse directed the caregiver to perform blood glucose levels twice a day. Subsequent nursing notes indicated the caregiver was performing the blood glucose levels four times a day. On x/x/x, new orders for sliding scale insulin were received and implemented by the nurse without a frequency for administration. The nurse did not address the sliding scale insulin coverage or the caregiver's ability to carry out the insulin administration during subsequent visits. There was no documentation of the sliding scale insulin being administered to the patient.

Issue - Failure to protect from undue adverse medication consequences and/or failure to provide medications as prescribed.

Trigger - Pattern of repeated medication errors without intervention, lack of diabetic monitoring resulting or likely to result in serious hypoglycemic or hyperglycemic reaction.

Issue - Failure to prevent neglect

Trigger - Failure to carry out doctor's orders

Decision Making;

- Has actual harm occurred? No
- Is there a likelihood of potential serious harm? Yes
- Does the potential serious harm meet the definition of Immediate Jeopardy, e.g., serious injury, harm, impairment, or death to an individual? Yes
- Is the potential outcome likely to occur in the very near future, if no action is taken? Yes.
- Did the entity have knowledge of the situation? Yes
- If so, when did they first become aware? When an incomplete doctor's order was received.
- Did they thoroughly investigate the circumstances? No
- Did they implement corrective measures? No
- Does this meet the definition of Immediate Jeopardy? Yes
- Which is the most appropriate tag to define the failed practice? Cite the most appropriate tag at the Condition of Participation level for Immediate Jeopardy.

Outcome - The State Agency attempted to hand deliver the completed Form CMS-2567. The HHA was closed with a sign posted on the door indicating the agency was moving and the administrative staff was in the field making discharge plans for the patients. An on-call number was given. The on-call nurse stated that all of the agency's patients had been discharged. The agency submitted a written notice of closure upon request. State Agency completed a referral to the Board of Nursing regarding the Director of Nursing.

IMMEDIATE JEOPARDY REMOVED, DEFICIENT PRACTICE STILL REMAINS

SNF/NF Failed Practice

Severity - Level 4, Scope - Isolated--The facility failed to prevent neglect, failed to provide appropriate emergency care, and failed to provide supervision to prevent accidents.

Summary - The resident had a diagnosis of Alzheimer's dementia with a history of falls and wandering. The resident ambulated with a special walker. The resident was found lying at the base of a flight of stairs, in a pool of blood, bleeding from the nose and ears with a large laceration on his head. The alarm on the door leading to the stairs had not been reset after a fire alarm. Following the resident's fall down the flight of stairs, the nurse talked to the resident, helped him to his walker and asked an aide to take him back to his room. The resident was not transported to his room, but was requested to ambulate using his walker with the stand-by assistance of an aide. The nurse returned to the unit, completed pending tasks and then called the doctor who directed her to call an ambulance. The resident was taken to the hospital and returned to the facility after a decision not to perform neurosurgery. The resident died 36 hours after the injury.

The resident fell while the nurse was off the unit in the boarding home giving medication. This was a regular part of the assigned duties for the nurse.

Issue - Failure to prevent neglect.

Trigger - Lack of timely assessment of individuals after injury and lack of supervision for individual with known special needs.

Decision-Making:

- Has as actual harm occurred? Yes
- Does the harm meet the definition of Immediate Jeopardy, e.g., serious injury, harm, impairment, or death to an individual? Yes
- Is the harm likely to recur in the very near future to this individual or others in the entity, if immediate action is not taken? Yes
- Did the entity have knowledge of the situation? Yes. If so, when did they first become aware? Prior to the fall, when a history of falls and wandering was documented.
- Did they thoroughly investigate the circumstances? Yes
- Did they implement corrective measures? No
- Does this meet the definition of Immediate Jeopardy? Yes
- Which is the most appropriate tag to define the failed practice? Cite the Immediate Jeopardy at the appropriate tag. Also document the remaining deficient practice under the same tag. Define the level of harm for the residents in the failed practice statement (e.g., the facility failed to prevent neglect for 1 of 10 residents (#8) which resulted in Immediate Jeopardy, and for 2 of 10 residents (#4 and #5) which resulted in harm).

Outcome - Revisit confirmed the removal of the Immediate Jeopardy; however, during revisit, another Immediate Jeopardy was recognized**.** A subsequent revisit confirmed the removal of the second Immediate Jeopardy identified. A deficient practice still remained. Termination stopped. Substantial compliance was reached 30 days later.

Attachment B

Documentation for Immediate Jeopardy should follow the Principles of Documentation. The following are examples of Forms CMS-2567 documenting Immediate Jeopardy.

Example for LTC: Failure to Prevent Abuse

F223

483(b) Requirements: Abuse

Scope and Severity B Level is J - The resident has the right to be free from verbal, sexual, physical and mental abuse, corporal punishment, and involuntary seclusion.

This requirement is not met as evidenced by the following:

Based on interview, and record reviews, it was determined the facility failed to assure that the female residents on the North Wing had an environment that was free from sexual abuse. The findings constituted an Immediate Jeopardy situation. Facility staff had knowledge of the inappropriate sexual behaviors of two male residents (Residents #12 and 27). The facility had not consistently identified the victims, had not conducted investigations, and had not implemented effective preventive measures to protect the female residents on North Wing from actual and potential sexual abuse. There were multiple incidents of actual harm with three identified sample residents (Residents #3, 14, and 25). There were three incidents of potential harm for three unidentified residents.

Findings include:

1. A review of Resident #12's record revealed a nurse's note dated xx/xx/xx, at 1:30 a.m., the resident was found sitting next to Resident #3 in the common area. Resident #12 had "one hand on [Resident #3's] buttock and one hand on the breast. [Resident #3] was attempting to push Resident #12's hand away." At 4:00 a.m., the same day, Resident #12 was found in the hallway with hands on an unidentified, nude female resident.

2. Resident #12 record revealed that on xx/xx/xx, at 11:30 p.m., the resident was found in an unidentified female resident's bed with both side rails up. Resident #12 had one hand directly on the female's labia. The female resident was unable to respond. The nurses notes dated xx/xx/xx, stated, "Resident #12 was sexually inappropriate with a female resident who could not give consent."

3. On xx/xx/xx, at 7:15 p.m., a nurses note in Resident #12's record stated that the resident was found standing in the hall, behind Resident #14, who was sitting in a wheelchair. Resident #12's hands were on Resident #14's breast. Resident #14 stated, "I am going to call the police."

4. Interview with the Administrator and DON on xx/xx/xx, confirmed that none of the incidents involving Resident #12 had been reported to the State per the State's complaint protocol.

5. On xx/xx/xx at 3:30 a.m., Resident #27's record revealed the resident was found in the room of Resident #25 (a severely cognitively impaired resident, who was unable to communicate) standing by the bed, with pajama bottoms down and hands in Resident #25's genital area. An incident report, dated xx/xx/xx revealed Resident #25 "looked frightened, with widened eyes, unable to defend self or call for help."

6. Nurses notes dated xx/xx/xx, at 10:30 p.m., revealed Resident #27 was found in an unidentified resident's room, with the covers pulled back, and hands in the resident's genital area.

7. There were no incident reports for xx/xx/xx or xx/xx/xx for Resident #27. Interview with the charge nurse on xx/xx/xx, revealed that she had no knowledge of the incidents, whether an investigation of the incidents had been conducted, or if efforts had been made to protect female residents.

Example for All Other Entities with Conditions of Participation or Conditions of Coverage: Failure to provide safety from fire, smoke and environmental hazards and/or failure to educate staff in handling emergency situations

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I 117

485.723 Condition: 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.

This Condition is not met as evidenced by the following:

Based on observation, interview and review of policies and procedures, the agency failed to assure patients were protected from fire hazards, failed to provide adequate egress for emergencies (refer to I-118) and failed to provide adequate protection from hazardous chemicals (refer to I-158). These deficiencies resulted in potential harm for 20 of 20 sample patients (#1-20) and the 90 additional patients receiving care at the agency. An Immediate Jeopardy to the patients and the public was created by these deficiencies.

I 118

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 organization 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:

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

    b. Free from obstruction at all times;

    c. In the case of stairwells, equipped with firmly attached handrails on at least one side;

    d. Lights are placed at exits and in corridors used by patients and are to be supported by an emergency power source;

e. A fire alarm system with local alarm capability and, where applicable, an emergency power source is functional;

f.. At least two persons are on duty on the premises of the organization whenever a patient is being treated; and

g. No occupancies or activities undesirable or injurious to the health and safety of patients are located in the building.

This Standard is not met as evidenced by the following:

Based on an observation and interview, the agency failed to provide unobstructed hallways and exits for 1 of 2 exit doors and hallways; failed to provide adequate maintenance of exit lighting for 1 of 2 exits and 2 of 4 emergency lights; and failed to provide a fire alarm system; resulting in the potential harm for all the agency's current patients including 20 of 20 sample patients (#1-20). This resulted in an Immediate Jeopardy.

Findings Include:

1. Observation of the passageway on xx/xx/xx at 3 p.m. and on xx/xx/xx at 10 a.m., revealed that the east hallway was partially obstructed with several items of furniture and other obstacles. During interview, at 11 a.m. on xx/xx/xx, the administrator stated that the building manager was temporarily storing these items in the hallway. The administrator was unable to provide a date when the items might be relocated.

2. Observation at 12 noon on xx/xx/xx, revealed that the exercise pool for the agency was located in the basement in a windowless room. The room had two exit doors, located at opposite ends of the pool with narrow walkways on each side of the pool. One of the emergency exit signs above the door was not illuminated. The other exit door, with the illuminated emergency light, was locked. Four small battery powered flashlights had been placed throughout the room. Two of the four lights failed to illuminate when activated. The two remaining lights, when activated, failed to provide adequate lighting to allow visibility for egress.

3. Review of the agency's policies and procedures indicated that, in case of fire, employees were to pull the manual alarm. Interview with staff during the survey revealed that seven of the seven staff members on duty were unable to identify where the pull alarm was located. Observation on xx/xx/xx at 10 a.m. failed to provide any evidence of a fire alarm. During interview with the administrator on xx/xx/xx at 12 noon, the absence of a fire alarm was confirmed.

I 158

485.723(b) Standard: Maintenance of Equipment/Buildings/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.

This Standard is not met as evidenced by the following:

Based on observation and review of the policies and procedures, the agency failed to provide preventative maintenance of the clothes dryer resulting in a potential fire hazard, and failed to properly store pool

supplies resulting in a potential chemical hazard for 20 of 20 sample residents (#1-20) and all of the current patients. This resulted in Immediate Jeopardy.

Findings Include:

1. Observation of the laundry room on xx/xx/xx at 12:50 a.m., revealed a large amount of dryer lint on top of the dryer and the water heater, behind the washer, dryers, and water heater, and covering the ceiling and the ceiling roof vent. The washing machine repairman, during interview on xx/xx/xx at 1 p.m., related the extent of the lint accumulation to a plugged dryer exhaust vent and stated that this was an "extreme fire hazard." The administrator was notified of the potential fire hazard on xx/xx/xx at 1:30 p.m.. The vent had not been cleaned, nor had the lint been removed by xx/xx/xx, even though the administrator had been notified of the potential hazard 2 days prior.

2. Observation of the storage area for pool supplies and equipment on xx/xx/xx at 2 p.m., revealed that the chlorine powder was stored in barrels with damaged lids which did not close properly. The chlorine powder had been spilled on the floor and had been tracked out into the pool area. Neither the storage area nor the pool area contained any hazardous chemical warnings. An interview with the pool maintenance staff on xx/xx/xx at 2:15 p.m., did not provide any evidence that the staff had been educated regarding the precautions for hazardous chemicals. The staff was unable to locate any policies or procedures regarding how employees should respond to a chemical spill.

Attachment C - Overview - Recommended Key Components of Systemic Approach to Prevent Abuse and Neglect

Examples--Key Components applied to the following provider types:

Key Components Applicable To All Providers

1. Prevent

The facility or system has the capacity to prevent the occurrence of abuse and neglect and reviews specific incidents for "lessons learned" which form a feedback loop for necessary policy changes.

Nursing Homes

Regulation Authority: 483.13(b), 483.13(c), 483.13(c)(3)

Survey Guidance - Surveyors determine if:

The facility must develop and implement written policies and procedures that include the seven key components: screening, training, prevention, identification, investigation, protection and reporting/response; the facility identifies, corrects and intervenes in situations in which abuse or neglect is more likely to occur, and the facility identifies characteristics of physical environment and deployment of staff and residents (e.g., those with aggressive behaviors) likely to precipitate abuse or neglect.

ICF/IID

Regulation Authority: 483.420(a)(5), 483.420(d)(1), 483.420(d)(1)(I)

Survey Guidance - Surveyors determine if:

The facility has and implements abuse prevention policies and procedures; and the facility organizes itself in such a manner that individuals are free from threat to their health and safety.

2. Screen

The facility or system provides evidence and maintains efforts to determine if persons hired have records of abuse or neglect.

Nursing Homes

Regulation Authority - 483.13(c)(1)(ii) (A)&(B)

Survey Guidance - Surveyors determine if: The facility screens potential employees for a history of abuse, neglect, or mistreating residents as defined by the applicable requirements.

ICF/IID

Regulation Authority - 483.420(c)(1)(iii)

Survey Guidance - Surveyors determine if: The facility screens potential employees to prohibit the employment of individuals with a conviction or prior employment history of child or client abuse, neglect, or mistreatment.

3. Identify

The facility or system creates and maintains a proactive approach to identify events and occurrences that may constitute or contribute to abuse and neglect.

Nursing Homes

Regulation Authority - 483.13(c)(2)

Survey Guidance - Surveyors determine if: The facility identifies events such as suspicious bruising of residents, occurrences, patterns and trends that may constitute abuse; and determine the direction of the investigation.

ICF/IID

Regulation Authority - 483.420(a)(5)

Survey Guidance - Surveyors determine if: The facility identifies patterns or isolated incidents of unexplained functional regression, or other evidence of physical, verbal, sexual or psychological abuse or punishment posing a serious and immediate threat to individuals.

4. Train

The facility or system, during its orientation program, and through an ongoing trainng program, provides all employees with information regarding abuse and neglect and related reporting requirements, including prevention, intervention and detection.

Nursing Homes

Regulation Authority - 483.74(e)

Survey Guidance - Surveyors determine if: The facility has procedures to train employees, through orientation and on-going sessions, on issues related to abuse prohibition practices.

ICF/IID

Regulation Authority - 483.420(d)(1), 483.430(e)(1)

Survey Guidance - Surveyors determine if: Facility ensures that staff can define what constitutes abuse and punishment and actively promotes respect for individuals; and facility assures that staff have received training, both upon hiring and on an ongoing basis, which results in the competencies needed to do their job.

5. Protect

The facility or system must protect individuals from abuse and neglect during investigation of any allegations of abuse or neglect.

Nursing Homes

Regulation Authority - 483.13(c)(3)

Survey Guidance - Surveyors determine if: The facility has procedures to protect residents from harm during an investigation.

ICF/IID

Regulation Authority - 483.430(d)(3)

Survey Guidance - Surveyors determine if: The facility prevents further potential abuse while the investigation is in progress.

6. Investigate

The facility or system ensures, in a timely and thorough manner, objective investigation of all allegations of abuse, neglect, or mistreatment.

Nursing Homes

Regulation Authority - 483.13(c)(2)(3)&(4)

Survey Guidance - Surveyors determine if: The facility has procedures to investigate different types of abuse; and identify staff member responsible for the initial reporting of results to the proper authorities.

ICF/IID

Regulation Authority - 483.420(d)(3)

Survey Guidance - Surveyors determine if: The facility investigates all injuries of unknown origin and allegations of mistreatment, neglect, or abuse.

7. Report/ Respond

The facility or system must assure that any incidents of substantiated abuse and neglect are reported and analyzed, and the appropriate corrective, remedial or disciplinary action occurs, in accordance with applicable local, State or Federal law.

Nursing Homes

Regulation Authority - 483.13(c)(1)(iii), 483.13(c)(2), 483.13(c)(4)

Survey Guidance - Surveyors determine if: The facility has procedures to report all alleged violations and substantiated incidents to the State agency and to all other agencies, as required, and to take all necessary corrective actions, depending on the results of the investigation; report to State nurse aide registry or licensing authorities any knowledge it has of any action by a court of law which would indicate an employee is unfit for service, and analyze the occurrences to determine what changes are needed, if any, to policies and procedures to prevent further occurrences.

ICF/IID

Regulation Authority - 483.420(1)(6), 483.420(d)(2), 483.420(d)(4)

Survey Guidance - Surveyors determine if: The results of all investigations are reported to the administrator or designated representative or to other officials in accordance with State law within 5 working days of the incident and, if the alleged violation is verified, appropriate corrective action is taken.

Field Resource Guide

Tab 3: Sanctions for ICF/IID—Non-Immediate Jeopardy

Section 3006.1

3006.1 Sanctions for ICFs-IID--for Non-Immediate Jeopardy.--

A. General.--The Balanced Budget Act (BBA) of 1997 provided the statutory authority for States to establish and impose sanctions that are additional to the already existing alternative sanction of denial of payment for new admissions, and which are alternative to termination in cases where the ICF/IID's deficiencies are not determined to pose immediate jeopardy to client health and safety. This strategy recognizes that deficiencies take on greater or lesser significance depending on the specific circumstances and client outcomes in each facility, and that additional enforcement options should be available so that the enforcement consequence to the facility is effective, proportionate, and appropriate to the specifics of the noncompliance.

B. Introduction.--Section 1902(i)(1)(B) of the Social Security Act (the Act), as revised by the BBA of 1997, provides that the State may establish alternative sanctions to use as enforcement remedies for deficiencies that do not constitute immediate jeopardy to client health and safety if the State can demonstrate to CMS's satisfaction that its alternative sanctions are effective in deterring noncompliance and correcting deficiencies (see §3006.6). One or more alternative sanctions may be imposed against private or State operated ICFs/IID instead of provider agreement termination, and may also be imposed instead of or in addition to the existing alternative sanction of denial of payment for new admissions. Examples of sanctions that may be appropriate as alternative sanctions are listed in subsection C.

C. Examples of Alternative Sanctions.--States should consider establishing the following alternative sanctions in their State plan for noncompliant ICFs/IID having non-immediate jeopardy deficiencies:

- Directed plan of correction;
- Directed in-service training; and
- State monitoring.

States are not limited to establishing and using these alternative sanctions and may submit others for CMS's approval. When the State wants to use alternative sanctions, it must be authorized to do so under its State plan by CMS (see §3006.6). In order to be approved, the State must provide specified information to indicate that the alternative sanction and its application is not inconsistent with applicable statutory and regulatory requirements, as well as demonstrate to CMS's satisfaction that the alternative sanction is effective in deterring noncompliance and correcting deficiencies. Many States already have experience in imposing the three intermediate sanctions specified above against nursing homes (SNF/NFs) that fail to meet participation requirements. States also have experience in imposing remedies under their State licensure authority and may also wish to submit any of those to CMS for approval as alternative remedies for ICF/IID. While we want States to have the three specified intermediate sanctions listed above available for ICF/IID enforcement purposes, States are free to submit others for CMS approval as well.

D. Alternatives to Termination in Non-immediate Jeopardy Situations.--When the facility is found to have deficiencies that do not immediately jeopardize the health and safety of individuals served, the State may, in lieu of terminating the facility's provider agreement:

1. Deny payment for all new Medicaid admissions to the facility after the effective date of the sanction;

2. Impose one or more of the alternative sanctions that CMS has approved; or

3. Do both (1) and (2) above. Deny payment for all new Medicaid admissions to the facility after the effective date of the sanction and impose one or more of the alternative sanctions that CMS has approved.

3006.2 Directed Plan of Correction (DPoC).--

A. Purpose.--A DPoC is a plan which the State develops to require an ICF/IID to take action within specified time frames. The purpose of the DPoC is to achieve correction and continued compliance with Conditions of Participation.

A DPoC differs from a traditional plan of correction (PoC) in that the State, not the facility, develops the PoC. Achieving compliance is the provider's responsibility, whether or not a DPoC was followed. If the facility fails to achieve substantial compliance after complying with the DPoC, the State may impose another alternative sanction (or sanctions) until the facility achieves substantial compliance or it is terminated from the Medicaid program.

B. Basis for Imposition of a DPoC.--Use of a DPoC should be dependent upon causal factors identified by the SA. For example, a DPoC may be an appropriate sanction when a facility has no system in place for detecting abuse and neglect. The DPoC would specify that the facility must develop a system and must have that system in place within a specified time frame.

C. Elements of a DPoC:--The DPoC includes all elements of a traditional plan of correction (see §3006.5C), as well as when the corrective action must be accomplished, and how substantial compliance will be measured.

D. Notice of Imposition of DPoC.--A DPoC may be imposed 15 days after the facility receives notice of this sanction. The date the DPoC is imposed does not mean that all corrections must be completed by that date.

3006.3 Directed In-Service Training.--

A. Purpose.--Directed in-service training is a sanction that may be used when the SA concludes that education is likely to correct the deficiencies. This remedy requires the staff of the ICF-MR to attend in-service training program(s). The purpose of the directed in-service training is to provide knowledge required to achieve compliance and remain in compliance with the Conditions of Participation.

B. Appropriate Resources for Directed In-Service Training Programs.--Facilities should use programs developed by well-established organizations of intellectual disabilities, developmental disabilities, mental health or health services education, such as special education departments in colleges or universities or schools of medicine, State departments/bureaus of mental health/intellectual disabilities or developmental disabilities; Developmental Disabilities Councils; Federally funded State protection and advocacy agencies serving people with developmental disabilities; professional organizations with expertise in developmental disabilities, and a State may provide special consultative services for obtaining this type of training. The SA may also compile a list of resources which can provide directed in-service training and could make this list available to facilities and interested organizations. Facilities may request to use training resources internal to the organization, if the trainer was not directly involved with the area sanctioned. Examples of directed in-service training topics include, but are not limited to, client rights issues, behavior intervention, active treatment, health and safety, and outcome measures.

C. Further Responsibilities.--The facility bears the expense of the directed in-service training. After the training has been completed the SA will assess whether agency staff has demonstrated competency in the area(s) of deficiency and whether compliance has been achieved. If the facility still has not achieved substantial compliance, the State may impose one or more additional sanctions.

D. Notice of Imposition of Directed In-Service Training.--Directed in-service training may be imposed 15 days after the facility receives notice of this sanction. The SA will determine time frames for completion of the directed in-service training.

3006.4 State Monitoring.--

A. Purpose.--A State monitor oversees the correction of cited deficiencies in the facility as a safeguard against further non-compliance when a situation with a potential for jeopardizing health and safety has occurred, but has not risen to the level of immediate jeopardy.

B. Qualifications.--State monitors are identified by the SA as appropriate professionals to monitor cited deficiencies. A State monitor:

- Is an employee or contractor of the SA;
- Is not an employee, designee or contractor of the monitored facility;
- Does not have an immediate family member who is a client of the facility;
- Is not a person who has been terminated for cause by the facility; and
- Is not a former contractor who had a contract cancelled for cause by the facility.

C. When to Impose State Monitoring.--When considering whether or not to impose State monitoring for current noncompliance, the State may want to consider whether:

- The facility has a history of noncompliance which may suggest that it would benefit from external surveillance during corrections;
- The facility has had numerous complaints; or
- The State is concerned that the situation in the facility has the potential to worsen.

States are not limited to considering only these factors and are free to consider any others that would assist them in making remedy determinations.

D. Frequency.--When State monitoring is imposed, the SA appoints a monitor or monitors. Monitoring may occur anytime in a facility; e.g., 24 hours a day, 7 days a week, if necessary or less often such as once a week to monitor specific areas. In all instances, monitors have complete access to all areas of the facility, as necessary, for performance of the monitoring activity. Factors used to decide how often a facility is monitored may include, but are not limited to, the following:

- The nature and seriousness of the deficiency(ies) as specified by the SA; and
- The timing and frequency of when the problems occurred; e.g., mealtimes, evening shifts, daily, etc.

Monitors may be assigned to the facility at these specific times for a specified number of days, as determined by the SA, to ensure corrective action.

E. Duration.--The sanction is discontinued when the facility's provider agreement is terminated or when the facility has demonstrated to the satisfaction of the SA that it is in substantial compliance with the Conditions of Participation.

F. Notice of Imposition of State Monitoring .-- Notice requirements for this sanction state that it may be imposed immediately. No notice is required because the sanction imposes no hardship or expense on the facility.

G. Payment for and Obligation of Funds by a State Monitor.--The facility will not be required to pay the salary of the State monitor; nor will the State monitor have managerial authority to obligate facility funds.

3006.5 Achieving Continuous, Substantial Compliance.--

A. Introduction.--In order to safeguard the health, welfare and safety of individuals served within a facility, it is imperative that a facility not only attain substantial compliance in each area of identified deficiency(ies), but that it maintain/remain in continuous compliance.

B. Duration of a Sanction.--A sanction is discontinued when the facility's provider agreement is terminated or when the facility has demonstrated to the satisfaction of the SA that it is in substantial compliance with the Conditions of Participation.

C. Achieving and Maintaining Substantial Compliance.-- The facilities must establish policies and procedures to remedy deficient practices and to ensure that correction is lasting. Facilities must take the initiative and responsibility for monitoring their own performance continuously to sustain compliance. In order for a PoC to be acceptable, it must include the following elements:

1. Core Elements of PoC:

a. How the corrective action will be accomplished for individuals found to have been affected by the deficient practice;

b. How the facility will identify other individuals who have the potential to be affected by the same deficient practice, and how the facility will act to protect individuals in similar situations;

c. What measures will be put into place or systemic changes made to ensure that the deficient practice will not recur;

d. How the facility will monitor its corrective actions/performance to ensure that the deficient practice is being corrected and will not recur, i.e. what program will be put into place to monitor the continued effectiveness of the systemic change to ensure that solutions are permanent; and

e. When corrective action must be accomplished.

3006.6 Criteria for Review of State Plans for Approval or Disapproval of Alternative Sanctions.--

A. Introduction.--This section implements §1902(i)(1)(B) of the Act and provides guidance to the RO relative to reviewing for approval or disapproval, State plan amendments for alternative enforcement sanctions.

B. Alternative Remedies.--If a State wishes to establish alternative sanctions in addition to the already existing alternative sanction of denial of payment for new admissions, to be used in situations of non-immediate jeopardy, the State plan should describe:

- Timing and notice requirements;
- When the remedy will be applied;
- How the alternative remedy is effective in deterring noncompliance; and
- Factors considered in selecting the remedy.

Field Resource Guide

Tab 4:
ICF/IID Forms

- Form CMS-3070G
- Form CMS-3070H
- Form CMS-3070I
- Form CMS-2567
- Form CMS-2567B
- Form HCFA-670

ICF/IID Form 3070G
Allegations of Abuse and Neglect and
Number of Deaths
Data Entry Instructions (revised 4/12/02)

M. Allegations of abuse and neglect

(W68) Number of allegations of abuse investigated.
(W69) Number of allegations of neglect investigated.

According to 42CFR §488.301:
Abuse is the willful infliction of injury, unreasonable confinement, intimidation or punishment with resulting physical harm, pain or mental anguish.

Neglect is the failure to provide goods and services necessary to avoid physical harm, mental anguish or mental illness.

Consistent with the referenced definitions, enter the number of allegations of abuse and or neglect investigated, including investigations resulting from complaints, follow ups, initials or recertifications.
If there is no information to report, leave the field blank.

(W70) Total
This field represents a combined total ofW68 (allegations of abuse investigated) and W69 (allegations of neglect investigated). The total for this field is program generated therefore, no data input is necessary.

N. Number of Deaths

(W71) Number of deaths related to unusual incidents.
Insert the number of deaths that occurred as a result of unusual incidents. This includes all unexpected or unanticipated deaths not included in W72 or W73.

(W72) Number of deaths related to restraints.
Insert the number of deaths that occurred as a result of the use of restraints.

(W73) Number of deaths for any reason.
Insert the number of deaths occurring for any reason. Do not include information contained in W71 and W72 above.

(W74) Total
This field represents a combined total ofW71 (number of deaths related to unusual incidents), W72 (number of deaths related to restraints), and W73 (number of deaths for any reason). The total for this field is program generated; therefore, no data input is necessary.

04/12/02

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0062

INTERMEDIATE CARE FACILITIES FOR INDIVIDUALS WITH INTELLECTUAL DISABILITIES SURVEY REPORT

1. Name of Facility	2. Street Address	3. City and/or County	4. State	5. ZIP Code

6. Medicaid Provider No.	7. Name of CEO	8. Telephone No W1

9. State/Region code W2	10. State/County code W3	11. Dates of Survey	(Begin) Month / Day / Year W4	(End) Month / Day / Year W5

12. Type of Ownership or Control (enter number in box below

☐ 1. Private (non-profit) 2. Private (proprietary) 3. State 4. City/Town 5. County 6. City/County 7. Other (specify)_____ W6

13. Is this ICF/IID a distinct part of a Hospital, SNF or NF?

☐ Yes ☐ No W7

14. If "Yes" to block 13, indicate either

A. Hospital Provider No. ..... ☐☐☐☐☐☐
B. SNF Provider No. ..... ☐☐☐☐☐☐
C. NF Provider No. ..... ☐☐☐☐☐☐ W8

15. Survey Team Composition

Column 1: Indicate the number of disciplines represented on the Survey team.

Column 2: Of the number in column 1 represented on the Survey team, indicate the number who also qualify as a QIDP. Indicate Name(s) and Title(s) on last page of this form.

	W9	W10
A. Administrator		
B. Nurse		
C. Dietitian		
D. Pharmacist		
E. Records Administrator		
F. Social Worker		
G. LSC Specialist		
H. Laboratorian		
I. Sanitarian		
J. Therapist		
K. Physician		
L. Psychologist		
M. Other (specify)		
N. Total number of Surveyors onsite W13		
O. Total number of QIDP Surveyors onsite W12		

17. Staffing: List the full time equivalents who function in this capacity:

A. Direct Care Personnel W23 (483.430(d)(3)) ..... ☐☐☐☐.☐☐

B. Registered Nurse W24 (483.480(d)(3)) ..... ☐☐☐☐.☐☐

C. Licensed Voc./Practical Nurse W25 (483.480(d)(2)) ..... ☐☐☐☐.☐☐

D. Total Personnel W26 ..... ☐☐☐☐.☐☐
(List the Full Time Equivalent for all employees)

16. Facility Data

A. Is this ICF/IID a residential unit within a larger organization or agency in the State that provides residential services to individuals with intellectual disabilities? (check one) ☐ Yes ☐ No
If "No", proceed to item C. W13

B. If "Yes," indicate name and address of larger organization.

Name

Address

City	State	ZIP Code

Name of CEO

Total Number of Beds ..... ☐☐☐ W14

Total Number of Clients ..... ☐☐☐ W15
(including ICF/IID clients directly served)

C. Total Number of ICF/IID Clients ..... ☐☐☐ W16

D. Is this ICF/IID community-based? *(check one)* ..... ☐ Yes ☐ No W17

E. Total number of ICF/IID beds under this Provider No ..... ☐☐☐ W18

F. Total number of discrete living units under this Provider No.. ☐☐☐ W19

G. Age range of clients served.....from ☐☐ W20 to ☐☐ W21

H. Total number of off-campus day program sites used by ICF/IID clients ..... ☐☐ W22

18. Off-Campus Day Programs:

A. How many clients in the sample attend off-campus day programs? ..... ☐☐☐ W27

B. In how many off-campus day program sites was an observation done by the Surveyor?..... ☐☐☐ W28

FORM CMS-3070G (03/13)

20. Individual Characteristics (Note: The total number in Items B-L (Col.(a)) may exceed the facility's population because some clients have multiple disabilities)

A.		
(1) Age		
under 22(a)		W29
22-45 (b)		W30
46-65 (c)		W31
66+ (d)		W32
	Total	W33
(2) SEX		
Male		W34
Female		W35
	Total	W36
B. DISABILITIES		
(1) Intellectual Disability		
Mild		W37
Moderate		W38
Severe		W39
Profound		W40
	Total	W41
(2) Autism		W42
(3) Cerebral Palsy		W43
(4) Epilepsy		
Controlled		W44
Uncontrolled		W45
	Total	W46

C. OTHER DISABILITIES		
(1) Non-ambulatory		
Mobile		W47
Non-Mobile		W48
	Total	W49
(2) Speech/Language Impairment		W50
(3) Hearing Impairment		
Hard of Hearing		W51
Deaf		W52
	Total	W53
(4) Visual Impairment		
Impaired		W54
Blind		W55
	Total	W56
D. MEDICAL CARE PLAN		W57
E. DRUGS TO CONTROL BEHAVIOR		W58
F. PHYSICAL RESTRAINTS		W59
G. TIME-OUT ROOMS		W60
H. APPLICATION OF PAINFUL OR NOXIOUS STIMU		W61
I. NUMBER ATTENDING OFF-CAMPUS DAY PROGRAM		W62
J. NUMBER OF COURT ORDERED ADMISSIONS		W63
K. NUMBER OF CLIENTS OVER AGE 18 WITH A LEGAL GUARDIAN ASSIGNED BY THE COURT		W64
L. OTHER (specify)		
(1)		W65
(2)		W66
(3)		W67

INTERMEDIATE CARE FACILITIES FOR INDIVIDUALS WITH INTELLECTUAL DISABILITIES SURVEY REPORT

M. ALLEGATIONS OF ABUSE AND NEGLECT	
no. of allegations of abuse investigated (a)	W68
no. of allegations of neglect investigated (b)	W69
Total	W70

N. NUMBER OF DEATHS	
no. of deaths related to unusual incidents (a)	W71
no. of deaths related to restraints (b)	W72
no. of deaths for any reason (c)	W73
Total	W74

ALLEGATIONS OF ABUSE AND NEGLECT AND NUMBER OF DEATHS DATA ENTRY INSTRUCTIONS

M. Allegation of abuse and neglect

(W68) Number of allegations of abuse investigated.
(W69) Number of allegation of neglect investigated.

According to 42CFR §488.301:

Abuse is the willful infliction of injury, unreasonable confinement, intimidation or punishment with resulting physical harm, pain or mental anguish.

Neglect is the failure to provide goods and services necessary to avoid physical harm, mental anguish or mental illness.

Consistent with the referenced definitions, enter the number of allegations of abuse and or neglect investigated, including investigations resulting from complaints, follow ups, initials or recertifications.

If there is no information to report, leave the field blank.

(W70) Total
This field represents a combined total of W68 (allegations of abuse investigated) and W69 (allegations of neglect investigated). The total for this field is program generated therefore, no data input is necessary.

N. Number of Deaths

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Insert the number of deaths that occurred as a result of unusual incidents. This includes all unexpected or unanticipated deaths not included in W72 or W73.

(W72) Number of death related to restraints.
Insert the number of deaths that occurred as a result of the use of restraints.

(W73) Number of deaths for any reason.
Insert the number of deaths occurring for any reason. Do not include information contained is W71 and W72 above.

(W74) Total
This field represents a combined total of W71 (number of deaths related to unusual incidents), W72 (number of deaths related to restraints), and W73 (number of deaths for any reason).
The total for this field is program generated; therefore, no data input is necessary.

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 0938-0062. 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.

ICF/IID Form 3070G
Allegations of Abuse and Neglect and
Number of Deaths
Data Entry Instructions (revised 4/12/02)

M. Allegations of abuse and neglect

(W68) Number of allegations of abuse investigated.
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04/12/02

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB NO. 0938-0062

INTERMEDIATE CARE FACILITY FOR INDIVIDUALS WITH INTELLECTUAL DISABILITIES DEFICIENCIES REPORT

Name of Facility

DEFICIENCIES		COMMENTS
1. DATA TAG NO.	2. COP/STND NO.	

FORM CMS-3070H (11/00)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB NO. 0938-0062

DEFICIENCIES		COMMENTS
1. DATA TAG NO.	2. COP/STND NO.	

FORM CMS-3070H (11/00)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB NO. 0938-0062

INTERMEDIATE CARE FACILITY FOR INDIVIDUALS WITH INTELLECTUAL DISABILITIES DEFICIENCIES REPORT

FOR INITIAL OR ANNUAL RECERTIFICATION SURVEY

I certify that I have reviewed the following requirements and condition for: (a) Full Survey ____, (b) Extended Survey ____, or (c) Fundamental Survey ____, and unless indicated on this form, the facility was found to be in compliance with the Standard and the Condition of Participation.

SIGNATURE	TITLE	DATE
SIGNATURE	TITLE	DATE
SIGNATURE	TITLE	DATE
SIGNATURE	TITLE	DATE
SIGNATURE	TITLE	DATE
SIGNATURE	TITLE	DATE
SIGNATURE	TITLE	DATE
SIGNATURE	TITLE	DATE
SIGNATURE	TITLE	DATE

FOR FOLLOW-UP SURVEY

For the purpose of this onsite visit, I certify that I have reviewed each Condition of Participation and related Standard(s) found not to be in compliance during the survey on _____, and unless indicated on this form, the facility was found to be in compliance with the Standard and/or the Condition of Participation.

SIGNATURE	TITLE	DATE
SIGNATURE	TITLE	DATE
SIGNATURE	TITLE	DATE
SIGNATURE	TITLE	DATE
SIGNATURE	TITLE	DATE
SIGNATURE	TITLE	DATE
SIGNATURE	TITLE	DATE
SIGNATURE	TITLE	DATE
SIGNATURE	TITLE	DATE

FORM CMS-3070H (11/00)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB NO. 0938-0062

INTERMEDIATE CARE FACILITY FOR INDIVIDUALS WITH INTELLECTUAL DISABILITIES DEFICIENCIES REPORT-INSTRUCTIONS

Evaluate each of the requirements identified in the ICF/IID Interpretive Guidelines, (Appendix "J" to the SOM). For each identified deficiency:

A. In the first column, identify the data tag number.

B. In the second column, write the regulatory citation. If it is a Condition of Participation, enter "CoP" below the regulatory citation.

C. In column three, describe deficient facility practice and supporting findings.

D. Draw horizontal lines to separate identified tag numbers.

E. If more space is needed, photocopy FIRST page (front and back).

F. Each surveyor must sign the certifying statement on the last page.

G. If there are more surveyors to sign the last page, than are lines available on which to sign, photocopy the last page, and add the additional signatures.

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 0938-0062. 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB NO. 0938-0062

INDIVIDUAL OBSERVATION WORKSHEET

Name of Facility	Date

Location/Start	Location/Start
Time/Start	**Time/Finish**
Surveyor	**Client Codes**

COLUMN 1 — TIME	COLUMN 2 — OBSERVATION

Form CMS-3070I (10/95)

COLUMN 1 — TIME	COLUMN 2 — OBSERVATION

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 0938-0062. The time required to complete this information collection is estimated to average 3 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 estimate(s) or suggestions for improving this form, please write to: CMS, Attn: PRA Reports Clearance Officer, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Printed: 10/22/2002
FORM APPROVED
OMB NO. 0938-0391

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
W 000	INITIAL COMMENTS	W 000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

POST-CERTIFICATION REVISIT REPORT

PROVIDER/SUPPLIER/CLIA/IDENTIFICATION NUMBER Y1	MULTIPLE CONSTRUCTION A. Building _____ B. Wing _____ Y2	DATE OF REVISIT Y3

NAME OF FACILITY	STREET ADDRESS, CITY, STATE, ZIP CODE

This report is completed by a qualified State surveyor for the Medicare, Medicaid and/or Clinical Laboratory Improvement Amendments program, to show those deficiencies previously reported on the CMS-2567, Statement of Deficiencies and Plan of Correction, that have been corrected and the date such corrective action was accomplished. Each deficiency should be fully identified using either the regulation or LSC provision number and the identification prefix code previously shown on the CMS-2567 (prefix codes shown to the left of each requirement on the survey report form).

ITEM Y4	DATE Y5	ITEM Y4	DATE Y5	ITEM Y4	DATE Y5
ID Prefix _____	Correction	ID Prefix _____	Correction	ID Prefix _____	Correction
Reg. # _____	Completed	Reg. # _____	Completed	Reg. # _____	Completed
LSC _____	____/____/____	LSC _____	____/____/____	LSC _____	____/____/____
ID Prefix _____	Correction	ID Prefix _____	Correction	ID Prefix _____	Correction
Reg. # _____	Completed	Reg. # _____	Completed	Reg. # _____	Completed
LSC _____	____/____/____	LSC _____	____/____/____	LSC _____	____/____/____
ID Prefix _____	Correction	ID Prefix _____	Correction	ID Prefix _____	Correction
Reg. # _____	Completed	Reg. # _____	Completed	Reg. # _____	Completed
LSC _____	____/____/____	LSC _____	____/____/____	LSC _____	____/____/____
ID Prefix _____	Correction	ID Prefix _____	Correction	ID Prefix _____	Correction
Reg. # _____	Completed	Reg. # _____	Completed	Reg. # _____	Completed
LSC _____	____/____/____	LSC _____	____/____/____	LSC _____	____/____/____
ID Prefix _____	Correction	ID Prefix _____	Correction	ID Prefix _____	Correction
Reg. # _____	Completed	Reg. # _____	Completed	Reg. # _____	Completed
LSC _____	____/____/____	LSC _____	____/____/____	LSC _____	____/____/____

REVIEWED BY STATE AGENCY ☐	REVIEWED BY (INITIALS)	DATE	SIGNATURE OF SURVEYOR	DATE
REVIEWED BY CMS RO ☐	REVIEWED BY (INITIALS)	DATE	TITLE	

FOLLOWUP TO SURVEY COMPLETED ON	☐ CHECK (√) FOR ANY UNCORRECTED DEFICIENCIES. WAS A SUMMARY OF UNCORRECTED DEFICIENCIES (CMS-2567) SENT TO THE FACILITY? ☐ YES ☐ NO

Form CMS-2567B (9-92)

This page is intentionally blank.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO 0938-0583

SURVEY TEAM COMPOSITION AND WORKLOAD REPORT

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Office of Financial Management, HCFA, P O Box 26684, Baltimore, MD 21207, and to the Office of Management and Budget, Paperwork Reduction Project (0938-0583), Washington, D C 20503.

Provider/Supplier Number	Provider/Supplier Name

Type of Survey *(select all that apply)*

A Complaint Investigation
B Dumping Investigation
C Federal Monitoring
D Follow-up Visit
E Initial Certification
F Inspection of Care
G Validation
H Life Safety Code
I Recertification
J Sanctions/Hearings
K State License
L CHOW
M Other

Extent of Survey *(select all that apply)*

A Routine/Standard Survey (all providers/suppliers)
B Extended Survey (HHA or Long Term Care Facility)
C Partial Extended Survey
D Other Survey

SURVEY TEAM AND WORKLOAD DATA

Please enter the workload information for each surveyor. Use the surveyor's identification number.

Surveyor ID Number (A)	First Date Arrived (B)	Last Date Departed (C)	Pre-survey Preparation Hours (D)	On-site Hours 12AM-8AM (E)	On-site Hours 8AM-8PM (F)	On-site Hours 8PM-12AM (G)	Travel Hours (H)	Off-site Report Preparation Hours (I)
Team Leader ID 1.								
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								

Total Supervisory Review Hours ..... [ ]

Total Clerical/Data Entry Hours ..... [ ]

Was Statement of Deficiencies given to the provider on-site at completion of the survey? ..... ☐ yes ☐ no

FORM HCFA-670 (12-91)

This page is intentionally blank.

Field Resource Guide

Tab 5: 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
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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				

Field Resource Guide

Tab 6:
HIPAA Memorandum

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations

Ref: S&C-03-15

DATE: **March 14, 2003**

FROM: Director
Survey and Certification Group

SUBJECT: Review of Protected Health Information and Applicability of Business Associate Agreements Under the Health Insurance Portability and Accountability Act (HIPAA) for the Purposes of Survey and Certification

TO: Survey and Certification Regional Office Management (G-5)
State Survey Agency Directors

The purpose of this letter is to provide guidance regarding the appropriateness of executing business associate agreements between the state survey agencies (SAs) and providers, and the provision of individually identifiable health care information during surveys under the HIPAA Privacy Rule. Several SAs have received requests from providers to enter into business associate agreements, which were addressed in the "Standards for Privacy of Individually Identifiable Health Information" (HIPAA Privacy Rule) published December 28, 2000, and most recently amended August 14, 2002 (65 Fed. Reg. 82462, as modified by 67 Fed. Reg. 53182). Additionally, several providers have expressed concern over the release of protected health information (PHI) to surveyors under the HIPAA Privacy Rule.

The Administrative Simplification provisions of HIPAA apply to health plans, health care clearinghouses, and health care providers that transmit individually identifiable health information in electronic form.

While the HIPAA Privacy Rule provides for certain privacy rights for the subjects of PHI, those rights have limitations. For example, the HIPAA Privacy Rule provides that PHI may be used and disclosed without the authorization of the subject of that information to the extent a law requires the production of that information. *(See 45 CFR 164.512(a))*. The HIPAA Privacy Rule also provides that PHI may be used and disclosed without the authorization of the subject of that information for health oversight activities that are authorized by law. Examples are inspection, licensure and other activities necessary for the appropriate oversight of entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards. *(See 45 CFR 164.512(d))*.

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To the extent that the information sought is PHI for survey and certification work that is responsive to a law that requires the production of that information, or to the extent the information sought is for health oversight activities authorized by law, the surveyed entity does not need to receive an authorization prior to releasing the necessary PHI to the SA under the HIPAA Privacy Rule.

Government regulatory programs that function as health oversight agencies that need PHI to determine a facility's compliance with program standards do not need to obtain an individual's authorization to use that individual's health records for the appropriate oversight of entities subject to that program's regulation. The health oversight agency must limit its uses and disclosures of this PHI to the minimum necessary to accomplish the program's regulatory purpose, and it may not use records obtained under this exception to investigate the individual whose records they have obtained. Disclosures made pursuant to a law that mandates the production of information are not subject to any limitations under the HIPAA Privacy Rule so long as the disclosure complies with and is limited to the relevant requirements of such law.

In summary, to the extent that the information sought by an SA is PHI for survey and certification work that is either 1) required by law or 2) for health care oversight activities, the surveyed entity does not need to receive an authorization prior to releasing the necessary PHI to the SA. Furthermore, surveyed entities do not need to execute a business associate agreement with SAs prior to releasing PHI as SAs are not business associates of the surveyed entities under the HIPAA Privacy Rule definition of "business associate." SAs do not conduct a function or activity of the surveyed entity on the surveyed entity's behalf. (*See 45 CFR 160.103).*

We have attached a suggested template for use by the SAs in response to requests to take part in business associate agreements with providers, and to address provider's concerns over the release of PHI for oversight activities.

Effective Date: April 14, 2003

Training: The information contained in this announcement should be shared with all survey and certification staff, their managers and the state/RO training coordinator.

/s/
Steven A. Pelovitz

Attachment

Mr. (Mrs., Ms.) X
Administrator
Facility Name
Street Address
City, State Zip Code

Re: Release of Patient Information for Survey and Certification Activities

Dear :

The purpose of this letter is to address your concerns about the release of protected health information (PHI) for the purpose of survey and certification activities.

The Standards for Privacy of Individually Identifiable Health Information, otherwise known as the Health Insurance Portability and Accountability Act or "HIPAA Privacy Rule" *(45 CFR Parts 160 and 164)* guarantee certain privacy rights to individuals. The HIPAA Privacy Rule provides that PHI may be used and disclosed without the authorization of the subject of that information to the extent a law requires the production of that information. (*See 45 CFR 164.512(a)*). The HIPAA Privacy Rule also provides that PHI may be used and disclosed to Health Oversight Agencies without the authorization of the subject of that information for health oversight activities that are authorized by law. Examples are inspection, licensure and other activities necessary for the appropriate oversight of entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards. *(See 45 CFR 164.512(d)).*

As such, an individual's authorization is not required for information supplied to government regulatory programs that qualify as health oversight agencies needing PHI to determine compliance with program standards as part of that oversight agency's appropriate oversight of entities subject to that program's regulation. A Health Oversight Agency (like those that conduct survey and certification activities) must limit its uses and disclosures of PHI to the minimum necessary to accomplish the program's regulatory purpose, and may not use records obtained under this exception to investigate the individual patient whose records they have obtained. Disclosures made pursuant to a law that mandates the production of information are not subject to any limitations under the HIPAA Privacy Rule so long as the disclosure complies with and is limited to the relevant requirements of that law.

To the extent that the information sought for survey and certification work is responsive to a law that requires the production of that information, or to the extent the information sought by a health oversight agency for health oversight activities authorized by law, the surveyed entity does not need an authorization prior to releasing the necessary PHI to the SAs. Nor do surveyed entities need to execute a business associate agreement with the SAs prior to releasing PHI as SAs are not business associates of the surveyed entities under the HIPAA Privacy Rule definition of "business associate."

If you have any further questions or comments on this matter, please contact NAME at NUMBER or ADDRESS.

Signature
Printed Name

Field Resource Guide

Tab 7: Clarifications

- S&C: 11-34-ICF/MR
- S&C: 11-14-ICF/MR
- S&C: 11-15-ICF/MR
- S&C: 10-26-LSC
- S&C: 09-47
- Clarification of Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs/IID) Regulations, April 14, 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop 02-02-38
Baltimore, Maryland 21244-1850

Center for Medicaid , CHIP, and Survey & Certification/Survey & Certification Group

Ref: S&C: 11-34-ICF/MR

DATE: **Friday, July 29, 2011**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: The Use of Video Cameras in Common Areas in Intermediate Care Facilities for the Mentally Retarded (ICFs/MR)

Memorandum Summary

- **Use of video cameras in ICFs/MR**: To ensure that client's rights are protected, the use of video cameras in the ICF/MR must be reviewed, approved and monitored by the Specially Constituted Committee (SCC) of the facility as constituted per 42 CFR 483.440(f)(3)(i-iii).
- **Informed Consent**: If approved by the SCC, written informed consent must be obtained from every affected client or designated guardian prior to the implementation of video cameras. Video cameras may be used in common areas within the ICF/MR facility.
- **Prohibitions:** Video cameras may *never* be used *for any reason* in areas where there are the highest expectations of privacy such as bathrooms, areas for private visitation or areas for private phone calls. Video cameras may not be used as a substitute for or supplement to adequate staffing or supervision protocols. The cost of the video cameras must be incurred by the facility and not the clients.

I. Background

The regulatory basis for this memorandum is found at the Condition of Participation §483.420 which requires that the facility must ensure the rights of all clients. Specifically, the facility must:

- ensure that clients are not subjected to physical, verbal, sexual or psychological abuse or punishment -§483.420(a)(5);
- provide each client with the opportunity for personal privacy and ensure privacy during treatment and care of personal needs -§483.420(a)(7); and
- ensure clients the opportunity to communicate, associate, and meet privately with individuals of their choice -§483.420(a)(9).

State and Federal surveyors have requested clarification as to whether the use of video cameras in the ICF/MR is consistent with the above regulations.

II. Discussion

The above referenced regulations do not unilaterally prohibit the use of video cameras within the ICF/MR. There may be instances where the use of video cameras may be helpful in ensuring that the clients are free from physical, verbal, sexual or psychological abuse, mistreatment or punishment. However, great care must be exercised to prevent any unintended violation of an individual's rights and privacy when such equipment is used in the facility.

Consistent with the regulations which require that the ICF/MR provider protect the privacy and rights of the clients in the facility, video cameras may only be used in the common areas or shared spaces of the ICF/MR where clients have lower expectations of privacy and where, in the normal course of their day, they may encounter visitors, staff, other clients, or medical personnel. Conversely, video cameras may ***never*** be used in areas where the clients have the highest expectations of privacy, such as client bathrooms, or areas where residents meet privately with visitors or make personal phone calls.

III. Required Safeguard

To ensure that any use of video cameras complies with regulatory requirements that client rights are fully protected, any use of video cameras in the ICF/MR must be approved by the Specially Constituted Committee (SCC) of the facility as constituted per §483.440(f)(3). Affected clients and their families or guardians must be informed of the SCC's approval to use video cameras in a specified area. Written informed consent must be obtained from every client or designated guardian living in the physical unit prior to the implementation of video cameras. If an ICF/MR consists of several physically separate living units, and the clients (and guardians if applicable) of a single unit have consented to the implementation of video cameras, it is not required that the clients residing in the other units (and their guardians as applicable) provide informed consent, since they would be considered guests when visiting this unit. However, the facility administration should still inform all clients living on the grounds (and their guardians if applicable) that camera use is in place on this specific unit.

To ensure the confidential use of the camera recordings, the facility must have policies and procedures in place that:

a) limit who has access to video viewing or use of the videos;
b) ensure that all staff with video viewing access are properly trained in the facility policies and the protection of client rights; and
c) ensure that adherence to the facility policies is monitored and that risks or breeches of the facility policies are promptly addressed.

The ICF/MR may not utilize video cameras in lieu of adequate staffing or supervision protocols. The use of video cameras must not replace or otherwise substitute for trained and available direct care staff at a sufficient level to provide active treatment and ensure client safety.

Page 3 - State Survey Agency Directors

The ICF/MR must incur the entire cost of any video camera usage in the facility. Clients or their families may not be charged.

If you have additional questions or concerns regarding the use of video cameras in the ICF/MR setting, please contact Ed Poindexter at 410-786-6574 or via e-mail at Edward.Poindexter@cms.hhs.gov

Effective Date: This clarification is effective immediately. Please ensure that all appropriate staff members are fully informed within 30 days of the date of this memorandum.

Training: This clarification should be shared with all survey and certification staff, surveyors, mangers and the State/RO training coordinators.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop 02-02-38
Baltimore, Maryland 21244-1850

Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group

Ref: S&C: 11-14-ICF/MR

DATE: **March 18, 2011**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Clarification of Self-Administration of Medications at 42 CFR §483.460(k)(4) Intermediate Care Facilities for the Mentally Retarded (ICFs/MR)

Memorandum Summary

It has been the expectation of ICF/MR surveyors pursuant to previous Centers for Medicare & Medicaid Services interpretations of §483.460(k)(4), that every client residing in an ICF/MR must participate at some level in a formal, self-administration program for medications.

- **Regulatory Requirement for Self Administration Programs**: There is no regulation that requires every client to have a formal, self-administration program for medications. The appropriateness of such a program for a client is determined by the interdisciplinary team in consideration of the comprehensive functional assessment data.
- **Regulatory Requirement for Those Clients Not in Self-Administration Programs**: The concept of continuous active treatment at §483.440(d)(1) requires that the facility utilize the time during medication administration by staff as a teaching opportunity for clients who have formal training programs for the development of skills that are transferrable to the drug administration process.

Discussion

Self administration of medication refers to the intentional, independent application or ingestion of over the counter or prescribed medications by an individual without assistance, instruction or direction. The regulation at §483.460(k)(4) requires the interdisciplinary team to develop and implement training objectives for individuals, "determined" to be appropriate for self administration of medications unless the client's physician specifies otherwise.

The interdisciplinary team must determine, based on comprehensive assessment, whether an individual possesses, or has the potential to develop, the requisite skill set needed to safely self administer medications and individually tailor training objectives to advance the individual toward the goal of self administration.

§483.460(k)(4) does not require that all individuals in an ICF/MR be engaged in self administration training programs. The interdisciplinary team decision that a self administration program is appropriate, as is the case for all formal training objectives, must be based upon accurate, current, valid assessment of the individual's skills and potential. The determination as to the appropriateness of a self administration program must never be made singularly on the individual's diagnosis or current functional abilities.

For individuals assessed to be inappropriate for a self administration program, but determined by the interdisciplinary team to possess the capacity to functionally, cognitively, emotionally or developmentally benefit from participation in the drug administration process, it is expected that the facility will provide opportunities for the client to participate in the medication administration process under direct supervision. This participation can include but is not limited to identifying the medication taken, reaching/grasping a cup of water during the process and placing oral medications in the mouth, etc.

During drug passes observe whether clients are offered the opportunity to participate consistent with their functional skill level and verify that the programs are being carried out consistently and in accordance with the written objective. For individuals not in need of formal self-administration programs who are not provided opportunities to participate in administration process, cite a deficiency at §483.440(c)(6)(vi).

If, as a result of observations and interviews, there are any concerns as to why a client is not on a formal program, the surveyor should review the associated assessments and interdisciplinary discussions. During this review look for evidence that the interdisciplinary team documented a justification as to why the client was not appropriate for a formal self-administration program and that the justification provided was based on an evaluation of the assessment results. Deficiencies for a failure by the facility to properly assess, to develop written self administration objectives or to carry out the self-administration programs consistently should be cited at §483.460(k)(4).

If you have additional questions or concerns regarding self administration programs in the ICF/MR please contact Kelley Leonette at (410)786-6664 or via electronic mail at Kelley.Leonette@cms.hhs.gov.

Effective Date: This clarification is effective immediately. Please ensure that all appropriate staff members are fully informed within 30 days of the date of this memorandum.

Training: This clarification should be shared with all survey & certification staff, surveyors, managers and the State and Regional Training Coordinators.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7000 Security Boulevard, Mail Stop 02-02-38
Baltimore, Maryland 21244-1850

Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group

Ref: S&C: 11-15-ICF/MR

DATE: **March 18, 2011**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Clarification of Reporting Mistreatment, Neglect and Abuse and Injuries of Unknown Source at 42 CFR § 483.420(d)(2) –Intermediate Care Facilities for the Mentally Retarded (ICFs/MR)

Memorandum Summary

- **Reporting Requirements**: The regulations for ICFs/MR at 42 CFR § 483.420(d)(2) require that the facility ensure that all allegations of mistreatment, neglect or abuse, as well as *injuries of unknown source*, are reported *immediately* to the administrator or to other officials in accordance with State law through established procedures.
- **Clarification of Definitions**: This memorandum clarifies the definitions for the terms "injury of unknown source," and "immediately". It also clarifies that the Centers for Medicare & Medicaid Services (CMS) expects that all allegations will be reported to the administrator of the facility unless he/she is suspected to be a party to, or otherwise involved in, the occurrence.

Background:

Section 42 CFR § 483.420(d)(2) of the ICFs/MR regulations addresses the obligation of the facility staff to report allegations of mistreatment, neglect or abuse, and injuries of unknown source immediately to the administrator of the facility or to other officials in accordance with State law through established procedures. Both State and Federal surveyors have requested further clarification regarding the parameters surrounding what constitutes "injuries of unknown source", the definition of "immediate" and to whom such allegations/injuries must be reported.

Discussion:

An injury should be reported as an "injury of unknown source" when:

1. The source of the injury was not witnessed by any person **and** the source of the injury could not be explained by the client; **and**

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2. The injury raises **suspicions** of possible abuse or neglect because of the extent of the injury **or** the location of the injury (e.g., the injury is located in an area not generally vulnerable to trauma) **or** the number of injuries observed at one particular point in time **or** the incidence of injuries over time.

It is important to note that members of the ICF/MR population are a mobile population and lead active lives. Therefore, they experience normal day-to-day bumps and minor abrasions as they go about their lives. These minor occurrences which are not of serious consequence to the individual and do not present as a suspicious or repetitive injury (as discussed above) should be recorded by the facility staff once they are aware of them and follow-up should be conducted as indicated. For injuries that do not rise to the level of reportable "injuries of unknown source", the facility should follow its policies and procedures for incident recording, investigation, and tracking.

42 CFR § 483.420(d)(2) further requires that allegations of mistreatment, neglect or abuse and injuries of unknown source must be, "reported immediately to the administrator or to other officials in accordance with State law, through established procedures". For the purpose of this regulation "immediately" means there should be no delay between staff awareness of the allegation and reporting to the administrator or other officials in accordance with State law unless the situation is unstable at the time the allegation comes to the attention of the staff. In this case, reporting should occur as soon as the safety of all clients is assured and all necessary emergency measures have been taken.

This reporting must be done on a 24/7 basis. Conformity with this definition will necessitate that the facility administration have procedures in place to receive reports, even on off-duty hours (e.g., electronic mail, answering machine, voice mail, and fax). It is critical that the administrator, as designated by the Governing Body under 42 CFR § 483.410(a)(2)-(3), be notified of such occurrences as quickly as possible to ensure the safety of all residents. There must also be evidence that the information was received, in a timely manner, by that facility administrator. When the administrator is not on duty, the facility policies and procedures should detail who (either by name or title) will be acting in the administrator's absence. The person(s) acting for the administrator must have the authority to immediately take whatever corrective action is necessary to ensure client health and safety. For example if an employee is to be removed from client contact pending an investigation, the acting administrator must have the authority to take this action without approval from another official.

CMS expects that such reporting is always made to the administrator of the facility (unless the administrator is suspected to be involved in the mistreatment, neglect or injury) and that the administrator then ensures that the appropriate State officials are notified. In any instance where a staff member is concerned that the administrator of the facility may have been involved in an incident of mistreatment, neglect, abuse or injury, the staff member should follow the facility policy for reporting to the appropriate person above the level of the administrator. The facility should have a written policy that directs the staff in these situations.

If you have any additional questions or concerns regarding the contents of this memorandum, please contact Douglas A. Thomas at (410) 786-0292 or at Douglas.Thomas@cms.hhs.gov

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Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

Training: This clarification should be shared with all survey and certification staff, surveyors, their managers, and the State/RO training coordinator.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

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, CHIP, and Survey & Certification/Survey & Certification Group

S&C-10-26-LSC

DATE: **July 23, 2010**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: 42CFR 483.470(i)(2)(i) Evacuation Drills for Intermediate Care Facilities for the Mentally Retarded (ICFs/MR) Certified Under the Life Safety Code NFPA 101, 2000 Edition

Memorandum Summary

- **Self-evacuation during an emergency** - Clients residing in ICFs/MR certified under Chapter 32/33 of the Life Safety Code NFPA 101, 2000 Edition (LSC) are expected to be capable of self-evacuation during an emergency.
- **Full evacuation drills** - All drills under this Chapter must be full evacuation drills unless the facility is designated as evacuation capability, "impractical."
- **Exceptions to full evacuation drills** - With a designation of evacuation capability "impractical" the facility must meet the requirements of Chapter 18/19 of the LSC as regards evacuation drills.

Discussion

Sections 32.7 of Chapter 32 and 33.7 of Chapter 33 of the LSC require that emergency drills be conducted not less than six (6) times per year on a bi-monthly basis. At least two of these drills must take place during sleeping hours. The drills may be announced in advance to the clients in the facility. Each drill must include the actual evacuation of all clients to a pre-arranged assembly location (per the emergency plan of the facility) and provide clients with experience in egress through all exits and means of escape. It is expected that ICF/MR clients who reside in a facility certified under this Section of the LSC will be capable of self-evacuation. Self evacuation in turn requires practice to familiarize the clients with the physical nuances of the facility. The actual evacuation drills provide them with this practice.

There are two exceptions provided to the above requirements:

1) The actual exiting by the clients from windows is not required for compliance with the Code. Opening the window and signaling for help is an acceptable alternative.

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2) Sections 32.7.3 and 33.7.3 of the LSC state that, in those facilities that have an evacuation capability classification of "impractical", as defined by chapter six (6) of NFPA 101A, 2001 Edition *Evacuation Capability for Board and Health Care Occupancies*, the residents who cannot meaningfully assist in their own evacuation or have special health needs shall not be required to actively participate in the drill. In these cases, (i.e., the facility has an evacuation capability classification of "impractical") Section 18.7 or 19.7 of the LSC would apply.

Sections 18.7 and 19.7 of the LSC require quarterly fire drills which simulate emergency fire conditions and are conducted to familiarize facility personnel with the emergency actions they may be required to perform. The general emphasis of these Sections of the Code is upon training of the staff and not upon providing practice for the clients. These Sections of the Code do not require the full evacuation of the clients but do imply that the clients are to be involved in the drills by adding an exception to the section that infirm or bedridden patients are not required to be moved during drills. However, the ICF/MR regulations at 42CFR 483.470(i)(2)(i) require that the facility must actually evacuate clients during at least one emergency drill each year on each shift.

Conclusion:

ICF/MR facilities that are certified under Section 32.7.3 or Section 33.7.3 of the LSC must conduct emergency drills no less than six (6) times per year on a bi-monthly basis. These drills must all be full evacuation drills and *all* clients residing in the facility must participate in *each* drill. At least two of these drills must take place during sleeping hours. This requirement is consistent with the requirements of 42CFR 483.470(i)(2)(i) which require actual evacuation of clients during at least one emergency drill each year on each shift.

ICF/MR facilities certified under Section 32.7.3 or Section 33.7.3 of the LSC with a capability classification of "impractical" must meet the emergency drill requirements found at Section 18.7 or Section 19.7 of the LSC. These sections require that the facility conduct fire drills which simulate emergency fire conditions on a quarterly basis. Since these drills are conducted to train staff rather the clients, the Code does not require full evacuation. However, the facility must *also* meet the ICF/MR regulations at 42CFR 483.470(i)(2)(i) which do require the actual evacuation of clients during at least one emergency drill each year on each shift. These drills are conducted primarily to prepare and train staff and it is critical that the staff from each shift participate in these drills. The facility may not elect to conduct night shift drills during another shift.

The LSC requires that the facility make the determination of "impractical" utilizing the criteria of the Code found in Sections 32/33.2.1.2.2 concerning the characteristics of the client population. The LSC surveyor verifies that the determination was correctly made at the time of the annual survey.

This memorandum addresses the requirements of *full evacuation* during a drill and is not intended to address the requirements for *frequency* of evacuation drills. The regulation at §483.470 (i) requires that evacuation/fire drills be conducted at all ICF/MR facilities on a quarterly basis on each shift. While this requirement supersedes the *number* of evacuation drills

required by the LSC under Chapters 32/33 it does not impact the requirements for full evacuation during such drills.

Effective Date: Immediately. Please ensure that all appropriate staff is fully informed within 30 days of the date of this memorandum.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

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-09-47

DATE: **July 10, 2009**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Intermediate Care Facilities for the Mentally Retarded (ICF/MR): Clarification of Protection of Client's Rights at 42 CFR §483.420(a)(4) - Ensure Right to Manage Financial Affairs

Memorandum Summary

- **Citing Deficiencies:** Surveyors currently cite a deficiency during the ICF/MR survey process if every client in the facility does not have a formal money management program in place.
- **Regulatory Provisions:** The regulations at 42 CFR 483.420(a)(4) state that clients in the ICF/MR must be allowed to manage their financial affairs and be taught to do so to the extent of their capabilities.
- **Determination of Compliance:** The determination as to the appropriateness of a formal money management program for an ICF/MR client is based upon the results of a comprehensive functional assessment and a consensus by the interdisciplinary team.

Background

Currently, surveyors cite a deficiency during the survey process if every client in an ICF/MR does not have a formal money management training objective included within their Individual Program Plan (IPP). For any instance where a client does not have a formal objective in place, regardless of the determination of appropriateness by the team, a citation is written at 42CFR 483.420(a)(4).

Discussion

42 CFR 483.420(a)(4) states that the facility must, "Allow individual clients to manage their financial affairs and to teach them to do so to the extent of their capabilities." The regulation is clear that in those cases where a client already possesses the skills necessary to independently manage their own financial affairs, the facility will allow the client to continue to do so. Formal training in financial management must be provided for all other clients in the facility to the *extent of their capabilities*. The regulation places the responsibility for determining the extent of the client's capabilities in this matter upon an assessment and interdisciplinary process within the facility.

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To reach a determination as to whether a money management program is appropriate, the facility interdisciplinary team (IDT) uses the comprehensive functional assessment (CFA) to evaluate the ability of each client to participate in such a program. Under 42 C.F.R. 483.440(c)(3), the team evaluation must establish, through documentation, that the IDT considers all of the objective data within the assessment in reaching their determination, especially the identification of client skills which can be used across training programs. Assessment findings to be considered by the team include skills that can be cross-utilized in training programs such as:

1. Fine motor coordination;
2. The ability to make choices;
3. The ability to identify preferences; and
4. Cognitive abilities including tracking, attention span, communication, and the individual's understanding of cause and effect. (The individual's understanding of cause and effect is significant in the determination.)

During surveyor observations note any client who is of the chronological age to utilize money management and exhibits the skills necessary to be on a formal money management program. Through observation and interview, determine the extent of any financial management program in which the client is involved. Review the client's CFA to confirm that the program is consistent with the findings of the assessment. The IPP must include measurable, individualized objectives to meet the various training goals consistent with the findings of the CFA and the IDT determination. The programs and strategies used to meet objectives should be detailed, understandable, and readily available for review and updating by staff in order to ensure a client's progress toward self-determination, choice, and independence. Such programs and strategies used to meet objectives may be established through documentation.

If the client is not on a formal money management program, the surveyor must review the IDT evaluation to determine whether the team addressed the results of the CFA and the identification of skills which can be cross-utilized in training programs. If this cannot be confirmed through documentation, a citation may be written.

Money management includes a broad spectrum of programs with varying levels of participation by the client ranging from the use of choice in money expenditures, to an understanding of the concept of money, and ultimately to actual money handling and budgeting. The IDT must not conclude that a money management program is inappropriate based solely upon the level of retardation or physical disability of the client.

The CFA must be reviewed at least annually per 42 C.F.R. 483.440(f)(2). As a part of this annual review, a client's ability to participate in money management will also be reviewed. The annual review should always include an update to the CFA and take into consideration any changes in the individual's circumstances since the last IDT.

Conclusion

The need for a formal money management program must be addressed in every client's IPP by the IDT on an annual basis.

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The determination of the appropriateness of a formal money management program is made by the IDT and must be based upon a CFA. The IDT discussions resulting in that determination must be established through documentation in the client's IPP.

Surveyors will question and cite any IDT team decision that a formal money management program is not appropriate when the client clearly exhibits and the CFA supports the skills needed to implement such a program.

If you have any additional questions, you may contact Kelley Tinsley, either by phone at 410-786-6664 or via e-mail at Kelley.Tinsley@cms.hhs.gov.

Effective Date: This clarification is effective immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Care Financing Administration

Center for Medicaid and State Operations
7500 Security Boulevard
Baltimore, MD 21244-1850

DATE: **April 14, 1999**

FROM: Acting Director
Disabled and Elderly Health Programs Group

SUBJECT: Clarification of Intermediate Care Facilities for Persons with Mental Retardation (ICFs/MR) Regulations

TO: Associate Regional Administrators
Division of Medicaid and State Operations
Regions I - X

The purpose of this memorandum is to provide clarification on survey issues with respect to regulations governing the Intermediate Care Facilities for Persons with Mental Retardation (ICFs/MR) program. This guidance is in response to questions received from State survey agencies, HCFA Regional Offices, and interested provider groups. Issues addressed in this clarification memo include: defining an in-depth interview; determining individual capability for self-medication; determining the sample for a follow-up survey; citing neglect at appropriate tags; facility reimbursement for respite care; defining the term "developmentally incapable," and addressing problems concerning survey findings that a facility poses a serious and immediate threat to the health and safety of clients.

We reviewed all written comments provided from participants during the Advanced ICF/MR Surveyor training course held June 16 - 19, 1998 in Baltimore, Maryland. Please note the final clarifications include revisions based on the comments received.

Please share this information with the State Medicaid agencies and survey agencies within your jurisdiction.

Theresa A. Derville

Attachments

ICF/IID Regulation Clarification
Questions and Answers

Q1. How is an in-depth interview defined?

A1. An in-depth interview is a process in which the surveyor gathers objective and subjective information to determine how the individuals receiving services perceive the services delivered by the facility; and how the individuals and families participate in service planning and in making choices about matters important to them. The interview should be held in strict privacy, although all information gathered by the surveyor does become a formal part of the survey record. (Reference: State Operations Manual (SOM) Appendix J, p. J-12, Section 8-C)

As established in the SOM Appendix J, p. J-8, once the overall survey sample is randomly drawn, 50 percent of the formal sample will then be selected for interviews, up to a maximum of 15 individuals. The surveyor has flexibility to select the individuals from the sample for interviews. Ideally, the surveyor will include people who can speak for themselves, people who have an active advocate or family member and people who rely on direct support staff for information. This would give the surveyor a full range of perspectives. There is no need to add anyone to the survey sample for the sole purpose of conducting an interview. However, interviews are a mandated component of the ICF/IID survey process.

The essential elements of an in-depth interview include:

1) Direct communication between the surveyor and the individual. If at all possible, conduct interviews in person. The hierarchy of interviews starts with the individual, then the family, guardian or advocate, then friends, then direct support staff. Interviews should be conducted with the individual present, even if a third person provides the majority of the information.

2) Introduction of the interviewer to the interviewee and explanation of the interviewer's role.

3) Questions asked by the surveyor focusing on eliciting information not obtainable by other means.

4) Specific, clear questions that have "yes" or "no" responses and/or open-ended questions. The question format depends on the individual's comfort level and ability to communicate.

5) Focus on expertise or the interests of the person being interviewed; and

6) Written record of the purpose of the interview, who was interviewed, what was discussed, the relationship of the person being interviewed to the individual (if the individual is not interviewed directly), and a summary of the surveyor's finding.

Q2. How can we determine if an individual is capable or incapable of self-administering his/her medication?

A2. In accordance with SOM Appendix J, p. J-135, Tag W373, the test of competency to self-administer medication is whether the individual can take the correct medication, in the correct dosage, at the correct time. Tag W373 states, "No person self-administers medication until he/she demonstrates the competency to do so…" Supervision is required during training. This supervision should be conducted by a licensed personnel (if required by State law) and should continue until the person safely and consistently demonstrates the ability to self-administer. Surveyors should ask the question (probe) on J-135, "Is there a pattern that all individuals self-medicate whether they can demonstrate the skill or not?"

Q3. How do we determine the sample for a follow-up survey?

A. As established in SOM Transmittal 278, Section E, J-8, sample selection for a follow up survey is dependent on the nature of the deficiencies for which the follow-up must be done. For a follow up survey, it is not necessary to do a full review of ALL services. Instead, focus the effort as follows:

1) Draw a sample of persons which reflects a proportionate representation of the individuals by the four functional levels (mild, moderate, severe, and profound);

2) Calculate the sample size by the number of individuals residing in the facility;

3) Determine the number of individuals to draw for the sample;

4) Determine the number of individuals to draw in each functional category based on the percentage occurrence of each functional level in the overall population;

5) For each individual in the sample, assess all applicable requirements of the ICF/IID Conditions of Participation based on the individual's need for that particular service,

6) Approximately 50 percent of the sample should be individuals who were not previously reviewed in order to assure systemic correction of the identified deficiencies.

7) For a follow-up survey, **when the previously cited deficiencies are limited to a specific need or service area**, the sample may be drawn from among those individuals presenting that need or affected by that service.

8) **The maximum required sample size on a follow-up survey is 30.**

Q4. Can we cite a condition level non-compliance outside of the four fundamental conditions of participation (CoP) during a fundamental/extended survey?

A4. No. According to SOM Appendix J, pp. J 3-4, Section 3—Survey Process, the protocol requires surveyors to move to a full survey if they need to investigate CoPs outside of the 4 fundamental CoPs. Surveyors do not have the option of "extending" for individual non-fundamental conditions.

Q5. Where do we cite problems at a day program?

A5. Each survey will have different issues that appear and surveyors will need to decide the best place for the citation. However, surveyors should cite problems at a day program under tag W120—"The facility must assure that outside services meet the needs of each client." **Tag W120 was added as a fundamental tag** (effective December, 1998). Tag W120 corresponds with 42 CFR 483.410(d)(3) which states, "Outside service providers meet the needs of each individual as identified by the interdisciplinary team." The interpretive guidelines define the word "assess" to mean the facility's staff actively participate with staff in outside programs in the assessment process and in development of objectives and intervention strategies.

Q6. Where should we cite neglect?

A6. Neglect falls under 42 CFR 484.420(d)(1), and is identified in SOM Appendix J, p. J-48 as tag W149. Tag W149 reads as follows: "(1) The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect or abuse of the client."

Q7. Should the Life Safety Code and fire drill reviews be reviewed on fundamental surveys?

A7. Yes, the fundamental survey is the starting point for most annual recertification surveys, and in accordance with SOM Transmittal 278, Section 3, p. J-3, "Every certification and annual recertification requires a complete Life Safety Code (LSC) survey." Every facility must undergo an LSC survey as part of each initial or recertification package. Fire drills are part of the LSC survey.

While some agencies subcontract fire drill reviews to the State Fire Marshall's Department, the reviews are still part of the LSC survey. Surveyors should check with the fire drill log as part of their record review. If surveyors find that fire drills have not been conducted, they can ask the facility to conduct a fire drill in order to determine whether or not clients can effectively evacuate the facility. (42 CFR 483.470(h)) **Tags W448 and W449 have been added as fundamental tags to ensure attention is focused on whether or not a facility is investigating all problems with evacuation drills, including accidents, and taking corrective action.**

Q8. Can a facility be reimbursed for respite care?

A8. Facilities cannot receive ICF/IID reimbursement for respite care. However, facilities can admit persons whose care is funded through private sources as long as the presence of private pay persons in the facility does not negatively affect services being provided to the ICF/IID residents; interfere with the delivery of active treatment to ICF/IID clients, or jeopardize the health and safety of either the ICF/IID residents or other people admitted for respite care. A facility can set aside a small number of non-certified beds for respite care under the following conditions:

1) The facility would still be engaged primarily in ICF/IID care;
2) Services provided to ICF/IID residents are not hampered;
3) The person is admitted to the ICF/IID if the stay will be over 30 days, and
4) The facility must have at least 4 beds for ICF/IID care.

In facilities of 6, no more than 2 beds can be set aside for respite care. In facilities of 7-15, no more than 3 beds may be set aside for respite care. In facilities of over 15, no more than 3 beds or 10 percent of beds may be set aside for respite care, whichever is greater.

Q9. How is "developmental incapability" define for tag W242—personal skills?

A9. "Developmental incapability" is a decision to be made by the interdisciplinary team based on assessment of the individual's developmental strengths and needs. Surveyors should look for how the team determined an individual is developmentally incapable, i.e. performance data, medical evidence, historical efforts at training. It should also be observed as to whether or not there is adequate documentation of consistent, appropriate attempts to teach individuals these skills, or specific evidence as to a medical condition which would preclude acquisition, prior to determination of developmental incapability.

Surveyors should observe whether or not training in personal skills has been provided to the individual determined to be developmentally incapable. Training as defined at tag W242 is an aggressive implementation of a systematic program of formal and informal techniques; continuously targeted toward the individual achieving the measurable behavioral level of skill competency specified in the individual program plan (IPP); conducted in all applicable settings, and conducted by all personnel involved with the client. Recognition is given to the fact that some individuals, however, have insufficient sensory and neuromuscular control to ever be totally independent in toileting skills. For most of this group, there are intermediate steps which can be achieved, including toilet scheduling, in which the individual is able to be trained to a schedule of elimination with needed assistance from staff.

Surveyors should also observe the attitude of staff, and if the attitude expressed supports individuals learning increasingly complex skills or accepts that individuals will not or cannot grow and change.

Q10. Where do we cite pervasive lack of grooming/hygiene when it is not a training issue for the individual?

A10. If individuals have no choice as to when or if they wanted/needed a haircut then that becomes and issue of choice, the best option for the surveyor would be to cite tag W247—client choice and self-management.

Q11. If a facility has a serious and immediate (S & I) threat related to tag W127—physical, verbal abuse, which then calls out tag W122—client protections, and they correct the S & I on-site, should the form 2567 still show the CoP of W122 not met?

A11. Yes, if a facility has a serious and immediate threat related to tag W127, which then calls out tag W122 client protections, and the facility corrects the S & I on-site, the S & I should still be recorded on form 2567. Whether the facility corrects an S & I 21 **days** into a 23-day (termination action) plan of correction or corrects

an S & I 21 **minutes** after the S & I was cited, the difference in correction is only in time and no in **substance and severity**.

For example, if a surveyor conducted a survey of a facility using a laptop computer, and found an S & I, and recorded this finding in the computer, the information would be stored automatically. Although surveyors use the form 2567, this does not minimized the importance of recording the S & I as observed. However, the form 2567 can also reflect that the S & I was corrected while surveyors were on site.

Q12. If a facility has a serious and immediate threat, and they submit a plan for correction, can we hold the facility responsible for what happens during the days while they are correcting the S & I?

A12. Yes, although the facility has submitted a plan of correction for a serious and immediate threat as cited by the survey team, they are still responsible for what occurs during the days they are correcting the S & I. The plan of correction should provide for a strategy to immediately address the S & I, with the understanding that the facility remains responsible for safety and well-being of its residents. If a facility is correcting an S & I under the plan of correction, and the survey team finds other S & Is, the team should cite the additional S & I.

Q13. What is the status of the Inspection of Care (IoC)?

A13. On December 17, 1997, Sally Richardson, Director of the Center for Medicaid and State Operations for the Health Care Financing Administration, sent a letter to all State Medicaid Directors providing guidance on the implementation of section 4751 of the Balanced Budget Act of 1997 (BBA). Section 4751 of the BBA eliminated the requirement for periodic inspections of care (IoC) for each Medicaid beneficiary receiving services in an intermediate care facility for indviduals with intellectual disability (ICF/IID) or in a Mental Hospital (MH). Prior to the enactment of the BBA, the Medicaid law contained minimum standards for medical review of care and services provided in ICF/IID and MHs. To ensure compliance with these standards, section 1903(g) of the Social Security Act provides for a reduction in Federal Medicaid funds for extended inpatient hospital stays, unless a State could document that it has an effective program of medical review in ICF/IID and MHs.

As part of the State's compliance, the Medicaid law further required each State to perform annual inspections of care of Medicaid beneficiaries in participating ICF/IID and MHs and to document those reviews quarterly. CMS was required to impose penalties on noncompliant States. Specifically, section 4751 of the BBA repeals the requirements formerly contained in Title XIX of the Social

Security Act (the Act). It provides that States are no longer required to conduct IoC reviews in ICF/IID and MHs.

Since the BBA failed, however, to eliminate the penalty provision in section 1903(g) of the Act, the literal interpretation of the statute would mean that States and CMS must follow the current law of 1903(g) and continue to conduct IoC reviews until section 1903(g) was amended or repealed. Nevertheless, consistent with its legislative history, and because not to do so would render the passage of section 4751 meaningless, CMS has interpreted the amendment made by section 4751, to mean that the penalty section 1903(g) of the Act no longer requires IoC reviews. Therefore, CMS will no longer enforce the sanctions contained in section 1903(g) of the Act beginning with the enactment of the BBA.

Q14. Regarding tag W156—results of investigations must be reported to the administrator or designated representative…in accordance with State law within five working days of the incident—how should a surveyor address the potential conflict between State laws and tag W156 (State Operations Manual, Appendix J, p. J-51). Some State laws say only the Office of Inspector General (OIG) can investigate abuse, and tag W156 requires surveyors to report the results of all investigations to the administrator or designated representative, or to other officials in accordance with State law within five working days.

A14. The intent of tag W156 is to assure that individuals are free from harm. Surveyors must assess measures taken by the facility to see if the facility took action to determine if the allegation was valid during the five days, and if the facility then took appropriate action, i.e. protecting the individual. We would expect a preliminary report to guide these actions while the facility waited for OIG to complete the investigation. Tag W156 specifically requires surveyors to report the results of all investigations to the administrator or designated representative, or to other officials in accordance with State law within five working days. Surveyors are not obliged to take any action which would be inconsistent with State law, such as reporting on confidential police or IG investigations, as long as the State obligations do not directly conflict with the facility's obligations under Federal law.

Even in states with laws requiring particular authorities to investigate allegations of abuse, a facility is still required to report within the established timeframe the results of its own internal investigation. In such circumstances, a facility would still be obliged, for example, to document the manner in which it reported abuse allegations internally and to other officials in accordance with State law (42 CFR 483.420(d)(2)), evidence of its own investigation and efforts to prevent further potential abuse while an investigation into the incident is underway (42 CFR 483.420(d)(3)), and the results of the investigations of the proper authorities as reported to the facility (42 CFR 483.420(d)(4)).

Q15. What does the Balanced Budget Act (BBA) put in place for alternative sanctions for ICF/IID?

A15. The BBA allows States to establish alternative sanctions for ICF/IID which are certified for participation under its plan but no longer substantially meets the requirements for such a facility under this title XIX, and further determines that the facility's deficiencies do not immediately jeopardize the health and safety of its patients. The alternative sanctions may be established in lieu of or in addition to terminating the facility's certification for participation under the plan. Information regarding specifics of the alternative sanctions will be contained in the State Operations Manual (effective December 1998).

Q16. Can a State operational facility prohibit an individual from having sex if the individual is determined to be legally incompetent? Can legal guardians say that their daughter/son cannot have sex?

A16. The only CMS regulation related to this issue is 42 CFR 483.420(a)(13), which requires as a condition of participation that all ICF/IID "permit a husband and a wife who both reside in facility to share a room." Beyond this requirement, all regulation of sexual activity of ICF/IID residents is a matter of State law.