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Provider Certification

Transmittal 91 Date: September 27, 2013

Human Services (DHHS) Centers for Medicare & Medicaid Services (CMS)

Department of Health &

SUBJECT: State Operations Manual (SOM) Chapter 2 Policy and Nomenclature Revisions for Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID)

I. SUMMARY OF CHANGES: Revisions have been made to Chapter 2, Sections 2130 – 2143, "Intermediate Care Facilities" to reflect current Survey and Certification policy memos regarding ICF/IID. Sections 2141A-2141D has been deleted because ICF/IIDs are no longer under Time Limited Agreements (TLAs). New Sections 2142 and 2143 have been added to reflect policy on evacuation drills for ICFs/IID certified under the Life Safety Code and the use of video cameras in common areas in ICF/IID.

In addition, other deletions and/or revisions have been made throughout Chapter 2 to reflect the new federally mandated ICF/IID nomenclature (the nomenclature is no longer ICF/MR).

NEW/REVISED MATERIAL - EFFECTIVE DATE*: September 27, 2013 IMPLEMENTATION DATE: September 27, 2013

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.) (R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

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^{*}Unless otherwise specified, the effective date is the date of service.

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2008F - SA Scheduling of Resurveys

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

Sections 1819(g)(2)(A)(iii) and 1919(g)(2)(A)(iii) of the Act require that each SNF and NF respectively be subject to a standard survey no later than 15 months after the previous standard survey and that the state-wide average interval between such surveys not exceed 12 months. Section 1891(c)(2)(A) requires that each HHA be subject to a standard survey within a 36-month interval. Since the law also prohibits the announcing of such surveys, utilize flexible survey schedules to ensure that these surveys are as "unpredictable" as possible. (Sections 1819(g)(2)(A)(i), 1919(g)(2)(A)(i), and 1891(c)(1) of the Act establish civil money penalties (CMPs) for any individual who notifies a SNF, NF, or HHA of a survey.) A facility should not be surveyed during the same month each year. The SA may conduct surveys of these providers as frequently as it deems necessary, but no more than 15 months after the last standard survey of any SNF or NF, or 36 months for any HHA.

In developing the SA survey schedule for HHAs, SNFs, and NFs (at a minimum), the SA utilizes information from SA files, the Online Survey Certification and Reporting System (OSCAR), and other sources at its disposal to identify those providers with poor performance records who should be resurveyed more frequently. Conversely, the SA utilizes the same information to identify those providers that have established a history of good performance, who could be resurveyed less frequently. (See §2702.)

For example, the SA may find that some facilities should be resurveyed within 4 months of the prior standard survey, while others may not require a resurvey for up to 15 months from the prior standard survey. The statewide average for SNFs and NFs may not exceed 12 months in a given Federal fiscal year. Schedule surveys to provide a "cushion" against any unforeseeable events, such as staff turnover. Section 1891(c)(2)(B)(ii) of the Act also requires conducting a standard survey (or abbreviated standard survey) of any HHA against which a significant number of complaints have been reported. Sections 1819(g)(2)(A)(iii), 1919(g)(2)(A)(iii), and 1891(c)(2)(B)(i) of the Act also state that such surveys of SNFs, NFs, and HHAs may be conducted within 2 months of any change in ownership, administration, management, and (for SNFs and NFs) director of nursing (DON) to determine whether the change has caused any decline in the quality of care furnished.

Based on documented evidence of current accreditation, the SA recertifies accredited entities on a schedule consistent with their accreditation interval. For example, for hospitals, that interval may be only every three years.

The timing of the Life Safety Code (LSC) survey is at the discretion of the SA. It may occur before, after, or simultaneously with the health portion of the survey. (See §7410 for more guidance on LSC for SNFs and NFs.)

2016A - Readmission Criteria

(Rev. 91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

After involuntary termination of a provider's agreement, an institution cannot participate in the Medicare or Medicaid program again unless:

The provider submits with its request for readmission sufficient justification to indicate that the reasons for termination no longer exist; and

All of the applicable statutory and regulatory requirements are met; or

There is reasonable assurance for Medicare entities or Medicaid ICFs/IID (terminated under §1910(b) of the Act by CMS) that the deficiencies that caused the termination will not recur.

2016B - Reasonable Assurance Concept

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

A Medicare provider terminated under <u>42 CFR 489.53</u> and reinstated under <u>42 CFR 489.57</u> or a Medicaid ICF/*IID* provider terminated pursuant to <u>§1910(b)(1)</u> of the Act is required to operate for a certain period of time without recurrence of the deficiencies which were the basis for the termination. The reasonable assurance concept also applies to terminated Medicare suppliers such as ASCs (<u>42 CFR 416.35(e)</u>), FQHCs (<u>42 CFR 405.2404(e)</u>), and ESRD facilities (<u>42 CFR 405.2180(c)</u>).

The length of this "reasonable assurance" period is determined by the RO after an evaluation of the provider or supplier's previous compliance history. Reasonable assurance periods are usually 30-120 days, but depending on the circumstances, can be for a shorter or longer period of time. Participation can only resume following that period if the provider or supplier has maintained compliance with program requirements.

The RO determines the reasonable assurance period for:

- Medicare suppliers;
- Medicare providers, including a SNF in a dually-participating facility, terminated pursuant to §1866(b)(2) of the Act; and
- ICFs/IID terminated by CMS pursuant to §1910(b)(1) of the Act.

In considering the decision to readmit a previously-terminated provider/supplier to the Medicare or Medicaid program, the RO takes into account not only certification, but also the intermediary's statement concerning the institution's financial responsibility and the OCR's report on compliance with civil rights requirements.

NOTE: There is no statutory or regulatory requirement that States must establish a reasonable assurance period for Medicaid-only facilities or a NF in a dually-participating facility that has been terminated by the SMA under §§1902(i) and 1919(h)(1) of the Act.

The reasonable assurance decision is an administrative action (not an initial determination) and is not subject to the appeals process at 42 CFR Part 498.3(d)(5).

NOTE: These provisions do not apply where a termination action was the result of a sanction imposed by the OIG. The RO forwards reinstatement requests involving these provisions to the OIG for appropriate action.)

To determine the reasonable assurance period, the RO will evaluate the following:

1. Provider's or Supplier's Compliance History

When the provider/supplier previously participated in either Medicare or Medicaid (ICF/*IID*), was compliance maintained historically?

Were PoCs implemented on time?

Does the provider/supplier have a history of making good faith efforts to correct deficiencies and to maintain compliance?

Does it have a record of being cited repeatedly for essentially the same problems?

Were previous adverse actions initiated, but not put into effect?

2. Previous Adverse Action

Has the applicant/institution previously been terminated and readmitted to the Medicare program? If yes:

How long was compliance maintained after being readmitted?

Have all deficiencies been corrected?

Are corrective actions permanent; i.e., is compliance likely to continue?

3. Other Factors Impacting Continued Compliance

Is the facility located in an area that is underserved by health professionals, meaning that staffing deficiencies may continue?

Does the applicant's pay scale or the facility's location deter the hiring and retention of staff?

Does it have inherent problems that are likely to cause recurrence of significant deficiencies?

Has there been a change in staff or services furnished that might affect continued compliance?

The following are examples using these criteria to determine reasonable assurance periods. (See Chapter 7 for examples for SNFs/NFs.)

EXAMPLE A:

Green Acres Community Hospital was terminated on November 1, 1996. The provider was cited as not meeting several CoPs. On December 1, 1996, the hospital board alleged to have corrected all deficiencies the SA found. While reviewing the provider's compliance history, the RO notes that one or more CoPs were cited in previous surveys, but the provider usually managed to achieve compliance just before termination.

Reasonable Assurance - The RO establishes 90 days from December 1, 1996, as reasonable based on the provider's history of not maintaining compliance.

EXAMPLE B:

Fox Chase General Hospital was terminated on December 21, 1996, for its failure to maintain required staffing in nursing, dietary, and medical records. On January 2, 1997, the provider alleged that he hired the necessary staff and requested readmission. Upon review, the RO finds that the provider is located in a remote, under-served rural area and has been unable to maintain staff since participation began in 1989.

Reasonable Assurance - The RO establishes 90 days from January 2, 1997, as reasonable on the grounds that the location of the provider has militated against staff retention, and that 3 months of continued compliance would evidence the provider's ability to retain qualified health professionals.

EXAMPLE C:

The XYZ Home Health Agency was terminated on September 15, 1997. On the four prior surveys the agency had been cited for failure to meet several of the CoPs, but had, until the most recent survey, achieved compliance before termination action was completed. On October 1, 1997, the agency alleged compliance.

Reasonable Assurance - The RO establishes a 120-day reasonable assurance period based on the provider's repeated failure to meet the CoPs necessary to ensure the health and safety of patients.

EXAMPLE D:

The Visiting Nurses, Inc., was readmitted following a 60-day reasonable assurance period. On the next survey, The Visiting Nurses, Inc., is found not to meet one or more CoPs and is again terminated. The provider corrects the deficiencies and requests readmission.

Reasonable Assurance - The RO establishes a 120-day waiting period based on prior termination and failure to maintain compliance following a 2-month reasonable assurance period.

EXAMPLE E

Pleasant Plains ICF/IID was terminated by CMS on January 10, 1996. The provider was terminated for deficiencies that posed a threat to client health or safety. The provider corrected its deficiencies and requested readmission on February 1, 1996. The SA surveyed the facility on February 10, 1996, and determined that the deficiencies that were the reason for the termination had been corrected and certified compliance. The documentation was forwarded to the RO on February 21, 1996. While reviewing all available documentation, the RO finds that the provider has a history of serious deficiencies. Moreover, the deficiencies that led to termination have been cited repeatedly.

Reasonable Assurance - The RO establishes a 180-day waiting period based on the provider's history of serious deficiencies and disregard for the health and safety of patients.

2016D - Reasonable Assurance Surveys

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

Upon receipt of the initial application packet from the SA, the RO will provide the SA with instructions concerning how to conduct the necessary reasonable assurance surveys. **Two surveys are required** to verify that the reason for termination no longer exists, and that the provider/supplier has maintained continued compliance. The first survey is a partial survey conducted at the beginning of the reasonable assurance period to document compliance with requirements for which there were previous deficiencies. The second is a full/standard survey at the end of the reasonable assurance period to document compliance with program requirements. (CMS, at its discretion, conducts the survey for a Medicaid ICF/IID it originally surveyed and terminated pursuant to §1910(b)(1) of the Act.)

The reasonable assurance period of time begins on the date of completion of the first survey (partial) documenting compliance with requirements for which there were prior deficiencies.

NOTE: The RO may authorize the SA to deviate from the requirement that **only the second** survey be a full/standard survey (i.e., two full surveys or one full/standard survey and then one partial survey). **However, at least one of the two surveys must be a full initial survey in order to ensure that all CoPs are met or the SNF is in substantial compliance.** (See §§7203.B and 7300.C.)

The SA conducts the first of the reasonable assurance surveys as instructed by the RO and submits the results of the survey (this may be submitted on Form CMS-2567) to the RO within 10 working days of the survey. Based on the results of this first survey, the

RO determines if the reasons for termination no longer exist, or for SNFs, the deficiencies that caused their termination are at the level of substantial compliance. The RO notifies the SA and the provider/supplier of its determination. If the RO determines that the reasons for termination no longer exist, or for SNFs that the deficiencies that caused the termination are at the level of substantial compliance, the reasonable assurance period begins effective with the last day of this first survey. If not, the provider must reapply.

Once the RO determines that the reasonable assurance period has begun, the SA will schedule a second survey to coincide with the end of the reasonable assurance period.

The SA informs the RO of the scheduled survey date. The SA conducts the survey, completes the Survey Report (as applicable), and prepares a statement to accompany Form CMS-1539 that includes:

- The finding that the deficiencies which led to termination of the provider agreement have (or have not) been corrected;
- The evidence showing that compliance has been maintained, and the reasons for concluding that the deficiencies will not recur; and
- A description of any other deficiencies and, if appropriate, an explanation as to why the facility is nevertheless in compliance with all CoPs or the SNF is in substantial compliance (see §§7203.B and 7300.C).

If the RO determines after the second survey that the reasons for termination continues to exist and/or determines that the provider/supplier does not meet the CoPs or the SNF is not in substantial compliance, the provider/supplier must again begin the reasonable assurance process to gain reentry into the program(s). (See §§7203.B and 7300.C for the exception for SNFs and NFs.)

If an involuntary terminated provider/supplier attempts to avoid the reasonable assurance provision at 42 CFR by seeking deemed status via accreditation, CMS may deny Medicare reentry. CMS may request a survey performed by the SA if it is not reasonably assured the provider/supplier meets the Medicare conditions.

In such cases, the RO will determine the **IF** (when it is reasonably assured that the reason for the termination will not occur), the **WHEN** (the reinstatement effective date) and the **HOW** (e.g., a survey by the SA) of the provider's return to Medicare. The RO will make an analysis of the facts in the case and issue a decision because receiving deemed status is a separate issue from reinstatement (Reasonable Assurance) following involuntary termination by CMS under 42 CFR 489.57.

The regulation at 42 CFR 489.57 does not apply to a provider's voluntary termination of its agreement under the provisions of the regulation at 42 CFR 489.52. In a scenario similar to the situation described above except that the provider's termination from

Medicare was voluntary, CMS (the RO) would still be responsible for the if, when and how of the provider agreement under 42 CFR 489.12. However, the provider's accreditation by a recognized accrediting body and subsequent deemed status would mean that compliance with the CoP would not be one of the unmet requirements under title XVIII of the Act that could be invoked under 42 CFR 489.12(a)(3). This is pointed out because some providers voluntarily withdraw from Medicare in the face of a proposed involuntary termination. A RO could decide to process an involuntary termination in such a case. In the absence of having processed an involuntary termination, the RO could apply 42 CFR 488.6(c)(2) in concert with 42 CFR 489.12(a)(3) in a case where a provider facing involuntary termination voluntarily withdrew from Medicare and subsequently attempted to re-enter the program through an accreditation program.

The regulation at 42 CFR 489.57 also does not apply to a provider's initial application for Medicare participation. Again, as with a voluntary termination, the CMS (RO) is responsible for the if, when and how of the provider agreement and a decision to deny the provider an agreement must be in accordance with 42 CFR 489.12. Also, if an accrediting organization has determined that the provider is accredited, the provider is deemed to meet the Medicare conditions and we would have satisfactory assurance of compliance with the conditions under 42 CFR 489.12(a)(3). However, as with a voluntary termination, we might look at 42 CFR 488.6(c)(2) in tandem with 42 CFR 489.12(a)(3) in an individual case. This means that we should notify accrediting bodies if and when we deny a provider entry into Medicare based on a State survey agency survey. This includes providers that are surveyed by the State but do not respond to a Statement of Deficiencies.

2016F - Readmission of ICF/IID After Termination (Rev. 91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

Before the SMA readmits an ICF/*IID* to the Medicaid program after termination by CMS pursuant to §1910(b)(1) of the Act, the RO must determine that the facility has provided the SA reasonable assurance that the deficiencies that were the cause for termination will not recur. The RO will determine the reasonable assurance period, and the RO, or the SA, at the RO's request, will monitor the facility to determine that it remains in compliance for the period of time designated by the RO as the reasonable assurance period. The SA or the RO will monitor the facility by conducting the necessary survey and revisits.

The reasonable assurance period must be satisfied before the SMA issues an agreement to that facility and before that facility can qualify for FFP. Failure to provide reasonable assurance is a basis for CMS to continue to disallow FFP for services furnished by that facility. (See 42 CFR Part 442.30 and 431.610(f)(1).)

2089 – Survey Requirements When the Hospice Provides Care to Residents of a SNF/NF or ICF/IID

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

When a SNF or NF is the hospice patient's residence for purposes of the hospice benefit, the SNF or NF must comply with the requirements for participation in Medicare or Medicaid. The Medicare/Medicaid regulations for long term care facilities regarding the completion and submission of the Resident Assessment Instrument/Minimum Data Set (RAI/MDS) data do not change when the resident elects the Medicare Hospice Benefit. This means the SNF or NF must assess the hospice resident using the RAI, and have a care plan and provide the services required under the plan of care. This can be achieved through cooperation between the hospice and facility staff with the consent of the resident. In these situations, the hospice IDG should participate with the facility in completing the RAI.

Similarly, the SNF/NF must complete the RAI for any hospice patient who receives short term inpatient care in a Medicare/Medicaid participating SNF/NF if the hospice patient resides in the facility for more than 14 days. For further information on the hospice requirements when it provides care in these settings, see 42 CFR 418.112.

Intermediate Care Facilities

2130 - ICFs/IID - Citations and Description

(Rev. 91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

2130A - Citations

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

An ICF/*IID* is defined in §1905(d) of the Act. The ICF/*IID* CoPs appear in 42 CFR Part 483 Subpart I. Regulatory requirements for ICF/*IID* services which appear in 42 CFR 435, Subpart K (Federal Financial Participation) and Part 440 Subpart A (Definitions), augment the CoPs listed in 42 CFR Part 483.

2130B - Definitions

(Rev. 91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

An ICF/*IID* is an institution that meets Federal CoPs and has as its primary purpose the provision of health or rehabilitation services to individuals with *intellectual disabilities* or related conditions receiving care and services under the Medicaid program.

The ICF/*IID* CoPs recognize the developmental, social, and behavioral needs of individuals with *intellectual disabilities* who live in residential settings by requiring that each individual both require and receive active treatment for the ICF/*IID* care to be eligible for Medicaid funding.

Active treatment means the aggressive, consistent implementation of a program of specialized and generic training, treatment, health, and related services directed toward the acquisition of the behaviors necessary for the individual to function with as much self-determination and independence as possible. It includes the prevention or deceleration of regression or loss of current optimal functional status.

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

- 1. The source of the injury was not witnessed by any person <u>and</u> the source of the injury could not be explained by the client; <u>and</u>
- 2. The injury raises <u>suspicions</u> of possible abuse or neglect because of the extent of the injury <u>or</u> the location of the injury (e.g., the injury is located in an area not generally vulnerable to trauma) <u>or</u> the number of injuries observed at one particular point in time <u>or</u> the incidence of injuries over time.

The definition of "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.

Section 42 CFR § 483.420(d)(2) of the ICFs/IID 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.

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

- 1. The source of the injury was not witnessed by any person <u>and</u> the source of the injury could not be explained by the client; <u>and</u>
- 2. The injury raises <u>suspicions</u> of possible abuse or neglect because of the extent of the injury <u>or</u> the location of the injury (e.g., the injury is located in an area not generally vulnerable to trauma) <u>or</u> the number of injuries observed at one particular point in time <u>or</u> the incidence of injuries over time.

It is important to note that members of the ICF/IID 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.

2134 - Distinct Part ICF/IID

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

Neither the law nor Federal regulations define or require ICF/IID services in terms of distinct parts. However, as a State Medicaid program requirement, States may provide for distinct part ICF/IID approvals. Where the SMA elects to define the ICF/IID program in terms of distinct parts, these additional Federal provisions must be met:

- The distinct part must be a clearly identified unit, such as an entire ward, wing, floor, building, or a number of designated rooms;
- The distinct part consists of all beds and related facilities in the unit; and
- The institution does not need require transfer of patients or individuals to or from the distinct part, where, in the opinion of the attending physician, transfer might be harmful to the physical or mental health of the patient or individual. Otherwise, the unit houses all ICF/IID residents in the institution.

2138 - Approval Procedures for ICFs/IID

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

2138A - Initial Certification of ICF/IID

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

Initial certification of ICFs/IID may be granted by the SA only as a result of a complete survey which has found the agency to comply with all of the CoPs specified in 42 CFR 483, Subpart I. A facility must be operational prior to scheduling an initial survey.

Even though a facility may be part of a larger corporation, the fact that it is separately certified means that it is an independent institution and must be capable of providing all of the services necessary to meet the client's needs. Therefore, the survey of each separately certified ICF/IID must ensure that any evidence used in the determination of compliance for the requirements stands on its own.

A facility may request that the SA review relevant aspects of its existing immediate track record as part of the initial survey process if the following is true. A facility must have been fully operational as a licensed group home or a distinct part that was never certified

because of physical plant limitations yet it provided treatment comparable to that required by a certified ICF/IID. For example, if the entity claims that it has provided active treatment to the same clients who will be certified, with the same staff, and consistent with the components of active treatment described in the Federal regulations, then an initial survey may be scheduled immediately. To the extent that a survey determines that the agency's current and immediate past practices comply with the ICF/IID requirements, the SA surveyor may utilize this information in making a compliance determination, as part of the survey, **but not as a substitution for the survey.**

There is no specific number of days that an ICF/IID must be operational prior to its initial survey, but in most cases approximately 30-35 days (except as described above) would be a general safety measure. This timeframe, however, is only a recommendation since 42 CFR Part 483.440(c)(4) only requires that the client's initial individual program plan (IPP) must be developed within 30 days after admission. 42 CFR Part 483.440(d)(1) requires that as soon as the IPP is developed, each client receives a continuous active treatment program. Therefore, should the facility wish to have its initial survey prior to being operational for 30-35 days, it should identify the date by which it will be able to demonstrate its compliance with 42 CFR Part 483.440(a) for each of its clients.

Additionally, for an initial survey, a facility may not demonstrate its "compliance" with active treatment based primarily on its policies and procedures. Policies and procedures are designed to describe how a facility **intends** to provide active treatment. This is inconsistent with §1905(d)(2) of the Act, which requires that each individual with *intellectual disabilities* for whom a request for payment is made is receiving active treatment.

For purposes of the initial survey of an agency in which clients have just moved to the agency, the following key components of the active treatment process that are most relevant to the survey methodology for the CoP, Active Treatment Services (data tag W 195; Appendix J) are:

- The comprehensive functional assessment (42 CFR Part 483.440(c)(3));
- The IPP (42 CFR Part 483.440(c)(4));
- Program implementation (42 CFR Part 483.440(d)); and
- Program documentation (42 CFR Part 483.440(e)).

It would not be necessary to measure the component of active treatment dealing with program monitoring and change (42 CFR Part 483.440(f)) unless it is determined through the survey that the initial program clearly does not meet the client's needs and there is no evidence of appropriate oversight and attention.

2138B - Multiple Certification of Dispersed Locations

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

When surveying ICFs/*IID* with more than one unit at dispersed locations, either for an initial certification or recertification, the SA surveys each unit. Even if a group of small ICFs/*IID* is centrally administered, the SA prepares a certification package for each unit.

2138C - Minimum Size of ICF/IID

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

An ICF/IID is defined as a facility that furnishes food, shelter, treatment, or services to 4 or more individuals unrelated to the proprietor. ICFs/IID vary in size from very large multi-unit, multi-level facilities with sophisticated programs to very small, home-like settings with required services provided through an arrangement with community organizations. "Satellite" facilities off the main grounds of an institution are certified as separate ICFs/IID. Each must meet the 4-individual minimum.

Not withstanding common ownership or unified administration, a "cluster" of separate facilities in the community cannot be considered as one establishment meeting the definition of "institution." Separate cluster facilities in the community must be viewed as separate establishments. Each must meet the 4-individual minimum to qualify as an "institution."

An individual living unit that is part of an overall ICF/IID may be separately certified under its own provider number if the living unit meets the criteria for a **freestanding** ICF/IID. Each separately certified facility, at any point in time, must be able to **independently** meet all standards and CoPs. This includes, among other things, maintaining independent staffing and management. Any services which are not provided directly by the separately certified facility would have to be provided through a written agreement with outside sources as required by 42 CFR Part 483.410(d).

It is unlikely that, for example, a facility with several units housed within one building sharing common corridors and utilizing a common kitchen/dining area could meet the requirements for maintaining independent staffing and management to meet the criteria for a freestanding ICF/IID.

There is no minimum number of individuals who must be in residence at the time of the initial survey. The facility must have enough individuals in residence to demonstrate that it is able to, and does in fact, provide services to the total number of individuals it proposes to serve. For example, a facility established to serve 4 individuals would need to show capacity to serve 4 people, even though not all 4 people would be required to have actually moved in at the time of the initial survey. (42 CFR Part 435.1009(b)(2) requires that a facility serve a minimum of 4 persons in order to meet the definition of an institution.)

2138D - Interpretive Guidelines for ICFs/IID

(Rev. 91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

Guidelines for surveying ICFs/IID are located in Appendix J. They provide an interpretation of the ICF/IID regulations that are applicable to all sizes of facilities that provide services. They focus on individual and staff performance rather than on compliance with process and paper requirements and reflect current philosophies and practices in training individuals with intellectual disabilities and related conditions.

2138E - Survey Report (Form CMS-3070G-I)

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

To survey ICFs/IID, the SA must use the Interpretive Guidelines and Survey Procedures (see Appendix J) in conjunction with Forms CMS-3070G-I. The forms and optional work sheet permit the SA to summarize pertinent facility, individual, and survey data, record observations about active treatment provided for individuals by staff, and summarize deficiency-related data on the standards and CoPs.

In an effort to monitor the number of allegations of abuse and neglect investigated and the number of deaths related to restraints and unusual incidents, CMS revised Form CMS-3070G, the ICF/*IID* survey report form, to now include an item "M" - Allegations of Abuse and Neglect, to capture this information. All surveys, including initials, recertifications, complaints, and follow-ups, occurring after January 2, 2002, must be entered into the Online Survey and Certification System (OSCAR).

2138F - Application of LSC to ICFs/IID of 16 Beds or Less (Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

When conducting a LSC survey, the SA applies the appropriate occupancy chapter (see <u>Appendix I</u>) of the LSC of the National Fire Protection Association (NFPA), 2000 edition.

2138G - Schedule for Recertification

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

The SA completes a recertification survey an average of every 12 months and at least once every 15 months (see §2141).

2139 - Assessment of ICFs/IID Based on CoPs for Active Treatment (Rev. 91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

To be certified as a Medicaid provider of ICF/*IID* services, a facility is required by §1905(d) of the Act to provide active treatment services for each individual for whom payment is claimed. Federal regulations in 42 CFR Part 435.1009 and 483, Subpart I outline the requirements for active treatment in ICFs/*IID*. While a facility must comply with the CoPs to be certified, the SA must place particular emphasis on an assessment of

whether active treatment **is in fact received by** individuals for whom payment is claimed. Appendix J contains a basic methodology for surveying these requirements.

The definition of "active treatment" in intermediate care facilities for *individuals with intellectual disabilities* in 42 CFR Part 435.1009 refers to treatment that meets the requirements specified in the CoPs for active treatment in 42 CFR Part 483.440(a). The components of the active treatment process most relevant to this survey methodology are:

2139A - Comprehensive Functional Assessment

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

Within 30 days of admission, the individual's interdisciplinary team must produce accurate comprehensive functional assessment data that identifies all her/his present problems and disabilities. Also, when possible, their causes; specific developmental strengths and needs; behavioral management needs; and the need for services without regard to the availability of those services.

1.Money Management Program

- Citing Deficiencies: Surveyors currently cite a deficiency during the ICF/IID 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/IID 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/IID client is based upon the results of a comprehensive functional assessment and a consensus by the interdisciplinary team.

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

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.

2.Self-Administration of Medications

It has been the expectation of ICF/IID surveyors pursuant to previous Centers for Medicare & Medicaid Services interpretations of §483.460(k)(4), that every client

residing in an ICF/IID 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.

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/IID 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).

2139E - Program Monitoring and Review

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

At least annually, the comprehensive functional assessment of each individual is reviewed by the interdisciplinary team for relevancy and updated as needed. The IPP is revised, as appropriate. The IPP must also be reviewed by a qualified *intellectual disabilities* professional and revised as necessary.

Approximately one-third of the ICF/IID CoPs (42 CFR Part 483, Subpart I) deals with the sufficiency and adequacy of staff to deliver each service. The regulations provide guidance about what constitutes active treatment and enable the SA to assess these standards from the standpoint of whether active treatment is being provided in a consistent and aggressive manner. SA entries on both Form CMS-3070G-I and Form CMS-2567 should reflect this approach.

Of greatest importance in determining if active treatment is being provided is whether the facility provides competently trained staff of all types and at all levels who, in fact, do implement individually identified objectives established for each individual. A correct certification addresses these objectives in terms of whether the services **are** being delivered to each individual whose IPP indicates that they are needed and whether adequate staff and facilities are engaged in furnishing them. A certification which affirms no more than that the services, staff, and facilities are **available** is incorrect and unacceptable. A provider agreement may be held invalid under <u>42 CFR Part 483.440(a)</u> of the CoPs if the regulation is not correctly applied.

If a facility has the necessary resources available but does not actually provide active treatment to individuals in accordance with identified needs or does not conduct the comprehensive functional assessment evaluations to identify individuals' needs, the SA denial, nonrenewal, cancellation, or termination of the agreement is supportable. The SA carefully explains the deficiency in the SA notice of determination.

2140 - Waiver and/or Variance of ICF/IID Requirements

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

2140A - ICF/IID Room Size and Occupancy

(Rev. 91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

No waivers are available to an ICF/*IID* to change the square footage requirements for bedrooms. <u>42 CFR Part 483.470(b)</u> allows as little as 80 square feet for individual bedrooms and 60 square feet for multiple individual bedrooms.

However, the SA may grant a variance to the requirement in 42 CFR Part 483.470(b)(iii) of no more than four individuals per room if a physician who meets the qualifications for a qualified *intellectual disabilities* professional in 42 CFR Part 483.430(a) and is also a member of the individual's interdisciplinary team has justified, in writing, in each IPP, the following:

- How the individual is so medically impaired as to require direct and continuous monitoring during sleeping hours;
- Whether the individual is on a medical care plan, as described in 42 CFR Part 483.460(a)(2);
- The extent of life support services needed to meet the individual's medical needs; and
- The specific reason why housing the individual in a room of four or fewer individuals would not meet the individual's medical needs.

The variance must not adversely affect the health or safety of the individual. The variance must assure that the minimum square footage requirements specified in 42 CFR Part 483.470(b) have been met. The variance expires unless renewed each time the ICF/IID is certified. It is not meant to justify the long-term continued use of open wards or nominally partitioned wards for housing individuals.

The only acceptable reason for individuals being housed in bedrooms serving more than 4 individuals is that the individual is in very fragile health and needs extensive life support services, such as posturing for clearing the airway, monitoring for uncontrolled seizures, etc. Each individual placed in the grouping must have such a high level of medical monitoring need as to require supervision which is possible **only through** the use of bedrooms housing more than four individuals.

2141 - Recertification - ICFs/IID (Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

• The regulation at §442.15 provides that provider agreements for ICF/IID's would remain in effect as long as the facility remains in compliance with the Conditions Of Participation (COP's). Regulations at §442.109 through §442.111.

- Beginning on May 16, 2012, ICF/IID's are no longer subject to time-limited agreements. However, they are to be surveyed for re-certification an average of every 12 months and at least once every 15 months.
- If during a survey the survey agency finds a facility does not meet the standards for participation the facility may remain certified if the survey agency makes two determinations The facility may maintain its certification if the survey agency finds Immediate Jeopardy doesn't exist, and if the facility provides an acceptable plan of correction.
- An ICF/IID may be decertified under procedures outlined in Section 3012 of the State Operations Manual. More specifically, a facility may be decertified if an immediate jeopardy finding remains unabated after 23 days or if it fails to regain compliance with conditions of participation after 90 days.

ICF/IID's will be subject to survey an average of every 12 months and at least every 15 months, the same period that is applied to Nursing Homes.

If a survey agency finds a facility deficient in meeting the standards for ICFs/IID, as specified under subpart I of part 483 of chapter 42, the agency may continue certification of the facility for Medicaid purposes as long as the agency finds the facility's deficiencies do not constitute immediate jeopardy or seriously limit the facility's capacity to provide adequate care. In addition, the agency must find the facility's plan of correction is acceptable.

The survey agency may conduct a revisit to assure the conditions for continued certification are maintained. A facility's certification may be terminated according to procedures set out in Section 3012 of the State Operations Manual.

2142 – Evacuation Drills for ICFs/IID Certified Under the Life Safety Code NFPA 101, 2000 Edition

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

- Self-evacuation during an emergency. Clients residing in ICFs/IID 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 to evacuation drills.

ICF/IID 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/IID 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/IID 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.

The requirements of full evacuation during a drill 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/IID facilities on a quarterly basis on each shift. 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.

2143 - The Use of Video Cameras in Common Areas in ICF/IID (Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

- Use of video cameras in ICFs/IID: To ensure that client's rights are protected, the use of video cameras in the ICF/IID 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/IID 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.

The Condition of Participation §483.420 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).

The above referenced regulations do not unilaterally prohibit the use of video cameras within the ICF/IID. 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/IID 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/IID 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.

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/IID 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/IID 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/IID 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.

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

2470B - Citations for Application to Provider Facilities

(Rev. 91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

The LSC is applied to hospitals under authority of §1861(e)(9) of the Act and by 42 CFR 482.41(b). SNFs and NFs must meet 42 CFR 483.70(a) that implements §\$1819(d) and 1919(d) of the Act. The LSC is applied to ICFs/IID under the authority of \$1905(d) of the Act and 42 CFR 483.470(j). It is applied to hospices furnishing inpatient care pursuant to 42 CFR 418.100(d) and to (ASCs) under 42 CFR 416.44(b). It is applied to Religious Nonmedical Health Care Institutions (RNHCI) under 42 CFR 403.744 and to Programs of All-Inclusive Care for the Elderly (PACE) under 42 CFR 460.72. (See Appendix I for interpretive guidelines.)

2470D - Special Application in ICFs/IID

(Rev. 91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

All ICFs/IID must meet the 2000 edition of the LSC.

2470E - Substitution of State Fire Code for the Life Safety Code (LSC) (Rev. 91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

The LSC is not applicable where CMS finds that a State has in effect a fire and safety code imposed by State law that adequately protects patients in health care facilities, except for small ICFs/*IID* surveyed under the Residential Board and Care Chapters (Chapters 32 and 33). (See §1863 of the Act.)

The State submits a request that State codes be utilized in lieu of the LSC to the CMS/RO. That office will forward the request to central office (CO) for a determination. Include a copy of the enabling legislation so that the CO can determine whether the applicable State law adequately protects patients in healthcare facilities.

Upon notification by CO, the RO advises the State authority that submitted the request whether the State code is acceptable in lieu of the LSC. State codes cannot be submitted for ICFs/IID since CMS has no authority to accept them in lieu of the LSC.

2472A - Authority to Grant Waivers for LSC Surveys (Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

The LSC provides that the authority having jurisdiction shall determine the adequacy of protection provided for life safety from fire in accordance with the provisions of the LSC. In cases of unreasonable hardship, 42 CFR 483.70(a)(2) specifies that a waiver may be granted where it would not adversely affect resident health and safety.

The Secretary has delegated to CMS the authority to grant waivers of LSC provisions for all facilities participating in Medicare and Medicaid with the exception of ICFs/IID. The State LSC surveyor recommends waivers, but CMS ROs grant the waivers. Therefore, LSC requests the SA receive from all providers except ICF/IIDs must be forwarded to the RO for adjudication. For ICFs/IID, the State has the authority to grant waivers of health care occupancy requirements. There is no authority for either the State or the RO to grant waivers of Board and Care Occupancy provisions.

2472B - Subagreements With State Fire Authorities (Rev. 91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

To assess facilities' compliance with the LSC and other Medicare and Medicaid fire safety requirements, the SA may enter into a subagreement or a contract with the State fire Marshal's office or other State agency responsible for enforcing State fire code requirements. Under this agreement, the designated State fire authority generally agrees to:

- Survey all non-accredited hospitals, hospices, ASCs, SNFs, NFs, CAHs, RNHCIs, PACE Facilities and ICFs/*IID* in accordance with schedules you furnished;
- Survey accredited hospitals selected for validation surveys or surveyed as a result of a substantial allegation of an unsafe conditions;
- Complete the appropriate Fire Safety Survey Report (Form CMS-2786);
- Prepare statements of deficiencies and review PoCs (Form CMS-2567);
- Make recommendations to you regarding facilities' compliance with program fire safety requirements; and
- Use only qualified fire safety inspectors in the performance of these surveys.

2472E - Involvement of SA Surveyors in LSC Surveys (Rev. 91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

A full-scale LSC survey need not be performed every year if building characteristics have not changed. As long as the fire authority surveys every third year and the institution remains in compliance, the SA surveyors can complete a Fire Safety Survey Report - Short Form (CMS-2786S) as part of the recertification survey in the intervening years. (See §2476.)

In surveys of ICFs/IID, fire authorities decide, in accordance with guidelines in <u>Appendix I</u>, which chapters of the LSC pertain in each instance and survey accordingly. However, the fire authority is not professionally trained to observe resident behavior and relies on information furnished by staff members to rate the level of mobility and self-preservation of residents. Consequently, when the SA surveys an ICF/IID, it takes a copy of the Worksheet for Rating Residents (F-1, Side 2, Form CMS-2786M) for each resident that

the fire authority completed, and takes a blank copy of the same worksheet. Complete Items I through VI of the Worksheet to corroborate the information used by the fire authority. The SA reconciles any discrepancies with the fire authority before certifying the facility.

Fire authorities are also advised in <u>Appendix I</u> to alert the SA to situations involving institutions not in compliance which present immediate jeopardy to residents so that the SA can initiate timely termination development without waiting for the written documentation of the LSC survey.

2474 - Fire Safety Survey Report Forms (Form CMS-2786 Series) (Rev. 91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

The Form CMS-2786 series contains the forms to be used for determining compliance with the LSC. There are currently 13 in this series:

- 1. Form CMS-2786M, Fire Safety Survey Rating Residents; 2000Code.
- 2. Form CMS-2786R, Fire Safety Survey Report 2000 Code-Health Care Medicare/Medicaid.
- 3. Form CMS-2786S, Fire Safety Survey Report Short Form; 2000 Code.

Form CMS-2786T, Fire/Smoke Zone Evaluation Worksheet For Health Facilities; 2000 Code.

Form CMS-2786U, Fire Safety Survey Report Ambulatory Surgical Centers; 2000 Code.

Form CMS-2786V, Fire Safety Survey Report ICF/*IID* -Small Facilities; 2000Code.

Form CMS-2786W, Fire Safety Survey Report ICF/*IID*-Large Facilities; 2000 Code.

Form CMS-2786X, Fire Safety Survey Report ICF/IID Apartment House; 2000 Code.

4. Form CMS-2786Y, Fire Safety Survey Report ICF/*IID*- Small FSES; 2000 Code.

They each contain four parts:

- I. LSC requirements New and Existing;
- II. Other Federal requirements; and
- III. Waiver recommendation form.

2476C - When NOT to Use Short Form

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

Instead of the SA using the short form in the following situations, the SA should have the State fire authority perform the survey using the **regular** Fire Safety Survey Report (Form CMS-2786R*):

- Initial survey;
- Survey of facilities with any construction or renovation since their last survey (facilities must report any construction or renovation to you);
- Facilities with uncompleted PoCs (including facilities with waivers to complete construction activities;
- ICFs/IID;
- ASCs;
- Surveys preceded by two successive certification surveys in which the Short Form was used; or
- When conducting the first LSC survey under the 2000 Edition of the LSC.

2476F - Waivers

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

Items that have been waived in the past **can continue to be waived** even if a Short Form is used. If the health surveyor marks an item not met and the provider requests a waiver, the SA should have the waiver reviewed by the fire authority. The fire authority must decide whether to recommend waivers in the case of SNFs, NFs, or ICFs/*IID*, however, CMS must grant the waiver, not the State. There are no waivers for ICFs/*IID* under the Board and Care provisions. In no case is the health surveyor to recommend, grant, or review a waiver.

2700B - SA Schedule for Conducting Health and Safety Resurveys (Rev. 91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

The SA resurveys and recertifies providers/suppliers on a cyclical basis in accordance with the survey coverage levels specified in the budget call letter. Surveys of SNFs, NFs, and HHAs must be on a flexible cycle in order to reduce the "predictability" of the survey. (See §2008.D.) SNFs and NFs must be subject to a standard survey no later than 15 months after the previous survey and HHAs must be subject to a standard survey within a 36-month interval. The SA surveys ICFs/IID no later than 15 months after the previous survey so that a timely certification can be ensured. The SA should consider geographical considerations and the scheduling of licensure visits so that coordinated visits can be made whenever possible. Change of Ownership (CHOWs) or other changes

that may affect a provider's/supplier's compliance status may necessitate adjustment of the SA survey interval. (See §2702.)

2706 - SA Survey Team Composition

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

Survey team size and composition vary according to the type of provider/supplier and the purpose of the survey. For routine SA certification surveys, professional disciplines and experience represented by the survey team is to reflect the expertise needed to determine compliance with the CoPs, standards, or requirements for that provider/supplier group. Also, the SA should consider the history or special characteristics of the provider/supplier in selecting members of the survey team. In all instances, members of the survey team must meet education and training qualifications specified in §4009.

In general, the size and type of the provider/supplier govern the size of teams. ICF/*IID* survey teams are to include personnel with expertise in developmental disabilities, and, except for LSC, all members are to survey together during the same time intervals. (See <u>§7201</u> for SNF/NF.)

2712 - Use of Survey Protocol in the Survey Process

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

Survey protocols are established to provide surveyors with guidance in conducting surveys to assess the compliance of providers and suppliers participating in the Medicare and Medicaid programs with certain regulatory requirements. Survey protocols appear in the various appendices to this manual. The purpose of the protocols is to provide instructions, check lists, and other tools for use both in preparation for the survey and when performing the survey. Survey protocols are to be used by all surveyors to measure compliance with Federal requirements. They are the authorized interpretations of mandatory requirements set forth in provisions of the Act, the Public Health Service Act (for laboratories), and the regulations.

Survey protocols identify relevant areas and issues to be surveyed as specified in each regulation, and, in some cases, the methods to be used to survey those areas and issues. These protocols promote consistency in the survey process. They also assure that a facility's compliance with the regulations is reviewed in a thorough, efficient, and consistent manner. At the completion of the survey, the SA should have sufficient information to make compliance decisions.

Included in the survey protocols are interpretive guidelines that serve to interpret and clarify the CoPs, conditions for coverage, and requirements of participation for specific types of entities. The interpretive guidelines contain authoritative interpretations and clarifications of statutory and regulatory requirements and are to be used to make determinations about a provider's compliance with requirements. These interpretive guidelines define or explain the relevant statutes and regulations and do not impose any requirements that are not otherwise set forth in the statute or regulations.

The SA conducts the surveys in accordance with the appropriate protocols, and looks to the substantive requirements in the statute and regulations to determine whether a citation of noncompliance is appropriate. The SA bases any deficiency on a violation of the statute or the regulations. The decision of whether there is a violation of the statute or the regulations must be based upon observations of the facility's performance, practices, or conditions in the facility.

Where the surveyor sees conditions or practices that are in conflict with a particular interpretive guideline, these observations are indications that the applicable provisions of the statute or regulation are not met. To make a determination whether the requirement is met, the SA should evaluate the observation in terms of frequency and/or severity of the condition or practice.

Moreover, the SA may find that a facility's deficiencies in meeting statutory or regulatory requirements may be based on observations other than those mentioned in the guidelines because the guidelines cannot provide an exhaustive, all-inclusive listing of all circumstances which might indicate violations of the requirements.

The following is an example of how an interpretive guideline may be used to support a deficiency citation:

EXAMPLE

- **Requirement**: The comprehensive functional assessment of the client must identify his/her specific developmental and behavioral management needs.
- Interpretive Guideline: Findings are reported in terms that facilitate clear communication. Diagnoses or imprecise terms and phrases (including, but not limited to, "developmental level,") in the absence of specific terms are not acceptable.
- Statement of deficiency: 42 CFR 483.440(c)(3)(iii): The comprehensive functional assessment must identify the client's specific developmental and behavioral management needs.

This Standard was NOT MET as evidenced by the following:

• For 2 of the 4 clients reviewed (clients #2 and 3), it was determined by record review and staff interview that the facility's functional assessment process required staff merely to identify the clients' diagnoses or overall level of functioning without identifying the clients' specific developmental needs.

The findings include:

• The record of client #3 included 11 evaluations conducted by the professional staff. None of these evaluations specified any skill deficits that may have contributed to the diagnosis of his reported developmental level of functioning.

This example illustrates how material in the ICF/*IID* interpretive guidelines can be used to support the citation. The critical factor is whether the evidence relates directly to the language of the regulation.

2714.1 - Application of Medicare/Medicaid Requirements to Private Pay Patients

(Rev. 91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

The CoPs/Requirements apply to the entire certified provider/supplier and to all patients/residents being served by the certified entity, regardless of payment source unless stated otherwise in the regulations. This means that the surveyors may review the care of private pay patients/residents when surveying a Medicare/Medicaid approved provider or supplier. This policy is based on the premise that it is the provider or supplier that is being approved, not just the beds of or care provided to Medicare/Medicaid beneficiaries.

Of course, this policy does not apply to patients/residents residing in non-certified portions of facilities (e.g., the non-certified portions of SNFs which have only a portion of their beds Medicare-certified as a distinct part SNF; or the non-certified buildings on the campus of large institutions such as psychiatric hospitals or ICFs/IID). (See §§2048 and 7016.)

In some cases it may not be immediately clear whether a division of the certified provider/supplier is covered by the certification. For example, an HHA may have a separate division in the organization that provides personal care attendant or homemaker services or that provides services to private pay patients. Unless the agency can demonstrate that the separate division is operated as a separate entity, the CoPs apply to all **home health services** provided by the entire HHA. If the SA cannot make a clear determination, it should consult the RO.

Also, certain provisions of the CoPs/Requirements specifically address patients of certain payment sources. For example, the CoPs for providers of OPT/OSP services contain certain requirements that apply **only** to Medicare patients. (See 42 CFR 486.155(b)(4).) SNF/NF requirements in 42 CFR 483.12(d)(3)(i) state, "A nursing facility may charge a resident who is eligible for Medicaid..." However, when the CoPs/Requirements refer to patients, residents, clients, or individuals in general terms and do not specifically limit the requirement to Medicare or Medicaid, those regulations apply to all persons served by the certified provider/supplier.

2716 - Special Survey of Pharmaceutical Service Requirements in SNFs, NFs, and ICFs/IID

(Rev. 91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

Appendix N describes the procedure(s) that must be applied when surveying a SNF/NF or ICF/IID for errors in medication dosage, administration, and recording. When detecting irregularities in pharmaceutical record keeping, the surveyor should begin a

probe into the matter immediately to determine if the errors go beyond record keeping to a more extensive problem of medication preparation and administration. Surveyors should begin a deeper probe of the flagged area. Also refer to the interpretive guidelines for ICFs/IID. (See Appendix J.)

2720A - Traditional SRF

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

The Medicare/Medicaid SRF is usually a booklet that serves as a "check list" during the onsite survey to determine if the provider or supplier meets the applicable CoPs or Conditions for Coverage. These SRFs contain all of the regulations that apply to a given provider/supplier. During the survey, the provider/supplier's conformance with every regulation in the booklet is evaluated.

The SRF is still utilized in conducting surveys of most providers/suppliers, including hospices, ASCs, ESRDs, CORFs, OPTs, RHCs, and others. The various editions of the LSC are also in the SRF format. However, the traditional SRF is no longer in use on health surveys of SNF/NFs, ICFs/IID, and HHAs. (See §2720.C. and D.) The SRF for hospitals and swing-bed requirements (both CAH and hospital) are optional note-taking tools that are used at the SA or individual surveyor's discretion. It is expected that other traditional SRFs will be phased out as survey protocols for other providers and suppliers are developed.

While the SRF is still in use for most provider types, use of the Automated Survey Processing Environment (ASPEN) obviates the need for recording deficiencies on the SRF when entering findings into ASPEN through the use of laptop computers. ASPEN automatically generates an official Statement of Deficiencies and Plan of Correction (Form CMS-2567). However, the surveyor should continue to record any information on the SRF that is not being collected on Form CMS-2567. This is especially important on initial surveys and adverse actions. However, surveyors do not duplicate information that is on Form CMS-2567. Instead, surveyors cross-refer to Form CMS-2567 at the beginning of the SRF to indicate where any information that would be duplicative has been collected.

Surveyors should continue to use the SRF as a checklist during surveys of those providers for which the SRF is required. If using the SRF for notes, it constitutes pre-decisional material and, like the worksheets, is not releasable under the Freedom of Information Act. Surveyors must continue to complete the various worksheets provided for the survey. It is still important to maintain accurate notes of observations to support SA findings.

Where ASPEN is not used, surveyors should continue to complete the SRF in its entirety. Deficiencies and negative findings are to be explained via narrative or data under "Remarks." Surveyors must fully document cases where enforcement action (such as termination) may ensue to substantiate the proposed action in the event of a hearing or court review, and record the status of each item at the time of the survey in the "Yes-No" or "Met-Not Met" columns, if applicable. Surveyors should use all available sources of information that will assist them in completing the SRF. If a standard or other requirement is not applicable, and therefore the "Yes-No" column is not checked, the

surveyors must give an explanation. Surveyors document key areas requiring judgment by giving their reasoning, and carefully address all explanatory comments to the correct computer tag number.

2720C - Completing ICF/IID Survey Report (Rev. 91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

Form CMS-3070G-I (see Exhibit 80) is keyed to the CoPs for ICFs/IID in the Medicaid program. Surveyors use the form in conjunction with the interpretive guidelines and survey procedures for ICFs/IID (see Appendix J) to identify the regulatory requirements and corresponding tag numbers on which to assess compliance. The cover sheet (Form CMS-3070G) is the vehicle for direct data entry into OSCAR about pertinent facility, individual, and survey-related data. The first page of Form CMS-3070H, a prototype designed to be reproduced to as many pages as needed, is used to record and summarize deficiency-related data on the Standards and CoPs. The last page of Form CMS-3070H includes a certification statement for each member of the survey team to sign and date. This statement attests that each CoP-related Standard has been reviewed, and unless indicated on Form CMS-3070H, the facility is found to be in compliance. In accordance with instructions in Appendix J, surveyors complete the optional individual observation worksheet for use in conjunction with the survey.

2724D - Closure

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

When you have completed the exit conference, explain the process to the provider. Inform the provider that you will send a formal statement of deficiencies, unless your procedures call for Form CMS-2567 to be left with the provider following the exit conference. Explain the due date for submitting a PoC and how the rest of the certification process works. If you have identified an immediate and serious threat to patient health and safety, explain the significance of that finding and the need for immediate corrective action. In this or any other instance when adverse action is anticipated, explain the implications. Make it clear that only compliance will stop the adverse action.

In an initial survey, the surveyor tells the provider or supplier to expect notification of initial approval or denial of Medicare participation from the RO, and notification by the SMA concerning Medicaid participation, if appropriate. The surveyor explains that the RO establishes the effective date of participation and notifies the provider or supplier in writing and that Medicare payment will not be made before the effective date.

Notices of Medicare recertification from the RO are not necessarily sent unless there are changes in approved services or in sizes of distinct parts certified. Notices of reapproval of NFs and ICFs/IID are made according to State policy.

2728F - Major Deficiencies Requiring Long-Term Correction in Hospitals, SNFs, NFs, SNF/NFs, and ICFs/IID

(Rev. 91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

Some LSC deficiencies will require longer-term PoCs. For example, the installation of a sprinkler system will usually take from 18 to 36 months. Since PoCs may not be accepted for a period to exceed 6 months for SNFs and NFs, and one year for hospitals and ICFs/IID, the following procedure should be followed:

- A LSC waiver should be recommended for the length of time to correct the deficiency including time for design and construction;
- A written schedule of milestones in the design and construction of the corrective action should be included in the waiver request to determine if the work is progressing in an acceptable manner during any subsequent revisits; e.g., has the State Fire Marshall approved the hydraulic plans for the sprinkler system; and
- In the interim, the facility should be certified as "Meets LSC based on waivers" rather than "Meets based on a PoC."

2736 - The Outcome-Oriented Survey Process

(Rev. 91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

The outcome-oriented survey process for SNFs, NFs, HHAs and ICFs/IID places emphasis on individual outcomes. The focus of the survey is to determine whether the facility is **actually** providing services rather than whether the facility is **capable** of providing them. See <u>Appendix P</u> for SNFs and NFs, <u>Appendix B</u> for HHAs, and <u>Appendix J</u> for ICFs/IID.

The outcome-oriented survey process for laboratories places emphasis upon performance. It determines whether the laboratory is **actually** providing accurate and reliable results rather than whether the laboratory is **capable** of providing them (see Appendix C).

2764 - SA Completion Instructions for Certification and Transmittal, Form CMS-1539 (Exhibit 9)

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

Except for the signatures and signature dates, the SA types all entries on Form CMS-1539.

NOTE: Within each item on Form CMS-1539 there are code numbers for data reduction purposes (e.g., (L1), (L2)). These codes are used only for data entry into the ODIE system. Disregard them in completing the form.

Item 1 - Medicare/Medicaid Provider No

Leave this item blank on all initial certifications. The RO assigns the identification numbers for all new providers and suppliers and furnishes the SA with the number via a

copy of the acceptance letter. On all subsequent certification actions such as resurveys, CHOWs, and name and address changes, the SA inserts the facility's assigned provider/supplier number.

Provider numbers for hospitals and LTC facilities with multiple components and/or distinct parts are assigned by the RO using the following criteria:

A - Long-Term Care Facilities with Distinct Parts

One provider number is assigned and only one Form CMS-1539 prepared for the following situations (see §2779):

- SNF/NF with a SNF or NF distinct part; and
- SNF with a NF distinct part.

B - LTC Distinct Part Units of Hospitals

Provider numbers are assigned in the following fashion:

1 - Hospital with Distinct-Part SNF

Two provider numbers are assigned, one for the hospital and one for the SNF. Prepare separate Forms CMS-1539 for certification actions regarding each component.

2 - Hospital with Distinct-Part NF

Two provider numbers are assigned, one for the hospital and one for the NF. Prepare separate Forms CMS-1539 for certification actions regarding each component.

3 - Ĥospital with Distinct-Part SNF/NF

Two provider numbers, one for the hospital and one for the SNF/NF, are assigned. Prepare separate Forms CMS-1539 for certification actions regarding each component.

C - "Swing-Bed" Hospitals

Two numbers are assigned, one for the hospital and one for the swing-bed portion. Prepare one Form CMS-1539.

D - PPS-Excluded Hospitals

Hospitals with psychiatric and/or rehabilitation units that are excluded from the PPS are assigned two and/or three numbers, as appropriate (e.g., XX-0000 and XX-S000 and/or XX-T000). Prepare one Form CMS-1539.

Item 2 - State Vendor or Medicaid Number

The SA completes this item only for those States that assign separate vendor (or Medicaid ID) numbers for internal controls or for billing purposes. The SA should leave this item blank if a State does not have such a system.

Item 3 - Name and Address of Facility

The SA enters the name, address, city, State, and zip code of the facility, and enters the 2-digit State abbreviation and zip code in the available blocks. A post office box without a street address is not sufficient.

Item 4 - Type of Action

In the block provided, the SA enters the appropriate code in accordance with the following explanations: Codes 2 and 4 are self-explanatory. Code 6 and 8 are no longer applicable.

A - Code 1 (Initial Survey)

In addition to initial certifications, the SA selects this code when recommending an initial denial of participation. The SA indicates in Item 15 that it is recommending denial.

B - Code 3 (Termination)

The SA selects this code for involuntary termination, voluntary termination/withdrawal, or change in status requiring a new provider number (e.g., when a NF elects to also participate as a SNF).

C - Code 5 (Sample Validation)

The SA selects this code for a complete survey in an accredited facility for sample validation purposes. The SA completes all appropriate blocks on the form including items 6 (survey date), 8 (accreditation status), and 10 (compliance provision).

D - Code 7 (Onsite Visit)

The SA selects this code for an **onsite** inspection of a facility for some other reason **not** outlined above. Examples include:

- 1. Onsite revisit to verify that the deficiencies cited on the original survey are corrected and a Form CMS-2567B is completed;
- **2.** Onsite visit to verify that a hospital meets the criteria for hospitals operating with multiple components; and
- 3. Onsite visit to verify that an HHA's satellite meets the branch/subunit criteria.

E - Code 9

The SA selects this code for any certification action not specified above (e.g., changes in effective date, size, facility name, or address). Whenever action code 9 is selected, the SA shows in Remarks, Item 16, the reason for completing Form CMS-1539.

Item 5 - CHOW Date

When Item 4 is marked CHOW (code 4), the SA enters the date the change occurred (e.g., 060782) in Item 5.

Item 6 - Survey Date

For providers who require a fire safety survey, the SA enters the date the health or fire safety survey is completed, whichever is later. For providers and suppliers who do not need a fire safety survey, the SA enters the date the health survey is completed (e.g., 060283).

Item 7 - Provider/Supplier Category

In the block provided, the SA enters the code that is most descriptive of the facility identified on the form. Some of the provider/supplier codes are further described below:

A - Code 02 - (SNF/NF)

Until Form CMS-1539 is revised to reflect changes made by P.L. 100-203, enter this code in the category block when a nursing home participates in both Medicare and Medicaid in its entirety.

B - Code 03 - (SNF/NF Distinct Part)

Mark code 03 in the block when **any portion** of the facility is designated as a NF or SNF distinct part. For example, enter code 03 if a 150-bed LTC facility has 50 NF distinct-part beds and the remaining 100 beds are SNF/NF dually participating and/or SNF beds only.

C - Code 04 - (SNF)

Enter code 04 in the category block when one of the following apply:

- **1.** Freestanding SNF; or
- 2. SNF distinct part of hospital.

D - Code 10 - (NF)

Enter code 10 when the facility is a freestanding NF or a NF distinct part of a hospital.

*E - Code 11 - (ICF/***IID**)

Enter code 11 in the available block when either the entire facility or part of a facility is certified as an ICF/*IID*.

The SA always completes this item for accredited providers. For nonaccredited facilities, the SA enters code 0. For accredited hospitals, ASCs, HHAs, and laboratories, the SA enters code 1 (JCAHO) or code 2 (AOA) to identify those accrediting bodies or enters code 3 for other accrediting organizations such as Community Health Accreditation Program (CHAP), American Association of Blood Banks (AABB), College of American Pathologists (CAP), American Society of Histocompatibility and Immunogenetics (ASHI) and Commission on Office Laboratory Accreditation (COLA).

Item 9 - Fiscal Year Ending Date

The SA enters the ending date (month and day) of the provider's/supplier's fiscal year (e.g., 0630).

Item 10 - State Agency Certification

2764C - Not in Compliance With Program Requirements (Denial of Payments for New Admissions for SNF, NF, and ICF/IID)

(Rev. 91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

1 - Denial of Payments Recommended

The SA marks "B" in the first block when a recertified SNF, NF, or ICF/IID is not in compliance with the program requirements and is a likely candidate for denial of payments for new admissions. The SA annotates Item 16, "Remarks" to indicate that a denial of payments may be applied.

2 - Resurvey Finds Substantial Compliance

Following a revisit, the SA marks "A" in the first block when the facility is found to be in substantial compliance with the program requirements. The SA annotates Item 16, "Remarks" to show that the denial of payments for new admissions should be ended.

2764D - Resurvey Does Not Find Significant Progress

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

Following the revisit, the SA marks "B" in the first block when a facility is still not in compliance with program requirements and significant progress in correcting the deficiencies cannot be documented. The SA annotates Item 16 "Remarks" to show that the denial of payments for new admissions should remain in effect or that a termination action is being initiated.

NOTE: In all cases, the appropriate SA documentation must accompany Form CMS-1539.

Item 11 - LTC Period of Certification

TLAs are required for ICFs/IID. The SA inserts the recommended beginning (FROM) and ending (TO) dates of the TLA. If ICFs/IID are not in compliance with the CoPs, the SA establishes a conditional period of certification subject to automatic cancellation. When this occurs, the SA includes the cancellation date in Item 16, "Remarks."

Item 12 - Total Facility Beds (Complete for Hospitals, SNFs, NFs, and ICF/IIDs)

The SA enters the total number of beds in the facility including those in non-participating and non-licensed components or areas. The Number of Beds in the Certified Portion of the Facility Must Not Exceed the Number of Total Beds.

NOTE: The number of total facility beds and beds in the certified portion of the facility on Form CMS-1539 is restricted to the entire facility or the distinct part identified in Items 1 (Provider Number) and 7 (Provider Category).

Item 13 - Total Certified Beds (Complete for Hospitals, SNFs, NFs, and ICF/IIDs)

The SA enters the number of beds in Medicare and/or Medicaid certified areas.

Item 14 - SNF, NF, and ICF/IID Certified Bed Breakdown

The total number of beds in the certified portion of the facility recorded in Item 13 must be divided in Item 14 according to type of program (i.e., Box A-18 SNF, Box B-18/19, Box C-19 NF, and Box E-ICF/*IID*). Boxes D and F are no longer applicable.

The SA completes boxes A, B, C, and E, as appropriate. These blocks must equal Item 13 (total beds in the certified portion of the facility).

The examples on the following pages illustrate how Items 1 (Provider number) and 7 (Provider category) must be completed in conjunction with Items 12-14 for all hospital, SNF, NF, and ICF/IID providers.

Item 15 - Nonparticipating Emergency Hospitals and NFs

The SA enters code 1 or 2 in the block provided.

The SA completes this block when a nonparticipating hospital meets the definition of an emergency hospital in order to claim payment for emergency services rendered to Medicare patients. For participating NFs, the SA enters the appropriate code when the facility meets, or does not meet, the §1861(j) of the Act definition for durable medical equipment (DME) and home health benefit purposes.

Item 16 - State Survey Agency Remarks

The SA uses this space for any required remarks. If the comments exceed the allotted space, the SA continues on a sheet of paper entitled "Item 16 Continuation for CMS-1539." The SA includes the provider number, if known, on the sheet for identification purposes. Whenever Item 4 is completed as "Other," the SA uses "Remarks" to indicate the reason for completing Form CMS-1539. The following is a list of remarks which must be entered whenever appropriate.

Remarks	SOM Reference
Exclusion from Certification (Non-PPS)	§§2026, 2048, 2134, and 7016
Loss of Accreditation - Will be Surveyed on	\$2022.C
Certification of Additional Services	§§3220, 3222
RHC Furnishes Home Health Services Determine Whether in HHA Shortage Area	§2246
Waiver(s) Recommended	§§2030, 2140, 2248, 2480, 7014
Multiple Locations	§§2024, 2182, 2184, 2302, 2344
Denial of Payments Is Recommended	§§3006, 7506

EXAMPLE 1

1. Provider Number

|X|X|0|0|0|0| (Hospital)

7. 12. 13. CATEGORY TOTAL FACILITY BEDS TOTAL

CERTIFIED BEDS

14. LTC Certified Bed Breakdown

| SNF | SNF/NF | NF | ICF/IID |

EXAMPLE 2: 250 bed hospital

Beds are distributed as follows: 200 beds in hospital portion 50 beds Title 18/19 DP SNF/NF

NOTE: Prepare two Forms CMS-1539 identifying the hospital and SNF/NF components.

•		
1. Provider Number		
$ X \mid X \mid 0 \mid 0 \mid 0 \mid 0 $ (Hospital)		
7. CATEGORY CERTIFIED BEDS	12. TOTAL FACILITY BEDS	13. TOTAL
<u> 0 1 </u> (Hospital)	200	200
14. LTC Certified Bed Breakdown SNF SNF/NF NF ICF/IID		
1. Provider Number		
X X 5 0 0 0 (SNF/NF)		
7. CATEGORY CERTIFIED BEDS	12. TOTAL FACILITY BEDS	13. TOTAL
<u> 0 2</u> (SNF/NF)	50	50
14. LTC Certified Bed Breakdown		
SNF SNF/NF NF ICF/IID 50		

EXAMPLE 3: 400 bed hospital

Beds are distributed as follows: 300 hospital beds 100 beds Title 19 DP NF

NOTE: Prepare two Forms CMS-1539	for hospital and LTC compor	ients.	
1. Provider Number			
X X 0 0 0 0 (Hospital)			
7. CATEGORY CERTIFIED BEDS	12. TOTAL FACILITY BEDS	13. TOTAL	
<u>0 1 </u> (Hospital)	300	300	
14. LTC Certified Bed Breakdown SNF SNF/NF NF ICF/IID			
1. Provider Number			
X X A,E, or F 0 0 0 (Title 19	NF)		
7. CATEGORY CERTIFIED BEDS	12. TOTAL FACILITY BEDS	13. TOTAL	
$\frac{ 1 0 }{0}$ (NF Distinct Part)	100	_	10
14. LTC Certified Bed Breakdown			
SNF SNF/NF NF ICF/ <i>IID</i> 100			

EXAMPLE 4: 44 bed hospital swing-bed facility

12. TOTAL FACILITY BEDS	13. TOTAL
4 4	44
(free standing)	
(tree-standing)	
er Medicare or Medicaid	
12. TOTAL FACILITY BEDS	13. TOTAL
100	60
	TOTAL FACILITY BEDS 44 (free-standing) er Medicare or Medicaid 12. TOTAL FACILITY BEDS

EXAMPLE 6: 75 bed Medicaid NF (free-standing)

1. Provider Number		
X X A, E or F 0 0 0 (Title 19 N	NF)	
7. CATEGORY CERTIFIED BEDS	12. TOTAL FACILITY BEDS	13. TOTAL
<u>1 0 </u> (NF)	75	<u>75</u>
14. LTC Certified Bed Breakdown SNF SNF/NF NF ICF/IID		
75 EXAMPLE 7: 150 bed SNF/NF and N	JF.	
Beds are distributed as follows: 100 beds SNF/NF	.	
50 NF beds		
1. Provider Number		
X X 5 0 0 0 (Title 18 & 19 S	SNF/NF)	
7. CATEGORY CERTIFIED BEDS	12. TOTAL FACILITY BEDS	13. TOTAL
<u>0 3 </u> (SNF/NF)	150	150
14. LTC Certified Bed Breakdown		
SNF SNF/NF NF ICF/IID 100 50		

EXAMPLE 8: 100 SNF/NF facility

100

100 beds - SNF/NF dually participating

NOTE: Blocks A-E within item 14 **must not exceed** the total number of certified beds recorded in item 13. Report dually-participating beds in block B (18/19 SNF). Block F is no longer applicable.

1. Provider Number		
X X 5 0 0 0 (18/19 SNF/NF))	
7. CATEGORY CERTIFIED BEDS	12. TOTAL FACILITY BEDS	13. TOTAL
<u>0</u> <u>2</u> (SNF/NF Dually- Participating)	100	100
14. LTC Certified Bed Breakdown		
SNF SNF/NF NF ICF/IID		

EXAMPLE #9: 125 bed SNF/NF facility

Beds are distributed as follows:

100 beds - Title 19 NF 25 beds - Title 18/19 St See Example #8 Note.	NF/NF DP	
Provider Number		
<u>X X 5 0 0 0 </u> (18/19 SNF/NF)	
7. CATEGORY CERTIFIED BEDS	12. TOTAL FACILITY BEDS	13. TOTAL
<u>0 3</u> (SNF/NF)	125	125
14. LTC Certified Bed Breakdown		
SNF SNF/NF NF ICF/ <i>IID</i> 25 100		
EXAMPLE 10: 150 bed Medicaid-on	lly NF	
Beds are distributed as follows: 125 beds - Title 19 NF 25 beds - not participating in Med	dicare or Medicaid	
1. Provider Number		
$ X \mid X \mid A, E, \text{ or } F \mid 0 \mid 0 \mid 0 $ (Title 19	NF)	
7. CATEGORY CERTIFIED BEDS	12. TOTAL FACILITY BEDS	13. TOTAL
<u>1 0</u> (NF)	150	125
14. LTC Certified Bed Breakdown		
SNF SNF/NF NF ICF/ <i>IID</i> 125		

EXAMPLE 11: 140 bed NF (free-standing)

1. Provider Number			
X X A, E or F $ 0 0 0$ (NF)			
7. CATEGORY CERTIFIED BEDS	12. TOTAL FACILITY BEDS	13. TOTAL	
<u>1 0 </u> (NF)	140	1	4 (
14. LTC Certified Bed Breakdown			
SNF SNF/NF NF ICF/IID 140			
EXAMPLE #12 - 30 bed ICF//	ID (free-standing)		
1. Provider Number			
$ X \mid X \mid G \mid 0 \mid 0 \mid 0 $ (ICF/IID)			
7. CATEGORY CERTIFIED BEDS	12. TOTAL FACILITY BEDS	13. TOTAL	
<u>1 1</u> (IMR)	30	3	0
14. LTC Certified Bed Breakdown SNF SNF/NF NF ICF/IID 30		ı	
30		I	

EXAMPLE #13 - 50 bed NF and ICF/IID facility

Beds are distributed as follows:

30 beds - Title 19 NF 20 beds - Title 19 ICF/ <i>IID</i>		
NOTE: Prepare two Forms CMS-13	539 identifying the NF and IC	F/IID components.
1. Provider Number		
X X A,E,or F 0 0 0 (NF)		
7. CATEGORY CERTIFIED BEDS	12. TOTAL FACILITY BED	DS TOTAL
1 0 (NF)	30	30
14. LTC Certified Bed Breakdown		
SNF SNF/NF NF ICF/IID 30		
1. Provider Number		
$ X \mid X \mid G \mid 0 \mid 0 \mid 0 $ (IMR)		
7. CATEGORY BEDS	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED
<u>1</u> 1 (I <i>CF/IID</i>)	20	20
14. LTC Certified Bed Breakdown		
SNF SNF/NF NF ICF/IID 20	I	

Item 17 - Surveyor Signature

The surveyor (or survey team leader) signs and dates Form CMS-1539 after ensuring that the certification documents are complete and accurate.

Item 18 - State Agency Approval

The authorized representative of the SA signs and dates Form CMS-1539 and forwards the certification material to the RO or SMA, as appropriate. His/her signature constitutes for Medicare the official "certification" that the information being reported is correct according to official State files. In Medicaid-only cases, the signature on this document represents the adjudicative decision of the SA on the qualifications of the institution to participate in the Medicaid program.

2764.1 - RO Completion Instructions for Certification and Transmittal, Form CMS-1539

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

The main purpose of Form CMS-1539 is to formalize the SA's certification that a facility meets or does not meet the requirements for participation. The SA completes all applicable parts for the first 18 items (L1-L20) for Medicare/Medicaid providers/suppliers. The RO, or the SMA, complete the remaining items 19-32 (L21-L33), as appropriate. The RO completes as follows:

Item 19 - Determination of Eligibility

Enter code 1 or 2 in the block provided following the RO review of the SA's findings and certification. Enter code 1 when the provider/supplier is found eligible to participate in the Medicare and/or Medicaid programs. Also enter code 1 when a denial of payment for new admissions is imposed, continued, or lifted. Enter code 2 when a facility is not eligible to participate.

Item 20 - Compliance with Civil Rights Act (Title VI)

For providers/suppliers needing OCR clearance, enter a 1 in the available block if the OCR requirements are met. If not in compliance with title VI, enter a 2 in the box that indicates that the provider is not eligible to participate. For Medicare Part B suppliers not requiring OCR clearance to participate, enter a 3 that indicates not applicable.

Item 22 - Original Date of Participation

Complete for initial certifications only. Determine when the facility is eligible to begin participation in Medicare and/or Medicaid. Enter the date in the blocks provided. The criteria for determining the effective date can be found at <u>42 CFR 489.13</u> for Medicare and <u>42 CFR 442.13</u> for Medicaid.

Items 23-25 - ICF/IID Certification Period

For all ICFs/IID, enter the *re*-certification findings of the SA (i.e., beginning, ending, and/or extension dates) and evidence provided in the certification documents accompanying Form CMS-1539. When an ICF/IID is not in compliance with program requirements and a denial of payment for new admissions is imposed, enter the beginning (Item 23) and ending (Item 24) dates of the **current** *re-certification survey*. In Item 25 (extension date), enter a date **not exceeding** the end of the *fifteenth* month following the month in which the sanction will be imposed.

Item 26 - Termination Action

If a provider's or supplier's participation in the Medicare/Medicaid program ends, record the reason (see below) in the accompanying block. Also complete Item 28 (termination date).

1 - Voluntary

- Code 1 Enter when a facility closes or merges.
- Code 2 Enter when a provider or supplier is voluntarily withdrawing because of dissatisfaction with reimbursement.
- Code 3 Enter when a facility is leaving the program because it is at risk of being involuntarily terminated.
- Code 4 Enter when a provider or supplier no longer wishes to participate in the program for some other or unknown reason.

2 - Involuntary

- Code 5 Enter when a facility fails to meet health or safety requirements.
- Code 6 Select this code when a provider fails to abide by the agreement.

3 - Other

- Code 7 Select this code when you terminate a currently assigned provider number. Examples include:
- Medicare SNF or dually-participating SNF/NF elects to participate in the Medicaid program only;
- Medicaid NF elects to participate in the Medicare or Medicare and Medicaid programs; and
- ASC, ESRD, or RHC facility elects to participate as free-standing instead of hospitalbased and vice versa.

In any of the above instances, the RO terminates the existing provider number (complete Items 26 and 28) and assign the new provider number. (See §1060.A.)

Item 27 - Intermediate Sanctions (ICF/IID Only)

When an ICF/IID provider is found not to meet the requirements of §1905(d) of the Act and the decision is made to apply an intermediate sanction rather than terminate, complete the pertinent items on Form CMS-1539 as follows:

1 - Suspension of Admissions

Enter the date in Item 27A that the payments for new admissions in the facility will be denied. In addition, mark Item 10 "B" (not in compliance with program requirements). Mark Item 19 A1" (eligible to participate). In Item 25 (extension date) enter a date **not exceeding** the end of the eleventh month following the month in which the denial of payments will be imposed. This date may not be extended.

2 - Rescind Suspension Date

a - Significant Compliance with Program Requirements

Enter the date the denial of payment is rescinded.

The SA will mark Item 10 "A" (in compliance with program requirements) and Item 19 A1" (eligible to participate). In Item 27B, the RO enters the date the denial of payment is rescinded.

NOTE: Items 23 and 24 can only be completed when Item 10 is marked 'A' (in compliance with program requirements).

b-Significant Effort or Progress

Item 27b may also be completed when Item 10 is marked "B" (not in compliance with program requirements) and Item 16 (SA Remarks) is documented to show that effort and progress has been made to correct the deficiencies. Item 25 (ICF/IID extension date) remains unchanged. Mark Item 19 "1" (eligible to participate).

NOTE: Pursuant to <u>42 CFR 442.119(a)</u>, the denial of payment for new admissions is to be rescinded if the provider can document good faith efforts to correct. Effort would not, however, constitute compliance with program requirements. Therefore, it is conceivable that:

- The denial of payments could be rescinded;
- Effort and progress would be documented;

- The SA would certify "not in compliance"; and
- The extension would remain in effect.

If the deficiencies are not corrected by the 11th month following the initial month of denial, the provider agreement must be terminated.

NOTE: Similar information for SNFs/NFs is extracted from the Form CMS-462L, Adverse Action Extract for SNFs and NFs.

Item 28 - Termination Date

Enter the effective date of the termination action specified in Item 26.

Item 29 - *Intermediary/Carrier Number*

Enter the five-digit number assigned to the intermediary or carrier servicing the provider or supplier of health services.

Item 30 – Remarks

Use this block for any remarks that cannot be covered in the structured items above. If comments exceed space allotted in this item, document the additional comments on a sheet of paper entitled: "Item 30, Continuation For Form CMS-1539."

Item 31 - RO Receipt of Form CMS-1539

Enter the date that a certification package is received.

For Medicaid-only providers, the SMA forwards the certification materials to the RO following review and completion. For Medicare, the SA forwards the package directly to the RO.

Item 32 - Determination Approval

Following review of the certification documents an authorized CMS or SMA representative must sign and date Form CMS-1539.

2777A - Medicaid-Only Certifications

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

With the exception of State-operated NFs, which are certified by CMS, the SA completes all Medicaid-only certifications and forwards them to the State Medicaid agency (SMA) within 45 days after the survey. The SMA initiates appropriate action based on the SA's certification of the Medicaid-only provider. After this action is completed, the SMA forwards the case (with the exception of Form HHS-441, Assurance of Compliance with the Department of Health and Human Services Regulations under Title V of the Civil Rights Act of 1964, or a comparable form) to the SA for entry into the OSCAR system.

Before the initial certification is entered into the OSCAR system, the SA assigns a provider number to the NF or ICF/*IID*. The OSCAR system screens the facility's current compliance record for Conditions of Participation (CoPs), Requirements (for NFs), and other RO flags.

2778 - Objectives of RO Certification Review

(Rev. 91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

The primary objective of the review is to assure that the certification, together with other documents, is adequate evidence of the identity of the certified institution and of its conformance to the laws and regulations governing program participation.

Since the RO certification specialist must process various request forms and notifications and assure that the documentation is complete, it is of paramount importance that the specialist perform a quality-oriented appraisal.

Before approving participation, the RO must be certain that the SA's certification of compliance is consistent with the documented findings. The RO considers the impact of deficient standards, elements, or Requirements (for SNFs and NFs) on the respective CoPs or Requirements; the provider's deficiency history profile; recent beneficiary complaints; or other external reports justifying further documentation of a provider's practices and consults with RO health professionals when appropriate.

Other objectives are accomplished by this review. The RO decides whether it agrees with the SA recommendation of compliance or noncompliance and its interpretation of reasonable time and reasonable plans for the correction of deficiencies and waivers. The RO reviews the Statement of Deficiencies and Plan of Correction, Form CMS-2567, to ensure that the SA's documentation supports the SA certification recommendation, acceptable plan of correction (PoC), or waiver request. The RO notes the timeliness and quality of SA processing, and extract information relating to administrative or program problems that the case reveals so that identified program problems can be corrected on the regional or national level.

In Medicaid-only cases, the SA certifies its determination as to the provider's compliance with the participation requirements. The SMA must accept certification determinations as final and may not enter into a provider agreement with a NF or ICF/IID unless the SA has certified the provider as in compliance with applicable requirements for program participation. It may, however, for good cause, refuse to execute an agreement with a NF or ICF/IID certified by the SA. (See 42 CFR 442.12(d).)

Certification documents are official statements of the SA that may not to be altered. The RO uses the Request for Additional Information, Form CMS-1666 (Exhibit 15), to request additional information or documentation. (See §2776.)

If a deficiency is subsequently corrected, the corrective action will be shown on Form CMS-2567 or the Post-Certification Revisit Report, Form CMS-2567B, as appropriate. If the deficiencies have not been corrected at the time of the revisit, they are shown on a new Form CMS-2567. The OSCAR system accumulates data on the ability of providers

and suppliers to meet program participation requirements at the time of the survey. OSCAR data from Form CMS-2567 and Form CMS-2567B are used to measure the extent of progress providers and suppliers make in complying with program requirements.

In case of an unreconciled interpretive disagreement with the SA, the RO can arrive at a determination disagreeing with the SA, **provided there is evidence to support a contrary decision**. If the RO disagrees with the SA certification, it justifies its rejection in writing and attempts to resolve the disagreement. If necessary, a disagreement over interpretive policy can be referred to CMS CO for resolution.

2779B – CMS Certification Numbers for Medicaid Providers (Rev. 91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

For certification purposes, title XIX-only providers are identified by a 6-digit alphanumeric identification number. The first two digits identify the State in which the provider is located. The third position, which is an alpha character, identifies the type of facility by level or type of care being provided. The last three digits make up a sequential number series beginning with 001.

The RO uses the following groups of alphanumeric numbers for the type of facility as indicated:

A001-A999	NF (Formerly assigned to Medicaid SNF)
B001-B999	NF (Formerly assigned to Medicaid SNF)
	Expansion of A001-A999
E001-E999	NF (Formerly assigned to ICF)
F001-F999	NF (Formerly assigned to ICF)
	Expansion of E001-E999
G001-G999	ICF/IID
H001-H999	ICF/IID
	Expansion of G001-G999
K001-K999	Medicaid HHAs
L001-L999	Psychiatric Residential Treatment Facilities (PRTF)
J001-J999	Medicaid-Only Psychiatric Hospitals
N001-N999	Medicaid-Only Non-Psychiatric Hospitals

2779D - Assigning LTC CMS Certification Numbers

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

The RO assigns only one CCN per facility. (For purposes of this section, "facility" means an institution providing SNF and/or NF or ICF/IID care at the same address.) Use

XX-5000 series for facilities providing Medicare or Medicare/Medicaid services, and the alphanumeric series (XX-A000 or XX-E000 or XX-G000) for Medicaid-only facilities, as shown in the following charts:

FREE STANDING LTC FACILITIES

FACILITY 18 or 18/19 19 NF ICF/IID

TYPE SNF

CCN XX-5000 XX-A000 or

XX-G000 XX-E000

SNF/NF DUALLY-PARTICIPATING AND/OR DISTINCT PART FACILITIES

FACILITY 18/19 18 SNF or 18/19 18 or

18/19

TYPE SNF/NF Dually participating

Dually participating

Dually with SNF or NF DP with SNF or NF

DP

participating

CCN XX-5000 XX-5000

XX-5000

FACILITY TYPE 19 NF 19 NF

With

ICF/IID DP

CCN XX-A000

XX-E000 or XX-G000*

XX-A000 d

*EXCEPTION: As the chart indicates, the RO always assigns a separate ICF/IID

(XX-

G000) number to an ICF/IID or ICF/IID DP.

NOTE: When a LTC facility is a unit of a hospital, the RO issues a number separate from the hospital number according to the above guidelines. A hospital is

permitted to have only one hospital-based SNF DP and one hospital-based NF DP.

2800 - Strikes at Participating Facilities

(Rev.91, Issued: 09-27-13, Effective: 09-27-13, Implementation: 09-27-13)

When employees of a participating hospital, SNF/NF or ICF/IID go on strike against the facility, the RO obtains a written report from the SA about that institution's continuing ability to furnish adequate care to its patients and on the steps taken to assure the health and safety of its patients based on the SA's onsite visit to the facility. If a strike takes place in an accredited facility, a visit by the SA to determine whether the strike has caused a decline in the quality of care furnished, is appropriate.

The report should focus on the specific situations. For example, if the nursing staff is on strike, the SA should indicate what the facility is doing to minimize any hazards that might arise due to inadequate nursing, such as securing temporary nurses and limiting admissions to emergency cases. The report should also describe the SA plans for monitoring the situation.

Because of the sensitive nature of this area, the SA and RO should not create the impression that the Federal Government is taking sides in a labor dispute. However, be alert to all types of situations that could lead to substandard care being provided to beneficiaries.