State Operations Manual
Chapter 2 - The Certification Process

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Identification of Providers and Suppliers and Related Presurvey Activities

2000 - Certification Surveys - Citations and Responsibility
(Rev. 1, 05-21-04)

Section 1864 of the Social Security Act (the Act) establishes the framework within which SAs, under agreements between the State and the Secretary, carry out the Medicare certification process. Sections 1902(a)(9) and (33) of the Act stipulate that the same agency is authorized to set and enforce standards for Medicaid. (The SA may partially redelegate the functions to local agencies.)

42 CFR 488 requires the SA to perform surveys to support its certifications. 42 CFR Part 431, Subpart M, sets forth the functions the SA performs for the SMA. SAs perform initial surveys and periodic resurveys of all providers and certain kinds of suppliers. These surveys are conducted to ascertain whether a provider/supplier meets applicable requirements for participation in the Medicare and/or Medicaid programs, and to evaluate performance and effectiveness in rendering a safe and acceptable quality of care.

Although the regional office (RO) is ultimately responsible for deciding whether a provider/supplier may participate in the Medicare program, certification is an SA function. After the SA completes an inspection for the Medicare program, it submits evidence and a certification recommendation for a final RO determination. When the SA certifies for Medicaid purposes, it is reporting its own adjudicative determination.

2002 - Meaning of Providers and Suppliers
(Rev .40, Issued: 03-20-09, Effective: 03-20-09, Implementation: 03-20-09)

The Medicare law differentiates between providers and suppliers. The general distinction between providers and suppliers is that providers are parties who care for patients awaiting, receiving, or recuperating from treatment by intervening practitioners. The term suppliers" includes those who furnish goods and services used in care and treatment. Medicaid terminology, by contrast, uses "provider" generically to include all health care vendors. (See 42 CFR 431.107(a) and 433.37.) Medicare providers and suppliers are defined at 42 CFR 498.2.

In Medicare, as specified in §1861(u) of the Act, providers include hospitals, critical access hospitals (CAHs), skilled nursing facilities (SNFs), home health agencies (HHAs), hospices and comprehensive outpatient rehabilitation facilities (CORFs). Under §1835(a)(2) of the Act, clinics, rehabilitation agencies, or public health agencies are included as providers if such clinic or agency meets the requirements of §1861(p)(4)(A).

Community Mental Health Centers (CMHC) are providers of services for partial hospitalization services only. Providers must meet CoPs or Requirements for SNFs to participate in Medicare. (See definitions at 42 CFR 498.2.)

Portable x-ray services, end stage renal disease (ESRD) facilities, ambulatory surgical

centers (ASCs), and organ procurement organizations (OPOs) are suppliers that must meet conditions for coverage to participate in Medicare; rural health clinics (RHCs) are suppliers that must meet conditions for certification to participate in Medicare.

Federally Qualified Health Centers (FQHCs) are also recognized as suppliers of services and provide ambulatory care services similar to those provided by RHCs. FQHCs may be located in urban, as well as rural, areas. FQHCs are required to meet the same health and safety standards as RHCs, with the exception of the certification procedures. FQHCs self-attest to their compliance with Medicare conditions for coverage and are only surveyed by CMS in connection with complaint investigations.

The above types of suppliers are distinguished from other suppliers, e.g., pharmacies, prosthesis suppliers, etc., for which there are no conditions for coverage or certification, and which qualify for Medicare through the enrollment process. Laboratories that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings are yet another category of suppliers and must meet Clinical Laboratory Improvements of 1988 Act (CLIA) requirements.

As previously stated, Medicaid does not distinguish between providers and suppliers. Section 1902(a)(27) of the Act provides for agreements with every person or institution providing services under the State plan. 42 CFR 431.107(a) refers to all providers of services (including individual practitioners and groups of practitioners).

2003 - SA Identification of Potential Providers and Suppliers
(Rev. 1, 05-21-04)

Often, first indications of interest in program participation by potential participants will be contacts with State licensing agencies. These contacts make the SA aware that a provider or supplier wishes to participate. The SA identifies, surveys, and makes certification recommendations to CMS or the SMA about providers and suppliers that are potential program participants.

2003A - Assisting Applicant Providers and Suppliers
(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

Pre-certification assistance to prospective providers and suppliers is a proper certification-related activity. It may take the form of providing them with a copy of the applicable regulations. The objective is to provide the party with information about the requirements of the certification component of the process for enrolling and participating in Medicare, including compliance with the requirements for SNFs and NFs, Conditions of Participation, Conditions for Coverage, or Conditions for Certification, as applicable. The effective date of Medicare participation in accordance with 42 CFR 489.13 may not be earlier than the date on which the applicant meets all the federal requirements.

2003B - Initial Certification “Kits”
(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

When an entity seeks to participate in Medicare, it must first complete and submit an enrollment application. Information on enrollment as well as applicable forms and instructions may be found at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html. Entities subject to survey and certification file either a CMS Form 855A -- Medicare Enrollment Application for Institutional Providers, or a CMS Form 855B--Medicare Enrollment Application for Clinics, Group Practices, and Certain Other Suppliers, or, in some cases, both. Prospective providers and suppliers should be aware that the initial review of the Form CMS-855A or Form CMS-855B by the Medicare Administrative Contractor (MAC) and its recommendation for approval must occur before the on-site initial certification survey is conducted and action is taken by the RO.

CMS has established Internet-based Provider Enrollment, Chain and Ownership System (PECOS) as an alternative to the paper enrollment process. Internet-based PECOS allows provider and supplier organizations to enroll, make a change in their Medicare enrollment, view their Medicare enrollment information on file with Medicare, or check on the status of a Medicare enrollment application via the Internet.

When the MAC completes its review of the application, it either: 1) sends the SA and the RO its recommendation to approve the applicant; or 2) denies the application. **The SA must not perform a survey of an initial applicant until it has received notice from the MAC that the information provided on the enrollment application has been verified and that the MAC is recommending approval of the application.** A SA may, however, start planning for an unannounced survey upon initial contact from an applicant.

(**NOTE:** SA surveys of initial applicants must be consistent with the priorities for Federal survey work, established by CMS each fiscal year. Depending upon available resources, initial surveys are typically a lower priority and SAs generally should not perform such work unless all higher priority Federal work will be completed. SAs may consult with the CMS Regional Office (RO) to determine whether a specific initial applicant would address an access to care issue and thus warrants an exception.)
The prospective provider/supplier must contact the SA for Medicare and/or Medicaid certification materials for their provider/supplier type. The SA mails the initial certification materials under cover of the appropriate form letter. (See Exhibits 1A-1F and Exhibit 63.) If the applicant has not contacted the SA before the SA receives the MAC's recommendation for approval, then the SA contacts the applicant using the phone number listed on the application.

Upon receipt of the completed certification materials from the prospective applicant, the SA reviews the materials to see that they are properly completed and secures any necessary changes or additional information. It makes sure any required SNF transfer agreements are received. If a distinct part of an organization is being considered for program participation, the SA reviews the diagram (or floor plan) submitted to make sure the size and location of the distinct part are clearly shown. The SA works in conjunction with the RO and the MAC to gather the appropriate documentation from the entity that supports its position of being a distinct part before forwarding the package to the RO, in

order to make a recommendation to the RO. Both copies of the signed provider agreement or supplier approval are sent to the RO, along with the Title VI Assurance of Compliance with Civil Rights (Form HHS-690). In title XIX-only cases, the SA sends the Form HHS-690 or comparable form to the SMA.

If the entity indicates that it is requesting a provider-based determination under the Medicare program, the SA must notify the RO immediately. Distinct Part and Provider-Based are not synonymous terms. Determinations concerning provider-based status are made by RO Financial Management personnel.

The SA refers questions about enrollment, MACs, payment rules, financial solvency, or title VI clearance to the RO or the State Medicaid agency, as appropriate. For questions concerning the downloading, completion, and submission of the Form CMS-855A or CMS-855B, the provider/supplier should be directed to the CMS Web site or the appropriate MAC.

Initial Certifications Involving New Owners who Reject Assignment of the Existing Medicare Agreement

In the case of a prospective applicant that is planning to acquire an existing Medicare-participating provider or supplier, the RO should provide pre-certification assistance to the prospective applicant which includes making the prospective applicant aware of the consequences of accepting or rejecting assignment of the existing provider's/supplier's Medicare agreement. The RO should be consulted if the prospective applicant is considering rejecting assignment of the agreement so that the RO can provide detailed information on the consequences of such action before the prospective applicant makes a final decision and submits an application.

In the case of an applicant that has acquired an existing Medicare-participating provider or supplier and has rejected assignment of that entity's Medicare agreement, that applicant is considered a new applicant seeking initial certification and the SA must prioritize scheduling an initial survey for that applicant accordingly. This includes adhering to workload priorities identified by CMS for surveys of initial applicants to enroll in Medicare. Unless specifically directed by the RO to do so, SAs must not conduct initial surveys unless they are able to complete their higher priority workload. For initial applicants that have an accreditation option, initial certification surveys are the lowest SA priority. When an SA conducts an initial certification survey of an applicant that acquired a provider/supplier but rejected assignment, the RO must review the facts of the case carefully to determine whether the SA deviated from CMS workload priorities as well as the SA's typical practice for initial applicants. Such deviation may raise reasonable doubt that the survey was unannounced.

Section 2700A of the SOM requires all surveys of providers and suppliers (other than clinical laboratories) to be unannounced. This requirement applies to AO as well as SA surveys. An unannounced survey provides an opportunity to assess how the provider or supplier typically operates. On the other hand, if a provider or supplier knows the exact or approximate date of a survey, it may temporarily adjust its typical practices to enhance its

compliance at the time of the survey. In doing so, it presents an unrepresentative picture to surveyors of the quality of care typically provided to its patients or residents. It is therefore in the best interest of patients and residents that surveys be unannounced.

Given the lead time normally required to schedule and prepare for a full survey, if an initial survey takes place shortly after the acquisition date, such timing suggests discussion with the new owner prior to the acquisition date to arrange the timing of the survey to occur shortly thereafter, compromising the requirement that the survey be unannounced. While the new owner, like any other initial applicant to the Medicare program, will be expecting to be surveyed at some point, there must be some degree of uncertainty about just when that survey will occur, in order to permit an assessment of compliance when the facility is operating in a typical manner.

The RO may refuse to accept a SA survey certifying compliance or an AO recommendation for deemed status if the survey timing creates reasonable doubt that the survey was unannounced. Each case must be assessed based on the facts specific to it; however, any survey that takes place within fourteen days after the effective date of an acquisition that involves rejection of assignment of the provider agreement may warrant closer review by the RO of the circumstances of the case and the timing of the survey. However, it is also possible that the facts of a specific case may indicate that an initial certification survey taking place at a later date was announced.

See Section 3210 for more information about policies and procedures related to acquisitions of Medicare-participating providers or suppliers.

2003C – Deemed Status Providers/Suppliers, Excluding CLIA

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

There is an alternative to SA surveys for demonstrating compliance with the applicable CoPs/CfCs/Conditions for Certification. Accreditation based on a survey by a CMS-approved Medicare accreditation program of a national accrediting organization may be used by CMS to "deem" a provider or supplier as complying with the applicable regulatory standards. For certain types of providers/suppliers, for example hospitals or psychiatric hospitals, Medicaid will also accept accreditation under a CMS-approved Medicare accreditation program as evidence of compliance for Medicaid purposes.

Section 1865(a) of the Act provides that CMS may recognize and approve national accrediting organization (AO) Medicare accreditation programs which demonstrate that their health and safety standards and survey and oversight processes meet or exceed those used by CMS to determine a health care provider's or supplier's compliance with applicable Medicare CoPs, CfCs, Conditions for Certification or requirements.

The regulations which govern Medicare survey, certification, and enforcement procedures are generally found in 42 CFR Part 488. Section 488.1 defines an accredited provider or supplier as "a provider or supplier that has voluntarily applied for and has been accredited by a national accreditation program meeting the requirements of and approved by CMS in accordance with §488.5 or §488.6." Accreditation under a CMS-approved Medicare

accreditation program is voluntary and is not required for Medicare participation.

Consistent with Section 1865 of the Act, 42 CFR §§488.5 and 488.6 permit deemed status certification for ambulatory surgical centers; comprehensive outpatient rehabilitation facilities; critical access hospitals; home health agencies; hospices; hospitals; clinics, rehabilitation agencies or public health agencies providing outpatient physical therapy, occupational therapy or speech pathology services; psychiatric hospitals; religious nonmedical health care institutions; rural health clinics; screening mammography services; skilled nursing facilities; and transplant centers, except for kidney transplant centers. However, at this time only certain AOs have requested CMS approval of Medicare accreditation programs, and those programs are only for some of these provider/supplier types. A current list of CMS-approved Medicare accreditation programs may be found at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Accreditation.html.

The enrollment and certification requirements also apply to providers/suppliers seeking deemed status through their accreditation by a CMS-approved Medicare accreditation program. AOs with approved Medicare accreditation programs are also required by CMS not to survey initial applicants until they provide evidence that the MAC has reviewed their application and recommended approval.

The prospective provider/supplier seeking deemed status through accreditation must still contact the SA for Medicare and/or Medicaid certification materials for their provider/supplier type. The SA mails the initial certification materials under cover of the appropriate form letter. (See Exhibits 1A-1F and Exhibit 63.) If the applicant has not contacted the SA before the SA receives the MAC's recommendation, then the SA contacts the applicant using the phone number listed on the application.

In the case of a "deemed" provider or supplier, the SA does not conduct a survey to initially certify or recertify compliance with the applicable Medicare CoPs, CfCs, or requirements. Rather, such providers or suppliers are under the jurisdiction of the AO, not the SA, for oversight of their ongoing compliance, unless the SA conducts a validation survey (either a representative sample or substantial allegation validation survey) at the direction of CMS and CMS determines as a result of such validation survey that the provider or supplier fails to comply with one or more CoPs, CfCs, Conditions for Certification or requirements.

Note that some AOs offer multiple accreditation programs for a given type of provider or supplier, but for each provider/supplier type an AO may offer no more than one CMS-approved Medicare accreditation program. In addition, some AOs may offer only one program for a provider/supplier type, but they offer this program to their customers with and without the option of the AO recommending Medicare deemed status to CMS. Thus, it is possible for a healthcare entity to be "accredited" without being "deemed" for Medicare participation. For certification purposes, CMS considers only accreditation under a CMS-approved Medicare accreditation program where the AO has recommended deemed status. SAs must enter information on the Deemed tab within the certification kit in ASPEN only for those initial applicants that are seeking deemed status on the basis of

accreditation under a CMS-approved Medicare accreditation program. CMS has established a process for AOs to provide notice to the applicable CMS Regional Office (RO) when it has accredited a provider or supplier under its CMS-approved Medicare accreditation program and is recommending the provider or supplier for deemed status. The RO forwards these notices to the applicable SA for inclusion in the certification kit that the SA subsequently forwards to the RO. In initial certification cases where there is no AO notice of accreditation under a CMS-approved Medicare accreditation program for the applicant, SAs must not use other sources of information about the applicant being "accredited" to conclude that the applicant is "deemed" and must not enter deemed status for the applicant in ASPEN.

An AO may not conduct an initial certification survey of a prospective provider or supplier for Medicare certification purposes until the MAC has completed its initial review of the enrollment application and has made a recommendation for approval to CMS. CMS requires AOs subject to its oversight to employ a survey process that is comparable to the process required for an SA, which may not conduct an initial survey until it receives notice from the MAC recommending approval of the applicant (see Section 2003B). Accordingly, an AO must also wait until the MAC has made its recommendation before it conducts an initial survey.

The MAC gives the applicant written notice when its review has been completed. Therefore, AOs must inform providers or suppliers seeking to participate in Medicare via the AO's CMS-approved Medicare accreditation program that an initial, unannounced survey will not take place until after the applicant has received notice from the MAC that it has completed its review of the enrollment application and that the MAC is recommending approval. If the MAC denies approval of the application, the AO must not proceed with a survey.

Notices that the MAC provides to the SA and RO are internal communications among CMS and its contractors. AOs are not entitled to receive copies of the MAC notice from the MAC, SA, or RO, but are expected to obtain copies of the MAC notice that was provided to the applicant.

In the case of an applicant that is planning to acquire an existing Medicare-participating provider or supplier and that is considering rejecting assignment of the prior Medicare agreement, the AO must refer the applicant to the RO, so that the RO can provide detailed information on the consequences of acceptance or rejection of assignment. In the case of an applicant that has acquired an existing Medicare-participating provider or supplier and has rejected assignment, the applicant is considered an initial applicant. Generally, it is not acceptable for the AO to schedule an initial survey to minimize the period of time between the termination of the prior Medicare agreement and the effective date of the new agreement. Surveys conducted either on the date an acquisition is effective or within days thereafter do not qualify as unannounced surveys and also are inconsistent with CMS regulations and policy that require such applicants to be treated in the same way as any other initial applicant. See Section 3210 for more information about policies and procedures related to acquisitions of Medicare-participating providers or suppliers.

The AO is required to notify CMS whenever it newly accredits and recommends Medicare deemed status for a provider or supplier seeking Medicare participation. This notice must be sent to both CO and the applicable RO via a designated email box (See Section 1022). However, the prospective provider or supplier must also provide the SA with documentation of the AO's accreditation decision and recommendation for deemed status. This documentation is included in and becomes part of the certification packet the SA submits to the RO. Therefore, AOs must instruct the prospective provider or supplier to furnish a copy of this documentation to the SA for inclusion in the applicant's certification packet.

2004 - Provider-Based Determinations

(Rev. 193, Issued: 09-20-19, Effective: 09-20-19, Implementation: 09-20-19)

"Distinct Part" and "Provider-Based" are not synonymous terms. When a location, department, remote location or satellite is established as being provider-based, it is an integral part of the provider, covered by the provider's Medicare agreement, and therefore subject to the same Medicare conditions of participation as any other part of that provider. Unless covered by a specific exception listed in the rule, the provider-based regulations at §413.65 apply to any provider of services under the Medicare program, as well as to physicians' practices or clinics or other suppliers that are not themselves providers, but which the provider asserts are an integral part of that provider.

Providers are not required to seek a determination from CMS that all of their provider-based components satisfy the provider-based rules at 42 CFR 413.65, but they may voluntarily seek such determinations. The RO Division of Financial Management makes provider-based determinations in response to a specific request. If a provider requests the SA for a provider-based determination under the Medicare program for one or more of its component services, the SA must notify the RO immediately so that the request can be routed appropriately to the RO Division of Financial Management. In the case of a request concerning an off-campus department, remote location or satellite, the provider's survey and certification file about the locations included under its provider agreement must not be revised to add the new location until and unless the provider is issued a positive determination about its request.

For Critical Access Hospitals (CAHs) adding a provider-based location – also see SOM Chapter 2, Section 2256H – Off-Campus CAH Facilities – Process Requirements.

2005 - Medicare Health Care Provider/Supplier Enrollment

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

The Centers for Medicare & Medicaid Services (CMS) is authorized to collect enrollment information in order to ensure that correct payments are made to providers and suppliers under the Medicare program established by Title XVIII of the Act for payment under Part A of Title XVIII [42 U.S.C. §1395f(a)(1) and 1395g(a)] and §1833(e) [42 U.S.C. §13951(e)] for payment under Part B. In addition, CMS is required to ensure that no payments are made to providers or suppliers who are excluded from participation in the Medicare program under §1128 of Title XVIII [42 U.S.C. §1320a-7], or who are

prohibited from providing services to the federal government under §2455 of the Federal Acquisition Streamlining Act of 1994 (P.L. 103-355) [31 U.S.C. §6101 note].

The primary use of this information is to verify the eligibility of providers/suppliers to participate in the Medicare program, which will more effectively prevent fraud and abuse. The protocol that CMS uses to ensure that providers/suppliers meet these requirements is referred to as the enrollment process. The enrollment process is also to be used for providers/suppliers that plan to seek certification for participation in Medicare based on deemed status through a CMS-approved Medicare accreditation program. An applicant must complete the enrollment application process in order for CMS to obtain certain required information before a certification survey is conducted or, in the case of an FQHC, the RO countersigns the self-attestation.

Providers/suppliers should be informed of the enrollment and certification process so that they do not have unrealistic expectations about the effective date of their provider or supplier agreement with Medicare, e.g., an applicant should not expect its effective date to be the date it submitted its enrollment application. Should the applicant have any questions concerning the enrollment process form, it should be referred to the following Web site: http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html.

The Medicare enrollment process is not applicable to the Medicaid program. State Medicaid Agencies use their own enrollment process.

2005A - Approval or Denial

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

2005A1 - Enrollment Denial Based on MAC Review

When the MAC determines, after reviewing the Form CMS 855 application, that an applicant has failed to meet the enrollment process requirements, the MAC will issue a written denial to the applicant. The RO is not involved in the issuance of the denial or in the processing of any request by the applicant for reconsideration or appeal. Reconsideration requests or appeals are handled by the Center for Program Integrity Provider Enrollment Operations Group in the CO.

Additionally, when an applicant is denied enrollment by the MAC, no survey is conducted.

2005A2 - Approval or Denial of Certification Based on Survey Findings

The SA (or RO, when applicable – all references below to SA surveys also apply to surveys conducted by the RO), surveys applicants that are subject to an on-site certification survey after it receives the recommendation of approval from the MAC, unless the applicant has the option of participation via deemed status (See Sections 2003C and 2005A4). Additionally, the applicant must be operational and providing care to patients/residents in order for a certification survey to be conducted. (See Section 2008A.)

All surveys are unannounced.

Applicant in Compliance - The SA surveys the applicant and certifies or recommends Medicare approval if it determines that the applicant is in compliance with all conditions of participation/coverage/certification or requirements, as applicable. (See Section 2008D for more information on the circumstances under which the SA certifies the applicant is or is not in compliance.) The SA forwards the survey results and certification kit to the RO which determines whether and when all Federal requirements have been met by the applicant. If all Federal requirements have been met, the RO proceeds with the provider's or supplier's Medicare participation approval. (In the case of HHAs, there is a requirement for the MAC to conduct a second verification of the enrollment information after the SA or accrediting organization survey is completed. However, a second MAC review that takes place after the on-site certification survey will only delay the effective date of the HHA's Medicare agreement if that review identifies noncompliance with any Federal requirements. If the HHA is found upon a post-survey second MAC review to continue to meet all requirements, there would be no change in the initial certification effective date previously provided by the MAC to the RO. However, if the MAC finds the HHA does not meet all Federal requirements during the second review, there would be a delay in the effective date of any provider agreement that might eventually be issued to the HHA applicant until all requirements are determined to be met.)

The RO will issue a provider or supplier agreement with an effective date, and assign a CMS Certification Number (CCN). (See Section 2008.) The RO will notify the MAC of the applicant's approval for participation in the Medicare program by sending the Provider Tie-In Notice (Form CMS-2007), and/or a copy of the approval letter that will include the CCN. The RO will send the SA a copy of the applicant's approval letter.

Applicant Not in Compliance – The SA surveys the applicant and certifies that the applicant is not in compliance with the conditions of participation/coverage/certification or requirements, as applicable. (See Section 2008D for more information on the circumstances under which the SA certifies the applicant is or is not in compliance.) The SA forwards the survey results to the RO, which will send the provider/supplier a denial letter. The RO will forward a copy of the denial letter to the MAC and to the SA. Claims will not be paid if the applicant is not approved through both the enrollment and the survey and certification processes.

The applicant is issued a denial letter for noncompliance with the conditions of participation/coverage/certification. The applicant may correct the deficiencies and reapply for certification. The applicant who reapplies for certification must undergo a new survey which is a full, standard survey, except:

- If on the first survey an applicant subject to the Life Safety Code (LSC) requirements was in substantial compliance with the LSC, the SA has the discretion to not resurvey for LSC compliance (although it must receive an acceptable Plan of Correction for any lower-level LSC deficiencies before it may recommend certification); and

- In the case of an applicant seeking to participate as a hospital, the SA has the discretion to conduct a new survey of only those conditions for which the applicant was found non-compliant during the prior survey. If the SA chooses to conduct such a focused subsequent survey, the hospital applicant must submit an acceptable plan of correction for all noncompliance identified in the prior survey, including for conditions where there were only lower-level deficiencies cited, before the SA may conduct the subsequent survey.

  NOTE: It is not possible for an initial applicant to seek CAH status; the applicant must first be certified as a hospital, and then subsequently the hospital may apply to convert to CAH status. This is technically a conversion, not an initial application. If the SA certifies that the CAH applicant is not in compliance, then the RO sends a letter denying the hospital's request to convert to CAH status. Unless the denial was based on the applicant not satisfying the CAH location requirements, the applicant may seek to be surveyed again for CAH conversion. As with initial hospital applicants, the SA has the discretion to conduct a new survey of only those conditions for which the CAH applicant was found non-compliant during the prior survey. If the SA chooses to conduct such a focused subsequent survey, the CAH applicant must submit an acceptable plan of correction for all noncompliance identified in the prior survey, including for conditions where there were only lower-level deficiencies cited, before the SA may conduct the subsequent survey.

In all cases the RO retains the authority to require a new full survey if it has concerns about a certification recommendation based on a focused survey after a prior survey identified substantial noncompliance. In cases where the RO anticipates that it will require a new full survey, it should notify the SA of this as soon as possible, to facilitate planning for the full survey by the SA.

If the SA continues to find the applicant is not in compliance with the conditions of participation/coverage/certification or requirements, as applicable, on the subsequent survey, the above process may be repeated. However:

- The applicant may submit no more than two reapplications for certification in connection with one enrollment application; and

- No more than six months may elapse between the date of the RO's first denial of certification and receipt by the RO of a second reapplication for certification (for a total of three certification applications).

If the applicant fails to demonstrate compliance by the end of this six month period, the RO not only issues a final denial of certification, but also sends a written recommendation to the MAC that the enrollment application be closed out as denied. If the applicant continues to seek enrollment and certification, the RO must receive a new MAC recommendation for approval before it may process a new certification application.

2005A3 - Reconsideration of Denial

Procedure for Reconsideration - An applicant has the right to request a reconsideration of an initial certification denial decision. See Chapter 3, Sections 3050 – 3054 for reconsideration procedures and timeframes. Note that the RO may not simultaneously process a certification reapplication and a request for reconsideration. However, in accordance with Section 3054A, the applicant may withdraw its reconsideration request and reapply for certification if it has corrected the deficiencies identified on the survey.

2005A4 – Deemed Providers/Suppliers, Excluding CLIA

Initial Survey by an AO with a CMS-Approved Medicare Accreditation Program

The AO's CMS-approved Medicare accreditation program must provide reasonable assurance that providers or suppliers accredited by the AO meet all Medicare Conditions of Participation (CoPs) or Conditions for Coverage/Certification (CfCs), as applicable. CMS evaluates and reviews AOs seeking recognition of their accreditation programs for Medicare participation on a number of factors specified in 42 CFR §488.8, including the AO's accreditation standards, survey and oversight processes, and their comparability to CMS' standards and processes. Furthermore, 42 CFR §489.13 governs how CMS determines the effective date of a provider's or supplier's Medicare agreement or approval, including provisions related to certification survey findings.

Accordingly, before the AO makes a recommendation to CMS that an applicant seeking initial certification and enrollment in Medicare be "deemed" to meet Medicare's health and safety standards, the AO must conduct a survey and determine that the applicant meets all requirements for accreditation, including compliance with all applicable Medicare CoPs or CfCs.

Applicant in Compliance

If the applicant is found to comply with all accreditation requirements, the AO may award deemed status accreditation, effective no earlier than the accreditation survey end date, and recommend the applicant to the RO for Medicare certification via deemed status. The AO must inform the applicant and the RO of the results of the initial accreditation survey and of its recommendation of the applicant for certification via deemed status, including the effective date of the applicant's accreditation.

If the applicant is found to be in substantial compliance, but has lower-level deficiencies, then the AO must receive an acceptable plan of correction (POC) for such deficiencies. (See Section 2008D.) Once the AO receives an acceptable POC from the applicant, the AO may award deemed status accreditation and recommend the applicant for Medicare certification via deemed status. The AO may not make the effective date of the applicant's deemed status accreditation prior to the date of receipt of a POC that the AO finds acceptable. The AO must inform the applicant and the RO of the results of the initial accreditation survey, the receipt of an acceptable POC, and its recommendation of the applicant for deemed status, including the effective date of accreditation. The AO must also send its survey report to the RO.

When the AO notifies CMS of an applicant's accreditation and the AO's recommendation of deemed status for that applicant, the RO reviews the AO's accreditation survey report and other documentation. If the RO accepts the AO's recommendation of deemed status, it forwards the AO's notice of accreditation and recommendation of deemed status to the SA. The SA must prepare an initial certification packet for the provider or supplier. The certification packet is sent by the SA to the RO, with the Medicare Health Insurance Agreement (Form CMS-1561, 1561A or 370, depending on provider/supplier type) submitted to the SA by the applicant, along with any other documentation required for initial certification of that provider/supplier type. (See Exhibit 63 for documentation requirements.) In the remarks section of the Form CMS-1539, the SA indicates that it is transmitting an initial certification kit for an accredited, deemed provider/supplier. Once the RO receives the certification packet, it proceeds as described in Section 2005A2. The RO must send to the AO in a timely manner a copy of its approval letter to the applicant. Among other things, the copy of the approval letter advises the AO of the CCN assigned to the new provider's/supplier's Medicare agreement, facilitating the AO's ability to report accurate data to CMS on its deemed status providers/suppliers.

If the RO's review of the accreditation survey suggests a problem, including, but not limited to:

- the AO's survey report describes findings which represent substantial noncompliance with a Medicare condition, but the AO awarded accreditation anyway; or

- the AO's survey report indicated the applicant was required to submit an acceptable POC for lower-level deficiencies, but the AO issued its accreditation effective on a date prior to its receipt of the POC; or

- the AO conducted an extension survey but the applicant is a new owner that rejected assignment of the prior owner's Medicare agreement and must therefore undergo a full accreditation survey;

the RO may, consistent with §488.6(c)(2), reject the AO's recommendation of deemed status. In such cases the RO contacts the AO to discuss its concerns and ways the AO may remedy them, if possible. If the problems are not remedied, the RO may issue a denial of certification to the applicant and provides a copy to the AO in a timely manner.

Applicant Not in Compliance

If the AO finds the applicant's failure to meet its CMS-approved Medicare accreditation program requirements represents substantial noncompliance with accreditation standards, including applicable Medicare CoPs or CfCs, the AO may **not** recommend the applicant for Medicare certification via deemed status. Rather, the AO must inform the applicant and the RO of the results of the initial survey and that it is not recommending the applicant for deemed status. The RO issues a denial of certification based on the AO's information, and provides a copy to the AO in a timely manner.

The applicant may, at the AO's discretion, continue to work with the AO to correct the deficiencies and again seek initial certification through deemed status. If the applicant is surveyed again by the AO the survey must be a new survey which is a full, standard survey, except:

- If on the first survey an applicant subject to the Life Safety Code (LSC) requirements was in substantial compliance with the LSC, the AO has the discretion to not resurvey for LSC compliance (although it must receive an acceptable Plan of Correction for any lower-level deficiencies before it may recommend deemed status); and

- In the case of an applicant seeking to participate as a hospital, the AO has the discretion to conduct a new survey of only those conditions for which the applicant was found non-compliant during the prior survey. If the AO chooses to conduct such a focused subsequent survey, the hospital applicant must submit an acceptable plan of correction for all noncompliance identified in the prior survey, including for conditions where there were only lower-level deficiencies cited, before the AO may conduct the subsequent survey.

  NOTE: It is not possible for an initial applicant to seek CAH status; the applicant must first be certified as a hospital, and then subsequently the hospital may apply to convert to CAH status. This is technically a conversion, not an initial application. If the AO advises CMS that it is not recommending the applicant for CAH deemed status or if the RO determines that the applicant does not satisfy the CAH location requirements, then the RO sends a letter denying the hospital's request to convert to CAH status. Unless the denial was based on the applicant not satisfying the CAH location requirements, the applicant may, at the AO's discretion, continue to work with the AO to correct the deficiencies and again seek CAH certification through deemed status. As with initial hospital applicants, the AO has the discretion to conduct a new survey of only those conditions for which the CAH applicant was found non-compliant during the prior survey. If the AO chooses to conduct such a focused subsequent survey, the CAH applicant must submit an acceptable plan of correction for all noncompliance identified in the prior survey for all noncompliance identified in the prior survey, including for conditions where there were only lower-level deficiencies cited, before the AO may conduct the subsequent survey.

In all cases the RO retains the authority to require a new full survey if it has concerns about a deemed status recommendation based on a focused survey after a prior survey identified substantial noncompliance. In cases where the RO anticipates that it will require a new full survey, it should notify the AO of this as soon as possible, to facilitate planning for the full survey by the AO.

If the AO continues to find substantial noncompliance on the subsequent survey, the above process may be repeated. However:

- The applicant may submit no more than two reapplications for certification in

connection with one enrollment application; and

- No more than six months may elapse between the date of the RO's first denial of certification and receipt by the RO of a second reapplication for certification (for a total of three certification applications).

If the applicant fails to demonstrate compliance by the end of this six month period, the RO not only issues a final denial of certification, but also sends a written recommendation to the MAC that the enrollment application be closed out as denied. If the applicant continues to seek enrollment and certification, the RO must receive a new MAC recommendation for approval before it may process a new certification application.

2005B - Deemed Providers/Suppliers Except CLIA – Additional Information

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

AO renewal of deemed provider/supplier accreditation:

AOs conduct re-accreditation surveys of Medicare-deemed providers and suppliers on a triennial basis. Upon awarding re-accreditation, the AO also makes a recommendation for the provider's or supplier's continued Medicare deemed status. The provider's or supplier's deemed status continues without interruption.

When the AO notifies CMS of its renewal of accreditation and recommendation of continued deemed status, the RO forwards the notice to the SA and the SA must prepare a recertification kit for the provider or supplier. The recertification packet is sent by the SA to the RO, with the Form CMS-1539 and any other documentation required for that provider/supplier type. (See Exhibit 63 for documentation requirements.) In the remarks section of the Form CMS-1539, the SA indicates it is transmitting an accredited, deemed provider/supplier update.

Termination/Withdrawal; Removal of Deemed Status

The AO must notify CMS whenever a provider's or supplier's accredited status is not renewed, as well as the reason for the loss of accreditation. If the AO notifies CMS that the AO has terminated a provider's or supplier's accreditation, or that the provider or supplier has voluntarily withdrawn from the AO's CMS-approved Medicare accreditation program, the RO must remove the provider's or supplier's deemed status, unless there is evidence of accreditation under another CMS-approved Medicare accreditation program. For example, if the provider or supplier was accredited simultaneously under two CMS-approved programs, and one AO notifies CMS of a termination or withdrawal, the provider/supplier would continue to have deemed status based on the other accreditation. However, if the notice of termination by the first AO indicates that the reason for termination was the provider's/supplier's failure to meet accreditation standards, the RO must consider this a substantial allegation of noncompliance with Medicare standards and must authorize the SA to conduct a complaint investigation.

If one AO provides notice of termination or withdrawal and concurrently another AO recommends deemed status, a recertification packet including the new AO recommendation must be submitted by the SA to the RO. (See also Section 3258.)

If the RO removes the provider's or supplier's deemed status, it places the provider/supplier under the jurisdiction of the SA and must advise the SA of the change in the provider's/supplier's status. The SA surveys the facility in order to provide assurance that the facility is in compliance with the applicable Medicare conditions. The timing of the SA survey depends on the reason for the provider's/supplier's loss of accreditation:

- If the AO terminates accreditation due to failure of the provider/supplier to meet accreditation standards, then the SA must conduct a standard survey within 45 calendar days of notification by the RO that deemed status has been removed. If the AO's reason for termination appears to be related to an immediate jeopardy, then the RO instructs the SA to conduct the standard survey as soon as possible.

- If the AO terminates accreditation due to voluntary withdrawal or failure to pay fees by the provider/supplier, the SA prioritizes the provider's/supplier's survey on the basis of the current CMS policy concerning survey frequencies and SA workload priorities, using the date of the most recent accreditation survey to calculate the survey interval, unless:

    - The facility is a home health agency (HHA). Then the SA must conduct the survey no later than 3 years after the last accreditation survey; or

    - The RO exercises its discretion to request the SA to conduct the survey by a specified date.

CMS may also temporarily remove deemed status (and therefore AO jurisdiction) when a SA or Federal survey team identifies condition-level non-compliance in a deemed provider or supplier during either a representative sample or substantial allegation validation survey. The RO advises the provider or supplier that its deemed status is removed and that it is being placed under SA jurisdiction. However, no change is made to the provider's or supplier's deemed status in the Automated Survey Process Environment (ASPEN). Instead, the placement of the provider or supplier under SA jurisdiction is noted under the Deeming tab within the certification kit in ACO.

The provider/supplier remains under SA jurisdiction until it either demonstrates substantial compliance or CMS terminates its Medicare participation. If the provider/supplier demonstrates substantial compliance to the SA, CMS restores its deemed status. Note that there is no prohibition against an AO also conducting its own survey of a provider/supplier that is temporarily under SA jurisdiction.

Other AO adverse actions

The AO is required to inform CMS of significant adverse actions it takes against the accreditation status of a provider/supplier participating through deemed status. However,

as long as the accreditation under the AO's CMS-approved Medicare accreditation program is not terminated, the provider/supplier's participation in Medicare is not affected. See Section 3258 for information on actions to take when an AO terminates the accreditation of a deemed provider or supplier.

The AO is also required to inform CMS by close of business the next day when it identifies an immediate jeopardy situation on a survey. In such cases, the RO generally triages this as an immediate jeopardy complaint and directs the SA to conduct a substantial allegation validation survey, based on the information provided by the AO.

2005C - Clinical Laboratory Improvement Amendments of 1988 (CLIA) Laboratories

(Rev. 1, 05-21-04)

The procedures for initial certification basically apply to CLIA laboratories with a few exceptions. The enrollment procedures for CLIA laboratories are outlined as follows. CLIA laboratories will be surveyed (if applicable) and registered for CLIA participation whether or not the laboratory enrolls in Medicare. The enrollment Form CMS-855A or CMS-855B process applies to all CLIA laboratories that participate in Medicare. This includes laboratories that have a certificate of waiver, certificate for physician performed microscopy procedures, certificate of accreditation, certificate of compliance, certificate of registration, or are state exempt. However laboratories that bill through the fiscal intermediary (are part of a Part A institutional provider, such as a hospital or SNF) will not need to complete the Form CMS-855A or CMS-855B.

The Form CMS- 855A or CMS-855B will be downloaded from the CMS Web site - http://www.cms.hhs.gov/forms/ and completed by the CLIA laboratory. The SA will mail out Form CMS-116, and any other form needed for CLIA registration to the laboratory. A CLIA laboratory is only required to complete a Form CMS-855A or CMS-855B if it decides to enroll in Medicare. At the time a laboratory initially applies for CLIA registration, inquire as to whether the laboratory intends to bill Medicare.

If the laboratory intends to bill Medicare, send the laboratory Form CMS-116 and Form CMS-855A or CMS-855B. Questions on the Form CMS-855A or CMS-855B, form should be addressed to the intermediary/carrier. The SA will send the laboratory the Form CMS-116. The laboratory will complete and return the Form CMS-116 to the SA and the Form CMS-855A or CMS-855B to the FI or Carrier. The SA will enter the Form CMS-116 into the CLIA data system, and the system will assign a CLIA number to the laboratory. For CLIA laboratories, the intermediary/carrier will be responsible for all aspects of the Form CMS-855A or CMS-855B and Medicare enrollment processing. After the intermediary/carrier has reviewed and verified the Form CMS-855A or CMS-855B, it will send a completed copy of the Form CMS-855A or CMS-855B to the RO and State survey agency along with its recommendation for approval or denial. (See §2005.A) for instructions regarding approvals, denials and appeals.) Processing of the Form CMS-855A or CMS-855B will not affect the scheduling of CLIA surveys since CLIA registration must occur regardless of Medicare enrollment. If a laboratory is denied for Medicare, follow the instructions for denials and take all appropriate CLIA-related

actions.

If the laboratory does not plan to bill Medicare, it should complete Forms CMS-116 and return it to the State survey agency.

2005D - Supplementary Applications
(Rev. 1, 05-21-04)

An additional application used for supplementary purposes to support the Form CMS-855A or the CMS-855B is The Medicare Individual Reassignment of Benefits Health Care Provider/Supplier Application (Form CMS-855R). The Medicare Change of Information Health Care Provider/Supplier Application (Form CMS-855C) is no longer used. The CMS-855A or the CMS-855 B is used to report changes to enrollment (see also §2003). The fiscal intermediary/carrier will send a copy of the Form CMS-855A or CMS-855B with the updated/changed information to the appropriate State Agency and RO.

2005D1 - Forms CMS-855A or the CMS-855B for Changes in Provider/Supplier Information
(Rev. 1, 05-21-04)

Application changes are changes to any items on the Form CMS-855A or CMS-855B. These changes require the submission of the appropriate updated sections of the Form CMS-855A or CMS-855B with a signed certification statement. The changes will be reviewed by the fiscal intermediary/carrier. The review will result in a recommendation for approval, denial, or return for additional information. The fiscal intermediary/carrier will send a copy of the Form CMS-855A or CMS-855B with the updated/changed information to the State agency or RO that distributed the initial application.

When a provider experiences a change of ownership the current owner will check the box marked “potential termination of current ownership” on the Form CMS-855A or CMS-855B.

Voluntary use of the Form CMS-855A or CMS-855B is encouraged for providers/suppliers that were previously certified without completing the Form CMS-855A or CMS-855B. However, these providers/suppliers may submit these changes in writing on letterhead with an authorized signature.

2005D2 - Form CMS-855R
(Rev. 1, 05-21-04)

In general, Medicare only makes payments to the individual or entity that directly provides services. However, an individual may reassign benefits to an eligible entity as defined in 42 CFR 424.80. This application must be completed when an individual practitioner is reassigning his/her benefits to an eligible entity. An eligible entity is a business organization that is eligible to receive reassigned benefits (e.g., employer, facility, health care delivery system or agent). Not every provider/supplier will need to complete the Form CMS-855R. Organizations that are likely to receive reassigned benefits

are: hospitals, hospices, SNF, ESRD, RHC, CORF, FQHC, and CMHC.

The Form CMS-855R is available to applicants for downloading via the CMS Web site at http://www.cms.hhs.gov/forms/. The State survey agency should inform the applicant that any questions concerning the Form CMS-855R should be directed to the intermediary or carrier. If the State agency receives the Form CMS-855R, it will forward the Form CMS-855R to the intermediary. After reviewing the application and making a recommendation, the intermediary will forward the package to the carrier for the carrier's review of the reassignment of benefits.

2005E - Changes of Ownership
(Rev. 1, 05-21-04)

See §3210 for a full discussion of change of ownership (CHOW). The following procedures apply to all provider/supplier types that are subject to survey and/or certification.

2005E1 - CHOW Occurs
(Rev. 1, 05-21-04)

For a CHOW, the current owners will submit a Form CMS-855A or CMS-855B citing the termination of current ownership. The current owner will check the box marked "potential termination of current ownership" on the Form CMS-855A or CMS-855B and complete Section 1 (Provider/Supplier Information), Section 8 (Potential Termination of Current Ownership), and Section 10 (Attestation Statement). The new owners will complete and submit a new Form CMS-855A or CMS-855B.

The current and new owners will submit the Form CMS-855A or Form CMS-855B along with any supporting documents to the FI or carrier. The RO has the delegated authority for making the determination if a CHOW actually exists. [However, the RO may delegate this responsibility to the State agency.] For complex or questionable situations, the FI/carrier will forward all documents to the RO for review. Upon review of all documents, the RO will make the decision as to whether or not a CHOW has occurred. The intermediary/carrier will verify the Forms CMS-855A or CMS-855B and may take one of three actions on a CHOW:

- Recommendation for approval;
- Recommend for denial; or
- Request for additional information.

Verification of Information From Intermediary/Carrier - After a complete review and verification of the application, if no additional information is needed, and there is no need to issue a denial, the intermediary/carrier notifies the RO/SA of its verification of information provided about the CHOW within 30 calendar days (absent extenuating circumstances) of the receipt of the completed enrollment applications. The notification

will be written and accompanied by a copy of the completed Forms CMS-855A or CMS-855B, if any changes were made to the forms.

RO Determines CHOW Has Occurred - If the RO determines that a CHOW has occurred, the RO waits until it receives the intermediary/carrier's verification of information about the CHOW before completing the process. When the process is completed, the RO will notify the provider/supplier, State agency and intermediary/carrier that a CHOW has occurred.

RO Determines CHOW Has Not Occurred - The RO makes the final decision whether a CHOW has actually occurred. If the RO determines that a CHOW has not occurred, the RO notifies the provider/supplier, the State survey agency, and the intermediary/carrier that a CHOW has not taken place. The notification should explain the reason(s) why a CHOW has not occurred.

Recommendation for Denial from Intermediary/Carrier - After a complete review and verification of the application, the intermediary/carrier may recommend a denial of the Form CMS-855A or Form CMS-855B based on one or more of the reasons for denial stated in §2005.A.3. The intermediary/carrier will send the recommendation of denial to the RO/SA.

For a CHOW, the provider agreement may be automatically assigned to the new owner. However, the new owner could choose to come into Medicare as a new applicant and should be advised of this option. In such a case if the new owner accepts the assignment it also assumes the former owners liabilities. (The new owner could also receive an outstanding underpayment under this scenario). The new owner must enroll the same as any other new applicant (see §3210), undergo the survey and certification process, and be issued a new provider agreement/number. The RO/SA processes a voluntary termination of the provider agreement of the former owner.

2005E2 - Change in Intermediary as Result of CHOW
(Rev. 1, 05-21-04)

Providers who are changing their intermediary as a result of a CHOW, acquisition, merger, or consolidation should submit the information to the new intermediary of preference. This information, which is required to be submitted by Form CMS-855A, should be promptly processed by the new intermediary. However, the provider should also request a change of intermediary from the RO. If an FI receives a Form CMS-855A for a CHOW that requires a change of intermediary, it should contact the provider and advise it to contact the current RO for a change of intermediary. The new intermediary shall contact the outgoing intermediary and provide it with the submitted information. If the provider mistakenly submits the CHOW information to the old intermediary, the old intermediary shall contact the new preferred intermediary and forward the submitted information to it. The new intermediary shall note on any recommendation for approval if a required change of intermediary request has not yet been approved by the RO.

NOTE: CHOW determinations are the responsibility of the RO unless otherwise

delegated.

2005E3 - CHOWs Involving Multi-Regional Chain Organizations
(Rev. 1, 05-21-04)

When a CHOW involves a multi-regional chain organization, a lead or coordinating RO is designated. This will typically be the RO serving the State in which the headquarters of the chain doing the acquiring is located. The coordinating RO will notify all other affected ROs and intermediaries involved in the CHOW determination and processing of enrollment activities. The lead RO may decide which intermediary(ies) will process the new CHOW applications. A separate Form CMS-855A is still required for each separately surveyed provider/supplier. However, they all may be processed simultaneously by the receiving intermediary when the incoming chain requests one intermediary for all the units. Each intermediary shall follow the instructions of the lead RO for CHOWs involving multi-regional chains.

For a CHOW which involves multiple incoming or multiple outgoing intermediaries handled by the same RO, the RO shall also direct where and how the new application should be reviewed, and serve as the coordinator for the CHOW in a manner similar to being the lead RO for a multi-regional CHOW.

2005E4 - Change of Owners, but Not CHOW
(Rev. 1, 05-21-04)

A partnership provider sometimes experiences an addition or deletion of personnel, but a CHOW does not occur. For example, a provider may add or delete owners without experiencing a CHOW. In these situations, the provider should complete section 10 (Ownership Information) on the Form CMS-855A or CMS-855B. It should also complete identifying information in section 1 (Applicant Information) and section 19 (Certification Statement). The rest of the form does not need to be completed. Advise the provider/supplier to submit the Form CMS-855A or CMS-855B directly to the intermediary/carrier. The intermediary/carrier will send a copy of the Form CMS-855A or CMS-855B to the SA/RO when it has completed its verification.

In certain situations, based on the review of a submitted Form CMS-855A or CMS-855B, the intermediary/carrier may suspect that a CHOW has occurred that the RO may not be aware of. In these cases, the intermediary/carrier may notify the State survey agency and RO and request a determination. The intermediary/carrier will send a letter to the State survey agency and RO, along with a copy of the Form CMS-855 or CMS-855B and any supporting documentation. The RO will determine whether a CHOW has actually occurred and report its findings to the intermediary and the State survey agency.

2005F - Voluntary Terminations
(Rev. 201, Issued: 06-19-20, Effective: 06-19-20, Implementation: 07-27-20)

A provider *agreement may be voluntarily terminated in accordance with the regulations at 42 CFR §489.52. The provider must send written notice of its intention, a letter on*

letterhead with an authorized signature, to its RO or SA within the timeframes addressed in §489.52. Suppliers must provide notice in accordance with the regulatory requirements specific for the supplier *type.*

Additionally, a provider/supplier *must properly complete and submit the applicable Form CMS-855A or CMS-855B* to the MAC. If the provider/supplier sends the Form CMS-855A or CMS-855B for voluntary termination directly to the *MAC*, then the *MAC* will notify the RO and *SA via email within three days from the receipt of the completed form.*

NOTE: *In a change of ownership situation, the rejection of automatic assignment of the existing provider/supplier agreement (by the new owner) is a voluntary termination of the agreement/approval, including its associated CCNs, in accordance with 42 CFR 489.52.*

Further, if the new owner rejects automatic assignment of the acquired facility's existing provider/supplier agreement, and that facility previously was deemed to meet the applicable conditions based on its accreditation under a CMS-approved Medicare accreditation program, the accrediting organization (AO) may not "extend" the facility's prior deemed status to the new owner. Instead, the AO must conduct a full initial accreditation survey of the facility under its new ownership after the acquisition date. The effective date of the new owner's Medicare provider agreement or supplier approval is established in accordance with the provisions of 42 CFR 489.13. For complete information on CHOWs, see SOM 3210.

NOTE: *A cessation of business is a voluntary termination under 42 CFR 489.52(b)(3).*

2008 - Prioritizing SA Survey Workload - Initial Surveys and Recertifications
(Rev. 1, 05-21-04)

2008A - Surveys of New Providers and Suppliers
(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

New providers/suppliers, including providers/suppliers whose previous Medicare agreement was terminated and are now seeking initial certification, must be in full operation and providing services to patients when surveyed. This means that at the time of survey, the institution must have opened its doors to admissions, be furnishing all services necessary to meet the applicable provider or supplier definition, and demonstrate the operational capability of all facets of its operations. To be considered "fully operational," initial applicants must be serving a sufficient number of patients so that compliance with all requirements can be determined.

A survey evaluates the manner and degree to which the provider or supplier satisfies the various requirements or standards within each condition. Surveyors must directly observe the provision of care and services to patients, and the effects of that care, in addition to interviewing staff and patients and reviewing medical records to assess whether the care provided meets the needs of individual patients and is in compliance with all requirements. Surveyors also review selected provider/supplier policy and procedure

documents if needed to support or clarify observations suggesting deficiencies.

When the provider/supplier notifies the SA of full operation, the SA documents the file with the date of notification. The SA conducts the survey in a timeframe consistent with CMS policy regarding budget and workload priorities.

2008B - Initial Surveys of HHAs

(Rev. 1, 05-21-04)

In addition to an onsite survey to determine compliance with the health and safety conditions of participation (CoP), an HHA applicant must now meet capitalization requirements, and complete the enrollment information contained on the Form CMS-855A or CMS-855B, which includes the HHA's ownership information. Also, the Centers for Medicare & Medicaid Services (CMS) is now requiring each HHA applicant to have provided skilled home health services to a minimum of 10 patients before a survey is conducted. At least 7 of the 10 required patients should be receiving care from the HHA at the time of the initial Medicare survey.

2008D - Effective Date of Medicare Provider Agreement or Approval for Suppliers

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

In accordance with 42 CFR 489.13, the effective date of participation in the Medicare program, i.e. the effective date indicated on the provider or supplier agreement issued by the RO, may not be earlier than the date on which the provider or supplier meets all federal requirements. Federal requirements include, but are not limited to:

- Meeting all Medicare enrollment requirements addressed in 42 CFR 424;
- Meeting all Medicare provider agreement requirements addressed in 42 CFR 489.10 and 42 CFR 489.12, and;
- Compliance with Medicare health and safety standards, i.e., the Conditions of Participation, Conditions for Coverage, Conditions for Certification, or long term care Requirements, as applicable.
    - For an agreement with a federally qualified health center (FQHC), no survey is required to determine compliance. The effective date is the date on which CMS accepts a signed agreement in which the FQHC attests that it meets all Federal requirements. For FQHCs, the RO uses as the effective date of the supplier approval the date that the MAC indicates it determined that the FQHC's enrollment application was complete and approvable.
    - A Medicare supplier approval of a laboratory is effective only while the laboratory has in effect a valid CLIA certificate issued under 42 CFR Part 493, and only for the specialty and subspecialty tests it is authorized to perform.

- Other types of providers and suppliers demonstrate compliance with applicable conditions or requirements via a standard survey by the SA (or Federal surveyors/contractors), or by an AO with a CMS-approved Medicare accreditation program.

    - If on that survey the provider or supplier meets all health and safety standards (including elements, where applicable), then the effective date of the Medicare agreement is the last day of the survey, **unless** there are other Federal requirements, such as providing evidence of compliance with Civil Rights requirements, that the provider or supplier has not yet met. The date when all other Federal requirements have been met is the effective date of the Medicare agreement.

    - If on that survey the provider or supplier does not meet all health and safety standards (including elements, if applicable), then, assuming all other Federal requirements have been met, the effective date of the Medicare agreement would be:

        - For SNFs, the date the SNF has been found to be in substantial compliance with the requirements for participation, and, if applicable, has submitted an approvable waiver request. (See 42 CFR 488.301.)

        - For non-long term care providers/suppliers, the date when the provider/supplier has:

            - Met all applicable conditions; **or**

Has been found to be in substantial compliance, but has standard-level (or element-level, where applicable) deficiencies and the RO (in the case of surveys conducted by contractors), SA or AO has received an acceptable plan of correction (POC) and/or CMS receives an approvable waiver request. If a provider or supplier submits both a POC and an approvable waiver request, the later of the dates of the two submissions would be the effective date.

2008E - Administrative Considerations

(Rev. 1, 05-21-04)

The SA will schedule more frequent surveys and follow-up visits for providers and suppliers with a history of poor performance. Keep in mind geographical considerations and the scheduling of licensure visits and coordinate visits whenever possible. Changes of Ownership (CHOWs) may necessitate adjustment of the survey interval. (See §2702.)

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.)

2010 - Ascertaining Compliance With Civil Rights Requirements

(Rev. 53; Issued: 10-16-09; Effective/Implementation Date: 10-16-09)

Before an agreement is executed with a provider to participate in the Medicare program or with a provider undergoing a change in ownership (CHOW), there must be a determination of compliance with civil rights requirements. OCR conducts necessary investigations and makes determinations related to compliance with the requirements. If the RO cannot secure an OCR clearance within 20 calendar days, it issues a restricted

provider agreement with a contingency clause, which states that if OCR approval is not obtained, payment will be recouped as of the date the provider agreement is effective.

The SA provides potential providers with the required OCR Civil Rights Certification Information Request Packet (Packet) for clearance. The SA collects the completed Packet (including the signed questionnaire, signed HHS-690 form, and policies and procedures) from potential providers and forwards them to the RO.

SAs should take the following steps:

- Include the Packet with the initial enrollment package that is sent to a potential provider or to a provider undergoing a CHOW;

- Ask the potential provider or provider undergoing a CHOW to return the completed signed questionnaire, HHS-690 Form, and civil rights policies and procedures to the SA with the rest of the Medicare application package;

- Ensure that completed OCR documents are included in the Medicare package before forwarding to the CMS RO; and

- Inform the potential provider or provider undergoing a CHOW that the Medicare application will not be forwarded to CMS until the civil rights documents and forms have been completed and returned to the SA.

NOTE: OCR has Civil Rights Corporate Agreements (Agreements) with certain health care corporations. Providers that belong to those corporations need to submit ONLY the signed certification sheets, as specified in the corporations' Agreements.

Processing OCR Documents - Upon receipt of the OCR documents, the CMS RO forwards them to the OCR for processing and clearance. The role of the SA and CMS is limited to obtaining the documents and forwarding them to OCR.

Copies of the current version of the Packet can be downloaded from http://www.hhs.gov/ocr/civilrights/resources/providers/medicare_providers/index.html. SAs must include this link with their initial certification and CHOW packages.

Regarding Medicaid-only providers, the States themselves are recipients of the Federal funds and may be considered to have a direct obligation to assure OCR of their compliance by assuring that funds go to providers who are in compliance. As with Medicare, potential providers or providers undergoing a CHOW must be determined to be in compliance with civil rights laws by OCR as a condition for approving the provider's participation in the Medicaid program.

2012 - SA Identifying Eligible Providers and Suppliers

(Rev. 1, 05-21-04)

Initial certifications of providers or suppliers involve steps, including enrollment, to survey applying providers/suppliers and confirm their eligibility. These steps are not repeated on cyclical recertification if the basic eligibility factors have not changed. Since the requirements in the statute and regulations differ for specific provider/supplier categories, the initial identification and screening procedures are unique to each type of provider or supplier.

For Medicare purposes, the SA initial certification of compliance occurs before the RO makes its official determination that the provider/supplier meets all necessary requirements. The SA may contact the RO for advice if some aspect of Medicare eligibility is in dispute. Ordinarily, the SA develops as much information on the issue as is appropriate, completes the certification, and forwards the documentation to the RO for its decision. The SA should use the following criteria:

- If the provider/supplier meets the CoPs, Conditions for Coverage, or in substantial compliance with the Requirements for SNFs, and is in full compliance with all other requirements, i.e., no deficiencies, send the Certification and Transmittal (Form CMS-1539) and all other documents to the RO within 10 calendar days of the survey; or

- When the provider/supplier meets the CoPs or Conditions for Coverage, but it fails to meet other requirements, i.e., it has deficiencies below the Condition level, transmit all documentation to the RO within 45 calendar days of the survey. A provider/supplier found to be deficient with one or more standards, or other requirements below the Condition level may participate if it has submitted an approved PoC for achieving compliance within a reasonable period of time. A PoC must be submitted within 10 calendar days of the facility's receipt of the official Form CMS-2567. The entity may be granted additional time if the plan is complex. (See Chapter 7 for SNFs and NFs.)

Provider institutions are often complex health care delivery institutions centered around primary short-term hospitals. Although a totally new hospital may be rare, provider complexes frequently re-combine and reform or merge. This may or may not create new certification entities. In general, if the statute or regulations provide for separate certification of related or satellite components, they must be separately certified, e.g., a distinct part SNF in a hospital.

In some instances a satellite's certification depends upon the primary provider being approved to participate, e.g., a hospital-based hospice or an ESRD transplant center. The SA should recognize and act upon organizational combinations, and complete Form CMS-1539 to reflect a change. A provider is the party having ultimate responsibility and liability for the operational decisions of the institution. Consequently, the SA should know what components are under the control of the provider's governing body (as opposed to being loosely affiliated), and when the governing body's control of a component has changed.

2016 - Readmission to Medicare or Medicaid Program After Involuntary

Termination - Reasonable Assurance
(Rev. 1, 05-21-04)

(See also Chapter 7 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 42 CFR 489.53 and reinstated under 42 CFR 489.57 or a Medicaid ICF/IID provider terminated pursuant to §1910(b)(1) 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 (42 CFR 416.35(e)), FQHCs (42 CFR 405.2440), RHCs (42 CFR 405.2404(e)), and ESRD facilities (42 CFR 405.2180(c)).

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.

2016C - Request for Readmission
(Rev. 1, 05-21-04)

A terminated provider or supplier may reapply for certification at any time. Upon receipt of a request from an involuntarily terminated entity that desires readmission to the program, the SA immediately contacts the entity and informs it of the requirements for readmission. If the reasonable assurance time-period was not established at the time of termination, the SA contacts the RO and requests that it establish the reasonable assurance period so that it may be included in the letter to the facility informing it of the requirements for readmission to the program. **(The RO may choose to delay establishment of the reasonable assurance period pending the results of the first survey.)** Use Exhibit 41 to inform the provider or supplier of the reasonable assurance provisions and to transmit the required documents necessary for future participation. (See the applicable initial certification section in Exhibit 63 for the required documents.)

If the institution then indicates that it meets the requirements for participation and returns the initial application packet, forward the application packet to the RO via a Form CMS-1539. The RO will contact the previous servicing intermediary. The intermediary, in turn, advises the RO whether there are any outstanding financial problems, such as overpayments, that need to be resolved before the institution is readmitted. In addition, the RO takes immediate action to obtain title VI clearance.

2016D - Reasonable Assurance Surveys
(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

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 for Medicare certification to verify that the reason for termination no longer exists, and that the provider/supplier has maintained continued compliance. At least one of these surveys must be a full/standard survey to ensure that all CoPs/CfCs are met or the SNF is in substantial compliance. The RO has the discretion to determine whether both surveys will be full/standard surveys, or whether one may be a partial survey to document compliance with requirements for which there were previous deficiencies. If the RO decides that one survey will be a partial survey, the RO also decides whether the partial survey will be the first or the second survey. (CMS, at its discretion, conducts the survey for a 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 documenting compliance with requirements for which there were prior deficiencies.

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 involuntarily terminated provider/supplier attempts to re-enter the Medicare program via deemed status accreditation under a CMS-approved Medicare accreditation program, it must still satisfy the reasonable assurance requirements at 42 CFR 489.57. The RO has the discretion to deny Medicare reentry based solely on deemed status accreditation surveys and may instead require two surveys be performed by the SA if it is not reasonably assured the provider/supplier meets the Medicare conditions. The RO also has the discretion to accept an accreditation survey for either the first or second of the reasonable assurance surveys. Generally an AO would not conduct both reasonable assurance surveys, but if it is willing to do so and the RO is reasonably assured that the provider/supplier meets the Medicare conditions, the RO may permit the AO to conduct both reasonable assurance surveys.

In cases involving readmission of an involuntarily terminated provider seeking deemed status, 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/supplier's reentry into the Medicare program. 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 accreditation under a CMS-approved Medicare 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.

2016E - Effective Date of Provider Agreement After Reasonable Assurance

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

If the provider or supplier has maintained compliance throughout the reasonable assurance period, it may reenter the program and be issued a new provider agreement or supplier approval. The effective date of the new Medicare agreement and Medicaid FFP is calculated based on the date of completion of the second reasonable assurance survey. See Section 2008D for details on the calculation of the effective date.

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).)

2016G - Under LSC at Time of Readmission

(Rev. 1, 05-21-04)

1. Termination Based on LSC or Health Conditions

Upon readmission, an institution that was terminated for noncompliance with the LSC must be surveyed under the edition of the Code in effect under current regulations.

2017 - Readmission Following Voluntary Termination of Program Participation

(Rev. 1, 05-21-04)

If termination action has been initiated but the entity is allowed to terminate Medicare participation voluntarily before the action is made effective, the reasonable assurance provision will be applied. If there is not a SA certification of noncompliance at the time a

provider/supplier notifies the RO of voluntary termination, the reasonable assurance provision does not apply.

2018 - Reinstatement Following Termination of Swing-Bed - Approval
(Rev. 1, 05-21-04)

If swing-bed approval has been terminated for any reason, there is a statutory 2-year minimum waiting period for reinstatement. Do not apply the “reasonable assurance” concept in these situations. (See §1883(c) of the Act.)

Hospitals

2020 - Hospitals - Definition and Citations
(Rev. 1, 05-21-04)

A hospital is defined in §1861(e)(1) of the Act. A hospital is an institution primarily engaged in providing, by or under the supervision of physicians, inpatient diagnostic and therapeutic services or rehabilitation services. The remainder of §1861(e) defines a hospital eligible for Medicare participation. Section 1861(f) defines Medicare eligible psychiatric hospitals. 42 CFR 482 sets forth the CoPs for hospitals, including psychiatric hospitals. The interpretive guidelines for hospitals appear in Appendix A and Appendix AA.

2021 – Non-deemed Hospitals
(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

2021A – Recertification of Non- deemed Hospitals
(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

Hospitals that are certified for Medicare participation based on a SA survey should be recertified on a schedule consistent with the survey guidelines for non-deemed hospitals issued by CMS each fiscal year. A recertification packet for each hospital is to be sent to the RO by the SA. Exhibit 63 has a complete list of documents to be completed and included in the recertification packet. The Certification & Transmittal Form, CMS-1539 (C&T), which is part of the recertification packet, should indicate in the "remarks" section that the C&T is transmitting a non-deemed hospital recertification. If the hospital has undergone a change of ownership with acceptance of assignment of the Medicare provider agreement by the new owner since the last recertification survey, also indicate if a Change of Ownership (CHOW) package was forwarded to the hospital by the SA.

In addition, the SA also updates Exhibit 286, the Hospital/CAH Medicare Database Worksheet, with any new information regarding the hospital. It is not permissible to forward the Hospital/CAH Medicare Database Worksheet to the hospital for completion. The SAs are not expected to conduct an onsite visit of the hospital solely to obtain information for the worksheet. However, the SAs may be able to use State licensure data to update the worksheet. The updated Hospital/CAH Medicare Database Worksheet should be forwarded with the recertification packet to the RO. The ASPEN system must also be updated to reflect any changes to the information on the Hospital/CAH Medicare Database Worksheet. This policy applies to ALL non-deemed hospitals.

2022 - Deemed Status: Hospitals Accredited by an Accrediting Organization with a CMS-approved Medicare Hospital or Medicare Psychiatric Hospital Accreditation Program
(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

2022A - Notice that a Participating Hospital Has Been Accredited and Recommended for Deemed Status

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

A hospital accredited and recommended for deemed status by a national accreditation organization with a CMS-approved Medicare hospital accreditation program may be deemed to meet all CoPs for hospitals (except the SNF Requirements for swing-bed designation and any higher-than-national standards approved by the Secretary for a State under §1863 of the Act). Additionally, a psychiatric hospital accredited and recommended for deemed status by a national accreditation organization with a CMS-approved Medicare psychiatric hospital accreditation program may be deemed to meet all CoPs for psychiatric hospitals.

When notified that a participating hospital or psychiatric hospital has been accredited and recommended for deemed status, the RO verifies the accreditation and recommendation for deemed status and notifies the SA. The SA executes Form CMS-1539 to report the accreditation and recommendation for deemed status.

2022B - Recertification

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

Hospitals or psychiatric hospitals that receive their Medicare certification via deemed status based on accreditation by a CMS-approved Accreditation Organization (AO) should be recertified by the State Survey Agency (SA) on a schedule consistent with the accreditation interval of the AO. Upon receipt of a notice from the AO indicating that it has renewed a hospital's accreditation and is recommending continued deemed status, a recertification kit should be created in the Automated Survey Processing Environment (ASPEN) or recertification packet for each deemed hospital or psychiatric hospital is to be sent to the RO by the SA. Exhibit 63 has a complete list of documents to be completed and included in the recertification packet. The Certification & Transmittal Form, CMS-1539 (C&T), which is part of the recertification packet, should indicate in the "remarks" section that the C&T is transmitting an accredited hospital recertification.

In addition, the SA also updates the Hospital/CAH Medicare Database Worksheet, Exhibit 286, with any new information regarding the hospital. It is not permissible to forward the Hospital/CAH Medicare Database Worksheet to the hospital for completion. The SAs are not expected to conduct an onsite visit of a deemed hospital solely to obtain information for the worksheet. However, the SAs may be able to use State licensure data to update the worksheet. The updated Hospital/CAH Medicare Database Worksheet must be entered into ASPEN and be included in the recertification kit forwarded to the RO; the recertification kit will not upload to the national data base unless a Hospital/CAH Medicare Database Worksheet has been completed.

2022C - Notification of Withdrawal or Loss of Accreditation

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

See Section 2005B.

2024 - Hospital Merger/Multiple Campus Criteria
(Rev. 1, 05-21-04)

When two or more hospitals merge, the SA ascertains whether to continue to certify the hospitals separately or to certify them as a single hospital (i.e., hospital with a main campus and an additional location). Also, when a hospital establishes an additional hospital facility, geographically separate but in the same metropolitan area, the SA determines whether the additional hospital facility will be certified as a separate hospital or whether it can be considered a single hospital. A hospital may establish an additional hospital facility so organizationally or geographically separate as to make it impossible to operate as a multi-campus hospital.

Each location of a single hospital must meet the applicable CoPs. A certification of non-compliance at the CoP level at any of the hospital locations affects the certification of the hospital as a whole. Consequently, when noncompliance at the CoP level is found, the hospital will either be denied participation or terminated from participation in the Medicare/Medicaid program. When a hospital is to be terminated, the SA follows the termination procedures contained in §3010 and 3012.
In addition, all locations of a single hospital must comply with applicable State licensure laws. When it is determined that any of the hospital locations does not comply with State licensure laws, the hospital as a whole will either be denied participation or terminated from participation in the Medicare/Medicaid program.

Where two or more previously separate hospitals merge, all locations of the surviving hospital must meet the criteria found in §2004. In addition, all non-hospital providers of service under Medicare that state they are part of a single hospital must meet the criteria for provider based designation in §2004 in order to be treated as a single hospital for payment purposes.

2026 - Certification of Parts of Institutions as Hospitals
(Rev. 1, 05-21-04)

2026A - Hospitals (Other Than Psychiatric Hospitals)
(Rev. 1, 05-21-04)

The SA evaluates each general hospital **as a whole** for compliance with the CoPs and certify it as a single provider institution including all components:

- Under the legal control of the hospital governing body and part of the same corporation or governmental administrative entity; and

- Subject to the direction of the hospital administrator and medical staff organization.

The SA evaluates and certifies the whole hospital even when the components are

separately housed.

It is not permissible to certify only part of a general hospital. However, the following are not considered parts of the hospital and are not to be included in the evaluation of the hospital's compliance:

- Components appropriately certified as other kinds of providers or suppliers. i.e., a distinct part SNF and/or distinct part NF, HHA, RHC or hospice; and

- Excluded residential, custodial, and non-service units not meeting the definitions in §1861(e)(1) or (j)(1) of the Act.

2026B - Excluded Non-Service Units May be Appropriate
(Rev. 1, 05-21-04)

The hospital ordinarily requests exclusion of a unit by a letter to the RO through the fiscal intermediary. The RO may then ask the SA to certify information it needs to make the exclusion. Otherwise, the SA excludes from any regular certification those portions of a hospital that are separately identifiable units that do not meet the §1861(e)(1) or (j)(1) definitions.

2030 - Temporary Waivers Applicable to Rural Hospitals
(Rev. 1, 05-21-04)

If a hospital is found to be out of compliance with the 24-hour registered nurse (RN) requirement, a temporary waiver may be granted by the RO. This waiver, however, may be approved only to the extent that it would not jeopardize or adversely affect the health and safety of patients. The waiver may be issued for any **one-year period or less** under certain circumstances, and may be withdrawn earlier if this action is necessary to protect the health and safety of patients. The hospital must meet all CoPs except for the waived requirement.

In determining whether a hospital qualifies for a waiver, the SA verifies that these additional criteria are met:

- The hospital is located in a rural region. The Census Bureau in the most recent census defines Rural as all areas not delineated as an "urbanized" areas. (Use the material in Appendix G, Standard II A, and Tabs A-C of Appendix G, to ascertain whether the area is rural or urbanized);

- The hospital has 50 or fewer beds. Exclude from the bed-count newborn and intensive care beds;

- The character and seriousness of the deficiencies do not adversely affect the health and safety of patients;

- The hospital has made and continues to make a good-faith effort to comply with

personnel requirements consistent with the waiver. Record information concerning the hospital's effort to employ additional RNs. Document the recruitment efforts of the hospital and whether the wage level offered is consistent with other hospitals in the area. Hospitals that pay below the wage level for the area might not be able to attract new personnel; therefore, the RO might determine that they are not making a good-faith effort to attract new nurses;

- The hospital's failure to comply with the 24-hour nursing requirement is attributable to a temporary shortage of qualified nursing personnel in the area in which the hospital is located. Obtain and include any information substantiating the prediction that the shortage is temporary, e.g., names of personnel scheduled to complete qualifying training or scheduled to be engaged and anticipated dates of arrival on duty;

- An RN is present on the premises to furnish or supervise nursing services during at least the daytime shift 7 days a week;

- On all tours of duty not covered by an RN, a licensed practical (vocational) nurse (LPN) is in charge.

The SA includes in the certification package documentation of the above requirements for waiver and the most recent 2-week duty roster for RNs and LPNs.

2034 - Time Limit on Temporary Waiver
(Rev. 1, 05-21-04)

A temporary waiver of the hospital 24-hour RN coverage requirement may not exceed a 12-month period and may not be renewed. A shorter period may be recommended. The RO notifies the hospital of:

- The duration of the waiver;

- A list of deficiencies; and

- A statement indicating that the waiver may be removed prior to its stated expiration date if the hospital fails to maintain its effort to correct its nursing deficiencies.

Regardless of the approved duration of the waiver, it may be withdrawn at any time patient health and safety are adversely affected. Therefore, the SA should plan frequent revisits, make telephone contacts, and request nurse staffing duty rosters to monitor the hospital's progress and to determine that patient health and safety are not jeopardized. The frequency of SA monitoring efforts depends on the hospital's efforts to make corrections, the number and types of patients served, functional arrangement and design of the patient care facility, and the number and qualifications of the RNs and auxiliary nursing personnel.

If the SA finds that continuation of the waiver is not appropriate, it documents the case for termination of the provider agreement. Conversely, if it finds that the hospital has corrected its nursing deficiency, it certifies the hospital without reference to the prior waiver.

2036 - Definition, Authority and Requirements for Hospital Providers of Extended Care Services ("Swing-Beds")

(Rev. 1, 05-21-04)

"Swing-bed" is a reimbursement term that means the care and reimbursement for the care of a patient in a small rural hospital or CAH "swings" from acute care to post hospital skilled nursing care (SNF). A swing-bed hospital means a hospital or CAH participating in Medicare that has an approval from CMS to provide post hospital SNF care and meets the requirements specified in §482.66 for a hospital or §485.645 for a CAH.

Certification to provide swing-beds is an approval separate from the certification to operate as a hospital or CAH. When a survey of swing-beds is completed, any deficiencies and Plans of Correction (PoC) must be documented on a separate Form CMS-2567. If the swing-beds are voluntary terminated or terminated by CMS, that action does not affect the continuing operation of the provider as a hospital or CAH. It terminates the approval to operate and receive reimbursement for the swing-beds.

The swing-beds in a hospital or CAH do not have to be separated from the acute patients although the facility may choose to do so. The patients do not have to move to a different location in the facility when changing from acute care status to swing-bed status unless the facility requires it.

There is no length of stay restriction for a swing-bed patient whether they are in a hospital or a CAH. There is no required discharge to a nursing home and no transfer agreement. Patients may be discharged to a nursing home as part of discharge planning, but it is not required.

A medical order in the chart by the physician is required to change status from acute care to swing-bed because the patient is being discharge from acute care status and admitted to swing-bed status. This is necessary for reimbursement purposes because the billing and reimbursement change or "swing." Accordingly, the facility is given a subprovider number for billing swing-bed services.

For Medicare patients, a 3-day qualifying stay in any hospital or CAH is required to prior to admission to a swing-bed and the admission must be for treatment of the same condition. This 3-day qualifying stay only applies to a Medicare patient.

Section 1883 of the Act authorizes payment under Medicare for post-hospital SNF services provided by any hospital that meets the following requirements at 42 CFR 482.66. These requirements include the following.

- The hospital has a Medicare provider agreement;

- The facility has fewer than 100 hospital beds, excluding beds for newborns and beds in intensive care type inpatient units;

- The hospital is located in a rural area. This includes all areas not delineated as "urbanized" areas by the Census Bureau, based on the most recent census;

- The hospital does not have in effect a 24-hour nursing waiver granted under 42 CFR 488.54(c);

- The hospital has not had a swing-bed approval terminated within the two years previous to application;

- The hospital meets the Swing-bed CoPs (see 42 CFR 482.66) on Resident Rights; Admission, Transfer, and Discharge Rights; Resident Behavior and Facility Practices; Patient Activities; Social Services; Discharge Planning; Specialized Rehabilitative Services; and Dental Services.

NOTE: The 30-day patient transfer notice requirement at 42 CFR Part 483.12(a)(5) does not apply to swing-bed hospitals.

2037 - Requirements Assessed Prior to Survey for Swing-Bed Approval
(Rev. 1, 05-21-04)

2037A - Request from a Medicare Participating Hospital to Add Swing-Bed Approval
(Rev. 1, 05-21-04)

The request can be initiated on the provider's letterhead stationery and sent to the SA. Acknowledgement and request for further information can be sent from the SA to the provider in a letter, see Exhibit 81, "Letter Transmitting Materials to a Hospital Requesting Swing-bed Approval."

2037B - Screening
(Rev. 1, 05-21-04)

Prior to scheduling a survey, the SA reviews the provider file as well as any other information maintained on the hospital to ascertain whether the six basic requirements are met. If these requirements are met and the hospital has begun to provide swing-bed services, the SA schedules a survey. No hospital may receive initial swing-bed approval without an onsite survey of the actual provision of such services. The SA may send a letter to the provider notifying them of the required documents for a future survey, see Exhibit 82, "Notification to a Hospital Regarding an Initial Survey for Swing-bed Approval." This notice acknowledges that a survey is required and the expectation for certain information that will be needed, but it does not disclose the date of the survey.

2037C - Provider Agreement
(Rev. 1, 05-21-04)

Prior to survey the SA verifies that the hospital has a valid Medicare provider agreement.

2037D - Calculation of Bed Count
(Rev. 1, 05-21-04)

Exclude from the bed count newborn and intensive care beds.

A hospital licensed for more than 100 beds may be eligible for swing-bed approval if it utilizes and staffs for fewer than 100 beds. The SA forwards to the RO documentation that the hospital is operating within the bed category. Include in the packet floor plans, bed assignments by room number, staffing schedules, and census information for the previous 12 months. The SA obtains written assurance from appropriate hospital officials that the hospital will not operate with a greater number of inpatient hospital beds than permitted by the category for which approval is requested.

2037E - Rural Area
(Rev. 1, 05-21-04)

The SA includes as eligible those facilities that are not located in an "urbanized area" based on the most recent census of the Census Bureau. Before concluding that a hospital is ineligible on the basis of location, the SA telephones the Census Bureau RO for verification.

2037F - Certificate Of Need (CON) Approval
(Rev. 1, 05-21-04)

States that have a CON requirement for the initiation or expansion of long-term care services may require a CON for a limited number of beds for LTC use. There is no federal requirement for a CON but CMS will not intervene if there is a state requirement.

2038 - Survey Procedures for Swing-Bed Approval
(Rev. 1, 05-21-04)

The SA surveys any hospital that meets the six items listed in §2036 and that has begun to provide post-hospital SNF and NF care services. The SA may choose to use the optional Swing-Bed Survey Report that can be found with the Appendix T to record survey findings.

The survey for swing-bed approval may be conducted at the same time as a survey of the hospital CoP at 42 CFR Part 482, although the findings must be documented on a separate Form CMS-2567.

2039 - Post-Survey Procedures for Swing-Bed Hospitals

(Rev. 1, 05-21-04)

To receive swing-bed approval, a hospital must be found in compliance with the provisions of 42 CFR Part 482.66 and the specific skilled nursing requirements in 42 CFR 483 that apply to swing-bed hospitals, see Appendix T. If a plan of correction is required following the survey, send a copy of Exhibit 162, "Request for a Plan of Correction Following an Initial Survey for Swing-bed Approval in a Hospital" to the provider.

Effective dates for all swing-bed approvals are based on the provisions at 42 CFR 489.13 that state the agreements will be effective on the date the onsite survey is completed if all Federal requirements are met on the date of the survey. If the provider fails to meet any of the requirements, the approval will be effective on the earlier of the following dates:

- The date on which the hospital meets all requirements, or
- The date the hospital submits a correction plan acceptable to CMS.

2040 - RO Approval Procedures for Swing-Bed Approval
(Rev. 1, 05-21-04)

The RO prepares a formal determination and notifies the hospital of its approval or denial. For approvals, see Exhibit 83,"Approval Notification for Swing-beds in a Hospital" or denials, see Exhibit 83B, "Denial for Swing-bed Approval in a Hospital."

If the provider is found to be in non-compliance after they have started to provide swing-bed services, a termination of the approval can be accomplished through a termination letter, see Exhibit 163, "Termination Letter for Hospital Swing-Bed Services." Failure to satisfy requirements for swing-bed approval does not affect Medicare approval as a provider of hospital services, but it does withdraw the approval to provide SNF level services at the hospital.

2042 - Psychiatric Hospitals
(Rev. 1, 05-21-04)

The statutory requirements for psychiatric hospitals are found in §1861(f) of the Social Security Act (the Act.) The regulatory requirements are found at 42 CFR 482.60 – 42 CFR 482.62. The term psychiatric hospital means an institution which:

- Is primarily engaged in providing, by or under the supervision of a Doctor of Medicine or Osteopathy, psychiatric services for the diagnosis and treatment of mentally ill persons;
- Satisfies the requirements of §§1861(e)(3) through (e)(9) of the Act (general hospital requirements);
- Maintains clinical and other records on all patients as the Secretary finds necessary

to determine the degree and intensity of the treatment provided to individuals entitled to hospital insurance benefits under Part A; and

- Meets such staffing requirements as the Secretary finds necessary for the institution to carry out an active program of treatment for individuals receiving services in the institution.

In the case of an institution that satisfies the first two criteria and contains a distinct part that also satisfies the last two criteria, the distinct part is considered to be a "psychiatric hospital."

There are some psychiatric hospitals that are designated as "forensic hospitals." These hospitals focus on serving individuals who are in the custody of penal authorities. As a general rule, institutions that house only prisoners are excluded from Medicare payment. However, in accordance with 42 CFR 411.4(b) payment may be made for services furnished to individuals who are in the custody of penal authorities if (1) State or local law requires such individuals to repay the cost of the medical services they receive while in custody and (2) the State or local government entity enforces the requirement by billing all individuals who are prisoners whether or not they are insured by Medicare on any other insurance program. The pursuit of repayment from the prisoners for Medical services must be done with the same vigor as would be done for the collection of any other debts owed the state. The determination of payment eligibility in these cases is made by the FI and CMS financial personnel.

Regardless of whether a state meets the payment requirements for prisoners housed in these hospitals, the hospital must apply the CoP, including the restraint and seclusion rules, to all patients including the prisoners. If a hospital wants to apply different health and safety rules to prisoners, it may want to consider establishing a distinct part.

Medicaid rules for institutionalized individuals are found at 42 CFR 435.1008 – 435.1009. If there is an issue concerning a Medicaid prisoner, contact the RO account representative for the particular state for resolution.

2044 - Psychiatric Hospitals and Deemed Status

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

Psychiatric hospitals have a Medicare accreditation option available to them. Prior to this being the case, however, CMS permitted a psychiatric hospital to have deemed status with respect to all hospital conditions (identified as "A" tags in ASPEN) except the special psychiatric CoPs at 42 CFR 482.60-62 (identified as "B" tags in ASPEN). Under this arrangement, the AO was responsible for assessing the psychiatric hospital's compliance with all other hospital CoPs, i.e., those provisions with A tags, and either the SA or CMS' contract surveyors assessed compliance with the special psychiatric CoPs, i.e., the B tags. Currently almost all deemed status psychiatric hospitals are accredited under the approved Medicare psychiatric hospital accreditation program, and their AO is responsible for assessing compliance under **both** the A and B tags.

Any psychiatric hospital seeking initial participation in Medicare through deemed status must be accredited under a CMS-approved Medicare psychiatric hospital accreditation program. This also is the case for any non-accredited participating psychiatric hospital seeking to switch to deemed status. CMS no longer permits a psychiatric hospital to seek participation through deemed status for the A tags only. However, there are a small number of participating psychiatric hospitals that were deemed to meet the requirements for the A tags only prior to CMS approving a psychiatric hospital Medicare accreditation program. CMS considers these hospitals to have grandfathered deemed status for the A tags only, and SAs or CMS contract surveyors remain responsible for B tag surveys in these facilities.

If a psychiatric hospital currently has deemed status for the A tags through accreditation by an AO which has a CMS-approved Medicare hospital accreditation program but does not have a CMS-approved Medicare psychiatric hospital accreditation program, and the psychiatric hospital wishes to be deemed for the special psychiatric hospital CoPs, it must seek accreditation from an AO with a CMS-approved Medicare psychiatric hospital accreditation program. In this instance, the psychiatric hospital may not choose to continue its current Medicare hospital accreditation with one AO in addition to obtaining its new Medicare psychiatric hospital accreditation with another AO; it must withdraw from its current Medicare hospital accreditation program and seek or maintain accreditation under a CMS-approved Medicare psychiatric hospital accreditation program only. It is **not** permissible for the psychiatric hospital to both be accredited by one AO under its hospital program and by another AO for the special psychiatric CoPs only.

When the SA is responsible for surveying the special psychiatric CoPs of an otherwise deemed psychiatric hospital, the SA completes the Medicare/Medicaid Psychiatric Hospital Survey Data, Form CMS-724, and all other relevant survey documents (Form CMS-2567, etc.) for the survey.

2048 - Distinct Part Psychiatric Hospital
(Rev. 1, 05-21-04)

2048A - General
(Rev. 1, 05-21-04)

A psychiatric hospital may elect to participate in its entirety, or it may designate a distinct part and apply for Medicare participation of that portion only (see §1886(d)).

The distinct part provisions of the law are designed to permit the participation of those identifiable sections of psychiatric hospitals that are adequately staffed, supervised, and equipped to provide active treatment on a continuing basis. The participating distinct part must meet the hospital CoPs and the two special CoPs and have appropriate treatment services available. Patients in the distinct part must be provided treatment that may reasonably be expected to improve their condition.

The provisions for certification of distinct parts of psychiatric hospitals apply only where the entire institution is primarily for the treatment of mental illness. Thus, a psychiatric

wing or building of a general hospital or of a large medical center or complex **may not be certified** as a "distinct part psychiatric hospital." Such facilities are included in the certification of the institution of which they are an integral part.

2048B - Physical Identification
(Rev. 1, 05-21-04)

To qualify for participation as a distinct part psychiatric hospital, the distinct part must be physically distinguishable from the larger institution or institutional complex; that is, a group of beds specifically for patients who need active treatment. The section(s) or unit(s) to be included in the distinct part certification must be clearly defined. An institution or institutional complex can only be certified with one distinct part. Multiple certifications within the institution or institutional complex are strictly prohibited. The distinct part can be a wing, separate building, a floor, a hallway, or one side of a corridor. The beds in the certified distinct part area must be physically separate from (that is, not commingled with) the beds of the institution or institutional complex in which it is located. However, the distinct part need not be confined to a single location within the institution or institutional complex's physical plant. It may, for example, consist of several floors or wards in a single building or floors or wards that are located throughout several different buildings within the institutional complex. Where an institution or institutional complex owns and operates a distinct part, that distinct part is a single distinct part even if it is operated at various locations throughout the institution or institutional complex. The aggregate of the locations represents a single distinct part subprovider, not multiple subproviders, and must be assigned a single provider number.

Specialized services such as physical therapy and occupational therapy services may be included in the distinct part certification. If any specialized services are included in the distinct part, the SA surveys the service and identifies them on Form CMS-1539.

2048C - Documentation of Findings
(Rev. 1, 05-21-04)

In the documentation on the survey report, the SA includes its observations about the distinct part and an assessment of the overall ability of the hospital to provide the services required. As appropriate, the SA must provide information about the entire hospital's staffing pattern, such as the number, kind, and location of patient care personnel, including physicians, nursing personnel in all categories, social workers, and occupational and other therapists.

The nonparticipating portion of an institution is required to meet the CoPs only insofar as it affects the health and safety of patients in the distinct part or provides facilities or services used by such patients. In certifying the distinct part, the SA considers the impact of nonparticipating sections of the institution to ascertain whether there are any hazardous conditions which might endanger patients in the distinct part; for example, the lack of adequate fire or sanitation safeguards, particularly where the distinct part is attached to the rest of the institution.

It is rare that a distinct part of a hospital is completely self-contained. Therefore, the SA evaluates services, facilities, and activities of the overall institution that are provided or made available to patients throughout the institution.

Inpatients of the distinct part may receive specialized services such as physical therapy or occupational therapy in a portion of the hospital not included in the distinct part. Services and facilities that may be shared vary with the type and size of the institution and the size of the distinct part. However, in most instances, the distinct part shares with the rest of the institution such central support services as dietary, housekeeping, maintenance, administration and supervision, and some medical and therapeutic services.

The primary consideration in evaluation of shared services is whether the sharing can be done without sacrifice to the quality of care given the patients in the distinct part and without endangering their health and safety.

Where personnel assignments are shared, the SA should show the extent of sharing. The SA verifies copies of staffing patterns and assignments furnished by the institution through personal observation, interviews with various personnel, examination of job descriptions and personnel records, and inspection of patient clinical records. The SA reviews medical records for an indication of the extent to which patients of the distinct part receive the services of skilled personnel.

In general, the distinct part, either by itself or in conjunction with the overall institution of which it is a part, must be able to demonstrate the capacity to provide the services, facilities, and supervision required by the CoPs to patients of the distinct part.

2050 - Medical-Surgical Unit of Psychiatric Hospitals
(Rev. 1, 05-21-04)

A medical-surgical unit of a psychiatric hospital may qualify for participation as a general hospital independent of the institution as a whole, regardless of whether the remainder of the institution is participating. The unit is regarded as a separate institution for this purpose since the law does not provide for the participation of a “distinct part general hospital.” It must be a separate, functioning entity that is a distinct and identifiable unit within the institutional complex and be in compliance with all the CoPs for hospitals. Although a medical-surgical unit may find it necessary to share some services with the nonparticipating part of the institution, the location of shared services in relation to the medical-surgical unit must clearly show that the latter meets the CoPs.

2052 - Nonparticipating Emergency Hospitals
(Rev. 1, 05-21-04)

2052A - Emergency Hospital Services
(Rev. 1, 05-21-04)

Any nonparticipating hospital meeting the definition of an emergency hospital for

Medicare purposes may claim payment for emergency inpatient and outpatient diagnostic services furnished to Medicare patients. There are six statutory requirements that a hospital must meet to qualify as an emergency hospital (§1861(e)(1), (2), (3), (4), (5), and (7)). The hospital must:

- Be primarily engaged in providing, by or under the supervision of physicians, to inpatients, diagnostic and therapeutic services or rehabilitation services;
- Maintain clinical records on all patients;
- Have bylaws in effect with respect to its staff of physicians;
- Have a requirement that every patient must be under the care of a physician;
- Provide 24-hour nursing service rendered or supervised by a registered professional nurse and have a licensed, practical, or registered professional nurse on duty at all times; and,
- Be licensed or meet standards for licensing pursuant to State and local law.

2052B - Preparation of Initial Certification
(Rev. 1, 05-21-04)

- For the initial certification, the SA obtains a completed Hospital Request to Establish Eligibility, Form CMS-1514. The SA annotates at the top; "Emergency Hospital Services Only." When possible, the SA evaluates the capability of an institution to meet the statutory requirements from information contained in State licensure files and other available State records or through previous contacts with the hospital.
- The SA prepares a Form CMS-1539, completing items 3, 4, 6, 7, 9, 12, 13, and 16 - 18.

2052C - Recertification and Follow-Up
(Rev. 1, 05-21-04)

The SA maintains an emergency hospital listing on a continuous basis and annually recheck it to ensure that the certifications are still correct. If a hospital no longer meets the definition of an "emergency hospital," the SA prepares a new Form CMS-1539.

2053 - Medicaid-Only Hospitals
(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

Many hospitals choose to participate in both the Medicare and Medicaid programs. However, a hospital may choose to only participate in Medicaid. Medicaid regulations at 42 CFR 440.10 and 42 CFR 440.140(a) require a hospital or psychiatric hospital (also referred to in Medicaid as an "institution for mental disease," which is defined at 42 CFR

435.1010) participating in Medicaid to meet the requirements for participation in Medicare in order to receive Medicaid payment. These regulations do not require a hospital or psychiatric hospital to enroll in the Medicare program in order to demonstrate compliance with Medicare participation requirements. The provider agreement rules at 42 CFR 489.10 establish the basic Medicare participation requirements for providers, including requirements for hospital participation. These requirements include, but are not limited to, complying with the following: applicable hospital Conditions of Participation (CoPs) at 42 CFR Part 482; specified Office of Civil Rights requirements; and the advanced directive requirements at 42 CFR 489.100 and 42 CFR 489.102.

2053A- Initial Certification of Medicaid-Only Hospitals

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

Hospitals seeking initial certification to participate in the Medicaid program only must contact the State Agency (SA), in accordance with §§1902(a)(9)(A) and 1902(a)(33) of the Act, to initiate the certification process. Requirements for this process are established in the Medicaid State Plan's required written agreement (or formal written intra-agency arrangement) between the State Medicaid Agency (SMA) and the SA (See 42 CFR 431.610(f).

The SMA must approve the hospital's request for enrollment into the Medicaid program prior to the initiation of the certification process by the SA.

2053B - Certification Surveys of Medicaid-Only Hospitals

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

Following verification by the SMA that the enrollment application process has been initiated by the hospital, the SA must determine if the hospital seeking Medicaid-only certification demonstrates compliance with requirements for Medicare participation, including all applicable CoPs, through the completion of an on-site survey. Hospitals have the option of establishing compliance with applicable CoPs through accreditation under 42 CFR 488.6(b) by a nationally recognized Accreditation Organization (AO) with a CMS-approved Medicare hospital or psychiatric hospital program. Hospitals choosing this option must provide the SA with a letter issued by the AO confirming its accreditation under a CMS-approved Medicare accreditation program and recommending deemed status as a Medicaid-only hospital. (As with Medicare-participating hospitals, it is possible that a hospital might be accredited, but not have deemed status. The AO letter must indicate the hospital is recommended for deemed status.) However, regardless of whether the survey is conducted by the SA or a CMS-approved AO, the SA must issue a determination to the SMA as to whether the hospital has met all Medicare participation requirements for Medicaid-only hospital participation.

Upon receipt of the SA's determination, the SMA issues an effective date for the hospital's participation in the State Medicaid program. The SA then compiles and forwards a Medicaid-only certification packet to the RO. This packet consists of the hospital's request for an applicable Medicaid-only hospital or psychiatric hospital CMS Certification Number (CCN), the SA's certification of compliance with Medicare CoPs,

and the SMA-issued State Medicaid program effective date. After review of all documentation, the RO issues the appropriate Medicaid-only hospital CCN.

2053C - Change in Certification

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

If the hospital decides to seek participation in Medicare as well as Medicaid, see Section 2777D3.

2053D - Termination

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

The SMA must terminate the hospital's Medicaid agreement when the SA determines that the hospital does not meet the applicable requirements. See Section 3005C-3.

2053E - Complaint Investigation

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

All allegations of non-compliance with Federal or State requirements in Medicaid-only hospitals must be referred to the SA.

Under 42 CFR 431.610, the SA in collaboration with the SMA must determine the policies and procedures for the intake, triage and investigation of all allegations of non-compliance in both deemed and non-deemed Medicaid-only hospitals. The SA is solely responsible for reporting complaint investigation findings to the SMA, including a determination whether a Medicaid-only hospital meets Medicare CoPs and other federal requirements in accordance with §1902(a)(33)(B) of the Act.

2054 - Religious Nonmedical Health Care Institutions (RNHCIs)

(Rev. 1, 05-21-04)

Section 4454 of the Balanced Budget Act of 1997 (BBA'97, Public Law No. 105-33, enacted August 5, 1997) deletes statutory references to Christian Science Sanatoria and amended the following sections of the Act: §§1821, 1861(e), (y) and (ss), 1869, and 1878 (Medicare provisions); 1902(a) and 1908(e)(1) (Medicaid provisions); and 1122 (h) and 1162 (conforming provisions). Additionally, §4454 provides for coverage of inpatient services furnished in qualified RNHCIs under Medicare and as a State Plan option under Medicaid. The new amendments make it possible for RNHCIs meeting the defining criteria in §4454 of BBA'97 or §1861(ss)(1), to participate in the Medicare and/or Medicaid program. The RNHCI provider is responsible for meeting both Conditions of Coverage and Conditions of Participation to qualify as a Medicare provider and that portion of the Conditions of Coverage that define an RNHCI and the Conditions of Participation to qualify as a Medicaid provider.

2054.1 - Certification of Religious Nonmedical Healthcare Institutions (RNHCIs)

(Rev. 1, 05-21-04)

The Boston Regional Office has the primary responsibility for the approval and certification process to ensure and verify that the RNHCI conforms to specific Conditions of Coverage and all of the Conditions of Participation. An RNHCI is a provider that meets the definition as described in §1861(ss)(1) of the Act and meets the following qualifying Medicare Conditions of Coverage provisions as specified in 42 CFR 403.720. To qualify as a Medicare or Medicaid RNHCI an institution must meet all ten of the following requirements:

- Is described in subsection (c)(3) of §501 of the Internal Revenue Code of 1986 and is exempt from taxes under subsection 501(a);

- Is lawfully operated under all applicable Federal, State, and local laws and regulations;

- Furnishes only nonmedical nursing items and services to beneficiaries who choose to rely solely upon a religious method of healing, and for whom the acceptance of medical services would be inconsistent with their religious beliefs. (**NOTE:** Religious components of the healing are not covered);

- Furnishes nonmedical items and services exclusively through nonmedical nursing personnel who are experienced in caring for the physical needs of nonmedical patients. For example, caring for the physical needs such as assistance with activities of daily living; assistance in moving, positioning, and ambulation; nutritional needs; and comfort and support measures;

- Furnishes nonmedical items and services to inpatients on a 24-hour basis;

- Does not furnish, on the basis of religious beliefs, through its personnel or otherwise, medical items and services (including any medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs) for its patients;

- Is not owned by, under common ownership with, or has an ownership interest of 5 percent or more in, a provider of medical treatment or services and is not affiliated with a provider of medical treatment or services or with an individual who has an ownership interest of 5 percent or more in a provider of medical treatment or services (permissible affiliations are described in §403.738(c));

- Has in effect a utilization review plan that meets the requirements of §403.720(a)(8);

- Provides information CMS may require to implement §1821 of the Act, including information relating to quality of care and coverage determinations; and

- Meets other requirements CMS finds necessary in the interest of the health and safety of the patients who receive services in the institution.

2054.1A - Other Medicare Conditions of Coverage
(Rev. 1, 05-21-04)

The remaining Conditions of Coverage are specific to Medicare; however, a State may elect to employ any or all of these requirements within their optional Medicaid State plan amendment.

2054.1B - Valid Election Requirements
(Rev. 1, 05-21-04)

The regulations at 42 CFR 403.724 present the elements necessary for a Medicare beneficiary to complete an election to receive care in an RNHCI. The RO determines whether or not the RNHCI has adequately ensured that the Medicare beneficiary's valid election statement has been included with the RNHCI's administrative records and/or patient care records.

NOTE: The facility is to provide the fiscal intermediary the original of the election statement, which will be used for each Medicare beneficiary in the RNHCI and retain a copy in its files.

The provisions for valid elections include the following general requirements:

- The election statement must be made by the Medicare beneficiary or by his or her legal representative. It must include written statements that:
    - The beneficiary is conscientiously opposed to acceptance of nonexcepted medical treatment;
    - The beneficiary acknowledges that acceptance of nonexcepted medical treatment is inconsistent with his or her sincere religious beliefs;
    - The beneficiary acknowledges that receipt of nonexcepted medical care constitutes a revocation of the election and may limit further receipt of services in an RNHCI;
    - The beneficiary acknowledges that the election may be revoked by submitting a written statement to CMS; and
    - The beneficiary acknowledges that the revocation will not prevent or delay access to medical services available under Medicare Part A in other types of facilities.

A valid election must also:

- Be signed and dated by the beneficiary or by his or her legal representative, not prior to reaching Medicare eligibility and beneficiary status;

- Be notarized;

- Include an original copy submitted on file to CMS (CMS is represented for this purpose by the intermediary); and

- Include any other information obtained regarding prior elections or revocations.

A beneficiary's election is revoked by one of the following:

- The beneficiary receives nonexcepted medical treatment for which Medicare payment is made; or

- The beneficiary voluntarily revokes the election and notifies CMS in writing.

NOTE: "Excepted" and "nonexcepted" medical care are defined are defined in 42 CFR 403.702. The receipt of excepted medical care or treatment as defined in 403.702 does not revoke the election made by a beneficiary.

The beneficiary's ability to elect is limited once the election has been made and revoked twice (see §403.724(c)).

Organ Transplant Programs

2060 - Organ Transplant Programs

(Rev. 190, Issued: 06-14-19, Effective: 06-14-19, Implementatiom: 06-14-19)

2060A – Citations

The Conditions of Participation (CoPs) for Transplant Centers were established under several statutory authorities. Section 1102 of the Social Security Act (the Act) authorizes the Secretary to publish rules and regulations "necessary for the efficient administration of the functions" with which the Secretary is charged under the Act. Section 1871(a) of the Act authorizes the Secretary to "prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title." Section 1881(b)(1) of the Act contains specific authority for prescribing the health and safety requirements for facilities, including renal transplant centers, that furnish end stage renal disease (ESRD) care to beneficiaries. Section 1861(e)(9) of the Act authorizes developing standards necessary for the health and safety of individuals furnished services in hospitals. Organ transplant programs are required to be in compliance with the federal requirements set forth in the Medicare CoPs in order to be eligible to receive Medicare payment. In addition to meeting the CoPs for Transplant Centers in 42 CFR Part 482, Subpart E, transplant programs must also meet the Hospital CoPs specified in §§482.1 through 482.57.

2060B – DEFINITIONS

(Rev. 190, Issued: 06-14-19, Effective: 06-14-19, Implementatiom: 06-14-19)

2060B-1 Organ Procurement and Transplantation Network (OPTN)

The OPTN is a public-private partnership that links all professionals involved in the donation and transplantation system. The OPTN operates the national network for organ procurement and allocation and works to promote organ donation. The OPTN was established by the National Organ Transplant Act of 1984 and is operated by United Network for Organ Sharing (UNOS) under a contract from the Health Resources and Services Administration (HRSA) in accordance with section 372 of the Public Health Service (PHS) Act. Through its policies, the OPTN works to increase the number of transplants, provide equity in access to transplants, improve outcomes for waitlisted patients, living donors and transplant recipients, and promote living donor and transplant recipient safety.

2060B-2 Scientific Registry of Transplant Recipients (SRTR)

The SRTR, founded in 1987, is a national database of transplant statistics that provides analytic support for the ongoing evaluation of the scientific and clinical status of solid organ transplantation in the United States. It was established pursuant to section 373 of the PHS Act.

2060C - Regulatory Background

(Rev. 190, Issued: 06-14-19, Effective: 06-14-19, Implementatiom: 06-14-19)

The Conditions of Participation for transplant programs were published in the Federal Register on March 30, 2007 (72 FR 15198) and became effective 90 days after publication on June 28, 2007.

2061 – Request for Medicare Approval of an Organ Transplant Program

(Rev. 190, Issued: 06-14-19, Effective: 06-14-19, Implementatiom: 06-14-19)

Effective January 1, 2019, transplant programs seeking to participate in the Medicare program must submit a request for Medicare approval to the applicable State Survey Agency and not the CMS RO. The SA will provide a packet of information to the applicant including a list of documents that must be submitted to the SA.

The hospital in which the transplant center is located must submit a revised CMS-855A to its Medicare Administrative Contractor (MAC) to indicate the addition of a service.

2061A Programs Serving both Adult and Pediatric Populations

A transplant program can apply for and be approved for both an adult (age 18 and over) and a pediatric (under age 18) transplant program for the same organ type. They can apply to be approved separately, but are not required to do so.

If a transplant program is seeking separate approval of its adult and pediatric programs, the programs will be surveyed separately. If a program seeks a single approval for both age groups, the program must apply for the primary age group that it serves. That is, a program that provides more than 50 percent of its transplants in a 12-month period to pediatric patients must apply as a pediatric program. A program that provides more than 50 percent of its transplants in a 12-month period to adults must apply as an adult program.

2061B Organ Procurement and Transplantation Network Membership

Membership in the OPTN by the transplant hospital in which the transplant program is located is a requirement for Medicare approval.

2062 - Survey and Approval Procedures for Organ Transplant Programs

**(Rev. 190, Issued: 06-14-19, Effective: 06-14-19, Implementatiom: 06-
14-19)**

2062A - The Transplant Program Quarterly Report (TPQR)

The TPQR is a pre-survey report generated by CMS. It conveys information from transplant program data received from the SRTR and the OPTN. The TPQR includes:

- Types of transplant programs;
- Program data including data submission, clinical experience (the number of transplants performed) and program outcomes for patient and graft survival.

During pre-survey, the survey team reviews the TPQR to determine the number of surveyors that will be indicated based upon the number of programs that will be reviewed. The team also identifies any non-compliance with the requirements of §482.80 and §482.82. Any non- compliance identified during the pre-survey will be communicated to the applicable program at the entrance conference of the survey. There is no additional survey activity required regarding the TPQR.

During the process of the transplant program survey, the surveyors review compliance with both the transplant program and general hospital regulations. If a deficiency with the hospital requirements is identified in the hospital in which the transplant program is located and that hospital is a deemed provider, the surveyor, (or their management) must contact the applicable CMS Regional Office for approval to investigate and cite the deficiency on a hospital survey report.

2062B Types of Surveys and Related Guidance

(Rev. 190, Issued: 06-14-19, Effective: 06-14-19, Implementatiom: 06-14-19)

2062B.1 Initial Survey for Medicare Approval

Once the MAC notifies the SA/RO of its approval of the revised CMS-855A, a survey may be scheduled. Initial surveys are unannounced. If the applicant transplant program is found to be in compliance with the CoPs, it is assigned a CCN. The program will not be issued a separate provider agreement. Once transplant program approval is completed, the RO will forward a form CMS-2007 (Provider Tie-In Notice) to the MAC. In order for CMS to make a compliance determination with §482.80, the applicant must have submitted sufficient data to the SRTR for CMS to review.

2062B.2 Re-approval Surveys

Once a transplant program has been approved to participate, it will be periodically re-surveyed for compliance with the CoPs. Re-approval surveys are unannounced surveys and are performed at a frequency consistent with the CMS Mission and Priority Document (MPD).

A transplant program may voluntarily declare an "Inactive Status" with the CMS and may remain inactive and retain its Medicare approval for a period not exceeding 12 months under §488.61(e). The program must provide immediate written notification to its SA of the anticipated inactivity period. Notification to the SA and to the potential recipients must occur prior to the beginning of the planned inactivity period. During its inactivity period, the program must continue to comply with all of the Medicare CoPs and routine surveys or complaint investigations should not be delayed based on an "Inactive Status." During survey activity either during the inactive status or following an inactive status, the surveyor should determine that:

- The patients on the waitlist during the period of inactivity were notified of the inactive status; and
- The notifications were accomplished in a manner consistent with §482.102(c)(3).

2062B.3 Outcomes Non-Compliance

2062B.4 Clinical Experience

To be considered for an initial approval, a transplant program must generally perform 10 transplants over a 12 month period. If the program performs at least eight

transplants over a 12 month period, it may be approved with an acceptable plan of correction.

Currently approved transplant programs must perform at least 10 transplants a year over the prior three years. Programs not meeting this standard should be cited for non-compliance at the Standard level. The program may be reapproved with an acceptable plan of correction if all other CoPs are in compliance.

2062B.4 Complaint Surveys

See SOM, Chapter 5, for a description of the general complaint investigation process.

For complaint investigations of a transplant program, the scope of survey activities is generally limited to the specific transplant CoPs associated with the allegation(s). If allegations are substantiated, the scope may be expanded to review any associated CoPs.

Complaints related to disease transmission via an organ from a deceased donor should be communicated to the RO for their determination of the need for an OPO complaint investigation.

* There must be a formal arrangement between the hospital in which the transplant program is located and any other hospital which provides living donor services for the transplant program. It is the transplant program's responsibility to ensure that the CoPs applicable to living donors are met by the associated hospital providing the living donor services. The medical record of the living donor must confirm that all the requirements of the CoPs were met.

2062C - Determining Level of Deficiency for Clinical Experience (Volume) and Outcome Requirements Standards:

(Rev. 190, Issued:06-14-19, Effective: 06-14-19, Implementatiom: 06-14-19)

Compliance with the clinical experience (volume) standards at 42 CFR §§482.80(b) and 482.82(b) and the outcome requirements standards at 42 CFR §§482.80(c) and 482.82(c) is determined by reviewing the program's performance compared to the objective standards outlined in the regulation. The goal of this section is to achieve consistency in determining the level of a deficiency citation, (i.e., condition level, or standard level) under these CoPs. The information outlined below will be provided to surveyors in the TPQR.

Determining the Level of the Deficiency for Non-Compliance with Clinical Experience Requirements:

A program's inactivation does not create an exception to the clinical experience requirement for the entire 3 year period.

Initial Approval of Transplant Programs under §482.80(b):
If the transplant program has not performed at least eight transplants in the past 12 months, a deficiency will be cited at the condition-level deficiency and it will not be approved for Medicare participation. If the program has performed at least eight but less than 10 transplants in that time period, a deficiency should be cited at the standard-level. The program may still be approved with a standard-level citation for Clinical Experience if an acceptable plan of correction is received and the program is in compliance with all remaining CoPs. Kidney programs that have not performed at least three transplants in a 12 month period may not be surveyed for initial approval.

Re-approval of Transplant Programs under §482.82(b):
If the transplant program has performed an average of less than 10 transplants per year over the re-approval period (three years), a deficiency should be cited at the standard-level. The program may be re-approved with a standard-level citation for Clinical Experience if an acceptable plan of correction is received and the program is determined to be in compliance with all remaining CoPs.

The determination of condition-level non-compliance is made based upon the extent of non- compliance findings with the standards within a Condition. A finding of non-compliance for the Clinical Experience standard alone with no other non-compliance within the Condition would generally not result in condition-level non-compliance at §482.80 or §482.82.

Determining the Level of the Deficiency for Non-Compliance with the Outcome Requirements at 42 CFR §482.80(c) and §482.82(c)

Compliance with outcome measures is assessed using data from the most recent Center-Specific Report from the SRTR. Surveyors must utilize the SRTR information reported in the TPQR that is provided by the CMS CO. The SRTR outcome measures

reported in the TPQR are risk- adjusted, 1-year post transplant graft and patient survival measures. The SRTR reports are released every six months and CMS compares the results for the programs' outcomes to the outcome requirements at 42 CFR §482.80(c) and §482.82(c) for transplants performed over a 2.5 year window (between one year prior and 3.5 years prior to the date the report is published) and enters the compliance determination onto the TPQR. The TPQR identifies the number of center- specific SRTR reports in that timeframe that failed to meet the outcome requirements. Surveyors do not conduct the statistical analysis to determine compliance nor may the program provide any information to the surveyor on-site to change the compliance determination.

The following transplant program types are subject to the outcome requirements:

- Adult Kidney-Only (AKO)
- Adult Heart-Only (AHO)
- Adult Lung-Only (ALO)
- Adult Liver-Only (ALI)
- Pediatric Kidney-Only (PKO) (includes only 1-year graft survival)
- Pediatric Heart-Only (PHO)
- Pediatric Lung-Only (PLO)
- Pediatric Liver-Only (PLI)

The following transplant program types are not subject to the outcome requirements:

- Adult Pancreas- (APA)
- Pediatric Pancreas- (PPA)
- Adult Intestine/Multivisceral- (AIM)
- Pediatric Intestine/Multivisceral- (PIM)

Standard – If the most recent SRTR report shows that the program did not meet outcome requirements, but none of the four outcome reports prior to the most recent one show that the program was out of compliance, a deficiency should be cited at **the standard-level.**

Condition – If the most recent SRTR report shows that the program has not met outcome requirements in two consecutive reports and there is either unchanged or a decline in outcome data, a deficiency should be cited at the **condition-level.**

Every six months, CMS CO receives a list of transplant programs that exceed the outcomes thresholds for patient and graft survival. When a program is identified to be out of compliance with the measures, CMS CO will notify the provider of its non-compliance. More current SRTR data will be reviewed by CMS to determine if the program is improving.

At the time of the next bi-annual SRTR report, if a program continues to exceed the acceptable patient and graft survival rate, with all thresholds crossed over, more recent SRTR data will again be requested and reviewed. If the more recent data indicates that the program's outcomes are not improving, CMS will consider the program to be non-

compliant at a condition level and an on-site survey may be scheduled to review/identify associated process requirement concerns.

Deficiencies for non-compliance with the outcome requirements, as well as any additional deficiencies identified at the time of the on-site survey, will be cited upon completion of the survey. If an on-site survey is not conducted, the program will be notified of its non-compliance with the outcome requirements by letter that includes the form CMS-2567.

If a transplant program is cited at a condition-level for §482.82, include the following language in the letter accompanying the CMS-2567:

"The prospective termination date based on noncompliance determination with 42 CFR §482.82 will be set at 210 days. This deficiency must be corrected by [Date] in order for Medicare approval to continue for the program. The program has two options for a plan of correction for
§482.82:

1. The program may state that it expects to be back into compliance with §482.82 within 210 days; or

2. The program will apply for mitigating factors review under §488.61(f)."

2062D - Post-Survey Activities

(Rev. 190, Issued: 06-14-19, Effective: 06-14-19, Implementatiom: 06-14-19)

- Following the survey, the surveyor will complete the following forms:
  1) Organ Transplant Hospital Worksheet;
  2) CM 670;
  and
  3) CMS-2567

Once the CMS-2567 is finalized, it will be forwarded to the hospital administrator with a request for a Plan of Correction (PoC) if substantial compliance with all the requirements was not found. The SA will review and accept or not accept the PoC. In the case of a finding of Immediate Jeopardy, see Section 3010B of the SOM for a description of the special procedures to be followed.

Plan of Correction Transplant Centers

The PoC should include plans for completion of corrective actions at a maximum of 90 days.

The PoC for all deficiency citations, with the exception of §482.80 or §482.82, must indicate projected correction within 90 days from the receipt of the notification of non-compliance. The plan of correction for §482.80 or §482.82 must indicate whether the provider intends to submit mitigating factors to CMS. Prior to the 90th day follow-up

by the SA should occur. If the provider has not been determined to have achieved compliance with the CoPs (other than
§482.80 or §482.82), the program approval must be terminated.

2062E - Transmission of Program Approval Information

(Rev. 190, Issued: 06-14-19, Effective: 06-14-19, Implementatiom: 06-14-19)

The RO will assign one CMS Certification Number (CCN), within the 9800 series, to all transplant programs operating within a single hospital. The Medicare approval date for the individual program will be determined as follows:

- When there are no deficiencies cited, the approval date is the last date of the survey.
- When there are standard-level deficiencies cited, the approval date is the date on which an acceptable Plan of Correction was received by the SA.
- When there are condition-level deficiencies cited, the approval date is the date on which the transplant program is determined to be back in compliance either through a revisit or, as determined by the CMS based on the approval of mitigating factors.

2062F-Mitigating Factors

(Rev. 190, Issued: 06-14-19, Effective: 06-14-19, Implementatiom: 06-14-19)

2062F.1 Medicare Approval Based on Mitigating Factors

Under §488.61(f), a transplant program may request that CMS consider mitigating factors in the initial approval and re-approval of a transplant program that does not meet the CoPs at §482.80 or §482.82. Mitigating factors will not, however, be considered in situations of immediate jeopardy.

§488.61(f)(1) describes the general areas that will be reviewed in determining whether a program can be initially approved or re-approved based on mitigating factors. These areas include (but are not limited to):

1. The extent to which outcome measures are not met or exceeded;
2. The availability of Medicare-approved transplant centers in the area;
3. Extenuating circumstances (such as natural disasters) that may have a temporary effect on the program;
4. Program improvements that substantially address root causes of graft failures or patient deaths, that have been implemented and institutionalized on a sustainable basis, and that are supported by outcomes more recent than the latest available SRTR report, for which there is a sufficient post-transplant patient and graft survival period and a sufficient number of transplants such that CMS finds that the program demonstrates present-day compliance with the requirements at §482.80(c)(2)(ii)(C) or §482.82(c)(2)(ii)(C);
5. Whether the program has made extensive use of innovative transplantation practices relative to other transplant programs, such as a high rate of

transplantation of individuals who are highly sensitized or children who have undergone the Fontan procedure, where CMS finds that the innovative practices are supported by evidence- based, published research or nationally recognized standards or Institutional Review Board (IRB) approvals, and the SRTR risk-adjustment methodology does not take the relevant key factors into consideration; and

6. If the program's performance, based on the OPTN method of calculating patient and graft survival, is within the OPTN's thresholds for acceptable performance and does not flag OPTN performance review under the applicable OPTN policy.

2062F.2 Mitigating Factors Application and Review Process

A. Intent to Apply for Review of Mitigating Factors

1. The program must state on the CMS-2567, which is submitted to the SA that it will apply for mitigating factors as its plan of correction (POC) for non-compliance with data submission, clinical experience, or outcomes noncompliance.
2. Upon receipt of a POC that includes an intent to apply for mitigating factors by the provider, the SA will provide a copy of the POC to the CMS CO mailbox at QSOG_TransplantTeam.cms.hhs.gov and the SA will refer the provider to 488.61(f) for the list of the information that should be submitted for the mitigating factors application.

B. Applying for Mitigating Factors

All information necessary for consideration of mitigating factors must be received within 120 calendar days of receipt of the formal written notification of noncompliance at§482.80 or §482.82. Failure to submit a complete and timely application within 120 calendar days may be the basis for denial of mitigating factors. See 488.61(f) for the materials required for a mitigating factors application.

A request for consideration of mitigating factors must include sufficient information to permit an adequate review of the transplant program, factors that have contributed to outcomes, program improvements or innovations that have been implemented or planned, and in the case of natural disasters, the recovery actions planned.

The provider must submit the specific information requested by CMS for review. Information and documents submitted for mitigating factors review must have all Personally Identifiable Information (PII) removed prior to its submission.

C. The CMS Process for Reviewing Requests for Approval Based on

Mitigating Factors

The CMS CO reviews all requests for mitigating factors review. It will include analysis by CMS staff with programmatic and clinical expertise for each transplant program and will be conducted on a case-by-case basis in accordance with §488.61.

D. CMS Determination

According to §§488.61(g)(1)(i)-(iii), CMS has three options after considering applications for mitigating factors. CMS may:

1. Approve or re-approve a program's request for approval based on the consideration of mitigating factors;
2. Deny the program's request for approval or re-approval based on the consideration of mitigating factors; or
3. Offer the program an opportunity to enter into a time-limited **Systems Improvement Agreement (SIA)** with CMS, under certain conditions.

2062 F.3 Processing Medicare Approval based on Mitigating Factors

If a request for approval based on a mitigating factors application is approved, the condition- level non-compliance under §482.80 or §482.82 is rescinded and the prospective termination date is rescinded. Generally:

1. The CO will send an approval letter for mitigating factors to the program with a copy to the SA and RO.
2. The RO will send an approval letter (if it is an initial application) or a letter that removes the prospective termination date (if it is already a Medicare-approved transplant program).
3. The SA/RO will enter an offsite revisit survey into ASPEN and the RO will document the program's approval based on the presence of mitigating factors.
4. The approval based on mitigating factors does not carry forward to future re-certification periods, and CMS may remove approval based on mitigating factors at any time if improvements are not sustained, subject to prior notice to the program and an opportunity to reply.

2062 F.4 Processing Denial of a Mitigating Factors Request

CMS will deny approval based on mitigating factors if it finds that a basis for approval consistent with §488.61(f) has not been adequately established by the transplant program.

If a mitigating factors request is denied, CMS CO will send a letter to the program

communicating its denial of the mitigating factors request and copy of that letter will be sent to the SA and RO.

2062 F.5 Systems Improvement Agreements (SIA)

When a transplant program has condition-level non-compliance with the CoP requirements at
§482.80 or §482.82 triggering a pending termination date, CMS may extend the termination date and offer the hospital the opportunity to enter into a time-limited Systems Improvement Agreement (SIA) with CMS. A SIA is a binding agreement that may be offered by CMS pursuant to §488.61(h). The SIA is entered into voluntarily by the hospital. Under an SIA, CMS extends the prospective Medicare termination date and offers the program additional time to achieve compliance with the CoPs, contingent upon the hospital's agreement to participate in a structured regimen of quality improvement activities, to demonstrate improved outcomes, and to waive their right to appeal the noncompliance determination leading to the termination.

To be considered for a SIA, the program must demonstrate that it has developed, implemented, and evaluated interventions that are designed to address root causes that are institutionally supported by the hospital's governing body on a sustainable basis and has requested more time for further improvements or demonstrate compliance with the outcome requirements. SIAs include a mechanism for monitoring the program to ensure that the terms of the SIA are being met and program efforts to undertake targeted and systemic improvements to ensure ongoing and sustainable compliance with the regulatory requirements are occurring.

The SIA is signed by program individuals who have the authority to commit the hospital to the terms of the Agreement. The Agreement is between CMS and the transplant hospital.

In exchange for the additional time to initiate or continue activities to achieve compliance with the CoPs, the hospital must agree to a regimen of specified activities, including (but not limited to) all of the following:

(i) **Peer Review:** An external independent peer review team that conducts an onsite assessment of the program. The peer review must include—

(A) Review of policies, staffing, operations, relationship to hospital services, and factors that contribute to program outcomes;

(B) Both verbal and written feedback provided directly to the hospital;

(C); and

(D) Onsite review by a multidisciplinary team that includes a transplant surgeon

with expertise in the relevant organ type(s), a transplant administrator, an individual with expertise in transplant QAPI systems, a social worker or psychologist or psychiatrist, and a specialty physician with expertise in conditions particularly relevant to the applicable organ types(s) such as a cardiologist, nephrologist, or hepatologist. Except for the transplant surgeon, CMS may permit substitution of one type of expertise for another individual who has expertise particularly needed for the type of challenges experienced by the program, such as substitution of an infection control specialist in lieu of, or in addition to, a social worker.

(iii) **Action Plan:** An action plan that addresses systemic quality improvements and is updated after the onsite peer review;

(iv) **Onsite Consultant:** An onsite consultant whose qualifications are approved by CMS, and who provides services for eight (8) days per month on average for the duration of the agreement, except that CMS may permit a portion of the time to be spent offsite and may agree to fewer consultant days each month after the first three (3) months of the SIA. The function of the onsite consultant is established under the discretion of the program.

(v) **Policy & Procedures Review:** A comparative effectiveness analysis that compares policies, procedures, and protocols of the transplant program with those of other programs in areas of endeavor that are relevant to the center's current quality improvement needs;

(vi) **Outcomes Data Proficiency:** Development of increased proficiency, or demonstration of current proficiency, with patient-level data from the SRTR and the use of registry data to analyze outcomes and inform quality improvement efforts;

(vii) **Staffing Review:** A staffing analysis that examines the level, type, training, and skill of staff in order to inform transplant center efforts to ensure the engagement and appropriate training and credentialing of staff;

(viii) **QAPI:** Activities to strengthen performance of the QAPI program to ensure full compliance with the requirements of §482.96 and §482.21;

(ix) **Monthly Dialogue:** Monthly (unless otherwise specified) reporting with designated monitor regarding the status of programmatic improvements, results of the deliverables in the SIA, and the number of transplants, deaths, and graft failures that occur within one (1) year post- transplant; and

(x) **Other:** Additional or alternative requirements specified by CMS, tailored to the transplant program type and circumstances.

The content elements under (v), (vi), (vii), or (viii) above may be waived if CMS finds that the program has already adequately conducted the activity, the program is already proficient in the function, or the activity is clearly in applicable to the deficiencies that led to the SIA.

When CMS has offered a SIA to a transplant program, and the program agrees to enter

into it, the following occurs:

1. CMS develops the initial draft of the proposed SIA, based on (i)-(x) above, and forwards the draft to the program for review and comment;

2. CMS reviews the program's comments and provides feedback regarding any changes to the SIA;

3. CMS and the program will negotiate the final SIA document.

4. CMS completes the final SIA and forwards it to the program for signature. The SIA becomes effective on the date CMS signs the agreement.

2063 - Relationship Between the Transplant CoPs and Hospital CoPs.

(Rev. 190, Issued: 06-14-19, Effective: 06-14-19, Implementatiom: 06-14-19)

The transplant program must be in compliance with all hospital CoPs as well as all transplant program CoPs. Certain hospital requirements are inherently included in the transplant program survey process. When hospital requirements are thought to be out of compliance and in need of investigation the transplant program survey team must contact their supervisor to consult with the CMS RO for further instructions on citing the hospital deficiencies and must notify the hospital administration of any such citation.

The transplant program and hospital survey findings are documented on separate CMS-2567 forms even though the surveys are conducted together.

Hospices

2080 - Hospice - Citations and Description

(Rev. 1, 05-21-04)

2080A - Citations

(Rev. 73, Issued: 12-02-11 Effective: 12-02-11, Implementation: 12-02-11)

Section 1861(u) of the Act establishes hospices as a provider of services. Section 1861(dd) of the Social Security Act (the Act) defines hospice care and the hospice program. 42 CFR 418 sets forth the Conditions of Participation (CoPs) that hospices must meet and applies to a hospice as an entity as well as to the services provided to each individual under hospice care. 42 CFR Part 418.110 is a condition applicable only to hospices that provide short-term inpatient care and respite care directly, rather than under arrangements with other participating providers. Section 1866(a)(1)(Q) of the Act requires hospices, among other providers, to file an agreement with the Secretary to comply with the requirements found in Section 1866(f) of the Act regarding advance directives.

The Centers for Medicare & Medicaid Services (CMS) has a Web site for survey and certification information including hospice policy memos, the State Operations Manual, §§2080-2089 relating to hospices, and Appendix M, "Hospice Survey Procedures and Interpretive Guidelines." This information is available at http://www.cms.hhs.gov/SurveyCertificationGenInfo/

Definition

A hospice is a public agency or private organization or a subdivision of either of these that is primarily engaged in providing care and services to terminally ill individuals, meets the CoPs for hospices, and has a valid Medicare provider agreement. The law governing the provision of Medicare hospice services is found at Section 1861(dd) of the Act. The law further clarifies that "terminally ill individuals" are individuals having a "medical prognosis that the individual's life expectancy is 6 months or less." This definition is further clarified at 42 CFR 418.3 to provide for a life expectancy of 6 months or less "if the illness runs its normal course." Although the law does not explicitly define its expectations for "primarily engaged," CMS has interpreted it to mean exactly what it says, that a hospice provider must be primarily engaged in providing hospice care and services (Section 1861(dd)(2)(A)(i)). "Primarily" does not mean "exclusively." This requirement does not preclude the hospice from providing services to terminally ill individuals who have not elected the hospice benefit or providing services to individuals who are not terminally ill, as long as the primary activity of the hospice is the provision of hospice services to terminally ill individuals and the hospice meets all requirements for participation in Medicare.

Hospice Benefit Periods

An individual may elect to receive Medicare hospice benefits for two periods of 90 days and an unlimited amount of periods for 60 days each. (See 42 CFR 418.21.)

Eligibility Requirements

In order to be eligible to elect hospice care under Medicare, an individual must be entitled to Part A of Medicare and be certified as being terminally ill. (See 42 CFR 418.20.) An individual is considered to be terminally ill if the individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course.

Referrals may come from any source, but patients must be assessed by the hospice medical director for appropriateness of admission in consultation with the patient's attending physician (if the individual has one). The hospice medical director must consider the diagnosis of the terminal condition of the patient, other health conditions, whether related or unrelated to the terminal illness, and current clinically relevant information supporting all diagnoses. The medical director may consult with the attending physician directly or through information obtained indirectly. Information could be obtained through the hospice nurse or others who would bring the attending physician's knowledge of the patient to the medical director when the admission decision is being

made.

The hospice must obtain written certification of terminal illness within 2 calendar days for each of the benefit periods listed in 42 CFR 418.21, even if a single election continues in effect for an unlimited number of periods. If the hospice cannot obtain the written certification within 2 calendar days, after a period begins, it must obtain oral certification within 2 calendar days and written certification before a claim for payment is submitted.

For the initial 90-day period, certification of terminal illness must be obtained from the medical director of the hospice or the physician member of the hospice interdisciplinary group (IDG) and the individual's attending physician (if the individual has one). Recertification for subsequent periods only requires the certification of the hospice medical director or the physician member of the IDG. Certification statements must be on file and dated by the physician before the hospice submits a claim for payment. (See 42 CFR 418.22.)

2080B - Description

(Rev. 69, Issued: 12-15-10, Effective: 10-01-10, Implementation: 10-01-10)

Hospice care means a comprehensive set of services described in Section1861(dd)(1) of the Act, identified and coordinated by the individual's attending physician, medical director and by an interdisciplinary group to provide for the physical, psychosocial, spiritual and emotional needs of a terminally ill patient and family members, as delineated in a specific patient plan of care.

Hospice uses an interdisciplinary approach to caring for terminally ill individuals that stresses palliative care as opposed to curative care. Palliative care means patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and facilitating patient autonomy, access to information, and choice. The emphasis of hospice care is on effective symptom management, with the goal of making the patient as physically and emotionally comfortable as possible, and enabling the patient to remain at home as long as possible with minimal disruption to normal activities. Counseling and respite services are available to the family of the hospice patient. Hospice considers both the patient and the family as the unit of care.

Although some hospices are located as part of a hospital, skilled nursing facility (SNF), and home health agency (HHA), hospices must meet specific CoPs and be separately certified and approved for Medicare participation as a hospice provider of services. (See Exhibit 129 for "Hospice Survey and Deficiencies Report," Form CMS-643, and Exhibit 72 for "Hospice Request for Certification in the Medicare Program," Form CMS-417.)

2080C - Hospice Core Services

(Rev. 73, Issued: 12-02-11 Effective: 12-02-11, Implementation: 12-02-11)

With the exception of physician services, substantially all core services must be provided

directly by hospice employees on a routine basis. These services must be provided in a manner consistent with acceptable standards of practice. The following are hospice core services:

- Physician services;
- Nursing services, (routinely available and/or on call on a 24-hour basis, 7 days a week) provided by or under the supervision of a registered nurse (RN) functioning within a plan of care developed by the hospice (IDG) in consultation with the patient's attending physician, if the patient has one;
- Medical social services by a qualified social worker under the direction of a physician; and
- Counseling (including, but not limited to, bereavement, dietary, and spiritual counseling) with respect to care of the terminally ill individual and adjustment to death. The hospice must make bereavement services available to the family and other individuals identified in the bereavement plan of care up to 1 year following the death of the patient.

The hospice may contract for physician services as specified in 42 CFR 418.64(a).

A hospice may use contracted staff, if necessary, to supplement hospice employees in order to meet the needs of patients under extraordinary or other non-routine circumstances.

2080C.1 - Waiver of Certain Staffing Requirements

(Rev. 73, Issued: 12-02-11 Effective: 12-02-11, Implementation: 12-02-11)

Hospices are prohibited from contracting with other hospices and non-hospice agencies on a routine basis for the provision of the core services of nursing, medical social services and counseling to hospice patients. A hospice may, however, enter into arrangements with another hospice program or other entity for the provision of these core services in extraordinary, exigent, or other non-routine circumstances. An extraordinary circumstance generally would be a short-term temporary event that was unanticipated. Examples of such circumstances might include unanticipated periods of high patient loads, caused by an unexpectedly large number of patients requiring continuous care simultaneously, temporary staffing shortages due to illness, receiving patients evacuated from a disaster such as a hurricane or a wildfire, or temporary travel of a patient outside the hospice's service area. The hospice that contracts for services must maintain professional management responsibility for all services provided under arrangement or contract at all times and in all settings. Regulations at 42 CFR 418.100(e) discuss the professional management responsibilities of the hospice for services provided under arrangement.

Hospices must maintain evidence of the extraordinary circumstances that required them to contract for the core services and comply with the following:

- The hospice must assure that contracted staff is providing care that is consistent with the hospice philosophy and the patient's plan of care and is actively participating in the coordination of all aspects of the patient's hospice care, and

- Hospices may not routinely contract for a specific level of care (e.g., continuous care) or during specific hours of care (e.g., evenings and week-ends).

2080C.2 - Contracting for Highly Specialized Services

(Rev. 69, Issued: 12-15-10, Effective: 10-01-10, Implementation: 10-01-10)

A hospice may contract for the services of a registered nurse if the services are highly specialized, provided non-routinely, and so infrequently that the provision of such services directly would be impracticable and prohibitively expensive. Highly specialized services are determined by the nature of the service and the nursing skill level required to be proficient in the service. For example, a hospice may need to contract with a pediatric nurse if it cares for pediatric patients infrequently, and employing a pediatric nurse would be impracticable and expensive. Continuous care is not a highly specialized service, because while time intensive, it does not require highly specialized nursing skills.

2080C.3 – Hospice Nursing Shortage Provision

(Rev. 69, Issued: 12-15-10, Effective: 10-01-10, Implementation: 10-01-10)

CMS has instituted a temporary measure for hospices that are unable to hire a sufficient number of nurses directly due to the nursing shortage. During the time period from October 1, 2010 – September 30, 2012, in order to qualify for an "extraordinary circumstance" exemption, a hospice must notify the state agency (SA) responsible for licensing and certification that it intends to elect an exception under the "extraordinary circumstance" authority. This may be accomplished by providing written notification to the SA when it believes that the nursing shortage has become an "extraordinary circumstance" in its ability to hire nurses directly, and it must estimate the number of nurses it believes it will currently need to employ under contract. Notification may be made prior to September 30, 2012, and should address the following:

- An estimate of the number of potential patients that the hospice has not been able to admit during the past --3 months due to the nursing shortage and provide the current and desired patient/nurse ratio for the agency;

- Evidence that the hospice has made a good faith effort to hire and retain nurses, including:

    - Copies of recent advertisements (e.g., in local newspapers, Web sites, etc.,) that demonstrate recruitment efforts;

    - Copies of reports of telephone contacts with potential hires, professional schools and organizations, recruiting services, etc., and

- Job descriptions for nurse employees;

- Evidence that salary and benefits are competitive for the area;

- Evidence of any other recruiting activities (e.g., recruiting efforts at health fairs, educational institutions, health care facilities, and contacts with nurses at other providers in the area);

- Ongoing self-analyses of the hospice's trends in hiring and retaining qualified staff; and

- Evidence that the hospice has a training program in place to ensure that contracted staff are trained in the hospice philosophy, and able to provide palliative care prior to patient contact;

Contracted nurses may only be used to supplement the hospice nurses employed directly and should not be used solely to provide the continuous nursing level of care or on call service. The hospice is expected to continue its recruitment efforts during the period that it is contracting for nurses.

No approval action is required on the SA's part when it receives written notification from a hospice for an exemption, as long as the hospice provides the appropriate information. The SA will maintain copies of each exception notification and validate the hospice's stated need for an exemption during complaint and re-certification surveys. Of particular importance will be the extent to which the hospice nurses have been trained in the hospice philosophy and are able to effectively provide care to the patients consistent with the patient specific plan of care established by the IDG.

NOTE: CMS has instituted a temporary measure to allow individual hospices to contract for nurses until September 30, 2012, if the hospice can demonstrate that the nursing shortage is creating an extraordinary circumstance that prevents it from hiring an adequate number of nurses.

2080D - Hospice Required Services

(Rev. 73, Issued: 12-02-11 Effective: 12-02-11, Implementation: 12-02-11)

Requirement for 24-Hour Services

The hospice is required by the CoPs at 42 CFR 418.100 to make nursing services, physician services, drugs, and biologicals routinely available on a 24-hour basis, 7 days a week. It also has to make all other covered services available on a 24-hour basis, 7 days a week, when reasonable and necessary to meet the needs of the patient and family.

In addition to the hospice core services (physician services, nursing services, medical social services, and counseling), the following services must be provided by the hospice, either directly or under arrangements, to meet the needs of the patient and family:

- Physical and occupational therapy and speech-language pathology services;

- Hospice aide services A hospice aide employed by a hospice, either directly or under contract, must meet the qualifications required by Section1891(a)(3) of the Act and implemented at 42 CFR 418.76;

- Homemaker services;

- Volunteers;

- Medical supplies (including drugs and biologicals on a 24-hour basis) and the use of medical appliances related to the terminal diagnosis and related conditions;

- Short-term inpatient care (including respite care and interventions necessary for pain control and acute and chronic symptom management) in a Medicare/Medicaid participating facility; and

- Continuous home care provided during a period of crisis. Nursing care may be covered on a continuous basis for as much as 24 hours a day during periods of crisis, as necessary to maintain the patient at home. 42 CFR 418.204(a) defines a crisis as the period in which an individual requires continuous care for as much as 24 hours to achieve palliation or management of acute medical symptoms. The care provided must require at least 8 hours of care in a 24 hour period, and the care must be provided predominantly by a licensed nurse (RN, LVN, LPN). Homemaker or hospice aide services or both may also be covered if needed.

Section 1861(dd)(5) of the Act allows CMS to permit certain waivers of the requirements that the hospice make physical therapy, occupational therapy, speech language pathology services, and dietary counseling available (as needed) on a 24-hour basis. CMS is also allowed to waive the requirement that hospices provide dietary counseling directly. These waivers are available only to an agency or organization that is located in an area which is not an urbanized area (as defined by the Bureau of Census) and that can demonstrate to CMS that it has been unable, despite diligent efforts, to recruit appropriate personnel. These waivers are codified at 42 CFR 418.74.

2080D.1 - Hospice Interdisciplinary Group (IDG)

(Rev. 69, Issued: 12-15-10, Effective: 10-01-10, Implementation: 10-01-10)

Hospices participating in the Medicare program must use an interdisciplinary approach to assessing and meeting the physical, medical, psychosocial, emotional, and spiritual needs of the hospice patients and families facing terminal illness and bereavement. The hospice IDG members include, but are not limited to, the hospice physician (doctor of medicine or osteopathy) who must be an employee of or under contract with the hospice, registered nurse, social worker, and pastoral or other counselor. The IDG is required to conduct a comprehensive assessment of the patient and update the assessment at required time points. In addition, the group, in consultation with the patient's attending physician, if the

patient has one, must prepare a written plan of care for each patient that reflects patient and family goals and interventions based on the needs identified in the initial, comprehensive, and updated assessments. The plan of care must include all services necessary for the palliation and management of the terminal illness and related conditions.

The attending physician may either be a doctor of medicine or osteopathy or a nurse practitioner. This person is identified by the individual, at the time he or she elects to receive hospice care, as having the most significant role in the determination and delivery of the individual's medical care. In the event that a beneficiary's attending physician is a nurse practitioner, the hospice medical director and/or physician designee must certify or re-certify the terminal illness. Nurse practitioners cannot certify a terminal diagnosis or the prognosis of 6 months or less, if the illness or disease runs its normal course, or re-certify a terminal diagnosis or prognosis.

The hospice IDG is responsible for developing and maintaining a system of communication, coordination, and integration of services that ensures that the plan of care is reviewed and updated no less frequently than every 15 calendar days. It is not permissible for either the attending physician or the hospice medical director to provide the sole guidance for the plan of care. The law and regulations require that it be the combined work of the IDG.

2081 - Revoking Election of Hospice Care

(Rev. 73, Issued: 12-02-11 Effective: 12-02-11, Implementation: 12-02-11)

The hospice patient or representative may revoke the patient's election of hospice care at any time during the election period according to 42 CFR 418.28. Revocation is a voluntary action taken by the patient or representative. The election of the hospice benefit is the beneficiary's choice rather than the hospice's choice, and the hospice cannot revoke the beneficiary's election. It is important for the hospice to educate the patient and family before the start of care that hospice entails certain limits in the way care will be provided, including restrictions on obtaining care outside the care arranged for or provided by the hospice, and the patient's liability for care received without the hospice's involvement. The hospice should neither request nor pressure the patient/family or representative in any way to revoke his/her election.

2082 - Discharge from Hospice Care

(Rev. 73, Issued: 12-02-11 Effective: 12-02-11, Implementation: 12-02-11)

Once a hospice chooses to admit a Medicare beneficiary, it may not automatically or routinely discharge the beneficiary at its discretion, even if the care promises to be costly, inconvenient, or the State allows for discharge under State law. The situations under which a hospice may discharge a patient are addressed in the regulation at 42 CFR 418.26 and include the following situations:

- The patient moves out of the hospice's service area or transfers to another hospice;
- The hospice determines that the patient is no longer terminally ill; and

- The hospice determines under a policy set by the hospice for the purpose of addressing discharge for cause, that the patient's (or other persons in the patient's home) behavior is disruptive, abusive, or uncooperative to the extent that delivery of care to the patient or the ability of the hospice to operate effectively is seriously impaired.

The hospice must do the following before it seeks to discharge a patient for cause:

- Advise the patient that a discharge for cause is being considered;
- Make a serious effort to resolve the problem(s) presented by the patient's (or other persons in the patient's home) behavior or situation;
- Ascertain that the patient's proposed discharge is not due to the patient's use of necessary hospice services; and
- Document in the clinical record, the problem(s) and efforts made to resolve the problem(s).

Prior to discharging a patient for any reason stated above, the hospice IDG must obtain a written physician's discharge order from the hospice medical director. If a patient has an attending physician involved in his or her care, this physician should be consulted before discharge and his/her review and decision included in the discharge note.

The hospice notifies its Medicare administrative contractor (MAC) and SA of the circumstances surrounding the impending discharge. The hospice should also consider referrals to other appropriate and/or relevant state/community agencies (i.e., Adult Protective Services) or health care facilities before discharge.

2083 - Hospice Regulations and Non-Medicare Patients

(Rev. 73, Issued: 12-02-11 Effective: 12-02-11, Implementation: 12-02-11)

The hospice CoPs apply to all patients of the hospice (Medicare and non-Medicare), with the exception of the following regulations, which apply only to Medicare beneficiaries:

- 42 CFR 418.100(d) - the continuation of care requirement, and
- 42 CFR 418.108(d) - the 80-20 inpatient care limitation.

In addition, the following CoPs regarding the certification and recertification of terminal illness are necessary to determine eligibility for Medicare and Medicaid patients and may or may not be a requirement by other payment sources:

- 42 CFR 418.102(c);
- 42 CFR 418.104 (a)(5); and
- 42 CFR 418.112 (e)(3)(iii).

2084 - Hospice Inpatient Services

(Rev. 73, Issued: 12-02-11 Effective: 12-02-11, Implementation: 12-02-11)

Hospices must make inpatient care available for pain control, symptom management, and respite purposes. This inpatient care may be provided directly by the hospice or indirectly under arrangements made by the hospice. If services are provided under arrangements, the hospice must ensure that the services are in full compliance with all applicable standards relating to inpatient care found at 42 CFR 418.110 and 42 CFR 418.108.

2084A - Hospice Provides Inpatient Care Directly

(Rev. 73, Issued: 12-02-11 Effective: 12-02-11, Implementation: 12-02-11)

When the hospice provides inpatient care directly, it may do so either in space that it owns or leases or in space shared with a Medicare certified hospital, SNF, or Medicaid certified nursing facility (NF).

- If the hospice provides care in its own inpatient facility, the care may be provided in space that the hospice either owns or leases from another facility or building. The inpatient unit may consist of several beds, a group of beds, or a wing and must meet all applicable Federal and State requirements and be surveyed for compliance with 42 CFR 418.110 prior to providing inpatient care to patients. This survey includes a Life Safety Code survey (which has currently adopted the 2000 edition of the Life Safety Code of the National Fire Protection Association) that must be done both at the time of initial certification of the inpatient facility and at the time of recertification surveys.

- If the hospice provides care directly with hospice staff in space shared with a Medicare-certified Hospital, SNF, or a Medicaid certified NF (for respite care only), the SA reviews the agreement and patient files for compliance with 42 CFR 418.110(b) and 42 CFR 418.110(e) since the location already meets the remaining requirements of 42 CFR 418.110 as a Medicare/Medicaid participating facility.

2084B - Hospice Provides Inpatient Services Under Arrangements

(Rev. 73, Issued: 12-02-11 Effective: 12-02-11, Implementation: 12-02-11)

When the hospice provides inpatient services under arrangements with a Medicare participating hospital or SNF, a Medicaid participating NF (for respite care only), or an inpatient unit of another Medicare-certified hospice, a separate survey of each site is not required. In these cases, the SA reviews the agreement and patient files to assure that the standards in 42 CFR 418.110(b) regarding 24-hour nursing service and 42 CFR 418.110(e) regarding comfort and privacy of patient and family members are satisfied. However, if in reviewing contracts and other documentation (e.g., clinical records, plans of care), questions arise concerning the contract arrangements, the SA conducts an onsite visit to the institution providing the inpatient services to review the care provided under arrangements, not to inspect the facility. This includes hospitals that are accredited by The Joint Commission or the American Osteopathic Association that are providing inpatient services under arrangements.

Applicability of Inpatient Care CoP 42 CFR 418.110

Location Where Inpatient Care is Provided	Applicability of Condition
Hospice freestanding inpatient facility	Survey for compliance with 42 CFR 418.110.
Medicare certified hospital or SNF and/or Medicaid certified NF (for respite care only.)	Survey for compliance with 42 CFR 418.110(b) and 42 CFR 418.110(e). The institution already meets the remaining requirements of 42 CFR 418.110 as a Medicare/Medicaid certified hospital or SNF/NF.

A hospice freestanding inpatient facility is defined in this context as a facility that is not a part of another Medicare/Medicaid certified facility (e.g., hospital or SNF/NF).

2085 - Operation of Hospice Across State Lines

(Rev. 69, Issued: 12-15-10, Effective: 10-01-10, Implementation: 10-01-10)

When a hospice provides services across State lines each respective State Agency (SA) must be aware of and approve the action. Each SA must verify that applicable state licensure, personnel licensure, and other State requirements are met in its respective State.

The provision of services across State lines is appropriate in most circumstances. Areas in which community services, such as hospitals, public transportation, and personnel services are shared on both sides of State boundaries are most likely to generate an extension of hospice services.

When a hospice provides services across State lines, it must be certified by the State in which its CMS certification number (CCN) is based, and its personnel must be qualified in all States in which they provide services. The appropriate SA completes the certification activities. The involved States must have a written reciprocal agreement permitting the hospice to provide services in this manner. The reciprocal agreement must indicate that both States are aware of their respective responsibilities for assessing the hospice's compliance with the CoP within their State. The agreement should assure that home visits are conducted to a sample of all patients, in all States served by the hospice.

The CMS Regional Office (RO) will review the required reciprocal agreement between the States to assure that the SA where the practice location resides is assuming responsibility for any necessary surveys of the location. If the SAs are unable to come to a reciprocal agreement on assuring the necessary surveys of the location, the location should not be approved as a part of the hospice. The provision of interstate service without a written reciprocal agreement could severely undermine the State's ability to fulfill its statutory responsibilities under Section 1864 of the Act to enforce Medicare's health and safety requirements. It is at the discretion of the States to decide whether entering into reciprocal agreements is in the best interest of their residents, provider markets, and quality assurance and oversight systems.

Exhibit 289 ”Model Reciprocal Agreement Survey and Certification” contains a model reciprocal agreement document for States to use to assist them in fulfilling their statutory responsibility to enforce Medicare’s health and safety requirements when a hospice provides services across State lines.

In States that have a reciprocal agreement in place, providers are not required to be separately approved in each State; consequently, they would not have to obtain a separate Medicare provider agreement/certification number in each State. Providers residing in a State that does not have a reciprocal agreement with a contiguous State are precluded from providing services across State lines.

In the event that the hospice operates in two CMS ROs, the RO responsible for the State in which the hospice provider agreement/certification number is based should take the lead in assuring that the required survey and certification activities are met.

2086 - Hospice Change of Address

(Rev. 73, Issued: 12-02-11 Effective: 12-02-11, Implementation: 12-02-11)

It is inherent in the provider certification process that a provider notifies CMS of its intent to change the location or site from which it provides services. Absent such notification, CMS has no way of carrying out its statutorily mandated obligation of determining whether the provider is complying with applicable participation requirements at the new site or location. It is a longstanding CMS policy that there is no basis for a provider to bill Medicare for services provided from a site or location that has not been determined to meet applicable requirements of participation. This guidance is contained in Chapter 3, section 3224 of Publication 100-07.

When an existing hospice intends to move from its surveyed, certified location to a new site or location, it notifies CMS either directly or through the SA, and, if deemed, it notifies its approved national accreditation organization (AO), in writing of the proposed change of location. The provider also notifies its MAC and submits all required documentation including an amended Form CMS-855A before CMS approval can be granted. The provider obtains CMS’ approval of the new address before it provides Medicare services from the new address.

Upon receipt of a provider’s notice and request for approval of the move to the new site or location, the RO will carefully evaluate the information, together with any supporting documentation from the provider and any other relevant information known to the RO in making its decision. If a decision can be made on the written application and supporting documentation, CMS will grant or deny an approval without requiring a survey. If, however, the RO concludes that circumstances warrant a survey to establish whether the new address complies with all applicable requirements, CMS will advise the provider and will make no further findings until a survey has been completed and submitted to CMS for its review. In either event, CMS will notify the provider of its decision in writing, as appropriate.

CMS generally will not approve a change of location of a primary hospice with one or more previously approved multiple locations if the new location increases the distance between the primary hospice location and its previously approved multiple location(s) to a point that prevents the hospice from exerting the supervision and control necessary at each multiple location to assure that all hospice care and services continue to be responsive to the needs of the patient/family at all times and in all settings. In that event, the application for approval of the new location would usually be denied without a survey, and the provider would apply for a new certification number for the new location. Request for approval of a proposed change of location of an approved multiple location is handled as a request for approval of a new multiple location, in accordance with the regulations and guidelines at 42 CFR 418.100(f).

NOTE: CMS will not approve a change of location for a hospice's own inpatient facility without a survey to assure that the facility meets all requirements specified at 42 CFR 418.110.

2086A - Effective Date

(Rev. 69, Issued: 12-15-10, Effective: 10-01-10, Implementation: 10-01-10)

A hospice may not bill for services provided from the new site or location and should not bill Medicare until the new site or location has been approved by CMS. The effective date of coverage for services provided from the new location is the date CMS grants approval to the hospice's request to change locations. The fact that a national AO has approved a new site or location will not affect CMS' decision. CMS' determination will be based on its independent application of its regulations to the facts in the case. Services provided before the effective date of approval should not be billed to Medicare.

2086B – Administrative Review

(Rev. 73, Issued: 12-02-11 Effective: 12-02-11, Implementation: 12-02-11)

CMS's decision on a request for approval of a change of address does not qualify as an initial determination subject to administrative review under 42 CFR 498.3. Such a determination does not affect the existing provider agreement, which continues in effect at the surveyed, certified location until voluntarily terminated by the provider pursuant to 42 CFR 489.52 or involuntarily terminated by CMS pursuant to 42 CFR 489.53. In the event approval of the new change of address is denied, the provider has the option of formally applying for initial certification of the new site or location as a separate Medicare provider of hospice services. In that event, an initial certification survey by CMS or the SA (or accreditation based on survey by a national AO with deeming authority) would be required.

2086C – Move after Certification Survey

(Rev. 73, Issued: 12-02-11 Effective: 12-02-11, Implementation: 12-02-11)

Requests for initial certification cannot be processed to completion if a prospective provider moves to a new location after it is surveyed and/or deemed to meet the CoPs by a national AO with deeming authority. If a prospective provider moves after its location

has been surveyed and/or accredited but prior to a certification determination by CMS, the prospective provider's application for certification becomes incomplete. Absent a survey of the new location to which the prospective provider has moved, CMS is unable to determine whether applicable program requirements are met at the new location, and therefore is prevented from completing its review of the pending application. In these circumstances, CMS advises the prospective provider that its application is incomplete. Such an incomplete application is held in abeyance pending receipt of a report of survey of the current location from the SA or a national AO with deeming authority meeting the requirements of and approved by CMS. The decision to hold an incomplete application in abeyance does not qualify as an initial determination as defined in 42 CFR 498.3.

2087 - Simultaneous Surveys

(Rev. 69, Issued: 12-15-10, Effective: 10-01-10, Implementation: 10-01-10)

If a hospice is established by an entity which participates in the Medicare program as another type of provider (hospital, SNF, HHA), the SA should attempt to coordinate simultaneous certification surveys of these entities, i.e., for compliance with hospice CoPs and for compliance with the other appropriate CoPs/requirements.

NOTE:Section 1861(dd)(4)(A) of the Act states that if a hospice is approved as being part of another type of provider, with a separate certification number, it shall be considered to meet those CoPs that are common to both the hospice and the other type of provider.

2088 – Multiple Locations

(Rev. 69, Issued: 12-15-10, Effective: 10-01-10, Implementation: 10-01-10)

When an existing hospice intends to add a multiple location, it must notify CMS, the SA, and, if deemed, it should notify its' approved national AO, in writing, of the proposed location if it expects this location to participate in Medicare or Medicaid. The hospice must also submit a Form CMS-855A Change of Information Request (including all supporting documentation) to its MAC before CMS approval can be granted. The provider must obtain CMS approval of the new location before it is permitted to bill Medicare for services provided from the new location.

Upon receipt of a hospice's notice and request for approval of a multiple location, the CMS RO will carefully evaluate the information, together with any supporting documentation from the hospice and any other relevant information known to the RO in making its decision. If a decision can be made based on the written application and supporting documentation, CMS will grant or deny an approval without requiring a survey. If, however, the RO concludes that circumstances warrant a survey to establish whether the new location complies with all applicable requirements, CMS will advise the provider and will make no further findings until a Medicare certification survey has been completed and submitted to CMS for its review. In either event, CMS will notify the provider of its decision in writing, as appropriate.

In evaluating a hospice's request for approval of a multiple location, the SA and RO should consider the following in determining whether the new location meets all

applicable Medicare requirements:

- Ability of the governing body to manage the location;
- Any changes made to the lines of authority, and professional and administrative control;
- Ability of the Medical Director to assume responsibility for the medical component of the hospice's patient care at all locations;
- Ability of the hospice to monitor and exercise control over services provided by personnel under arrangements or contracts at the multiple location;
- Changes in the IDG(s) providing hospice services;
- Changes in staffing or the client population, or both;
- Changes in the way clinical records are maintained, protected and safeguarded against loss, destruction or unauthorized use; and
- Ability of the hospice to provide all hospice services at the multiple location.

A hospice may not bill Medicare for services provided from a multiple location until the new site or location has been approved by CMS. The fact that a national AO with deeming authority has approved a new site or location will not affect CMS' decision. CMS' determination will be based on its independent application of its regulations to the facts in the case. Services provided before the effective date of approval should not be billed to Medicare.

If the hospice does operate at multiple locations, a deficiency found at any location will result in a compliance issue for the entire hospice.

For further information on hospice multiple locations, see 42 CFR 418.100(f) and 418.116.

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 **and** the source of the injury could not be explained by the client; **and**

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

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 **and** the source of the injury could not be explained by the client; **and**

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

It is important to note that members of the ICF/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 Appendix I) 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).

2139B - Individual Program Plan (IPP)
(Rev. 1, 05-21-04)

The individual's interdisciplinary team must prepare an IPP which identifies the discrete, measurable, criterion-based objectives the individual is to achieve; the timetables for expected mastery; and the specific individualized program of specialized and generic strategies and techniques to be employed. The IPP must be directed toward the acquisition of the behaviors necessary for the individual to function with as much self-determination and independence as possible and the prevention or deceleration of regression, or loss of current optimal functional status.

2139C - Program Implementation
(Rev. 1, 05-21-04)

Each individual must receive continuous active treatment consisting of needed interventions and services in sufficient number and frequency to achieve the IPP objectives. Each individual's IPP must be implemented by all staff working with the individual, except where only licensed personnel may implement certain areas of the program.

2139D - Program Documentation
(Rev. 1, 05-21-04)

Accurate, systematic, behaviorally-stated data about an individual's performance toward meeting the criteria in the IPP objectives must be documented and serve as the basis for changes and revisions, whenever necessary.

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 42 CFR Part 483.440(a) 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. 42 CFR Part 483.470(b) 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.

2140B - Waiver of LSC
(Rev. 1, 05-21-04)

See §2472.

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.

Spell of Illness Certifications

2160 - Purpose of Certifying §§1861(e)(1) and 1819(a)(1) of the Act Status of Hospitals and SNFs
(Rev. 1, 05-21-04)

2160A - Benefit Period Provision
(Rev. 1, 05-21-04)

A Medicare beneficiary is limited to a specific maximum number of days of covered inpatient hospital care and covered post-hospital extended care in a SNF within a period of time known as a spell of illness or benefit period. Once these benefit days have been used, additional benefit days are not available until the spell of illness ends and a new benefit period begins.

Section 1861(a) of the Act defines the term "spell of illness" and states that to end a spell of illness, a beneficiary must not have been an inpatient of any hospital as defined in §1861(e)(1) of the Act or a resident of a facility described in §1819(a)(1) (formerly §1861(j)(1)) of the Act for 60 consecutive days.

NOTE: Section 1819(a)(1) of the Act's basic definition of a SNF for spell of illness purposes was formerly contained in §1861(j)(1) of the Act. Thus, a reference to §1861(j)(1) of the Act in older material should be read as a reference to §1819(a) of the Act.

Therefore, to enable beneficiaries, providers, and intermediaries to ascertain eligibility for additional benefits, classify institutions to which a beneficiary may have been removed on the basis of whether the institutions meet the §§1861(e)(1) or 1819(a) definitions.

2160B - Defining Medicare Eligible Individual's "Home" for Purposes of Durable Medical Equipment (DME) and Home Health Benefits
(Rev. 1, 05-21-04)

Sections 1861(s)(6) and 1861(n) of the Act provide that purchase or rental of DME such as iron lungs, oxygen tents, hospital beds, or wheelchairs may be covered under Part B of the Medicare program if used in the patient's home. Similarly, home health benefits can be paid for certain services that are furnished in a patient's home. An institution that meets the requirements of §1861(e)(1) or §1819(a)(1) of the Act **cannot** be considered a patient's home for purposes of this benefit. If a facility is certified as a hospital, a Medicare SNF, or any other facility that meets the requirements of §1861(e)(1) or §1819(a)(1) of the Act, it is not considered the patient's home. Therefore, the institution's §1861(e)(1) or §1819(a)(1) status is used for these purposes also.

2160C - Defining "Institution" for Ambulance Benefit
(Rev. 1, 05-21-04)

Another use of §1861(e)(1) or §1819(a)(1) of the Act's definitions is to help determine whether ambulance benefits can be paid. The benefit requires that transportation be to or from an institution (i.e., other than the patient's "home").

2162 - Defining Hospital for Spell of Illness, DME, and Home Health Benefit Purposes

(Rev. 1, 05-21-04)

The term "hospital" as used in §1861(e) of the Act and State licensure laws has a generally accepted meaning that is seldom questioned. A problem arises, however, with respect to distinct parts of hospitals that render types of care other than hospital care (e.g., LTC). For example, a hospital may have separate wings or buildings for services ranging from residential to skilled nursing services. The SA evaluates these non-hospital parts in terms of whether they meet the definition of "hospital" in §1861(e)(1) of the Act. The SA also states whether these parts meet the definition of "skilled nursing facility" in §1819(a)(1) of the Act.

Although a psychiatric hospital is precluded from participating in the Medicare program as a SNF, the spell of illness test is applied to such institution, and any non-hospital portions must be certified for spell of illness purposes.

2164 - When to Make Spell of Illness Certification

(Rev. 1, 05-21-04)

It is not necessary that the SA makes §1861(e)(1) or §1819(a)(1) determinations for Medicare-certified hospitals or Medicare-certified SNFs. Section 1861(e)(1) of the Act contains a basic definition that all hospitals meet. Similarly, §1819(a)(1) of the Act contains the statutory definition of a SNF, which is the basis for Medicare certification requirements of SNFs in 42 CFR 483, Subpart B.

In many States, licensing laws for all nursing homes have incorporated the requirements of §1819(a) or §1919(a) of the Act or the criteria contained in §2166. When this is the case, any nursing home licensed in such States cannot be considered a resident's home for purposes of spell of illness, DME, ambulance, and HHA benefits. In other States it may be necessary for the SA to make §1861(e)(1) or §1819(a)(1) certifications, as appropriate, in the following instances:

- Nonparticipating parts of newly certified Medicare distinct part SNFs;
- Nonparticipating parts of Medicare SNFs that change from complete to distinct part certifications or that change the size or location of the participating distinct part;
- Terminated, denied, or withdrawn Medicare SNFs;
- New institutions offering any level of nursing care or rehabilitation which do not intend to participate in Medicare;

- Changes in the §1819(a)(1) status of facilities that come to the SA's attention through licensure, surveys, or other means; and

- Parts of hospitals providing patient care but not rendering hospital services.

Routine periodic recertifications of spell of illness requirements are not required.

2166 - Criteria for Certifying §1819(a)(1) of the Act Status of LTC Facilities Other Than SNFs
(Rev. 1, 05-21-04)

As indicated above, SNFs meet §1819(a)(1) requirements, as do LTC facilities in States where licensure laws require it. In other situations, a facility or a part of a facility meets the standard set forth in §1819(a)(1) of the Act for purposes of determining spell of illness status if it meets **each** of the following: (See Exhibit 10, Form CMS-1539A, "Certification and Transmittal for Spell of Illness Determination.")

2166A - Nursing Services
(Rev. 1, 05-21-04)

Nursing services are provided under the direction or supervision of one or more RNs or licensed practical or vocational nurses without regard to whether the facility has the nurse staffing requirement "waived." The SA considers this condition met even if the nurse is also the administrator of the facility or is employed on a part-time basis.

2166B - 24-Hour Nursing Services
(Rev. 1, 05-21-04)

Nursing personnel are on duty 24 hours a day. The term "nursing personnel" includes RNs, licensed practical or vocational nurses without regard to whether they are "waived," practical nurses, student nurses, nurse aides, and orderlies.

2166C - Nurse-Bed Ratio
(Rev. 1, 05-21-04)

The number of full-time equivalent nursing personnel to the number of beds is not less than an average ratio of 1 to 15 per shift.

NOTE: Generally, there will be a close equivalency between the number of beds and the average number of patients in an institution. When circumstances indicate a significant discrepancy in these factors, the ratio of nurses to the average patient census should be used in certifying §1819(a)(1) status.

A facility that has three 8-hour shifts must have a minimum of the equivalent of three full-time nursing personnel during a 24-hour period for each 15 beds. It is not necessary that the 1 to 15 ratio be maintained for each shift, but the average of all shifts must be at least 1

to 15. In determining the ratio, the SA counts nurses who are also administrators as nursing personnel.

2166D - Other Services
(Rev. 1, 05-21-04)

Bed and board are provided to inpatients in connection with the furnishing of nursing care, plus one or more medically-related health services such as physicians' services, physical, occupational or speech therapy, diagnostic and laboratory services, and administration of medication. (Social, diversional, or recreational services provided by the institution are not considered medically-related health services.)

2168 - Additional Development Required for Spell of Illness Certifications
(Rev. 1, 05-21-04)

Ordinarily, the SA has sufficient information available in certification, licensure, welfare, or other records to certify the spell of illness status of an institution under the rules and criteria set forth in the previous sections.

If the facility assigns staff specifically to separate patient care units, the SA records separate data for each such unit on the appropriate survey report (i.e., page 12 of Form CMS-1537 for hospitals or Form CMS-671 for LTC facilities), identifying the location of the units or the room numbers of each unit.

A. Additional Development

Where existing records are inadequate, the SA uses any reliable method (e.g., letters and phone calls) to obtain additional evidence to determine spell of illness status. If any doubts exist, the SA visits to verify.

B. Institution Consists of Single Building

If an institution consists of a single building, the SA completes separate spell of illness determinations for the nonparticipating part(s) of the institution.

C. Institution Consists of More than One Building

If an institution consists of more than one building, the SA completes separate spell of illness determination for the nonparticipating parts of the institution in each building.

Home Health Agencies (HHAs)

2180 - HHA – Citations and Description
(Rev. 1, 05-21-04)

2180A - Citations
(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

The statutory authority for applying CoPs to HHAs is found in §§1861(o) and 1891 of the Act. The regulations are found in 42 CFR Part 484 (§484.) Appendix B contains Investigative Procedures and Interpretive Guidance for surveyors.

The CMS has a web site for information pertaining to HHA survey and certification, including links to HHA policy memos, HHA-related information in the State Operations Manual, §§ 2180 - 2202.19, and Appendix B, Part I-Investigative Procedures and Part II Interpretive Guidelines available at:
http://www.cms.gov/Medicare/Provider-EnrollmentandCertification
/SurveyCertificationGenInfo/index.html?redirect=/SurveyCertificationGenInfo/

Additional information can also be found at the Home Health Agency (HHA) Center at:
http://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html?redirect=/center/hha.asp.

2180B - Types of Agencies
(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

An HHA may be a public, nonprofit or proprietary agency or a subdivision of such an agency or organization.

1. Public agency is an agency operated by a State or local government. Examples include State-operated HHAs and county hospitals. For regulatory purposes, "public" means "governmental."

2. Nonprofit agency is a private (i.e., nongovernmental) agency exempt from Federal income taxation under §501 of the Internal Revenue Code of 1954. These HHAs are often supported, in part, by private contributions or other philanthropic sources, such as foundations. Examples would include non-profit visiting nurse associations or non-profit hospitals.

3. Proprietary agency is a private, profit-making agency or profit-making hospital.

2180C - General Requirements
(Rev. 1, 05-21-04)

Section 1861(o) of the Act defines an HHA as an agency or organization which:

- Is primarily engaged in providing skilled nursing services and other therapeutic

services;

- Has policies established by a group of professionals (associated with the agency or organization), including one or more physicians and one or more registered professional nurses, to govern the services which it provides;

- Provides for supervision of above-mentioned services by a physician or registered professional nurse;

- Maintains clinical records on all patients;

- Is licensed pursuant to State or local law, or has approval as meeting the standards established for licensing by the State or locality;

- Has in effect an overall plan and budget for institutional planning;

- Meets the CoPs in the interest of the health and safety of individuals who are furnished services by the HHA; and

- Meets additional requirements as the Secretary finds necessary for the effective and efficient operation of the program.

For purposes of Part A home health services under Title XVIII, the term "home health agency" does not include any agency or organization which is primarily for the care and treatment of mental diseases.

The CoPs for a Medicare-approved HHA found in 42 CFR Part 484 are also based on §1891 of the Act. These CoPs are listed in Appendix B, Interpretive Guidelines for HHAs. Section 1891 of the Act requires, among other things, that the HHA:

- Protect and promote the rights of each individual under its care;

- Disclose ownership and management information required under the Act;

- Not use as a home health aide (on a full-time, temporary, per diem, or other basis) any individual to provide items and services described in §1861(m) of the Act, unless the individual has completed a training and competency evaluation program (CEP) or a CEP that meets minimum standards established by the Secretary, and is competent to provide such items and services;

- Operate and provide services in compliance with all applicable Federal, State, and local laws and regulations (including the requirements of §1124 of the Act);

- Operate and provide services in compliance with accepted professional standards and principles which apply to professionals providing items and services for the HHA;

- Include an individual's plan of care (PoC) required under §1861(m) of the Act as part of the clinical record described in §1861(o)(3) of the Act; and

- Comply with the requirements of §1866(f) of the Act relating to maintaining written policies and procedures respecting advance directives.

2180D - Services Provided

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

All HHAs must provide skilled nursing services and at least one of the following other therapeutic services: physical therapy, speech language pathology, or occupational therapy, medical social services, or home health aide services in a place of residence used as a patient's home. The HHA must provide at least one of these services (i.e., skilled nursing, physical therapy, speech language pathology, occupational therapy, medical social services, or home health aide services) directly and in its entirety by employees of the HHA. The other therapeutic services and any additional services may be provided either directly or under arrangement.

An HHA is considered to provide a service "directly" when the person providing the service for the HHA is an HHA employee. For the purpose of meeting §484.14(a), an individual who works for the HHA on an hourly or per visit basis may be considered an agency employee if the HHA is required to issue a Form W-2 on his/her behalf.

An HHA is considered to provide a service "under arrangements" when the HHA provides the service through contractual or affiliation arrangements with other agencies or organizations, or with an individual(s) who is not an HHA employee. The HHA is responsible for ensuring that the applicable CoPs are met, as though the HHA was furnishing the services directly.

When hourly or per visit contracts are used, or when services are provided under arrangement, there must be a written agreement or contract between such personnel, or this agency or organization, and the HHA which specifies:

- Patients are accepted for care only by the primary HHA;

- The services to be furnished under the contract or agreement;

- The necessity to conform to all applicable agency policies, including personnel qualifications;

- The responsibility for participating in development of plans of care;

- The manner in which services will be controlled, coordinated, and evaluated by the primary HHA;

- The procedures for submitting clinical and progress notes, scheduling of visits, periodic patient evaluation; and

- The procedures for payment for services furnished under the agreement or contract.

2180E – Application of Home Health Agency Conditions of Participation to Patients Receiving Chore Services Exclusively

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

In addition to the home health services listed in §1861(m) of the Act, and Medicaid State Plan services identified in §1905(a) of the Act, some HHAs choose to offer additional services which are clearly non-medical in nature. Such services are typically comprised of housekeeping, chore, or companion services. The HHA makes these services available to individuals who choose to pay for them privately, and/or individuals who are provided these services from other programs, such as a State Medicaid Home and Community-Based Services (HCBS) Waiver Program under §1915(c) of the Social Security Act. The HHA may offer these services to current patients of the HHA (to supplement the skilled services available), to previous patients who have been discharged from skilled care, and to other individuals in the community who request them.

Many individuals who receive these non-medical services are frail, elderly or disabled and request these services because they are unable to perform them independently and need this kind of assistance to remain in the home environment.

In addition to promoting the health and safety of individuals, §1891(b) of the Social Security Act also directs the Secretary to ensure that requirements "promote the effective and efficient use of public moneys." This statutory direction is especially pertinent in the question of whether expenses ought always to be incurred for a comprehensive assessment and care plan when the only service requested from an HHA by an individual is a chore or other clearly non-medical service. When this is the case, we will <u>not</u> consider the individual to be a patient of the HHA in the traditional sense of the term, and requirements that must apply to patients will not be required in such limited situations (e.g., the requirement for a comprehensive assessment under §484.55 will not apply).

The Medicare HHA CoPs do not apply to those individuals who receive <u>only</u> chore services or other clearly non-medical services from the HHA. Non-medical services include chore services, companion services, household maintenance and repair services, lawn and tree services, and clearing walkways. To the extent that there is ambiguity as to whether a service is non-medical or medical, we will incline towards the medical interpretation and consider the CoPs to apply.

CMS considers as a medical service any hands-on service, personal care service, cueing, or activity that is in any way involved in monitoring the patient's health condition. As soon as the HHA provides any Medicare service to an individual, or any standard service permitted by Federal law under the Medicaid State Plan (such as personal care), we will consider the individual to be receiving medical care. The CoPs will apply for all services rendered to such an individual. For example, the CoPs would apply in the case of an individual who received both chore services and personal care (regardless of funding

source), but would not apply in the case of an individual receiving only chore services from the HHA.

HHAs are required as a part of the patient rights CoP to advise the patient of the extent to which payment for HHA services may be expected from Medicare or other sources and the extent to which payment may be required from the patient. The HHA should explain to a beneficiary who is ending a Medicare episode and continuing to receive chore services that Medicare does not pay for those services.

HHAs may develop their own comprehensive assessment for each required time point under the regulations at §484.55 for those patients receiving personal care services only regardless of payer source. The assessment may be performed any time up to and including the 60th day from the most recently completed assessment.

The HHA must continue to meet all State licensure and State practice regulations governing the provision of service to this population. Where state law is more restrictive than Medicare, (e.g., State law or State Medicaid HCBS requires the HHA to comply with CoPs when providing only chore services) the provider needs to apply the State law standard as well.

Note that this instruction does not supersede any current policy related to Medicare coverage and eligibility rules or instructions from the Medicare Administrative Contractors (MACs). The HHAs that provide non-medical services must also ensure that fiscal accounts are structured and maintained in conformance with CMS regulations and generally accepted accounting standards.

2182 - Organization of HHA

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

It is permissible for an HHA to be located at a single site or have a parent site with services available at other approved locations, unless prohibited by State law or regulation. If there is more than one site, there must be a designated parent site with any other designated sites (branches and/or subunits) being part of that agency as described in more detail below. The parent, branch or subunit must be operational during normal business hours as defined by the parent or subunit.

Subdivisions

A subdivision is a component of a multi-function health agency, such as a hospital-based HHA or the nursing division of a health department, which independently meets the CoPs for HHAs. A subdivision would need to meet all requirements for the initial survey including completing the CMS Form-855A and having this form verified by the assigned MAC. A subdivision may have subunits and/or branch offices and, if so, is regarded as a parent agency.

Parent HHA

The parent HHA is that part of the HHA that develops and maintains administrative control of all approved locations. The parent is listed on the Medicare Enrollment Application (Form CMS -855A.) The parent HHA is responsible for all services provided at the parent and those provided at any of its approved branch locations. The parent HHA must also submit any relevant updates for all approved locations on the Form CMS-855A.

Branch Offices

A branch office is a location or site from which an HHA provides services within a portion of the total geographic area served by the parent agency. The branch office is part of the HHA and is located sufficiently close to the parent agency so that it shares administration, supervision, and services with the parent agency on a daily basis. The branch office is not required to independently meet the CoPs as an HHA. When the surveyor is conducting a survey of an HHA with branch offices, ascertain from HHA records whether the branch offices are provided adequate supervision by the parent agency and whether they are, in fact, sufficiently close to the parent agency to be considered branch offices rather than subunits. If this judgment cannot be made without direct observation, the surveyor should visit the branch office to make this determination. When reviewing records and conducting visits to patients' homes, the surveyor selects some records and/or schedules some home visits to patients who are served by each branch office. The surveyor may also conduct a standard survey of the HHA at a branch office. When conducting a survey at a branch, the surveyor may request that all necessary documentation for review be transported to the branch. This may include, but not be limited to, a sample of clinical records from the parent and any other branches, governing body minutes, personnel records, etc.

Subunits

A subunit is associated with the parent HHA but is a semi-autonomous organization that:

(1) Serves patients in a geographic area different from that of the parent agency; and
(2) Must independently meet the conditions of participation for HHAs because it is too far from the parent agency to share administration, supervision, and services on a daily basis.

The standards on governing body, administrator, and under the circumstances noted here, the group of professional personnel, will be found met by subunits if they are met by the parent agency. The parent agency's group of professional personnel may serve as the subunit's group of professional personnel if that group is effectively pursuing its responsibilities for the HHA and its subunits. The parent agency's and subunit's records, i.e., policy statements and minutes of group meetings, must establish that attention is being paid to the subunit's operation in delivering services. The subunit may establish its own group, or the parent HHA may have a subcommittee of its group deal specifically with the subunit's policies and procedures.

The subunit must submit an initial enrollment application Form CMS-855A and undergo an onsite initial survey from the State Agency (SA) or a National Accreditation Organization (AO) with deeming authority, before it is approved to participate in

Medicare. The SA completes the Form CMS-2567, or the AO completes the equivalent, and all other applicable documents for the parent organization and each subunit. The SA or AO does not conduct the initial survey of a subunit prior to the initial survey of the parent agency. The CMS certification numbers (CCNs) are assigned numerically by the Regional Office (RO).

NOTE: Some states do not allow HHAs to operate subunits. If an HHA resides in a state with this prohibition, the HHA must comply with the more stringent State requirement.

2182.1 - Characteristics Differentiating Branches From Subunits of HHAs

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

The comparisons on the following pages identify and clarify policies that assist in making a distinction between a branch and a subunit. The surveyor discusses any discrepancies with the administrator or his/her designee and alerts the SA supervisor who then notifies the CMS RO.

Administrative Functions (Relationship with Parent Agency)

> Branch - Not autonomous. Is part of the HHA and shares administration, supervision and services with the parent agency on a daily basis. The administration at the parent agency is aware of the staffing, patient census and any issues/matters affecting the operation of any given branch. The branch location provides the same services as the parent within a portion of the total geographic area served by the parent agency.
>
> Subunit - Semi-autonomous and located at such a distance from the parent agency that it is incapable of sharing administration, supervision, and services on a daily basis. Serves patients in a geographic area different from that of the parent. A subunit may have a branch.

Compliance with CoPs

> Branch - Does not have to independently meet the CoPs as an HHA.
>
> Subunit - Independently meets all CoPs as an HHA.

Organizational Structure (See §484.14.)

> Branch - The lines of authority and professional and administrative control are clearly delineated in both organizational structure and in practice and can be traced to the parent agency.
>
> Subunit - The lines of authority and professional and administrative control are clearly delineated in both organizational structure and in practice.

Supervision (See §484.2.)

Branch - Supervision is shared between the parent agency and the branch. However, if the branch is so large (i.e., has a large staff and serves many patients) or is so distant that it is impossible for a supervisor of a specific discipline to accomplish adequate supervision, the branch must convert to a subunit.

Subunit – It is too far from the parent agency to share supervision on a daily basis. The subunit functions independently of the parent, and consequently, supervision is provided by staff designated by the subunit.

Administrator (See §484.4.)

Branch - The administrator of the HHA maintains an ongoing management of the branch staff and liaison with the group of professional personnel. In order to accomplish this activity, sufficient time must be allocated for sharing information with all the parties mentioned. The branch is located sufficiently close to the parent to share administration. The administrator is apprised of and resolves issues affecting patients in branch(es) as well as the service area(s) covered by the parent.

Subunit - It is too far from the parent agency to share administration on a daily basis. Is semi-autonomous and maintains its own administrative staff (e.g., supervising physician or registered nurse). It functions as an independent entity.

Supervising Physician or RN (See §484.14(d).)

Branch - The location of the branch, in relation to the parent, is such that the parent is able to assure adequate supervision during all operating hours. (See §2182.4B)

Subunit - Supervisory M.D. or RN is available during all operating hours.

Personnel Policies (See §484.14(e).)

Branch - The parent office maintains current personnel records on all staff. A statement of personnel policies is maintained in each branch for staff usage.

Subunit - Personnel policies and records must be maintained at the subunit.

Coordination of Patient Services (See §484.14(g).)

Branch - Information concerning care provided to patients is communicated to staff in branches and parent agency, particularly when staff of one organizational unit (e.g., branch) does not base its practice at that site. (Example: A physical therapist (PT) provides services to patients managed by the parent agency as well as patients managed by the branch. Most of the PT's time is spent with patients from the branch, although occasionally a patient followed by the parent agency is included in his/her workload. The PT is expected to coordinate care with staff in

each organizational unit [i.e., branch or parent] as required by the patient's needs and as practice dictates.)

Subunit - Since the subunit is a semi-autonomous entity, coordination is simplified because staff is generally available on a regular basis or can easily be reached to discuss and implement the coordination of patient care.

Services Under Arrangements (See §484.14(h).)

Branch - Contracted arrangements with various entities are the responsibility of the parent agency, even when the contracted services are used exclusively by the branch.

Subunit - Maintains contracts with various entities to provide services. The subunit is responsible for the administration and supervision of those services. Parent agency monitors subunit services provided under arrangements.

Group of Professional Personnel (See §484.16.)

Branch - The annual review of the agency's policies is conducted by a group of professional personnel. Their focus is directed on service delivery throughout the entire agency including the parent agency and branch(es).

Subunit – The subunit may establish its own group of professional personnel or it may form a subcommittee of the parent HHA's group which deals specifically with the subunit's policies and procedures at that subunit. The parent agency and subunit's policy statements and minutes of group meetings must include specific references to issues addressed in the delivery of home health services.

Clinical Records (See §484.48.)

Branch - Should retain the clinical records for its patients, since the branch site is where the professionals providing the services are located. Duplicate records need not be maintained at the parent agency, but must be made available to the surveyor upon request.

Subunit - Maintains clinical records on all its patients.

2182.2 - Guidelines for Determining Parent, Branch, or Subunit
(Rev. 1, 05-21-04)

The following guidelines should be used when making a determination as to whether a proposed HHA unit is a parent, branch, or subunit as defined at 42 CFR Part 484.2:

A. Supervision

Supervision of the branch staff is critical to the provision of quality care for patients. The

regulations require the branch to be within the parent's geographical service area and close enough to the parent to share supervision, administration, and services on a daily basis. Supervision means authoritative procedural guidance by a qualified person for the accomplishment of a function or activity. Supervision at the branch must be adequate to support the care needs of the patients.

Supervision of services requires that a qualified person be physically present to directly supervise the provision of services by any individual who does not meet the qualifications specified at 42 CFR Part 484.4. For individuals that do meet the qualifications specified at 42 CFR Part 484.4, the supervisor does not have to be physically present during the provision of all services. The use of telephones, pagers, facsimile machines, or other electronic devices does not eliminate the requirement for the physical presence of the supervisor. The parent may appoint an effective full time branch supervisor or manager as long as this individual is and remains under the supervision of the parent.

B. Distance

Mileage and travel times from the parent to the branch are significant factors to consider because they are implicitly referenced in the regulations. However, each alone would not be the single issue in determining appropriateness. The regulations require that a branch be "sufficiently close" to share administration, supervision, and services in a manner that makes it unnecessary for the branch to meet the CoPs on its own. To accomplish this, the parent agency must be physically located so that sharing of administration, supervision, and services with the branch can occur on a daily basis. If the parent is not capable of sharing such functions with the branch on a daily basis, then the non-parent office or location must independently meet the CoPs.

C. Geographic Area

"Geographic area" generally means the location, i.e., address of the clients served by the parent and non-parent. If the non-parent office is located within a portion of the total geographic area served by the parent, but serves patients outside the geographic area, then the non-parent should not be a branch and would be classified as a subunit. (If the State does not recognize subunits, the HHA would seek a new provider number and establish a parent location.) This is consistent with the subunit definition that applies to a non-parent office that serves patients in a geographic location different from the parent.

D. Sharing Administration, Supervision, and Services

In addition, consider that the sharing of HHA administration, supervision, and services may occur at any time and could flow in either direction, i.e., parent to branch or branch to parent.

If an entity within the HHA's organizational structure reports directly to the home or corporate office or some other office other than the alleged parent HHA, it is more likely a subunit rather than a branch. As a subunit it would need to independently meet the CoPs.

If the parent HHA and the non-parent use totally different staffs, it is less likely they are sharing functions on a daily basis, and it is therefore less likely that a parent/branch relationship exists.

The fact that the non-parent office is located in a different metropolitan statistical area (MSA) from that of the parent is a consideration in making determinations about geographic areas. Commuting patterns are one consideration in the establishment of MSAs. If the parent and non-parent are in different MSAs, it may reflect that the non-parent is not within sufficient proximity to the parent to share functions on a daily basis. This is especially true if the parent and non-parent are in non-contiguous MSAs.

If the parent and non-parent are incapable of sharing emergency functions, including services, on a daily basis, the non-parent is probably not a branch.

State licensure laws that define parent, branch, and/or subunit are a consideration in making non-parent determinations, but it is the definitions in the Federal regulations (42 CFR Part 484.2) that must be satisfied in making parent, branch, or subunit determinations. If an HHA operates across State lines, follow the instructions in §2184 of the State Operations Manual. The SA in the State in which the parent is located should take the lead in coordinating with the adjacent State to resolve parent and non-parent issues.

The fact that the Joint Commission on the Accreditation of Healthcare Organizations or the Community Health Accreditation Program has awarded branch status to a location will not affect CMS' parent/non-parent decision. CMS' determination will be based on its independent application of its regulations to the facts in the case.

2182.3 - Processing A Change From Branch to Subunit
(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

When a determination is made that a previously approved branch should become a subunit, either through a request from an existing provider or through a determination by CMS, an initial survey and certification is required, as with any new provider. In such a situation, follow the existing survey and certification rules for conducting an initial survey and issuing a provider agreement and CCN to the subunit. Similarly, if a location is discovered that has never been identified to the SA or CMS that is subsequently determined to be a subunit, an onsite survey in accordance with the usual survey and certification rules will apply. The subunit, as a new provider, must also meet all requirements for initial certification, including completing the CMS-855A and having this form verified by the assigned MAC. Note that a subunit may have branches. (See Medicare Program Integrity Manual, Chapter 15, Medicare Enrollment, Section 15.19.)

2182.4 - CMS Approval Necessary for Non-Parent Locations
(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

As part of the provider certification process, an existing Medicare-approved HHA must provide notification to CMS through the SA of its proposal to add a non-parent location,

i.e., branch or subunit. (See §3224.) In the absence of notification by the HHA to add a branch office, CMS cannot determine whether the requirements critical to health and safety are met at the non-parent location. A provider may not bill Medicare for services provided by either a branch or subunit where the branch or subunit is not a part of an approved HHA or where the branch or subunit has not been determined to meet the applicable CoPs.

The Form CMS-855A applications are used to gather information on providers for the purpose establishing eligibility to furnish services to Medicare beneficiaries. 42 CFR 424.540(a)(2) requires a provider or supplier to update its enrollment information, and recertify its accuracy when any changes are made. Additionally, §424.515 requires revalidation of the enrollment information by providers and suppliers every 5 years and (every 3 years for suppliers of durable medical equipment, prosthetics, orthotics and suppliers) or when determined by CMS policy. See also Chapter 10 and 15 of the Program Integrity Manual which can be found at: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c10.pdf and http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c15.pdf

Before a subunit can be approved, it must seek initial certification and apply to CMS to receive a separate provider agreement and CCN. These steps are outlined in Part I of Appendix B of the SOM under the section on Initial surveys.

2182.4A - Notification by HHA to Add a Branch

(Rev 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

When an HHA requests approval to add a branch location, it should contact the SA and provide the following information:

Address and phone number of the branch;

Organizational chart delineating lines of authority, professional and administrative control for the HHA, including the branch;

Defined geographic service area (counties, cities, zip codes), and any intention to cross State lines (which would require a reciprocal agreement between the affected States as well as RO approval);

Services shared with the HHA parent;

Services provided directly and under arrangement;

Contracts for any services provided under arrangement;

Identification of any high-tech services provided (e.g., infusion therapies such as artificial nutrition and hydration, or chemotherapy, mechanical ventilation, tracheostomy care, etc.);

Names of all branch staff and their job descriptions;

Proof of branch staff qualifications (resume, licensure, aide training, etc.);

Explanation of how supervision by the HHA parent will occur;

Identification of the person who will resolve patient care issues at the branch;

Explanation of how staff will coordinate care and services;

Policies for addressing clinical and other emergency situations;

Plans for addressing staff absenteeism; and

State issued certificate of need, if applicable.

2182.4B - SA Review of Request for Branch Determination

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

The decision to approve a branch should be based on the HHA's ability to adequately supervise the branch and monitor all services to assure that the quality and scope of items and services provided to all patients promotes the highest practicable functional capacity for each patient so as to meet their medical, nursing, and rehabilitative needs.

The SA reviews the ability of the branch location to meet the definition of a branch as provided in §484.2. The regulations require the branch to be within the HHA parent's geographical service area and sufficiently close enough to the HHA parent to share administration, supervision, and services on a daily basis.

The SA should review the HHA's request to open a branch and consider the HHA's ability to comply with the following:

Administration, Supervision and Services:

- The HHA's governing body is responsible for the overall operations of the parent and branch.

- The lines of authority and professional and administrative control are clearly delineated in the HHA's organizational structure and in practice and are traced to the HHA parent.

- Supervision means authoritative procedural guidance by a qualified person for the accomplishment of a function or activity. Supervision at the branch must be adequate to support the care needs of the patients. The HHA's supervising nurse or physician, as required by § 484.14(d), is available at all times by phone or other means of communication during operating hours for individuals who meet the

qualifications specified at §484.4. Supervision of services requires that a qualified person be physically present to directly supervise the provision of services by any individual who does not meet the qualifications specified at §484.4. The HHA may formally appoint a supervisor or manager who is under the direct supervision of the HHA parent to assist with supervision at the branch. (The HHA parent may use technological means for supervision in conjunction with periodic onsite visits. However, the use of telephones, pagers, facsimile machines, or other technological or electronic devices does not eliminate the requirement for the physical presence of the supervisor when required.)

- The group of professional personnel required by §484.16 reviews the agency's policies and service delivery throughout the entire agency, both parent and any branch(es).

- The HHA parent is aware of the staffing, patient census and any issues/matters affecting the operation of the branch.

- The HHA administrator maintains an ongoing liaison with the branch to ensure that staff is competent and able to provide appropriate, adequate, effective and efficient patient care and to ensure that any clinical and/or other emergencies are immediately addressed and resolved.

- The HHA maintains a system of communication and integration of services throughout the agency, whether provided directly or under arrangement, that ensures the identification of patient needs, an ongoing liaison between all disciplines providing care, and physician availability when necessary for relevant medical issues.

- The HHA parent has a system in place to review patient records and care at the branch to ensure that the branch is implementing all policies and procedures and complying with the CoPs for all patients.

- The HHA parent monitors branch activities (clinical and administrative) and the management of services, as well as personnel and administrative issues. Depending on the organization, the administrator, quality improvement personnel, supervisory personnel, etc. should conduct periodic on-site visits to the branch to ensure the delivery of quality care.

- The HHA parent provides ongoing in-service training to ensure that all staff are competent to provide care and services;

- The HHA parent is responsible for any contracted arrangements with any individuals or organizations, even when the contracted services are used exclusively by the branch;

- Services offered by the HHA parent are also offered by the branch.

Distance

- While mileage and travel times from the parent to the branch are significant factors to consider because they are implicitly referenced in the regulations, each factor alone should not be the single issue in determining approval or denial of the branch. The HHA may use current technology to meet the requirement for shared supervision, administration and services with the branch where onsite supervision is not required. A detailed description, including examples, of the application of this technology must be included in the HHA's request to add a branch.

- If the parent and non-parent location are incapable of sharing functions, including services on a daily or emergency basis, the non-parent location is probably not a branch.

Geographic area

"Geographic area" generally means the location, i.e., address of the clients served by the parent and non-parent location(s).

- The branch and its service area are located within the HHA parent's geographic service area. If the branch is extending the current geographic service area, the new geographic area must be contiguous. If the non-parent location is located within a portion of the total geographic area served by the parent, but serves patients which are located outside of and non-contiguous to that geographic area, then the non-parent would be classified as a subunit (not a branch) and be required to submit an enrollment application and to seek a separate CCN. (If the State does not recognize subunits, the HHA would not be classified as a subunit and would seek a new CCN and become a separate HHA provider.)

- The fact that the non-parent office is located in a different core based statistical area (CBSA) from that of the parent is a consideration in making determinations about geographic areas. Commuting patterns are one consideration in the establishment of CBSAs. If the parent and non-parent locations are in different CBSAs, it may reflect that the non-parent is not within sufficient proximity to the parent to share functions on a daily basis. This is especially true if the parent and non-parent locations are in non-contiguous CBSAs.

- If the state has a Certificate of Need requirement or other restrictions on geographic area or expansion of areas, the state rules apply.

- If the HHA intends to operate across State lines, follow the instructions in §2184 of the State Operations Manual. The SA in the State in which the parent is located should take the lead in coordinating with the adjacent State to resolve parent and non-parent issues.

In addition, the SA should review the HHA's past compliance history, including prior complaints, survey results, number of CoPs and standards out of compliance, and length

of participation in Medicare.

While the HHA may notify the SA (or AO as applicable) of its proposal to establish a branch, and the SA or AO may make a recommendation to the CMS RO in a particular case, it is the CMS RO (not the SA or AO) that has the authority for approving the request for a Medicare approved branch.

The CMS RO will review each HHA's request for a branch office on a case-by-case basis, and consider all the CMS guidance. The CMS RO will communicate its final decision in writing to the parent HHA with a copy to the SA or AO and the HHA's Medicare Administrative Contractor (MAC). The approval letter should include notification of the branch approval and the assigned Federal branch ID number and effective date, if approved. The effective date of coverage for services provided from the branch is the date RO determines that the branch meets all CMS requirements. The RO should enter the branch ID number into the Automated Survey Processing Environment (ASPEN) prior to sending the approval letter to the HHA, so that the branch can begin providing services and collect and submit OASIS data. Any decision to deny the request for a branch office should include the full range of the reasons supporting the denial and include discussion of the above criteria. Use the Model Denial Letter, Exhibit 284, as appropriate and copy the SA.

2182.4C - Onsite Monitoring of Approved Branches by the SA

(Rev 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

During a survey of an HHA with approved branch offices, the surveyor will ascertain from HHA records whether the branch office is provided adequate supervision by the parent agency and whether they are, in fact, sufficiently close to the parent agency to be considered a branch office rather than subunit.

When reviewing records and conducting visits to patients' homes, the surveyor will select records and/or if possible, schedule home visits to patients who are served by each branch office. The surveyor may conduct a standard survey of the HHA at a branch office instead of the parent location. When conducting a survey at a branch location, the surveyor may request that all necessary documentation for review, such as a sample of clinical records from the parent and any other branches, governing body minutes, personnel records, etc., be transported to the branch.

When reviewing branches during the survey process, the operations of an approved branch must demonstrate that:

A copy of the HHA's policies and procedures is maintained in each branch. Branch office personnel should be knowledgeable of the policies and consistently apply them;

- Methods of communication between HHA parent and branch assure that all patients receive the necessary care and services identified through the comprehensive assessment and plan of care;

- The branch retains the active clinical records for its patients. Duplicate clinical

records need not be maintained at the HHA parent, but must be available to the surveyor upon request;

- Patients are receiving appropriate care and services at the branch, and
- The HHA is in compliance with OASIS submission requirements.

To assist in the decision making process of determining adequate branch supervision by the parent and whether the branch is sufficiently close to the parent, the surveyors may review and utilize the HHA's branch-specific outcome based reports during the survey and determine if the CoPs continue to be met with the inclusion of the additional location.

2182.4D - Drop Sites

(Rev 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

Where permitted by state and local law, an HHA may utilize a drop site for field staff convenience. These drop sites are not considered branches and should not meet the Medicare definition of a branch or operate as such. HHAs that allow these locations to cross the line from drop site to branch are out of compliance with the Medicare requirements. The HHA should not assign staff to these locations, accept referrals at these locations, advertise them as a part of the HHA, or operate them in any other way as branches of the HHA. HHAs that are unsure if the location meets the definition of a branch may seek advice from the SA. If the location does meet the definition of a branch, it must request CMS approval before providing services from this location. The HHA's policies on drop sites should reflect current Federal and State requirements, including compliance with the Health Insurance Portability and Accountability Act of 1996 privacy requirements. While these sites would not be subject to routine surveys, they may be subject to state or RO inspection at any time. Any violation would be addressed by the SA and referred to the CMS RO for any necessary program integrity investigation and follow up.

2182.5 - Branch Identification Numbers

(Rev 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

CMS assigns an identification number to every Medicare approved HHA branch (of either a parent or subunit). The identification system uniquely identifies every branch of every HHA certified to participate in the Medicare home health program. It also links the parent or subunit to the branch. Having a system to identify branches gives CMS the capability of associating quality outcome results with individual HHA branches. Also, submission of branch identification numbers on Outcome and Assessment Information Set (OASIS) assessments provides the capability of developing outcome reports that will help HHAs differentiate and monitor the quality of care delivered by their agencies down to the branch level.

ROs are responsible for assigning branch identification numbers according to the RO's existing policies and HHAs and their respective branches are informed of their assigned branch identification number(s). A sample letter is available at Exhibit 290. HHAs will

need to enter this branch identification number on OASIS item M0016 (Branch ID). Detailed instructions for completion of M0016 by parent HHAs, subunits, branches, and HHAs and subunits without branches are included in M0016 Branch ID in Chapter 3 of the OASIS Guidance Manual.

Each branch is numbered with the same Federally assigned CCN as the parent or subunit with two modifications. There is a "Q" between the state code and four-digit provider designation plus three more digits for a 10-character branch identifier. Branch identification numbers are to be used only once. In the event that an HHA branch closes, its unique branch identification number is terminated and not re-used to identify another branch of that HHA or subunit.

EXAMPLE:

ABC Home Health Agency in Alabama has three branches.

ABC Home Health Agency in Alabama = CCN number 017001.

ABC's branches would be assigned the branch identification numbers 01Q7001001, 01Q7001002, and 01Q7001003.

Collection Of Branch Information During Survey

The Form CMS-1572, the Home Health Agency Survey and Deficiencies Report, captures survey and deficiency information and requests branch information at field G17 that includes the HHA's total number of branches and name and address of each branch location. This information should be entered into ASPEN after every survey as part of the survey kit. As surveys are conducted, SAs should verify that the information they have on branch locations is current and accurate.

Branch Identification Numbers and MACs

The RO notifies the MACs of the branch identification information when it is assigned. This communication may occur electronically or through a written letter to the provider.

2183 - Separate Entities (Separate Lines of Business)

(Rev 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

The surveyor must be able to identify the corporate, when applicable, and organizational boundaries of the entity seeking certification or recertification. The Medicare CoPs apply to the HHA as an entire entity and in accordance with §1861(o)(6) of the Act, are applicable to all individuals served by the HHA and not just to Medicare beneficiaries. While the purpose of the CoPs is to help ensure proper care for Medicare beneficiaries, the CoPs do this by defining the standards for an HHA in which Medicare beneficiaries may be treated, instead of establishing requirements applicable only to Medicare beneficiaries served by the HHA. If however, the HHA is able to demonstrate that it operates a "separate entity" or separate line of business to which the CoPs do not apply, it must

provide the surveyor with the information to differentiate the separate line of business from the HHA.

Neither the Act nor the Medicare regulations define a “separate entity” with respect to HHAs that Medicare approves as an HHA in accordance with the Act and the CoPs. When an HHA alleges that it is operating a separate line of business to which the CoPs do not apply, ask the HHA to produce information to enable the surveyor to differentiate between it and the HHA.

Use the following guidelines, on a case-by-case basis, to assist in determining if a separate entity exists. The following criteria should be considered in making a decision regarding a separate entity:

- Operation of the HHA;
- Consumer awareness; and
- Staff awareness.

2183.1 - Operation of the HHA
(Rev. 1, 05-21-04)

Ask the HHA administrator to describe the organizational, functional, and clinical boundaries of the Medicare-certified program in relation to any other programs the larger organization offers. Other programs should be separate and distinct from the HHA. Ensure that the HHA has:

- Separate policies and procedures for admission to the HHA, including separate consent forms;
- Separate clinical records for all patients receiving HHA services;
- Current licensure, in accordance with State requirements. In States which license HHAs, review if the State has licensed separately the approved HHA and the separate entity, or has licensed the separate entity as another type of provider or supplier;
- Current listing of staff employed by or contracted to the HHA;
- Personnel records;
- Time sheets or other records to demonstrate distinct assignment of personnel to the HHA; and
- Separate budgets.

2183.2 - Consumer Awareness

(Rev. 1, 05-21-04)

The organization should differentiate the services of the HHA from other services offered by the larger organization. Ask the HHA for a copy of any brochure the HHA uses to describe itself to the community. Any applicable brochures should identify the HHA services as separate and distinct from other programs, departments, or entities operated by the HHA. The HHA should be differentiated from other programs, departments or entities of the organization in listings, advertisements, etc. Written material should clearly identify the HHA as separate and distinct from other programs, departments or entities of the organization.

2183.3 - Staff Awareness

(Rev 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

The HHA staff should be knowledgeable about the HHA's policies and procedures, the regulatory requirements related to their role in the delivery of care in an HHA, and be able to identify the difference in services they provide for the HHA and other programs, departments, or entities of the organization.

Personnel who divide time between the separate entity and the HHA must be appropriately trained to deliver HHA services. The HHA maintains separate time sheets for each individual's assigned time to the HHA.

If the SA determines, based on the information provided by the HHA or for other reasons, that the HHA does not have a separate entity, or if the HHA or parent organization is unable or unwilling to provide the information, inform the HHA that:

- It is in violation of the provisions of §§1861(o) and 1891 of the Act which require compliance with the CoPs, particularly those conditions that relate to clinical records and disclosure of the ownership of the HHA;

- It is in violation of its agreement with the Secretary under §1866 of the Act and the regulations related to this agreement (§489.53(a)) because it has failed to provide information about ownership and information concerning clinical records;

- It is in violation of §1128(b)(12)(A) of the Act because it has denied access to records to determine compliance with the CoPs, including those that relate to the OASIS requirements; and

- It may be in violation of various requirements related to its Medicare cost reports, which mandate information about all of the HHA's clients in order to properly pay Medicare costs, and that the HHA's MAC must be notified about the allegation of separate entities. (See §413.5(b)(3), §413.9, §413.13(f)(2)(ii), §413.17, §413.50(b), §413.53(a), and §413.80(d).)

The SA must report these separate entity situations to the CMS RO, along with any recommendations the State has concerning the operation of two distinct entities. The State

must also indicate whether the HHA refused access to records or information that make it impossible for the surveyor to make a determination concerning whether the applicant or approved HHA complies with the HHA CoPs.

The surveyor will inform the approved HHA that the SA must report the alleged separate entity to the CMS RO that in turn must report this information to the MAC and, if necessary, to the State Medicaid Director.

2184 - Operation of HHAs Cross State Lines

(Rev 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

When an HHA provides services across State lines, whether through its own personnel, or a branch, or subunit, each respective SA must be aware of and approve the action. Each SA must verify that applicable State licensure, personnel licensure, and other requirements are met in its respective State. Any branch or subunit of the HHA must meet applicable State and local laws in the State that it is serving.

The provision of services across State lines is appropriate in most circumstances. Areas in which community services, such as hospitals, public transportation, and personnel services are shared on both sides of State boundaries are most likely to generate an extension of HHA services.

When an HHA provides services across State lines, it must be certified by the State in which its CCN is based, and its personnel must be qualified in all States in which they provide services. The appropriate SA completes the certification activities. The involved States must have a written reciprocal agreement permitting the HHA to provide services in this manner. The reciprocal agreement must indicate that both States are aware of their respective responsibilities for assessing the HHA's compliance with the CoPs within their State. The agreement should assure that home visits are conducted to a sample of all patients, in all States served by the HHA.

The CMS RO will review the required reciprocal agreement between the States to assure that the SA in which the branch resides is assuming responsibility for any necessary surveys of the branch. If the SAs involved are unable to come to an acceptable arrangement on assuring the necessary surveys of the branch, even though there may be an existing reciprocal agreement between the States, or if the reciprocal agreement cannot assure the necessary surveys, the branch should not be approved. The provision of interstate service without a written reciprocal agreement could severely undermine a State's ability to fulfill its statutory responsibilities under §1864 of the Act to enforce Medicare's health and safety requirements. It is at the discretion of the States to decide whether entering into reciprocal agreements is in the best interest of their residents, provider markets, and quality assurance and oversight systems.

Exhibit 289 contains a model reciprocal agreement document that States may use to assist them in fulfilling their statutory responsibilities under §1864 of the Act to enforce Medicare's health and safety requirements when an HHA provides services across State lines. In those States that have a reciprocal agreement, providers are not required to be

separately approved in each State; consequently they would not have to obtain a separate Medicare provider agreement/number in each State. Providers residing in a State that does not have a written reciprocal survey agreement with a contiguous State are precluded from providing services across State lines.

If a State does not have a written reciprocal agreement with other States, the HHA must establish a separate parent agency or subunit in the State in which it wishes to provide services.

In the event that an HHA operates in two CMS ROs, the RO responsible for the State in which the HHA provider agreement and CCN is based should take the lead in assuring that the required survey and certification activities are met.

A CMS approved branch office may be physically located in a neighboring State if the SAs responsible for certification in each State approve the operation.

Subunits of an HHA may be physically located in more than one State. A separate certification is made by the SA where each subunit is located.

While the HHA may notify the SA of its proposal to provide services on an interstate basis, and the SA may make a recommendation to the CMS RO in a particular case, it is the CMS RO that has the Medicare approval authority of the parent HHA and assumes final responsibility for approval of the operation across State lines.

2185 – HHA Change of Address

(Rev. 146, Issued: 09-04-15, Effective: 09-04-15, Implementation: 09-04-15)

It is inherent in the provider certification process that a provider notifies CMS of its intent to change the location or site from which it provides services. Absent such notification, CMS has no way of carrying out its statutorily mandated obligation of determining whether the provider is complying with applicable participation requirements at the new site or location. It is longstanding CMS policy that there is no basis for a provider to bill Medicare for services provided from a site or location that has not been determined to meet applicable requirements of participation. This guidance is contained in §3224.

When an existing HHA intends to move from its surveyed and certified location to a new site or location that is within the current approved geographic area, it notifies its MAC within 90 days of the move, and submits all required documentation including an amended Form CMS -855A. The RHHI reviews the form and makes a recommendation to the RO. The RO then makes the final decision to approve the change of location. The provider notifies CMS either directly or through the SA, and, if it is a provider deemed to meet the requirements, it notifies its AO, in writing of the change of location.

Upon receipt of the MAC's approval notice, the RO will carefully evaluate the information, together with any supporting documentation from the provider and any other relevant information known to the RO in making its decision. If a decision can be made on the written application and supporting documentation, CMS may grant or deny an

approval without requiring an onsite survey. See §2702B regarding when a resurvey is necessary based on change of a provider's size or location.

CMS generally will not approve a change of location of an HHA with one or more previously approved branches if the new location increases the distance between the parent HHA and its previously approved branch(es) to a point that prevents the HHA from exerting the supervision and control necessary to assure the provision of quality care for the patients served by the branch. If the location change is not approved, the provider may consider applying for a new provider number at the new location. CMS will consider the information contained in section 2182.4B in its assessment of the parent's ability to supervise the branch before approving or denying the request.

2185.1 – Move after Certification Survey and Before Final Medicare Approval

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

Requests for initial certification cannot be processed to completion if a prospective provider moves to a new location after it has been surveyed but before the entity receives a determination from the RO to participate in Medicare. If a prospective provider moves from its reported location after that location has been surveyed and/or accredited but prior to signing a provider agreement with CMS, the prospective provider's application for initial certification becomes incomplete. Absent a survey of the new location to which the prospective provider has moved, CMS is unable to determine whether applicable program requirements are met at the new location, and therefore is prevented from completing its review of the pending application. In these circumstances, CMS advises the prospective provider that its application is incomplete and is denied.

2186 - Health Facility-Based HHAs

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

An HHA based to a hospital, SNF, hospice, or rehabilitation facility is expected to be an integral but subordinate part of the institution. Administrative and fiscal controls may be exercised over the HHA. However, the HHA's policies, personnel files, and clinical records must be separate and identifiable. Time records must be maintained for all personnel who provide home health services and must be identifiable as home health regardless of whether they are part-time or full-time. The HHA's use of personnel who are also concurrently employed by a hospital, SNF, hospice, or rehabilitation facility is acceptable provided the HHA's operating hours are definite and not arbitrarily subject to the operation of the other institution, and provided the other institution's operation does not interfere with the HHA's maintaining compliance with the CoPs.

An HHA's services must be supervised by an employee of the HHA. If members of the institution's governing body serve the HHA as the group of professional personnel, minutes must reflect meetings of this group. Clinical records may be maintained in the record room or department. However, the clinical records must contain information pertinent only to the delivery of home health services, and should be readily available for either claims review or review by the SA.

In surveying the health facility-based HHA, the SA or AO considers the institution's ability to share its administrative structure and personnel in fulfilling the needs and requirements of the HHA on a continuing basis. The CoPs for HHAs must be applied and met independently.

2188 - Survey of State-Operated HHAs
(Rev. 1, 05-21-04)

The same general procedures applicable to surveying other types of HHAs apply to HHAs operated by a State. However, individuals associated with the HHA in an administrative, supervisory, or service capacity must not be involved in the certification and consultation functions of the SA.

2194 - Surveying Health Maintenance Organization (HMO)-Operated Home Health Agencies (HHAs) Providing Home Health Services Through Medicare Survey and Certification Process
(Rev. 1, 05-21-04)

The HMOs (Medicare+Choice) which contract with Medicare to furnish HHA services may provide such services either directly by the HMO or through Medicare-approved HHAs that have a provider agreement/number with Medicare. (See 42 CFR Part 417.416(a) and 42 CFR Part 422.20(b)(3).)

If an HMO provides home health services directly as an integral part of the HMO, the HHA is still required to meet the HHA CoPs, including the OASIS requirements, have a Medicare provider number, enter into a provider agreement with the Secretary, and meet other survey and certification requirements, including Office of Civil Rights and enrollment requirements, that an HHA approved under 42 CFR Part 484.1 would have to comply with.

When the SA receives a request to survey an HMO-operated HHA for compliance with the HHA CoPs, it schedules an unannounced standard survey. The SA conducts the survey, and documents its findings on Form CMS-1572. The SA completes Form CMS-2567, obtains a PoC when necessary, and sends this information along with a completed Form CMS-1539 to the CMS RO.

The SA resurveys approved HMO-operated HHAs according to the survey frequency allowed by the Secretary and determined by the SA to assure quality care and to ascertain whether they continue to meet the HHA CoPs. In essence, these HHAs are surveyed and certified the same as any other Medicare-approved HHAs.

2195 – Guidelines for Determining Standard Survey Frequency
(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

Section 1891(c)(2)(A) of the Act states that standard surveys will occur not later than 36 months after the previous standard survey, and that the Secretary shall establish a

frequency for surveys within this 36-month interval commensurate with the need to assure the delivery of quality home health services.

CMS will identify HHAs to be surveyed each fiscal year according to specific criteria and budget allowances. This list will contain the names of HHAs that have not been surveyed for 24 months or longer, and that are due for survey during the coming fiscal year. CMS will send this list to the State Survey Agencies each year. The annual budget criteria also specify the priority for complaint surveys, validation surveys and any other targeted surveys for the upcoming fiscal year.

NOTE: The survey process guidance is now found in Part I of Appendix B.

2197 – Surveyor Worksheets

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

The following surveyor worksheets are used during each home health survey to assist the surveyor's determination of the agency's compliance with the home health conditions of participation.

HHA Survey Investigation Worksheet 1 – Patient Sample:
Complete one patient sample investigation worksheet for each patient record and home visit selected. Use the worksheet to collect and record patient information and findings related to record review and home visit information to determine the appropriateness of care or services being furnished. Note interviews with clinicians, record review findings and observations. In addition to completing the worksheet, it may be appropriate to request the HHA to copy the most current plan of care for each patient in the survey sample that identifies baseline medical information for attachment to the patient's worksheet. Additional documentation, including assessments, medication profiles, visit notes, aide plans or orders may be copied to support findings. Complete each section with comments related to potential tags identified or indicate "Not Applicable/NA."

HHA Survey Investigation Worksheet 2 – Agency Summary:
Use the survey investigation worksheet 2 to record a summary of any deficient practices identified during the survey. Also record the type of survey(s) performed, the number of agency admissions in the previous 12 months as well as the number of records reviewed and home visits completed.

HHA Survey Investigation Calendar Worksheet:
Use the Calendar Worksheet to determine compliance with §484.18(a) and (b) and §484.55 regarding compliance with orders for service and the findings of the comprehensive assessment. Services ordered can be compared to services provided to determine compliance with visits.

2202 - Outcome and Assessment Information Set (Oasis) Requirements

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

The home health regulations at §484.55 require that each patient receive from the HHA a patient-specific, comprehensive assessment. As part of the comprehensive assessment of adult skilled patients, HHAs are required to use a standard core assessment data set, the OASIS. See note below for information regarding collection of OASIS data on the non-Medicare/non-Medicaid patients of an HHA.

The regulations also require that OASIS data be electronically transmitted to the SA or CMS OASIS contractor. These requirements are detailed at §484.20. This regulation is referred to as the "reporting regulation."

The CMS uses the data to achieve broad-based improvements in the quality of care furnished, through measurement of that care, as well as to maintain a home health prospective payment system.

In addition to requiring the reporting of OASIS data, the OASIS regulations at §484.11 require HHAs to maintain privacy of their OASIS data and not release patient identifiable OASIS information to the public. Regulations concerning State survey, certification, and enforcement responsibilities are found at §488.68.

Effective July 19, 1999, all HHAs participating in the Medicare/Medicaid program have been required to comply with the comprehensive assessment and OASIS reporting regulations.

NOTE: HHAs must comply with the comprehensive assessment regulation at §484.55 for all its patients. However, until further notice, HHAs are not required to incorporate OASIS items into their patient-specific comprehensive assessment for the HHA's (1) non-Medicare/non-Medicaid patients, (2) patients under the age of 18, (3) patients receiving maternity services, or (4) patients receiving personal care services only (regardless of payer source). (See additional information in section 2180E.)

- The collection of OASIS data on the non-Medicare/non-Medicaid patients of an HHA was temporarily suspended on December 8, 2003, as a provision of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. HHAs must continue to comply with the aspects of the regulation at §484.55 regarding the comprehensive assessment of patients. HHAs must provide **each** agency patient, regardless of payment source, with a patient-specific comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward the achievement of desired outcomes. The comprehensive assessment must also identify the patient's continuing need for home care, medical, nursing, rehabilitative, social, and discharge planning needs.

- HHAs may continue to collect OASIS data on their non-Medicare/non-Medicaid patients for their own use.

- Surveyors must continue to examine the completeness of the comprehensive assessment for all patients during a survey. However, surveyors must not investigate whether the HHA included the specific OASIS items in its patient-

specific comprehensive assessments of non-Medicare/non-Medicaid patients, nor cite deficiencies based solely on this finding.

- HHAs must continue to collect, encode, and transmit OASIS data for their non-maternity Medicare and Medicaid patients that are age 18 and over and receiving skilled services.

2202.1 - OASIS Related Definitions

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

OASIS – Outcome and Assessment Information Set - Scientifically tested data items developed for the purpose of measuring outcomes (and patient risk factors that affect outcomes) for HHA patients. These data items alone do not constitute a comprehensive assessment; they must be collected as part of the assessment process at various time points during a patient's admission to an HHA.

CMSnet (formerly known as Medicare Data Communications Network-MDCN**) -** A private communications network CMS purchased to ensure the security of OASIS and Minimum Data Set (MDS) data transmissions to the state. This system replaces the previous process of direct dial-up by public telephone lines to the SA and reflects the latest technology available for securing the privacy of data during transmission. In addition to increased security, another benefit of the CMSnet is that it is provided at no cost to the HHAs. HHAs may also apply for a CMSnet user identification and password for each of their branches for direct transmissions from their branches. Use of the CMSnet allows for all data submitted to the CMS OASIS State System to be encrypted during the transmission process precluding any unauthorized sources from intercepting identifiable data. Similarly, data reports, which are sent by the OASIS State System to the HHA across the CMSnet, are also automatically encrypted and decoded. This network encryption occurs automatically when the HHA uses the CMSnet and requires no special action on the part of the HHA other than using browser software that supports industry standard encryption.

Comprehensive Assessment - An assessment of a patient's condition that accurately and completely reflects the patient's current health status at the time of the evaluation. This assessment must identify the patient's continuing need for home care and must meet the patient's medical, nursing, rehabilitative, social, and discharge planning needs. An HHA must include the collection of specific OASIS data items at specific time points during a patient's admission as part of its comprehensive assessment process for all adult Medicare and Medicaid patients receiving skilled care unrelated to pregnancy or delivery. The specific OASIS items associated with each assessment time point are summarized in each version of the OASIS data set. The required OASIS data set and its time point related versions include (1) Start of Care (SOC)/Resumption of Care (ROC), (2) Follow-up, (3) Transfer, and (4) Discharge. HHAs must use the most current version of the OASIS. The most current version of OASIS is available on the OASIS Web site.

Encode - To enter OASIS data into a computer using the Home Assessment and Validation Entry (HAVEN) software (provided by CMS) or other HAVEN-like software

(developed by private vendors). HAVEN-like software must meet CMS' data and edit specification requirements.

Encryption - A system to translate plain text into scrambled code. Encryption offers a higher level of security when electronically transmitting information. The sender "locks" the data before transmitting. The receiver "unlocks" the data upon receipt.

HAVEN – Home Assessment and Validation Entry - A software program provided by CMS, free of charge, for use by HHAs to encode their OASIS data and save as electronic files for electronic transmission to the SA. The HAVEN software automatically applies date range and consistency checks according to CMS' published data specifications, which serve as an electronic safety net to preclude the transmission of erroneous or inconsistent information.

Header Record - Contains basic information that identifies the HHA submitting OASIS data, as well as, contact persons and telephone numbers to be used in the event the file is in error.

Initial Assessment - The HHA's first visit to the patient after referral. In the absence of a specified start of care date, the initial visit is the first visit made to the patient within 48 hours of the referral. If the physician specifies a particular start of care date, then the initial visit is the date specified by the physician and includes performance of the skilled care ordered. In accordance with the regulations, the initial visit must be made by a registered nurse except for therapy-only cases, in which the initial assessment visit can be made by a qualified therapist.

Incorporate/Integrate - Incorporating/integrating the OASIS data items into an agency's assessment process means replacing similar questions on the agency's existing assessment tool with the corresponding OASIS data items. Agencies must merge the OASIS data items into their existing assessment process rather than simply appending them without considering which OASIS items could replace similar items on the agency's assessment tool. Simply appending the OASIS items adds time to the assessment process and renders it burdensome and duplicative. Since the OASIS items are not intended to constitute a complete comprehensive assessment, agencies should gather other pertinent assessment information not included in the OASIS data items in order to create a comprehensive assessment. Except as required to meet other Federal, State, or accreditation standards, agencies are at liberty to determine what other information they require as part of the comprehensive assessment.

Late Assessment - An assessment transmitted after the specific time frames defined in the regulations. 42 CFR 484.20(a) requires the HHA to transmit the assessment within 30 days of completing the assessment.

Masking - A term used to describe software that conceals individually identifiable data elements. When required, HHAs will mask these data elements prior to transmission and keep the masked identifiers and the original data in their records. Private Pay assessments are no longer accepted by the State System. If M0150 items 1, 2, 3 and 4 are all equal to

‘0’ unchecked, the state system rejects the record. Any private pay assessment entered into HAVEN will be marked as ‘Complete’ and is excluded from the export process in HAVEN.

Outcome - Changes in a patient’s health status between two or more time points.

Outcome-Based Quality Improvement (OBQI) - Performance improvement based on outcome measurement and reporting.

Outcome-Based Quality Monitoring (OBQM) Reports - The OBQM reports include the agency patient-related characteristics report and potentially avoidable events outcome reports.

Overdue OASIS - OASIS assessments not received by the OASIS System within the specific time frames defined by the regulations. (See also Late Assessment.)

Process Based Quality Improvement (PBQI) - Evaluating or investigating the use of specific best care processes (such as conducting falls risk assessments or providing drug education) by reviewing the care provided to determine any needed changes in care delivery.

Quality Improvement and Evaluation System (QIES) - An online system that supports the CMS mission and initiatives to improve the quality of care for Medicare beneficiaries (Providers: Skilled Nursing Home, Home Health Agencies, as well as State Survey Agencies). (Includes CASPER, MDS, OASIS, RAVEN, HAVEN, and ASPEN).

Reason For Assessment (RFA) - Reason for conducting the assessment, e.g., Start of Care (SOC), Resumption of Care (ROC), and Follow-Up found in M0100.

Resumption of Care (ROC) – The day that care resumes after an inpatient stay. The HHA must complete an OASIS assessment and obtain the necessary physician change orders reflecting the change in the treatment approach in the patient’s plan of care. The ROC is to be done within 48 hours of the patient’s return home. If the physician’s order requests that the HHA resume care at a point later than 48 hours or if the patient refuses a visit within this 48-hour period, a note to this effect should be documented in the patient’s chart for future reference.

Significant Change in Condition (SCIC) - A SCIC is defined as a significant change in the patient’s condition during a 60-day episode that was not envisioned in the original plan of care. While this no longer creates a new case-mix for payment, the HHA must complete an OASIS assessment and obtain the necessary physician change orders reflecting the significant change in the treatment approach in the patient’s plan of care. The SCIC relates to the OASIS data set “other” Follow-Up (RFA5).

Start of Care (SOC) – The day care begins after the referral is received. SOC currently relates to the “first billable visit.” The “first billable visit” approach was selected largely because of the Medicare payment requirements and the fact that the first billable visit

defines SOC and start of the episode for Medicare purposes.

Time Points - Specific times during an episode of care when collection of OASIS data items is required as part of a comprehensive assessment. They are start of care, resumption of care, recertification, follow-up, and transfer to an inpatient facility, death at home, and discharge from agency.

Trailer Record - Indicates the end of the submission file. The trailer record includes a count of the total records in the file, including the header and trailer records.

2202.2 - History of OASIS

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

The OASIS is a group of data items developed, tested, and refined over the past decade for the purpose of enabling the systematic measurement of HHA patient care outcomes. Initially, the OASIS was a 79-item data set first published in 1994 by the Center for Health Services and Policy Research at the University of Colorado. Over the years, it has been modified as a result of input from a variety of home care experts, including representatives of all home health care disciplines. Future modifications to the OASIS are expected as we learn more about outcome measurement as well as determine what information would best serve the continued maintenance of a case-mix adjusted home health PPS.

Relative to OASIS, the definition of outcomes is very specific: outcomes measure changes in a patient's health status between two or more time points. The data are collected at specific time points following a patient's admission to an HHA to determine whether appropriate progress toward desired outcomes is being achieved. These data items must be incorporated into the agency's overall patient assessment process as OASIS was not developed to be a complete comprehensive assessment instrument. HHAs will find it necessary to integrate the OASIS items into their own process in order to comprehensively assess the health status and care needs of their own patient population. Effective, January 1, 2010, the OASIS data set was significantly modified to include process measures. Some points to remember about the uses of OASIS data items into an HHA's assessment process can be found in Appendix C of the OASIS-C Guidance Manual.

2202.2A - Current Version of OASIS

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

The current version of OASIS and the Guidance manual is found on the CMS Web site at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIOASISUserManual.html.

2202.2B - OASIS as Part of the HHA's Comprehensive Assessment

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

OASIS data items are not meant to be the only items included in an agency's assessment process for Medicare and Medicaid patients. They are standardized assessment items that

must be incorporated into an agency's own existing assessment policies process. An example of a comprehensive assessment showing an integration of the OASIS data items with other agency assessment items can be found in Appendix C: Sample Clinical Records Incorporating OASIS Data Set, in the OASIS User's Manual. For a therapy-only case, the comprehensive assessment should include OASIS data items as well as other assessment data items the agency currently collects for therapy-only cases.

2202.2C - Incorporation of OASIS Data Items Into the Comprehensive Assessment **(Refer to §484.55(e))**
(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

In accordance with the regulations, agencies MUST incorporate the language of OASIS data items exactly as they are written into their own assessment process. Agencies are expected to replace similar items/questions on their current assessment as opposed to simply adding the OASIS items at the end of their existing assessment tool. For agencies electronically collecting assessment data using software that does not accommodate bolding or underlining for emphasis of words in the same manner as the current OASIS data set, capitalizing these words is acceptable. It is also recommended that HHAs include the data set numbers (M numbers) when incorporating the OASIS. In this way, the clinician will know that the M labeled items are items that MUST be assessed, completed, and reported. This will minimize delays in encoding due to incomplete OASIS data items. Agencies may wish to incorporate the assessment categories (e.g., Activities of Daily Living (ADLs)/Instrumental Activities of Daily Living (IADLs), Medications, etc.) into their own assessment process in a different order than presented on the OASIS form. While HHAs are encouraged to integrate the OASIS data items into their own assessment instrument in the sequence presented on the OASIS form for efficiency in data entry, they are not precluded from doing so in a sequence other than that presented on the OASIS form. However, this is not recommended because of the skip patterns built into the OASIS form.

2202.3 - Applicability
(Rev. 1, 05-21-04)

2202.3A - Medicare and Medicaid Patients
(Rev. 1, 05-21-04)

In general, the comprehensive assessment and reporting regulations apply to any HHA required to meet the Medicare CoPs for any reason and are applied to all patients of that HHA unless otherwise specified. This includes Medicare, Medicaid, Medicare and Medicaid Managed Care, and private pay patients served by the agency. It also includes Medicaid waiver and State plan patients to the extent they do not fall into one of the exception categories listed below, and are required by the State to meet Medicare CoPs. HHAs providing services under Medicaid's home health benefit must meet the CoPs for Medicare, as specified at 42 CFR 440.70(d). As such, HHAs servicing only Medicaid patients (Medicaid-only HHAs) must meet Medicare CoPs, including the comprehensive assessment and OASIS reporting requirements.

Health maintenance organizations serving Medicare/Medicaid patients can either provide home health services themselves or can contract out for those services. If they provide home health services themselves, they must meet the Medicare home health CoPs. If they contract out for home health services, they must contract with a Medicare-approved HHA in order to serve Medicare/Medicaid patients. (See 42 CFR 417.416 and §2194.)

The HHA's requirement to conduct comprehensive assessments that **include** OASIS data items applies to each patient of the agency receiving home health services with certain exceptions:

- Patients under the age of 18;
- Patients receiving maternity services;
- Patients receiving housekeeping or chore services only; and
- Patients receiving personal care services only.
- Patients for whom Medicare or Medicaid insurance is not billed.

The comprehensive assessment and reporting regulations to patients receiving personal care only services, regardless of payor source is not applicable.

2202.3B - OASIS and the Medicare Home Health Benefit

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

The comprehensive assessment and OASIS data collection requirements apply to Medicare beneficiaries as described below:

- Medicare beneficiaries, using the Medicare home health benefit provided under either Part A, Part B, or Part C;
- Medicare beneficiaries who require therapy services provided outside the home for special equipment needs, and who are using the Medicare home health benefit.

If a Medicare beneficiary is under a home health plan of care, all therapy services, that is physical therapy, occupational therapy, speech language pathology (PT, OT, SLP), delivered under the home health benefit whether they are furnished directly by the HHA or under arrangement on behalf of the HHA are bundled into the PPS payment rate as part of the consolidated billing requirements.

The consolidated billing governs Medicare home health PPS effective October 1, 2000 and requires that payment for home health services (including medical supplies described in §1861(m)(5) of the Act, but excluding DME to the extent provided for in §1861(m)(5)) furnished to an individual who (at the time the item or service was furnished) is under a plan of care of a HHA, be made to the agency (without regard to whether or not the item or service was furnished by the agency, by others under arrangement with them made by

the agency, or under any other contracting or consulting arrangement, or otherwise). The services included in the consolidated billing governing home health PPS are:

- Part-time or intermittent skilled nursing services;
- Part-time or intermittent home health aide services;
- Physical therapy;
- Speech-language pathology services;
- Occupational therapy;
- Medical social services;
- Routine and non-routine medical supplies;
- Covered osteoporosis drug as defined in §1861(kk) of the Act, but excluding other drugs and biologicals; and
- Home health services defined in §1861(m) provided under arrangement at hospitals, SNFs or rehabilitation centers when they involve equipment too cumbersome to bring to the home or are furnished while the patient is at the facility to receive such services.

If a Medicare beneficiary under a home health plan of care is receiving therapy services from another provider (either an inpatient or outpatient provider) under arrangement made by the HHA as part of the home health benefit simply because the required equipment cannot be made available at the patient's home, the Medicare CoPs apply, including the comprehensive assessment and collection and reporting of OASIS data by the HHA.

1. Medicare Advantage Plans.

Medicare Advantage Plans are health plan options that are part of the Medicare program. Medicare beneficiaries who elect to have Medicare services provided by a Medicare Advantage Plan are entitled to all the Medicare-covered services that are available to beneficiaries residing in the plan's geographic area.

Medicare Advantage Plans, like a Medicare Health Maintenance Organization (HMO) or Preferred Provider Organization (PPO), which contract with Medicare to furnish HHA services may provide such services either directly by the Plan or through Medicare-approved HHAs that have a provider agreement and CCN with Medicare. (See §417.416(a)). If the Medicare Advantage Plan provides home health services directly as an integral part of the Plan, the HHA is still required to meet the HHA CoPs, including the OASIS requirements, have a Medicare CCN, enter into a provider agreement with the Secretary, and meet other survey and certification requirements, including Office of Civil Rights and enrollment requirements, with which an HHA certified under §484.1 would

have to comply.

When the SA receives a request to survey an HMO-operated HHA for compliance with the HHA CoPs, it schedules an unannounced standard survey. The SA conducts the survey, completes the Form CMS-2567, obtains a PoC when necessary, and sends this information along with a completed Form CMS-1539 to the CMS RO.

The SA resurveys approved HMO-operated HHAs according to the survey frequency allowed by the Secretary and determined by the SA to assure quality care and to ascertain whether they continue to meet the HHA CoPs. In essence, these HHAs are surveyed and certified the same as any other Medicare-approved HHAs.

2. Medicaid Home Health Programs/Medicaid Waiver Programs

The comprehensive assessment regulations apply to HHAs that are required to meet the Medicare home health CoPs. An HHA that currently must meet the Medicare CoPs under Federal and/or State law must meet the Medicare CoPs related to OASIS and comprehensive assessment and reporting. If an HHA provides skilled services to individuals under Medicaid, then OASIS applies. If the patient is not receiving skilled nursing, physical therapy, occupational therapy, or speech language pathology services, then OASIS does not apply. The requirement to collect OASIS on patients receiving only personal care services has been delayed until further notice.

3. Medicare Hospice Benefit

The comprehensive assessment and OASIS data collection requirements do not apply to any individual receiving hospice services from a Medicare-approved hospice. A hospice patient may receive covered home health services for a condition unrelated to the treatment of the terminal condition for which hospice care was elected. This type of patient would be subject to the regulations governing the HHA services, including OASIS collection and reporting.

4. Outpatient Therapy Benefit

If a Medicare beneficiary not under a home health plan of care is receiving therapy services under the Medicare Part B outpatient benefit from another Medicare provider, the OASIS collection and reporting requirements do not apply.

5. SNF or Inpatient Hospital Benefit

The comprehensive assessment and OASIS data collection requirements do not apply to Medicare beneficiaries who are inpatients at a SNF or a hospital because these services are not considered home health services and the OASIS comprehensive assessment does not need to be conducted. The MDS is required in certified skilled nursing facilities.

The following table summarizes the type of Medicare/Medicaid service and the application of the Federal OASIS requirements:

Type of Medicare/Medicaid Service	Further Description	Application of OASIS
Home Health Benefit	Part A	Yes
Home Health Benefit	Part B	Yes
Home Health Benefit	Terminal Care	Yes
Home Health Benefit	Therapy services provided either directly or under arrangement while under a home health PoC during an open episode.	Yes
Medicare Home Health under a Medicare Advantage plan	The selected HHA must be Medicare approved	Yes
Medicaid Home Health Benefit	Skilled services provided including expanded home health services, that are skilled, provided under a Home and Community–based Waiver	Yes
Medicaid Home Health Benefit	Waiver service or home health aide services only provided without skilled services	No
Medicare Hospice Benefit	Inpatient or at home	No
Outpatient Therapy Benefit (patient not under a home health plan of care)	Provided in a clinic, rehabilitation agency, a public health agency or other provider of services	No
Skilled Nursing Facility, Hospital	Inpatient services	No

The guidance above applies to all HHAs that participate in Medicare and to HHAs that are required to meet the Medicare CoPs, including Medicaid HHAs.

2202.3C - Non-Medicare/Non-Medicaid Patients

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

The collection, encoding, and transmission requirement for non-Medicare and non-Medicaid patients receiving skilled care is temporarily suspended. While HHAs are not required to collect OASIS for non-Medicare/non-Medicaid patients, HHAs may continue to collect OASIS data for their own use but they may not submit the data for these patients to the state. The state system will reject any assessment with a M0150 value of ‘0’ (unchecked) for items 1, 2, 3 and 4. Also, HAVEN will not include these assessments in

the submission file, but will mark them as complete.

2202.3D - Skilled Versus Nonskilled Care
(Rev. 1, 05-21-04)

Until the comprehensive assessment and reporting requirement resumes for all patients, regardless of type of care provided, the following definitions apply for determining skilled versus non-skilled care for comprehensive assessment purposes only:

- Skilled Services for Medicare Patients - The provision of skilled service is a pre-condition for Medicare payment for home health care. Therefore, all patients receiving Medicare (traditional) home health services are, by definition, receiving skilled care.

- Skilled Services for Non-Medicare Patients - For comprehensive assessment purposes, skilled services are services which can only be provided by a registered nurse (RN) (or a licensed practical nurse under the supervision of an RN), a physical therapist (PT), occupational therapist (OT), or a speech language pathologist (SLP), licensed by the State. Most States define the kind of care that is allowed by these practitioners under State practice acts.

The former requirement to conduct an initial evaluation of a patient is expanded in the comprehensive assessment regulations. The regulations now require that, in addition to an initial evaluation, the agency must also conduct a comprehensive assessment of a patient with updates at certain time points. These updates include different combinations of OASIS data items. An agency that currently must meet the Medicare CoPs under Federal and/or State law will need to meet the comprehensive assessment and OASIS encoding and reporting CoPs and apply them to each patient of the agency for whom home health services are rendered, with the exceptions listed in A. above.

2202.3E - Agencies Serving Medicaid Waiver and State Plan Patients
(Rev. 1, 05-21-04)

If home care is provided by an entity required to meet the Medicare CoPs for any reason, then the entity must apply all the requirements of the CoPs, including the comprehensive assessment and OASIS data reporting requirements, to all patients of the agency, including patients treated under a Medicaid waiver or State plan, as applicable. The same exceptions apply as listed in A. above, i.e., patients under the age of 18; patients receiving maternity services; patients receiving housekeeping or chore services only; and until sometime in the future, patients receiving personal care services only.

If home care is provided by an entity that is not required to meet the Medicare CoPs, then the provider must comply with only those requirements imposed under State or local law. In this case if the provider treats patients under a Medicaid waiver or State plan, then none of the Medicare CoPs for HHAs, including the comprehensive assessment and OASIS data reporting requirements, apply. See §2183 for information on separate entities.

2202.3F - Patients Turning 18
(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

A patient who is under age 18 and turns 18 while under the care of an HHA is to receive a comprehensive assessment (including OASIS, if Medicare or Medicaid is billed) at the next appropriate time point. Any assessments due under the regulations at the time the patient turns 18 would be conducted, including the collection and reporting of OASIS data, if Medicare or Medicaid is billed.

EXAMPLE

If on 1/5/2013 a patient under the care of the agency turns 18 and is transferred to an inpatient facility on or after 1/5/2013, a transfer assessment with the corresponding OASIS data items must be collected. If the patient was discharged on his/her 18th birthday, a discharge assessment with the corresponding OASIS data items must be collected.

From the day the patient turns 18, any assessment required per the regulations at the next particular time point is required. Agencies are not expected to collect and report start of care OASIS data on patients admitted to the agency prior to turning 18.

2202.3G - Patients Receiving Maternity Services
(Rev. 1, 05-21-04)

The HHA should not collect data on patients receiving maternity services, i.e., prenatal, antepartum, and postpartum. The patient is not exempt from OASIS data collection if under the care of a physician for a condition unrelated to pregnancy or delivery.

2202.4 - Comprehensive Assessment and OASIS Reporting **(Refer to §484.20 and §484.55)**
(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

All HHAs participating in the Medicare/Medicaid program are required to comply with the comprehensive assessment and OASIS reporting regulations as summarized in the following chart.

PATIENT CLASSIFICATION	COLLECT	ENCODE	TRANSMIT
SKILLED Medicare (traditional fee-for service) Medicare (HMO/Managed Care) Medicaid (traditional fee-for-service) Medicaid (HMO/Managed Care)	Yes	Yes	Yes
SKILLED Non-Medicare/Non-Medicaid:	No	No	No

PATIENT CLASSIFICATION	COLLECT	ENCODE	TRANSMIT
Workers' Compensation Title Programs Other Government Private insurance Private pay patients under a HMO/ PPO/Managed Care plan Self-pay; other; unknown	Temporarily Suspended		
PERSONAL CARE ONLY Medicaid (traditional fee-for service) Non-Medicaid: Workers' Compensation Title Programs Other Government Private insurance Private HMO/Managed Care Self-pay; other; unknown	No	No	No
Patients under age 18; Patients receiving pre and postpartum maternity services; Patients receiving only chore and housekeeping services	No	No	No

2202.4A - Comprehensive Assessment and OASIS Collection

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

The comprehensive assessment regulations require a comprehensive assessment (that includes certain OASIS data items) be conducted at specific time points during a patient's admission. Those specific times are:

1. SOC

After admission to the HHA, the SOC comprehensive assessment should be completed in a timely manner consistent with the patient's immediate needs but no later than 5 calendar days after the SOC.

2. ROC

The comprehensive assessment is completed within 48 hours of the patient's return to the place of residence or of the HHA's knowledge of the patient's return after an inpatient admission of 24 hours or more for any reason other than diagnostic tests. This applies when the patient was not discharged from the HHA during the inpatient admission. If the physician's order requests that the HHA resume care at a point later than 48 hours or if the patient refuses a visit within this 48-hour period, a note to this

effect should be documented in the patient's chart for future reference.

3. Follow-Up - The comprehensive assessment that is performed at the end of the current 60-day period. This assessment must be performed within the last 5 days of the current 60-day episode. For example:

Start of Care	Certification Period	Follow-Up Assessment Due
1/15/20xx	1/15/20xx - 3/14/20xx	3/10/20xx - 3/14/20xx
1/15/20xx	3/15/20xx - 5/13/20xx	5/09/20xx - 5/13/20xx
1/15/20xx	5/14/20xx - 7/12/20xx	7/08/20xx - 7/12/20xx

4. Transfer to an Inpatient Facility

An assessment update is performed when a patient is transferred to an inpatient facility for 24 hours or more for any reason except diagnostic testing, regardless of whether the patient is discharged from the HHA at that time. The update must be completed within 48 hours of the patient's transfer to the inpatient facility or within 48 hours after the HHA becomes aware of the transfer and includes a limited number of OASIS items.

5. Discharge

The comprehensive assessment is performed when a patient is discharged from home care. These updates must be completed within 48 hours of the discharge/death or within 48 hours after the HHA becomes aware of the discharge/death.

2202.4B - OASIS Encoding and Locking

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

HHAs should use HAVEN or HAVEN-like software to encode or enter OASIS data into their computers. HAVEN will accommodate data entry of OASIS items from all required time points. Regardless of the time point, OASIS data items should be encoded, and checked for errors using HAVEN or HAVEN-like software, and made export/transmission-ready.

1. Availability of HAVEN

The HAVEN software is available for downloading free of charge from the CMS OASIS and QIES Technical Support (QTSO) Web site. See https://www.qtso.com/havendownload.html

The HAVEN help line can be reached at: 1-877-201-4721.

Specific information describing how to operate the HAVEN software can be found at

https://www.qtso.com/download/haven/hhahelp32.pdf.

2. Errors and Warnings in Encoding

See Error Messages and Description Guide --
https://www.qtso.com/download/Guides/hha/errors/Errors_sec2.pdf
HHAs may experience two types of messages at completion of data entry.

a. Error Message.

If the HHA uses HAVEN for data entry, an error message may occur if a mandatory field is left blank. The HHA will receive an error that the field must be filled in before the assessment can be marked as complete. HHAs should correct their errors before an assessment may exported to the OASIS Data Management System. Along with the error message is the name of the window tab where the error was detected.

b. Warning Message

If the HHA uses HAVEN for data entry, a warning message may occur if timing criteria for date fields do not match OASIS data specifications. These messages are informational only and do not preclude an HHA's assessment from being exported. Along with the warning message is an explanation of that message and direction on where the discrepancy was detected.

2202.4C - OASIS Reporting (Refer to §484.20)

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

1. HHA Submissions

HHAs must submit their OASIS data within 30 days of the M0090 date, date assessment completed. Data received outside of this time frame is considered overdue. Specific information describing how HHAs are to transmit OASIS data to the SA is in the OASIS System Users Guide.

2. Errors and Warnings in OASIS Reporting

When submitting OASIS records, a fatal error message may occur if the HHA's data record layout does not follow OASIS data specifications. This message should not occur if the HHA is using the HAVEN software to encode the OASIS items.

3. SA Access

In States where the non-long term care agency is in a location separate from the OASIS State System (where the MDS Data System resides and is not under the direct jurisdiction of the home health survey agency), CMS provides access to the OASIS State System by installing a computer work station at the home health survey agency

address to link to the OASIS State System.

The CMS will provide additional support to the SA to access and operate the off-site server by providing appropriate software, and technical assistance from CMS and the CMS OASIS contractors.

2202.5 - Outcome-Based Quality Improvement (OBQI)

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

OBQI is a systematic approach that HHAs can implement and follow in order to continuously improve the quality of care they provide. OBQI manuals are available on the CMS Home Health Quality website. Under OBQI, quality is measured against the ultimate yardstick - patient outcomes. OBQI is fundamentally a two-stage process that requires the collection of OASIS data for all patients in the agency, except those excluded by exemption.

The first stage of OBQI is outcome analysis based on the OASIS data. The analysis is based on an agency-level report showing the agency's present performance regarding patient outcomes relative to a national measure of HHA patients. Outcome reports are generated at the SA and retrieved by the HHA through the same communication process the HHA uses to transmit OASIS data. Subsequent outcome reports contain comparisons of an agency's present patient outcomes performance relative to the preceding time period for the agency and relative to a national measure of HHA patients. From these reports, HHAs can target areas for improvement as part of their overall quality assurance process.

The second stage of OBQI is outcome enhancement, whereby the agency, using the data from its outcome analysis, identifies opportunities to improve care and develops plans. HHAs are provided with reports on a series of outcomes for their patients in the current year that compares its performance to the prior year and to the national reference (i.e., benchmarking) values.

2202.5A - Using Outcome Based Quality Monitoring (OBQM) and Risk Adjusted OBQI Reports in the Survey Process

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

The OBQM reports consist of the patient-related characteristics and potentially avoidable event outcome reports, which are derived from the OASIS data that HHAs submit to the State. The agency patient-related characteristics and potentially avoidable event reports can be used by HHAs for quality monitoring and improvement purposes. The risk-adjusted OBQI reports provide measures of patient care based on all of the OASIS data items. These reports allow an HHA to proceed to outcome enhancement. It is the outcome enhancement activities that allow an HHA to focus its quality (or performance) improvement activities on select target outcomes, to investigate the care processes that contributed to these outcomes, and to make agency-specific changes in clinical actions that will lead to improved patient outcomes. Using these reports is a first step toward full implementation of the OBQI program. As a part of the pre-survey preparation, surveyors should access and review the OBQM and OBQI reports before surveying an HHA. These

reports contain valuable information that may assist surveyors in identifying areas to review during the survey and possibly identify individuals or types of patients to include in the sample selection when on site following guidance provided in the Home Health Survey Protocol Enhancements, effective May 1, 2003 published February 13, 2003 as S&C Memorandum 03-13. The OBQM Manual, (titled "Quality Monitoring Using Case-Mix and Adverse Event Outcome Report" available on the OASIS Web site), provides examples of possible surveyor actions related to adverse event outcomes. The OBQI Manual (titled Outcome-Based Quality Improvement Implementation Manual provides guidance to HHAs for establishing a quality improvement program using the risk-adjusted OBQI reports. This manual is also available on the OASIS Web site.

1. Agency Patient-Related Characteristics Report

The agency patient-related characteristics report presents a picture, or snapshot, of an HHA's patients at the beginning of a care episode for the time period selected for the report. The beginning of a care episode is marked by either a SOC assessment or a ROC assessment. The body of the case-mix report describes the characteristics of an HHA's Medicare and Medicaid patients receiving skilled services compared to the rest of the Medicare and Medicaid patients receiving skilled home health services across the country during the same time period. Surveyors should review the case-mix outcome report as described in the OBQM Manual and the Appendix titled "Guidelines for Reviewing Agency Patient-Related Characteristics and Potentially Avoidable Event Reports." Any significant results should be identified after reviewing the report, and highlights noted. This will allow surveyors to begin to identify potential clinical groups of patients that can be included in the case-mix stratified sample for record review and home visits, as part of the onsite survey.

2. Potentially Avoidable Event Reports

The Potentially Avoidable Event Report displays incidence rates for untoward events (or outcomes) comparing one HHA's patients to patients in the CMS OASIS National repository for the same time period.

Potentially avoidable events serve as markers for potential problems in care because of their negative nature and relatively low frequency. The Patient Listing can be used to investigate the care processes that contributed to these outcomes and to make agency-specific changes in clinical actions that will lead to improved patient outcomes. As a part of the pre-survey preparation, surveyors should access and review the OBQM and OBQI reports before surveying an HHA. These reports contain valuable information that may assist surveyors in identifying areas to review during the survey.

Surveyors do not look at the potentially avoidable event report in a vacuum. They review this report in light of the actual circumstances surrounding the delivery of care to the specific patients.

As a part of the CoPs (§484.16, Group of Professional Personnel and §484.52, Evaluation of the Agency's Program), HHAs are required to conduct an annual

evaluation of their total program, including patient services. HHAs are also required to conduct quarterly clinical record reviews to evaluate the care provided under the HHA's policies. The CoPs require an agency to have policies and procedures to promote patient care that are appropriate, adequate, effective and efficient. HHAs have access to the OBQM reports and the OBQI reports and may incorporate a review and investigation of these reports into their evaluation and patient care review programs and include them as part of their quarterly record review.

3. Risk Adjusted OBQI Reports

The risk adjusted OBQI reports are the third and final of the OASIS-based reports. These agency-level reports allow individual HHAs to assess their own performance with respect to patient outcomes and compare their performance to a national reference or benchmark. In addition, HHAs can use the OBQI data to target and develop plans of action to improve or maintain HHA performance and patient outcomes. The risk adjusted OBQI reports became available to all HHAs in February 2002.

CMS anticipates that HHAs will choose to use the OBQI reports for quality improvement and for consumer education. In CMS-sponsored demonstrations where the OBQI process has been tested, many HHAs have demonstrated significant improvements in targeted patient outcomes. These data rich reports now represent a decade of benchmarking that is risk adjusted for each HHA. This means that every HHA can be compared to the national reference values, regardless of the types of patients it serves, when compared to another HHA. Therefore, an HHA that strives to provide quality care services to its patients will be able to determine its performance and to identify areas for improvement or reinforcement with the quality reports available to them.

Process Measures were added to the OASIS in 2010. For further information, refer to the PBQI Manual which is located at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/PBQIProcessMeasures.html

The OASIS C Process Measure Reports are now available in the CASPER Reporting System. The reports are located in the OASIS C - Quality Improvement report category.

Resources are located on the following CMS websites:

- PBQI – http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/PBQIProcessMeasures.html

- OBQI - http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIOASISOBQI.html

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Process Measures were added to the OASIS in 2010. For further information, refer to the PBQI Manual which is located at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/PBQIProcessMeasures.html

The OASIS C Process Measure Reports are now available in the CASPER Reporting System. The reports are located in the OASIS C - Quality Improvement report category.

Resources are located on the following CMS websites:

- PBQI – http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/PBQIProcessMeasures.html

- OBQI - http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIOASISOBQI.html

- OBQM http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIOASISOBQM.html

2202.5B - Case-Mix Stratified Sample
(Rev. 1, 05-21-04)

Surveyors will continue to select a case-mix stratified sample for record reviews and home visits since this requirement is explicitly referenced in §1891 of the Act. For example, surveyors will continue to routinely assess the ability of the HHA to provide quality care by conducting the following activities:

- Evaluating the current status of the patient as reflected in the comprehensive assessment, plan of care and visit notes;

- Verifying that all drugs and treatments are provided according to a physician's order and that the HHA has reviewed all drugs for potential adverse effects and drug reactions;

- Reviewing the plan of care to identify whether the HHA used the comprehensive assessment to make sound care planning decisions appropriate to the patient's needs;

- Reviewing the timeliness of services provided to the patient;

- Evaluating the HHA's ability to coordinate care and services;

- Reviewing the patient's progress toward the achievement of desired outcomes;

- Verifying that any changes in the patient's medical condition were reported to the physician and recorded, including documentation of verbal orders with written confirmation; and

- Evaluating the appropriateness of patient's continuation of services or discharge at the time of record review.

However, the scope of patients eligible for the case-mix stratified sample may include both current and discharged patients. Surveyors may also identify clinical areas and select patients for review on site as part of their off-site survey preparation. The outcome reports may point to concerns that surveyors need to address during the survey and surveyors will now be able to include in the sample patients representing the identified concerns.

The surveyor should continue to use the HHA's current visit schedule (or plans for visits) during the week that the surveyor(s) is on site to develop the sample for clinical record

review with home visits. The sample for clinical record review without home visits may include records of patients that have been discharged by the HHA.

2202.5C - Privacy Act Requirements

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

1. SA/RO Use of OASIS Data

Each SA or RO user authorized to access and use the OASIS data or reports derived from OASIS data must comply with the provisions governing the privacy and security of this Federal information system. Each user with authorized access to the system, records, and reports must agree to effectively maintain CMS approved administrative, technical, procedural, and physical safeguards to ensure protection of the confidentiality of the patient identifiable data and to prevent unauthorized access to the data. Each user is required to have individual valid user identification and a secure password. Each user is obligated to protect the confidentiality of the OASIS data. As noted in the June 18, 1999, December 27, 2001, and November 13, 2007 "Federal Register" notices of the OASIS system of records: "No user shall disclose, release, reveal, show, sell, rent, lease, loan or otherwise grant access to the data to any person." The Federal Privacy Act of 1974 provides criminal penalties and fines for certain violations. The November 13, 2007 Notice describes routine uses.

2. HHA Use of OASIS Data

The HHAs are required, as a part of the CoPs to maintain the confidentiality of all patient identifiable information contained in the clinical record, including OASIS data and reports, and may not release patient identifiable OASIS information to the public. Therefore, neither the State nor the HHA may release any of the OBQM or OBQI reports or the information contained in them.

2202.5D - Accessing the OBQM, OBQI, and Process Based Quality Improvement (PBQI) Reports

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

The authorized SA and RO user needing access to these reports must have a valid user identification and a secure password. These are obtained by submitting a request to the CMS Central Office via the State system coordinator through the CMS RO. Approved requests will be assigned the required user identification and password. SAs and ROs will access the OBQI, PQBI and OBQM reports from the Certification and Survey Provider Enhanced Reports (CASPER) link located under the CASPER title on the QIES to Success Web site. The CASPER Home page will display, requiring entry of the login ID and password necessary to access the reporting tool. For most SA and RO users, this login ID and password are the same that are currently used when accessing the OBQM Reports. HHAs access their OBQI and OBQM reports in the same way they access their OASIS validation reports, by connecting to the OASIS State System via the CMSnet and selecting the applicable menu option.

The CASPER Reporting User's Guide is located on the state OASIS Welcome page.

2202.5E - Role of the OASIS Coordinators in OBQI
(Rev. 1, 05-21-04)

The OASIS coordinators work directly with the HHAs to help them access and review the OBQM, risk-adjusted OBQI, and Data Management System reports. In addition, the OASIS Coordinators support and train State surveyors to access, review, and interpret the reports as needed. States do not advise HHAs on which outcomes to target nor do they provide advice on care practices.

2202.6 - OASIS Instructions
(Rev. 1, 05-21-04)

2202.6A - OASIS Guidance Manual
(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

The OASIS Manual was intended for use by HHAs in implementing the regulations for comprehensive patient assessments, including data collection and reporting using the OASIS.

The original OASIS User's Manual, "Implementing OASIS at an HHA to Improve Patient Outcomes," has been archived and can be found at the following web address: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIArchives.html

The current OASIS manual is the OASIS Guidance Manual and can be found at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIOASISUserManual.html.

The OASIS Guidance Manual provides guidance for HHAs on how to ensure the collection of high-quality (accurate) OASIS-C data. It includes both general data collection conventions and item-specific guidance, as well as links to quality-related resources for agencies. It is a streamlined and updated version of the original OASIS Implementation Manual. It covers the overall OASIS implementation process from a clinical and management perspective and includes detailed information needed to train HHA clinical staff to use OASIS as part of the comprehensive assessment and materials to assist operationally in the implementation of OASIS data collection and data reporting. While the manual has been revised several times over the past decade to reflect changes to the OASIS, the basic structure of the manual has not changed. It provides:

- Specific item-by-item information on completion of each OASIS item;
- General information relevant to OASIS data collection versions of OASIS-C for each OASIS data collection time point;
- Sample pages of clinical record forms for OASIS data time points illustrating how the relevant OASIS items can be integrated;
- Relevant resources for HHAs, with hyperlinks when available;

- Information on OBQI;
- Home health care regulations related to OASIS data collection; and
- Recommendations for ensuring accuracy of OASIS data.

Additional Manuals associated with OASIS:

- **The Outcome-Based Quality Monitoring (OBQM) Manual** can be used in the agency's quality improvement program. The two reports discussed in this manual have been renamed. The Agency Patient-Related Characteristics Report (formerly the Case Mix Report) presents characteristics of the agency's patients at the start or resumption of care. Potentially Avoidable Event Reports, (formerly the Adverse Event Outcome Report) displays incidence rates for infrequently occurring untoward events (outcomes).
- **The Outcome-based Quality Improvement (OBQI) Manual** is written for agencies wishing to implement activities to improve or maintain OASIS outcomes.

- **The Process Based Quality Improvement (PBQI) Manual** is written to assist agencies with the use of the process measure reports which can be used in their annual program evaluation or internal quality improvement activities. This could include the development of and use of best practices within the agency.

- **OASIS National Automation Project: HHA System User's Guide** covers the data submission process for HHAs, including how they are to access the OASIS State System, procedures for electronically submitting data (including corrections of previously submitted data), and interpretation of feedback reports from the OASIS State System. Materials are updated as needed. Updates are posted on both the CMS and the QIES Technical Support Office (QTSO) websites.
- **OASIS HAVEN System Reference Manual** covers the use of HAVEN software, which was developed to provide HHAs with software for data entry, editing, and validation of OASIS data. It includes information on setting up the software, defining agency and employee information, entering patient and assessment data, and data management functions. This manual, in electronic form, is also included with the HAVEN software. These are updated as needed and updates are posted on both the CMS and QTSO websites.

As updates are made to the OASIS Manuals, States are notified through the CMS contractor of any updates. In addition, all updates to the manuals are posted on the CMS and QTSO Web site.

2202.6B - Other Manuals

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

For SAs only, there is a detailed User's Manual for SA System Administrators who, pursuant to the regulations, are required to administer and maintain the OASIS system at the State level. This manual includes an overview of the components of the OASIS State System and provides the instructions necessary to administer and maintain them.

- OASIS Validation Report Messages and Descriptions (December 2009). This updated manual provides the HHAs with guidance which describes the types of reports and messages they can expect to see in response to their electronic submission of OASIS data. This manual is based on version 2.00 data specifications, available in HAVEN 10.0. This manual assists HHAs in interpreting their feedback reports.

- OASIS-B1 HAVEN System Reference Manual (December 2007). This manual addresses the use of the current recommended version of the Home Assessment Validation and Entry (HAVEN) System software which is available online. This manual includes information on setting up the software, defining agency and employee information, entering patient and assessment data, and data management functions.

2202.6C - Other Teaching Tools

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

In addition to the OASIS Guidance Manual for HHAs, there are other sources of information available to help States implement OASIS. They are:

OASIS-C Educational Resources - http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/EducationalResources.html

CMS Sponsored Calls - http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/EducationalResources.html

OASIS Training - http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/Training.html and http://surveyortraining.cms.hhs.gov/index.aspx

- **QIES QTSO Web site** - In addition to the above sources of information available to help States implement OASIS, IFMC's QTSO Web site contains current and relative OASIS information, training manuals, HAVEN software, software patches, slides from past OASIS conferences and video files that can be viewed on line at http://www.qtso.com/

- **OASIS Web site** - (http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/index.html) - The CMS OASIS Web site stores and disseminates policy and technical information related to OASIS for use by the home health community. The information posted on the OASIS Web site is intended to assist HHAs, SAs, software vendors, professional associations, and other Federal agencies in implementing and maintaining OASIS as efficiently as possible. CMS continually updates and modifies the OASIS Web site in an effort to provide HHAs and other principals with information necessary to understand and implement OASIS.

- **OASIS Help Lines** - In addition to the OASIS Web site, QTSO Web site, OASIS User's Manual, OASIS Training Manual and CBT modules available through each SA, HHAs can access help through telephone and e-mail hot lines:

    - The telephone hotline for assistance with HAVEN and OASIS data submission is: 1-877-201-4721. This is a toll-free number available from 7a.m. - 7 p.m. Central Time. After hours, a voice-mail box is available to record inquiries.

    - The e-mail address for assistance with HAVEN and OASIS data submission is. help@qtso.com

    - SA and RO OASIS staff have different telephone, FAX, and e-mail hot lines in place for assistance with their clinical questions concerning HAVEN and OASIS data submission. These hot lines are designed for use by SA and RO staff only. SA personnel should contact their State OASIS Coordinator, RO OASIS Coordinator, or central office OASIS staff for this information.

  HAVEN System Reference Manual - This manual includes information on setting up the software and data management functions.

  http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/HAVEN.html or https://www.qtso.com/havendownload.html

2202.7 - OASIS and the Home Health Prospective Payment System (PPS)

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

The home health PPS helps to ensure appropriate reimbursements for quality, efficient home health care. Under prospective payments, Medicare pays HHAs a predetermined base payment. This payment is adjusted for the health condition and care needs of the beneficiary. The payment is also adjusted for the geographic differences in wages for HHAs across the country.

This and other PPS information is available on the CMS Web site at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/index.html.

The following are highlights of the home health PPS system:

- Episode - Medicare pays HHAs for each covered 60-day episode of care. As long as beneficiaries continue to remain eligible for home health services and episodes are not overlapping and are medically necessary, they may receive an unlimited number of episodes of care. Payments cover skilled nursing, home health aide visits, covered therapy, medical social services and routine and non-routine

medical supplies.

- Home Health Resource Groups (HHRG) - A case mix methodology adjusts payment rates based on characteristics of the patient and his/her corresponding resource needs (e.g., diagnosis, clinical factors, functional factors, and service needs, etc.). The 60-day episode rates are adjusted by case mix methodology based on payment policy data elements from the OASIS. The data elements of the case mix adjustment methodology are organized into several dimensions such as clinical severity factors, functional severity factors, and service utilization factors resulting in Home Health Resource Groups (HHRG), a patient payment classification described as case mix.

- Request for anticipated payment (RAP) - To ensure adequate cash flow to HHAs, the home health PPS has set forth a split percentage payment approach to the 60-day episode. The split percentage occurs through the request for anticipated payment (RAP) at the start of the episode and the final claim at the end of the episode. For the initial episode, there is a 60/40-split percentage payment. An initial percentage payment of 60 percent of the episode is paid at the beginning of the episode and a final percentage payment of 40 percent will be paid at the end of the episode, unless there is an applicable adjustment. For all subsequent episodes for beneficiaries who receive continuous home health care, the episodes are paid at a 50/50 percentage payment split.

- Outlier - Additional payments will be made to the 60-day case-mix adjusted episode payments for beneficiaries who incur unusually large costs. These outlier payments will be made for episodes whose imputed cost exceeds a threshold amount for each case-mix group. The amount of the outlier payment will be a proportion of the amount of imputed costs beyond the threshold. Total national outlier payments for home health services annually will be no more than a fixed percent of estimated total payments under home health PPS.

- Partial episode payment (PEP) - The partial episode payment allows the 60-day episode clock to end and a new clock to begin if a beneficiary transfers to another HHA or is discharged with goals met but returns because of a decline in their condition to the same HHA within the 60-day episode. When a new 60-day episode begins, a new plan of care and a new assessment are necessary. The original 60-day episode payment is proportionally adjusted to reflect the length of time the beneficiary remained under the agency's care before the intervening event. The new episode is paid an initial episode payment rate. The 60 day clock is restarted.

- Consolidated billing - Under the PPS a HHA must bill for all Medicare home health services which includes nursing and therapy services, routine and non-routine medical supplies, home health aide and medical social services, except durable medical equipment (DME). DME is excluded from the consolidated billing requirement. The law requires that all home health services paid on a cost basis be included in the PPS rate. Therefore, the PPS rate will include all nursing and

therapy services, routine and non-routine medical supplies, and home health aide and medical social services.

- Low Utilization Payment Adjustment," (LUPA) - An episode with four or fewer visits is paid as a LUPA, which is the national per visit amount by discipline adjusted by the appropriate wage index based on the site of service of the beneficiary. Such episodes of four or fewer visits are paid the wage adjusted per visit amount for each of the visits rendered instead of the full episode amount. Beginning January 1, 2008, an additional payment is made for the first visit in a LUPA episode. Payment rule refinements often impact policy and are published annually at: http://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html.

Exceptions to OASIS Collection and Reporting Procedures Under PPS

There are some exceptions to the general OASIS collection and reporting procedures that are unique to Medicare PPS patients. There is information on the OASIS Web site that is provided to help HHAs integrate the home health PPS into their existing OASIS data collection procedures. A summary of that information with regard to OASIS data collection and the appropriate M0100 (Reason for Assessment) and M2200 (Therapy Need) response selection is provided below.

A - PPS Start-up

For new patients after October 1, 2000, any applicable (skilled care) patients (not just Medicare patients) accepted for care on or after October 1, 2000, are assessed according to the established time points at §484.

EXAMPLE: A patient whose SOC date is October 15 would be re-assessed for the need to continue services for another certification period during the last 5 days of the current 60-day certification period. In this example, the follow-up assessment would be conducted during the period 12/9/00 through 12/13/00.

B. First 60-day Episode

SOC: M0100 = RFA 1 and M2200 = 0-No or 1-Yes.

C. New 60-day Episode Resulting From Discharge With All Goals Met and Return to Same HHA During the 60-Day Episode. (PEP Adjustment)

SOC: M0100 = RFA 1 and M2200 = 0-No or 1-Yes.

D. New 60-Day Episode Resulting From Transfer to HHA With No Common Ownership (PEP Adjustment to Original HHA)

PEP Adjustment does not apply if patient transfers to HHA with common ownership during a 60-day episode. Receiving HHA completes OASIS, as applicable, on behalf of

transferring HHA. Transferring HHA serves as the billing agent for the receiving HHA. Transferring HHA may continue to serve as the billing agent for receiving HHA or conduct a discharge assessment at end of episode. Receiving HHA starts new episode with SOC (if original HHA discharges at end of episode): M0100 = RFA 1 and M0825 = 0-No or 1-Yes.

E Subsequent 60-Day Episode Due to the Need for Continuous Home Health Care After an Initial 60-Day Episode

Recertification (Follow-up): (M0100) = RFA 4 and (M2200) select 0-No or 1-Yes.

F. Patient's Inpatient Stay Extends Beyond the End of the Current Certification Period. (Patient Returns to Agency After Day 60 of the Previous Certification Period)

SOC: M0100 = RFA 1 and M2200 = 0-No or 1-Yes. When patient returns home, new orders and plan of care are necessary.

At time of transfer to an inpatient facility, the HHA completes the transfer. If transferred without discharging, a new episode is started and a new SOC assessment is completed when the patient returns home.

2202.8 - Surveying for the OASIS Requirements
(Rev. 1, 05-21-04)

The comprehensive assessment regulation requires that HHAs use a standard core data set, i.e., OASIS, when evaluating adult, non-maternity Medicare and Medicaid patients (except those receiving exclusively homemaker or chore services.) The OASIS meets the condition specified in §1891(d) of the Act, which requires the Secretary to designate an assessment instrument in order to evaluate the extent to which the quality and scope of services furnished by the HHA attained and maintained the highest practicable functional capacity of the patient as reflected in the plan of care. These regulatory changes are an integral part of CMS' efforts to achieve broad-based improvements in the quality of care furnished through Federal programs and in the measurement of that care.

Since the requirement to report OASIS data to the OASIS State System is not part of the standard survey process, while determining compliance with the comprehensive assessment of patients is, both offsite and onsite monitoring are required to determine compliance with the OASIS CoPs. The State OASIS Educational and Automation Coordinators can assist with the offsite monitoring for OASIS compliance and in providing available OASIS reports, (e.g., data management, quality monitoring and quality improvement reports) to surveyors. HHAs that do not collect and report accurate and complete OASIS data for all applicable HHA patients risk citations at the standard and condition levels. HHAs found not to be in compliance may be subject to enforcement actions and/or termination from the Medicare program.

2202.8A - Condition of Participation: Comprehensive Assessment of

Patients (See §484.55)
(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

This CoP states that a comprehensive assessment of the patient, in which patient needs are identified, is a crucial step in the establishment of a plan of care. In addition, a comprehensive assessment identifies patient progress toward desired outcomes or goals of the care plan. HHAs complete the OASIS items as part of the clinician's total assessment process. This process is not based solely on interviewing the patient. Conducting a patient's comprehensive assessment involves both observation and interview. These data collection techniques complement each other. Many HHA clinicians begin the assessment process with an interview by sequencing questions to build rapport and trust. Others choose to begin the assessment process with a familiar procedure such as taking vital signs in order to demonstrate clinical competence to the patient before proceeding to the interview. HHAs are expected to complete all OASIS items as accurately as possible while minimizing burden and intrusion on the patient.

HHAs should not force patients to cooperate with the assessment process; rather, they must do the best they can to assess patients who do not fully cooperate with the assessment process. Since collecting OASIS information rarely depends solely on patient interview, HHAs are expected to complete, encode, and transmit all OASIS data items. If patients refuse to answer some questions that are part of the OASIS assessment, HHAs may still deliver care to the patient as long as they complete and submit the OASIS assessment to the best of their ability.

States may advise HHAs that seem to report difficulty with specific OASIS items to review the processes of performing a comprehensive assessment with their staff. Sometimes such difficulties indicate that staff might benefit from additional training or retraining in assessment skills. The OASIS Web-based Training Internet site provides additional guidance on "OASIS and the Comprehensive Assessment" and "How to effectively conduct a comprehensive assessment" for clinicians who are challenged by these activities.

As stated in the CoPs, each patient (except those under 18; receiving maternity services; receiving only services such as homemaker or chore services; or, until sometime in the future, receive personal care services only), regardless of payer source, is expected to receive from the HHA a comprehensive assessment that accurately reflects the patient's current health status and incorporates the exact language of the OASIS data items required for the time points specified in this condition.

The requirement to collect OASIS data as part of the comprehensive assessment for non-Medicare /non-Medicaid patients is temporarily suspended, effective December 8, 2003, as a provision of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. HHAs must continue to comply with the aspects of the regulation at §484.55 regarding the comprehensive assessment of patients. HHAs must provide **each** agency patient, regardless of payment source, with a patient-specific comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward the achievement of desired

outcomes. The comprehensive assessment must also identify the patient's continuing need for home care, medical, nursing, rehabilitative, social, and discharge planning needs.

- HHAs may continue to collect OASIS data on their non-Medicare/non-Medicaid patients for their own use.

- Surveyors must continue to examine the completeness of the comprehensive assessment for all patients during a survey. However, surveyors must not investigate whether the HHA included the specific OASIS items in its patient-specific comprehensive assessments of non-Medicare/non-Medicaid patients, nor cite deficiencies based solely on this finding.

The CoP is comprised of the following five standards.

1. Initial Assessment Visit

This standard requires that an initial visit be performed to determine the immediate care and support needs of the patient. The initial assessment visit requirement is intended to confirm beneficiary eligibility, to ensure that the patient's most critical needs for home care services are identified and met in a timely fashion, and to perform the skilled care that was ordered. It is not required that a SOC comprehensive assessment be completed at this visit, although the HHA may choose to do so. If the HHA does not complete the SOC comprehensive assessment during the initial visit, then the comprehensive assessment must be completed and updated according to the required time points.

- The initial assessment visit is conducted by a registered nurse and must occur either within 48 hours of referral or within 48 hours of the patient's return home from a hospital stay of 24 hours or more for any reason other than diagnostic testing, or on the SOC date ordered by the physician.

- For Medicare patients, the initial assessment visit must include a determination of the patient's eligibility for the home health benefit. Verification of a patient's eligibility for the Medicare home health benefit including homebound status does not apply to Medicaid patients, beneficiaries receiving Medicare outpatient services, or private pay patients.

- When rehabilitation therapy (speech-language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate rehabilitation professional. For the purpose of the initial visit, a therapy case that includes knowledge of skilled nursing for a one-time visit to remove sutures or draw blood is not considered a therapy-only case. The initial visit must be conducted by the qualified registered nurse.

NOTE: While Medicare pays for occupational therapy, eligibility for the Medicare home health benefit cannot be established based solely on the need for that service. The need for occupational therapy does not establish eligibility for the Medicare home health

benefit. However, the Medicare home health patient with multiple service needs can retain eligibility if, over time, the only remaining need is for occupational therapy. Therefore, under the Medicare benefit, the Occupational Therapist (OT) cannot conduct the initial assessment. An OT can conduct the Follow-Up assessment and those associated with transfers and discharges. Occupational therapy, could, however, establish eligibility, in some States, under the Medicaid program. In the case of Medicaid patients (or Medicare patients receiving therapy services), if the need for a single therapy service either establishes eligibility or allows eligibility to continue once it is otherwise established, the corresponding practitioner, (including a PT, SLP, or OT) can conduct any of the designated assessments.

2. Completion of the Comprehensive Assessment

- When a patient is first admitted to the HHA, a comprehensive assessment must be completed no later than 5 calendar days after the SOC date. The comprehensive assessment for all Medicare and Medicaid patients receiving skilled services must include OASIS data. OASIS data is not required for non-Medicare/non-Medicaid patients at this time. However, HHAs may include OASIS data if they choose. Additional comprehensive assessments are required throughout a patient's course of treatment.

- A registered nurse must complete the comprehensive assessment and, for Medicare patients, confirm eligibility for the Medicare home health benefit.

- When physical therapy or speech-language pathology is the only service ordered by the physician, the PT or SLP may complete the comprehensive assessment. For the purpose of the SOC comprehensive assessment, a therapy case that includes skilled nursing for a one-time visit to remove sutures is not considered a therapy-only case. The SOC assessment in this case should be conducted by the qualified registered nurse but may be completed by the qualified therapist at subsequent time points. The same discipline is not required to complete the subsequent assessments at every required time point. The HHA can decide how best to approach the assessment process at the required time points. For other than Medicare, OTs may complete the SOC assessment when the need for occupational therapy establishes program eligibility. (See **NOTE** above concerning eligibility for the home health benefit and occupational therapy services.)

- The SOC comprehensive assessment may be completed in more than one visit as long as it is completed within the 5-day time frame required by the regulations.

- Non-clinical staff, i.e., those not qualified by current regulation, may not assess patients or complete assessment items; however, non-clinical staff or data entry operators may enter the OASIS data collected by the qualified skilled professional into the computer. Many elements in the Clinical Records Items section (which identifies the patient) of each OASIS data set may be completed initially by clerical staff as part of the intake/referral process; but should be verified by the qualified clinician doing the assessment.

Master of Social Work Only Evaluations

Visits for medical social work assistance only are frequently requested by case managers. A visit for medical social work in order to evaluate the patient's need or eligibility for community services generally is not considered a visit to conduct a comprehensive assessment of the patient and would not solely qualify a patient for Medicare home care eligibility. If a physical assessment of the patient is conducted, as is required by the comprehensive assessment regulations, it must be done by a qualified person. In this case, that qualified person must be an RN, PT, SLP or OT (as applicable).

Drug Regimen Review

The drug regimen review requirement was moved from the previous plan of care requirements to the new comprehensive assessment requirement to reflect the true nature and purpose of this activity. The comprehensive assessment must include a review of all medications the patient is currently using in order to determine compliance with drug therapy, significant side effects and drug interactions, potential adverse effects and drug interactions, ineffective drug therapy, and duplicate drug therapy.

The previous requirements for drug regimen review were modified by eliminating the actual identification of "adverse actions" and "contraindicated medications" and substituting the requirement to review drug therapy compliance, drug interactions, and duplicative drug therapy.

3. Update of the Comprehensive Assessment

In order to have data that is comparable across HHAs, OASIS data must be collected at uniformly defined time points including recertification. This requirement is not expected to add to the number of skilled visits provided by the HHA. Many HHAs arrange visit schedules to accommodate home health aide supervisory requirements and patient and care giver schedules. HHAs are expected to similarly adjust the patient's visit schedule in order to accommodate OASIS time points. OASIS reassessment visits that are not part of a treatment visit are overhead/administrative costs and not separately billable visits. They do not require a physician order.

The comprehensive assessment, which includes the OASIS data items for Medicare and Medicaid patients, should be updated and revised no less frequently than:

- During the last 5 calendar days of the current 60-day certification period beginning with the SOC date (Follow-up OASIS data set); or within 48 hours of (or knowledge of) the patient's return home from a hospital stay of 24 hours or more for any reason except diagnostic tests (ROC OASIS data set). If these two assessment time periods fall within the five day window, only the ROC assessment must be completed;

- Within 48 hours of (or knowledge of) transfer to an inpatient facility (Transfer to

an Inpatient Facility OASIS data set, with or without agency discharge);

- Within 48 hours of (or knowledge of) the patient's return home from an inpatient stay other than a hospital. (See major decline or improvement in the patient's health at 4. below;)

- Within 48 hours of (or knowledge of) discharge to the community or death at home (Discharge OASIS data set); and

- For non-Medicare/non-Medicaid patients, HHAs must provide each agency patient with a patient-specific comprehensive assessment at the above time points to accurately reflect the patient's current health status and the patient's progress toward achievement of desired outcomes.

In a case involving more than one discipline, the SOC assessment should be conducted by the qualified registered nurse but may be conducted by the qualified therapist at subsequent time points. The same discipline is not required to complete the subsequent assessments at every required time point. The comprehensive assessment updates should include the appropriate OASIS items as indicated on the data set for the respective time points, (i.e., SOC, ROC, Follow-Up, transfer to inpatient facility with or without discharge, discharge, and death at home).

If home health care is resumed after an inpatient stay, the comprehensive assessment must include the OASIS items appropriate for assessment after an inpatient stay. If the patient is not formally discharged at the time of transfer to an inpatient facility, the agency completes a comprehensive assessment that includes the ROC OASIS data items.

If the patient is formally discharged from the HHA, the data collection proceeds on the basis of a new agency SOC date that follows the inpatient stay; therefore, a SOC comprehensive assessment is conducted. The ROC and SOC (minus the Patient Tracking Sheet) OASIS data sets are actually the same data set. For purposes of OASIS data collection, the HHA can establish its own internal policies regarding criteria for formal discharge versus interrupting home care services but maintaining the patient on the HHA admission roster, i.e., placing the patient on "hold" status. (See OASIS and the Home Health Prospective Payment System for exceptions to this general rule.)

If the patient is under the care of the HHA and is not formally discharged prior to the end of the current 60-day period, the HHA conducts the next comprehensive assessment during the last 5 days of the current 60-day period beginning with the original SOC date. For example, if the SOC date were June 25, 2014, the patient would be reassessed between August 18 and August 22, 2014.

If the HHA transfers a patient to an inpatient facility and places the patient on "hold" status, no further assessments are conducted and no data is collected while the patient is in the inpatient facility. The HHA is not providing care while the patient is on "hold" during the inpatient stay. At the time the patient is transferred to the inpatient facility, a transfer assessment (response 6 selected for M0100) is completed. When the patient returns to

home care, the HHA completes the ROC assessment (response 3 selected for M0100). (See OASIS and Home Health Prospective Payment System for exceptions to this general rule.)

The ROC assessment is required within 48 hours of the patient's return home from the inpatient facility unless otherwise determined by physician's orders. The Follow-up assessment is required during the last 5 days of the current 60-day (recertification) period. It is possible for these two time periods to overlap. If they do, M0100, ROC (response 3), should be marked. If these two periods DO NOT overlap, two comprehensive assessments should be completed in accordance with the regulations. One assessment is done for the ROC while the other is done for the follow-up time point. (See OASIS and Home Health Prospective Payment System for exceptions to this general rule.)

4. Major Decline or Improvement in the Patient's Health Status

The OASIS regulations require that assessments with OASIS data collection be performed at certain time points. In the event an HHA determines that a patient's condition has improved or deteriorated significantly at a point in the episode of care that is not already captured at a required time point, the HHA should collect and report additional assessment information. Each HHA should define major declines or improvements in the patient's health status. Thus, the term "major decline or improvement in the patient's health status" is the impetus for collecting and reporting OASIS data to:

- Assess a patient on return from an inpatient facility other than a hospital, if the patient was not discharged upon transfer (ROC OASIS data set); and

- As defined by the HHA (Other Follow-up OASIS data set).

5. Incorporation of OASIS Data Items

Integrating the OASIS items into the HHA's own assessment system in the order presented on the OASIS data set facilitates data entry of the items into the data collection and reporting software. Agencies may integrate the items in such a way that best suits their assessment system. Some agencies may wish to electronically collect their OASIS data and upload it for transmission to the State. As long as the HHA can format an output file for transmission to the State (that is, in the 1448-byte data string format specified by CMS), it doesn't matter in what order it is collected; however, this is not recommended because of the skip patterns that are built into the OASIS data set. In accordance with the regulations, data MUST be transmitted in the sequence presented on the OASIS data set. The HAVEN software will prompt HHAs to enter data in a format that will correctly sequence it and ultimately be acceptable for transmission.

HHAs collecting data in hard copy or electronic form must incorporate the OASIS data items into their own assessment instrument using the exact language of the items. Agencies are expected to replace similar items/questions on their existing assessment tool as opposed to simply adding the OASIS items at the end. For agencies using software that does not accommodate bolding or underlining for emphasis of words in the same manner

as the current OASIS data set, software that capitalizes these words is acceptable, including the M numbers when integrating is also recommended. In this way, the HHA will know that the M labeled items are items that MUST be assessed and completed. This will minimize delays in encoding due to incomplete OASIS data items.

HHAs may wish to incorporate the assessment categories (e.g., ADLs/IADLs, Medications, etc.) into their own assessment instrument in a different order than what is presented on the OASIS data set; however, as stated above, the agency must consider any skip instructions contained within the questions in the assessment categories and provide the proper instructions.

2202.8B - Record Keeping

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

Since the OASIS data set is incorporated into the HHA's comprehensive assessment, the clinical record must be maintained according to existing CoPs for clinical records. Records of both active and discharged patients must be readily retrievable for use by SA staff.

Surveyors may need to ask for orientation to the HHA Electronic Health Record, as providers have the right to use whatever system of medical records they choose. Surveyors will cooperate and work with facilities that use Electronic Health Records. During the entrance conference, surveyors will establish with the agency the process they will follow in order to have unrestricted access to the medical record. Electronic access to records will not eliminate the need for a surveyor to print a paper copy or to request a paper copy of certain parts of a record. However, the surveyor shall make reasonable efforts to avoid, where possible, the printing of entire records. The surveyor should print or request a paper copy of only those parts of records that are needed to support findings of noncompliance, unless protocols for particular types of surveys require otherwise.

Although not required, it is recommended that the HHA print hard copies of the electronic validation records received from CASPER and store the validation records in an electronic format for twelve months, until the next set of OBQI reports are available. The validation reports may be needed as evidence if the HHA receives a denial from the MAC for missing OASIS assessments.

The OASIS Activity Report in CASPER provides a list of assessments that were submitted and accepted by a HHA in the previous calendar month. Information provided in these activity reports includes Patient ID, SSN, Patient Name, RFA, Effective Date and Submission Date. This report is generated automatically on the 5th of each month. Rejected records are not reported within the Activity Report as the patient information is not stored for rejected records.

The activity reports can be found with the validation reports under the naming convention of ARmmyyyy.txt. For example reports completed with data submitted and accepted in the month of September 2010 will display as AR092010.txt.

Note: The Activity Reports are deleted from the state servers on the same cycle as the validation reports, therefore it is essential to either save the reports to a secured network as a text file OR print and save the report.

2202.8C - Condition of Participation: Reporting OASIS Information

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

Except as specified in the June 18, 1999 notice, HHAs must report OASIS data on all patients (except those under 18, those receiving maternity services, and those receiving housekeeping or chore services only) in a format that meets CMS specifications. HHAs or contracted entities acting on behalf of the HHA can report OASIS data to the SA using the HAVEN software CMS provides or by using HAVEN-like software that conforms to the same specifications used to develop HAVEN. Once reported to a CMS central database, the compiled, aggregate OASIS data (i.e., outcome reports) can be used by the HHA to determine how it is performing in terms of patient outcomes compared with other HHAs.

1. Encoding OASIS Data

   HHAs must encode (that is, enter OASIS data into a computer using HAVEN or HAVEN-like software) and finalize (make export ready) data entry for all applicable patients in the agency within 30 days of the M0090 date of an OASIS data set.

   Once the OASIS data set has been collected at the specified time points described above, HHAs may take up to 30 calendar days after the M0090 date of collection to enter the assessment into their computer systems. For example, if the comprehensive assessment is completed on May 1, the data must be encoded by May 31. (HHAs should consider implementing a tracking system that considers the window for correcting OASIS assessments that need corrections before submission.) HHAs will enter their OASIS data into their computers using HAVEN or HAVEN-like software.

   HAVEN will automatically review the data for accuracy and consistency; it will alert the HHA to make any necessary changes in order to finalize or lock the data. The locking mechanism is necessary to ensure the accuracy of the patient assessment at the point in time that the assessment took place. The locking mechanism will prevent the override of current assessment information with future information. HHAs will be prompted by HAVEN to export and store encoded data into an electronic file. The export file is transmitted to the State by the HHA.

2. Accuracy of Encoded OASIS Data

   Encoded OASIS data must accurately reflect the patient's status at the time the information was collected. In preparation for transmission to the State, the HHA should ensure that data encoded into the computer is identical to the OASIS data items completed by the skilled professional. HHAs should, therefore, develop systems to ensure that encoded data matches the OASIS data items completed by

the skilled professional. Such a monitoring system could include staff appointed to audit sample OASIS records after data is encoded as part of the agency's overall quality assurance program.

3. Transmission of OASIS Data

After being exported to a transmission-ready file, the export ready data should be transmitted to the State or CMS contractor. HHAs transmit OASIS data at least monthly. By the last day of each month, HHAs should electronically transmit all OASIS data made export ready during the previous month for each patient (as applicable based on M0090 date) to the SA.

NOTE: CMS requires the encoding and transmission of OASIS information only on patients who are receiving Medicare/Medicaid benefits. This means that for patients with payer source (1) Medicare (traditional fee-for-service), (2) Medicare (HMO/Managed Care), (3) Medicaid (traditional fee-for-service), or (4) Medicaid (HMO/Managed Care) on OASIS item M0150, the HHA must collect, encode and transmit all required OASIS information to the SA. If Medicare/Medicaid is contributing to the payment of the patient's episode of care, the patient is considered a Medicare/Medicaid patient. The payer source for services provided as part of a Medicaid waiver or home and community-based waiver program by a Medicare-approved HHA are coded as (3) Medicaid (traditional fee-for-service) at item M0150.

For non-Medicare/non-Medicaid patients (patients with only pay sources other than M0150 response 1, 2, 3, or 4, the HHA is not required to assess and collect OASIS as part of the comprehensive assessment and agency medical record. Alternatively, the HHA must use its own comprehensive assessment as the requirement to collect OASIS data is temporarily suspended. Non-Medicare/non-Medicaid payer sources include private insurance, private HMO/Managed Care, self pay, programs funded under the Act: for example, Title III, V, XX, or other Government programs.

HHAs must have a computer system that supports transmission of OASIS data via the CMSnet to the SA (or other designated location), transmits the export file, and receives validation information. CMS provides HHAs access to the CMSnet, a private communications network CMS purchased to ensure the security of OASIS data transmissions to the State. Use of the CMSnet allows for all data submitted to the OASIS State System to be encrypted during the transmission process precluding any unauthorized sources from intercepting identifiable data. Similarly, data reports, which are sent by the OASIS State System to the HHA across the CMSnet are also automatically encrypted and decoded. This network encryption occurs automatically when the HHA uses the CMSnet and requires no special action on the part of the HHA other than using browser software that supports industry standard encryption.

HHAs need two different sets of user identification numbers and passwords; one

set to access the CMSnet and one set to access the OASIS System. User identifications and Passwords to access the OASIS State System to submit assessments or obtain CASPER reports are now specific to individuals(2) and should not be shared. The CMSnet is how HHAs transmit their OASIS data. HHAs must install the communications software, which is separate from the HAVEN software, which will allow them to access the CMSnet.

1.) The supported version of the dialer/CMS vendor is posted on the CMSNet page on https://www.qtso.com/mdcn.html. The helpdesk that supports the CMS vendor is the CMSnet Help Desk. Their phone number is: 1-800-905-2069 Opt 2.
In the event that CMS changes telecommunication vendors, updates to requirements will be made known on the All State Technical Call and on the QTSO website.

2.) Instructions for downloading and installing this software are available on the OASIS Web site. Alternatively, HHAs can call the HAVEN help desk at 1-877-201-4721 for help in obtaining and installing this software.

When the OASIS System receives a transmission file, it validates the reported information while the HHA remains on-line to ensure that some basic elements conform to CMS requirements, such as proper format and HHA information. Once these file checks are complete, a message indicating whether the file has been accepted or rejected is automatically sent back to the HHA's computer via the agency's communication link. If the submission is rejected, an informative message is sent to the HHA.

A file may be rejected for a variety of reasons. For example, the HHA Facility ID in the header record may be incorrect and not match the Facility ID at the State, or the number of records indicated in the trailer record is different from the actual number of records submitted. The HHA needs to make the corrections and re-submit the file to the State. If the submission passes the initial validation check, the file is checked further for errors or exceptions to the data specifications and a Final Validation Report is generated up to 48 hours later.

4. Data Format

The format used for encoding and transmitting OASIS data should conform with software available from CMS or other software that conforms to the CMS standard layout, edit specifications, and data dictionary including the OASIS data set. Details regarding these specifications are available on the OASIS Web site. The software must also include the most current version of the OASIS data items which will be available on the OASIS Web site at all times. CMS provides registered HAVEN users with instructions for any revised HAVEN software.

HAVEN will prompt the user to enter the data items associated with a required time point by providing the user with the correct screens for the specific type of assessment data required. HHAs will be able to use HAVEN to encode OASIS

data, maintain agency and patient-specific OASIS information, and create export files to submit OASIS data to the OASIS System. HAVEN provides comprehensive on-line help for encoding, editing, and transmitting these data sets. Additionally, the HAVEN help line (1-877-201-4721) is available to HHAs with questions concerning the installation and use of HAVEN.

The export function in HAVEN produces an ASCII text file from the HAVEN database. The file meets the OASIS data specifications that must be transmitted to the system. The OASIS System will reject all assessments with a non-Medicare/non-Medicaid payment source; therefore HAVEN will not include these assessments in the export file.

The following chart summarizes the required time points and time frames outlined in the regulations for collection, encoding, and reporting OASIS data.

OASIS ASSESSMENT REFERENCE SHEET

RFA = Reason For Assessment

RFA Type	RFA Description	Assessment Completed	Locked Date	Submission Timing
01	SOC - further visits planned	Within 5 calendar days following the SOC Date (M0030)	Effective 6/21/2006 No required lock date	Effective 6/21/2006 Transmission required within 30 calendar days of completing the assessment (M0090)
02	SOC - no further visits planned	Within 5 calendar days following the SOC Date (M0030)		
03	ROC - after inpatient stay	Within 2 calendar days following the ROC Date (M0032)		
04	Recertification - Follow-up	Completed (M0090) every 60 days following SOC: no earlier than day 56 and no later than the day (day 60) on which the certification period ends		
05	Other Follow-up	Complete assessment (M0090) within 2 calendar days following identification of significant change of patient's condition		

RFA Type	RFA Description	Assessment Completed	Locked Date	Submission Timing
06	Transferred to inpatient facility - not discharged from agency	Within 2 calendar days following or knowledge of disch/trans/death date (M0906)		
07	Transferred to inpatient facility - discharged from agency	Within 2 calendar days following or knowledge of disch/trans/death date (M0906)		
08	Died at home	Within 2 calendar days following or knowledge of disch/trans/death date (M0906)		
09	Discharged from agency: Not to inpatient facility	Within 2 calendar days following or knowledge of disch/trans/death date (M0906)		

2202.8D - Condition of Participation: Release of Patient Identifiable OASIS Information

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

This CoP states that an agent acting on behalf of the agency, in accordance with a written contract, must ensure the confidentiality of all patient identifiable information contained in the clinical record, and may not release it to the public.

The purpose of this provision is to ensure that access to all OASIS data (hard copy as well as electronic data) is secured and controlled by the HHA. This requirement mandates that the HHA ensures the confidentiality of all patient identifiable OASIS information contained in the clinical record and may not release it for any reason other than for what it is intended, which is to transmit to the SA for the development of outcome reports. The HHA's policies should include assignment and maintenance of secure passwords required for encoding and transmitting OASIS data. Policies should narrowly define the qualifications of individuals having access to the OASIS software. For security reasons, passwords are required in the HHA for access to the agency's computer system. A separate password is required for transmitting the OASIS data files to the SA. Privacy and confidentiality of OASIS data are extremely important. Coverage under the Federal Privacy Act of 1974 begins when the data reaches the SA. The Privacy Act protects OASIS data from unauthorized use and disclosure and has been effective in ensuring confidentiality of Medicare data.

HHAs may choose to encode and transmit OASIS data to the SA themselves, or may contract with an outside entity (agent) to fulfill these requirements. Agents acting on behalf of the HHA, such as a data entry and submission vendor or contractor, guided by a written contract, are bound by the same confidentiality rules. The HHA is ultimately responsible for compliance with the confidentiality requirements and is the responsible party if the contractor does not meet the requirements. HHAs using HAVEN are prompted to enter agent information during set up of the HAVEN program.

Data in the hands of an entity contracted by the HHA for data transmission is not covered by the protections of the Privacy Act, therefore policies related to the security of the OASIS data set are required. HHAs contracting with outside entities for data submission are ultimately responsible for the confidentiality and use of that data. Agreements between HHAs and their contractors should specify that the data is only to be used for its intended purpose, that is, to create outcome reports. As such, identifiable data must be treated in accordance with State law and must not be disclosed without patient consent. Violations of data confidentiality by an entity contracted by the HHA are the responsibility of the HHA and would constitute condition-level non-compliance.

Agents must be aware of the requirements and security policies of the HHA and the SA concerning passwords, as well as the requirements of the OASIS System of Records and the Privacy Act.

2202.9 - Patient Notification of OASIS Collection and Reporting
(Rev. 1, 05-21-04)

Under existing patient rights regulations (42 CFR 484.10(a) and (d), the HHA must provide the patient with a written notice of the patient's rights to confidentiality of medical records in advance of furnishing care to the patient. As part of the patient's rights, the HHA is required to notify the patient of its policies and procedures for disclosure (confidentiality) of clinical records at the time of admission. The HHA must maintain documentation showing that this requirement has been completed; therefore, HHAs must develop admission policies that encourage patient compliance with assessment procedures. Failure to collect and report accurate and complete OASIS data on all applicable patients places the HHA at risk of losing its Medicare certification. States will be able to monitor whether HHAs are submitting the required OASIS information through use of data management reports. While patients have the right to refuse to answer questions posed by the HHA, very few OASIS data items rely solely on direct patient questioning. Therefore, HHAs must complete all OASIS data items as best they can, using their assessment skills.

2202.9A - Informing Patients of OASIS Collection and Reporting
(Rev. 1, 05-21-04)

On or after July 19, 1999, HHAs were required to provide existing patients with privacy notifications. To properly inform patients of their rights under the Privacy Act, the provider must furnish each patient with information required by the Privacy Act. Under the authority of the Privacy Act, notices must contain the following information:

- The right to be informed that OASIS information will be collected and the purpose of collection;

- The right to have the information kept confidential and secure;

- The right to be informed that OASIS information will not be disclosed except for legitimate purposes allowed by the Federal Privacy Act;

- The right to refuse to answer questions; and

- The right to see, review, and request changes on their assessment.

The statements of patient privacy rights with regard to the OASIS collection (one for Medicare/Medicaid patients, one for all other patients served by the HHA) are available on the OASIS Web site as part of the June 18, 1999, "Federal Register" notice. HHAs must include these statements as part of their admission information. Effective December 8, 2003, HHAs who choose to collect OASIS data on their non-Medicare /non-Medicaid patients must continue to comply with informing patients with privacy notifications. HHAs that do not collect OASIS data on non-Medicare/non-Medicaid patients are no longer required to provide the Privacy Act notification.

2202.9B - Right to See, Review, and Request Changes

(Rev. 188, Issued: 04-26-19, Effective: 04-26-19, Implementation: 04-26-19)

The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.

The "Federal Register" notice of June 18, 1999, requires that, under the Privacy Act, Medicare/Medicaid patients have the right to see, review, and request changes in their assessments. HHAs must accommodate patients (or their representative), who request this review. If the patient disputes OASIS information collected as part of a comprehensive assessment, the HHA has two options; it can agree or disagree with the dispute.

1. The HHA Agrees.--If the HHA agrees with the patient's request, it accepts the request, and changes the applicable OASIS data item(s) on the assessment. A corrected assessment can be submitted to the State, using the terms of the OASIS correction policy.

2. The HHA Disagrees.--If the HHA disagrees with the patient's request, the patient should request written documentation that the disputed information will not be changed by the HHA including the reason(s) why.

If a patient chooses to pursue his/her request at the Federal level, he/she may contact CMS

at 1-800-Medicare, toll free, for further review of the disputed issue. The individual contesting a record will be advised to write to the Privacy Officer, CMS, 7500 Security Boulevard, Baltimore, Maryland, 21244-1850, identify the record, and specify the information being contested. This correspondence must include the HHA's written documentation refusing the change. It must also state the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with the Department's regulations (45 CFR 5b.7.) To preserve the privacy of the OASIS/HHA system of records, the Privacy Act Privacy Officer may require that the individual provide the following information for verification purposes: The system name, Medicare beneficiary identifier, and, for verification purposes, the individual's name (woman's maiden name, if applicable), social security number, address, date of birth, and sex. (Furnishing the social security number is voluntary, but it may make searching for a record easier and prevent delay.) This information must be notarized to preserve the confidentiality of this process.

The HHA Medicare/Medicaid patient who wants to know if there is a record belonging to him/her in the OASIS/HHA system of records, or wants to review the record contained in the CMS OASIS/HHA system of records repository would follow the same process. The patient can contact CMS toll free at 1-800-Medicare to get instructions for how to pursue his/her request.

2202.10 - OASIS and HHAs Seeking Initial Certification

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

Prior to receiving Medicare approval, HHAs must meet certain requirements, including enrollment and capitalization, and must provide skilled home health services to a minimum of 10 patients (not necessarily Medicare patients) that is consistent with the Medicare home health CoPs. This includes compliance with the OASIS collection and transmission requirements. New HHAs must demonstrate that they can transmit OASIS data prior to the initial certification survey. Specifically, new HHAs must apply for a user identification number and password from the State OASIS automation coordinator in order to register for an individual user identification and password which is used to electronically transmit to the OASIS System any encoded and locked SOC or ROC OASIS assessment record(s) for applicable Medicare and Medicaid patients in a test mode. HHA survey staff must communicate with the OASIS coordinators to determine this aspect of compliance prior to the initial onsite survey. SAs and AOs with deeming authority should not schedule initial surveys until the SA or AO has determined the HHA's status with the OASIS transmission requirement. AOs may contact the state directly to determine the status of the new HHA's activities concerning the OASIS transmission process prior to scheduling the onsite survey. The names and phone numbers of the State OASIS contacts are found on the OASIS Web site.

To acquire an HHA personal login ID, agencies will be required to complete and submit the CMSNet Access Request form and the OASIS Individual User Account Request form. The forms are available on the QIES Technical Support Office website (https://www.qtso.com/). To meet the OASIS transmission requirements prior to the initial certification survey, new HHAs need two different sets of user identification

numbers and passwords; one set to access the CMSnet and one set to access the OASIS System.

The OASIS automation coordinator in each SA should assist the new HHA in obtaining the user identification numbers and passwords and guide HHAs through registration for an individual user identification and password prior to the initial certification survey. Once the communications software and access are in place, the new HHA must demonstrate that it can transmit OASIS data to the OASIS System by (1) making a test transmission of any SOC or ROC OASIS data that passes CMS edit checks; and (2) receiving validation reports back from the OASIS System confirming data transmission.

Transmissions of test data prior to the OASIS System successfully uploading the certification kit in ASPEN will result in any submission file being processed as a test submission. The user will receive a final validation report showing any warning and fatal error messages associated with each record. However no data will be stored on the database until the initial certification kit has been successfully uploaded. Unless submitted as a test, once the certification kit is successfully uploaded all assessment data will be treated as live data and stored on the database.

2202.10A - Determining Compliance With the OASIS Transmission Requirements

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

Depending on the method of transmission the HHA chooses, the SA needs to determine compliance in one of the following ways:

- If the new HHA chooses to independently transmit OASIS data from its own office, the State HHA survey team and OASIS coordinator must communicate with each other to establish that the new HHA has successfully transmitted test OASIS data using the appropriate user identification numbers and passwords, prior to onsite survey. The HHA should maintain all copies of validation reports for its records.

- If the new HHA chooses to use a software vendor to meet the OASIS encoding and/or transmission requirement on its behalf, the HHA must still establish connectivity to the OASIS System via the software vendor. The HHA should have a written contract that describes this arrangement. The vendor and/or other certified HHA will need to apply for access to this agency as a Third Party Submitter. Forms are available on QTSO at: https://www.qtso.com/accesshha.html.

- The HHA or its software vendor must apply for the applicable user identification numbers and passwords from the SA in order to establish connectivity with the OASIS System. As described above, the HHA survey team and OASIS coordinator must communicate with each other to establish that the software vendor, on behalf of the new HHA, has successfully transmitted test OASIS data using the appropriate user identification numbers and passwords, prior to onsite

survey. The HHA should obtain copies of all validation reports from its software vendor for its records.

- If the new HHA chooses to use another certified HHA to meet its transmission requirements, for example, another established HHA in the chain or other established but non-related HHA, the HHA must still demonstrate connectivity to the OASIS System via the other established certified HHA. The new HHA or other HHA must apply for user identification numbers and passwords, unique to the new agency, from the SA, in order to establish connectivity with the OASIS System. The new HHA must have clearly written policies outlining the procedures in place with the other HHA with regard to OASIS collection, encoding and submission to the OASIS State System and the sharing of feedback reports from the OASIS System with the new HHA.

2202.10B - HHAs Seeking Initial Certification Through Deemed Status

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

An HHA may choose to obtain initial Medicare certification by electing the deemed status option through an approved AO that has been granted deeming authority for Medicare requirements for HHAs. There are currently three AOs with deeming authority for HHAs - the Joint Commission (TJC), the Community Health Accreditation Program (CHAP), and the Accreditation Commission for Health Care, Inc. HHAs seeking initial certification through the deemed status option must still apply to the SA for user identification numbers and register as an individual in order to demonstrate compliance with OASIS submission requirements prior to approval.

When the SA receives a request from an HHA interested in seeking Medicare deemed status through accreditation by an AO with deeming authority, the State ensures that the HHA understands its obligation to meet the OASIS requirements, even when the AO conducts the initial certification survey. This includes compliance with the OASIS collection and transmission requirements.

If the SA receives a certification packet from an HHA seeking Medicare certification based on its accreditation through a deemed status program, it is the SA's responsibility to determine that the HHA meets its OASIS transmission responsibilities. The OASIS transmission responsibility may be met in one of the three ways described above.

2202.10C - Exceptions to Demonstrating Compliance With OASIS Submission Requirements Prior to Approval

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

New HHAs that intend to admit or treat only patients to whom OASIS currently does not apply, i.e., patients under 18, maternity, and patients receiving only unskilled care or chore services are not expected to demonstrate compliance with OASIS submission requirements prior to approval.

These HHAs must attest this intention to the SA. After certification, if there is a change in

the HHA's policies that includes the acceptance of patients to whom OASIS applies, the HHA is expected to install the necessary communications software and contact the SA and CMSnet for the applicable user identification numbers and passwords.

2202.10D - Compliance Dates and PPS

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

Compliance with the rest of the CoPs is determined via an onsite survey by the SA and any applicable subsequent actions or revisions required of the HHA following the initial survey. After survey, the new HHA cannot bill Medicare for payment of services to Medicare beneficiaries until the effective date for Medicare participation has been determined by the CMS RO.

Realistically, notification of the effective date may come many weeks after the initial survey of the HHA. In addition, the date of official compliance may vary depending on the outcome of the onsite survey. As described in §2780, the date of compliance is either:

1. The date the onsite survey is completed if, on the date of the survey the HHA meets all CoPs and any other requirements required by CMS; or

2. If the HHA fails to meet any of the requirements as a result of the onsite survey, compliance is the earlier of:

    - The date the HHA meets all enrollment requirements; or

    - The date the HHA meets all the CoPs and submits an acceptable plan of correction for standard level deficiencies.

Payment under Medicare for services provided prior to the effective date for Medicare participation is not permitted. As such, it is important that new HHAs seeking payment under Medicare establish the required 60-day episode on or after the effective date of their Medicare participation.

2202.10E - Instructions for Handling Medicare Patients in HHAs Seeking Initial Certification

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

The Medicare OASIS submission and billing process cannot begin until the effective date of the HHA's CCN, which is assigned after the RO has done the review of the initial survey findings, plan of correction if one was necessary, documentation on whether the HHA has met the enrollment requirements, and documentation that the MAC has completed the second capitalization review. Enrollment requirements include completion of the CMS Form 855A, first capitalization review, completion of a survey by a SA or RO with the HHA in compliance with the CoPs, additional development by the MAC and second capitalization review by the MAC. After it is assigned its CMS certification number (CCN) by the RO, the HHA should do a new SOC assessment (RFA 1) on each of its Medicare eligible patients. This assessment visit date should be consistent with the

first billable visit date after Medicare participation becomes effective.

Once the CCN has been assigned, the HHA can go back and encode the collected OASIS information, obtain the necessary payment system codes for billing under PPS, and transmit the information to the OASIS State System as production (i.e., "live") data. The date of this assessment will become day 1 of the HHA's first 60-day episode under Medicare, as long as the assessment was done in conjunction with a billable visit. Warning messages related to noncompliance with timing requirements are unavoidable and are to be expected in this situation.

If compliance (i.e., the effective date) is not the date of the onsite survey, it will be based on D.2. above, as further outlined in §2780. The HHA should, again, do a new SOC assessment (RFA 1) on each of its Medicare patients at the first billable visit after the anticipated date of compliance, delay encoding and transmitting the assessment until the CCN is assigned, and continue as outlined in the paragraph above. That is, the HHA should go back and encode the collected OASIS information, obtain the necessary payment codes for billing under PPS, and transmit the information to the OASIS State System as production data. As above, warning messages related to noncompliance with timing requirements are unavoidable and are to be expected in this situation.

If the new HHA did not conduct a SOC (RFA 1), ROC (RFA 3), or Follow-up (RFA 4) OASIS assessment during the time between the effective date for Medicare participation and the date the HHA learns of its approval, the HHA should conduct a SOC assessment, as soon as possible. This assessment can be used to generate the payment code used for billing under Medicare. The SOC date should reflect a date that is consistent with the first billable visit after the effective date for Medicare participation, as stated above.

2202.10F - Instructions to New HHAs Concerning all Other Patients

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

Non-Medicare and Non-Medicaid patients do not require OASIS collection or transmission.

For all other patients treated by the HHA (i.e., non-Medicare or non-Medicaid patients), if a new start of care date is not required by the patient's payer source, the HHA should encode and transmit all OASIS assessments as required by current regulation that were collected after the effective date of Medicare participation. These assessments should be submitted in the production mode using the newly assigned provider number. The HHA should continue with the OASIS assessment schedule already established based on the patient's admission date.

2202.11 - Correction Policy

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

HHAs have the ability to electronically correct nearly all errors found in their production OASIS submissions. SAs should not be accepting requests for manual key field changes. Instead, HHAs should use the inactivation procedures to correct assessments containing

key field errors. HAVEN 5.0 and above will give HHAs the ability to electronically correct nearly any kind of assessment errors.

CMS strongly recommends that all HHAs install the most updated version of HAVEN. OASIS HAVEN software may be adjusted over time to incorporate changes in system components as well as incorporate bug fixes. Adjustments will be posted to the HAVEN Data Entry Software web page on the CMS Web site at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/index.html?redirect=/oasis/and on the OASIS State Systems.

Key Fields and Non-Key Fields

A description of key fields is below. Non-key fields are all other fields making up the OASIS data set that are not key fields.

KEY FIELDS	
Patient Identifiers:	
M0040_PAT_LNAME	Patient last name
M0040_PAT_FNAME	Patient first name
M0064_SSN	Patient social security number
M0066_PAT_BIRTH_DT	Patient date of birth
M0069_PAT_GENDER	Patient gender
HHA Identifiers:	
HHA_AGENCY_ID	Unique Agency ID code
Assessment Event Identifiers:	
M0100_ASSMT_REASON	Reason for completing assessment
M0090_INFO_COMPLETED_DT	Date assessment information completed (This is a key field only on recertification or follow-up assessments where RFA = 04 or 05)
M0030_START_CARE_DT	SOC date (This is a key field only on SOC assessments where RFA = 01)
M0032_ROC_DT	ROC date (This is a key field only on ROC assessments where RFA = 03)
M0906_DC_TRAN_DTH_DT	Discharge, transfer, death date (This is a key field only on transfer to inpatient facility assessments where RFA = 06 or 07, death at home assessments where RFA = 08 and discharge assessments where RFA = 09)

HHAs can electronically correct key field errors in production records in addition to non-key field errors and also remove erroneous records using an automated methodology called inactivation. With the ability to inactivate erroneous OASIS assessments, as described below, HHAs will be able to remove assessments from the OASIS State System's active database that have been submitted in error. These records are not actually deleted, but are moved from the active database to a history database that contains records

that have been modified or inactivated. This approach keeps an audit trail of modified and inactivated records, but "hides" them from the normal OASIS State System reporting procedures.

2202.11A - Determining When to Inactivate an Assessment

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

If an error has been made in one or more key fields, or if an assessment was submitted in error, the HHA should electronically inactivate it. Use of the inactivation procedure is not applicable to correcting assessments with only non-key field errors. In other words, if an assessment contains errors in only non-key fields, then correction type 3 described at C.3. below should be used. In order to determine whether to submit an inactivation request, the user should apply the following rules:

1. Assessment Submitted in Error

   If an assessment was submitted in error (i.e., it should never have been submitted), it must be inactivated. For example, if a discharge assessment was submitted by the therapist; however, the patient is still being visited by the nurse, an inactivation request must be submitted for the erroneous discharge record. Another reason to inactivate an assessment would be if the submitted assessment contained the wrong patient name.

2. Error in Key Field

   If an assessment was submitted which contained an error in any of the key fields listed above, then an inactivation request must be submitted. Normally, the HHA will also submit a new, corrected assessment in this situation. For example, if the HHA discovers that the patient's last name on the SOC assessment is spelled "Smyth," while on the Follow-up assessment it is spelled "Smith," it needs to make the appropriate correction. When the HHA determines the discrepancy, the incorrect record must be inactivated and a new corrected record must be submitted.

3. Submission of Incorrect Format

   Private Pay assessments are now rejected upon submission and do not require inactivation.

NOTE: There is no automatic mechanism to reactivate a record that has been inactivated. Consider the case where a discharge assessment is submitted to the OASIS State System for a patient, but is inadvertently inactivated. There is no means to "undo" the inactivation and thereby "reactivate" this discharge. Instead the HHA must submit the discharge record again. An inactivated record can only be "undone" by the re-submission of the record.

2202.11B - Deleting Assessments

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

In certain infrequent situations, inactivation is not sufficient to correct assessment errors

since inactivation alone does not remove the assessment record from the OASIS System. Two situations require deletion of an erroneous assessment, rather than inactivation. States will need to continue to submit deletion requests on behalf of HHAs, upon request, to the CMS Division of National Systems (DNS) contractor when the following situations occur.

1. Assessment Deletion

The HHA submits identifiable data on patients not defined by the OASIS system of records. The OASIS repository is limited to the collection of identifiable data on patients who are Medicare and/or Medicaid patients receiving skilled care with certain exceptions, i.e., under 18 and maternity patients. In instances where the OASIS System has received OASIS data on patients not included as part of the OASIS System of Records, the data needs to be deleted.

EXAMPLE: The HHA checks Response 1, 2, 3, and/or 4 in the Current Payment Source (M0150 field) for that assessment record **and it should not have**. The record is transmitted to the OASIS System and accepted. The HHA determines that the response for M0150 is in error. The patient was not a Medicare or Medicaid patient; therefore, this data should not be stored on the OASIS database.

EXAMPLE: The HHA submits an incorrect birth date on a patient who is a year old, which was accepted because the birth year identified the patient as being over 18. The patient was actually under 18 and the assessment should be deleted.

Deletion Request forms are located on the State password protected Page of the QTSO website. CMS requires the signature of the agency administrator and of the SA before the deletion will be processed.

The HHA must send the Deletion Request Form in writing to the State OASIS coordinator to request deletion of an assessment. The State will then send in writing to DNS contractor, the reason this data should be removed from the State's database.

*Effective dates are:

M0030_START_CARE_DT for RFA types 01;

M0032_ROC_DT for RFA type 03;

M0090_INFO_COMPLETED_DT for RFA types 04 & 05; and

M0906_DC_TRAN_DTH_DT for RFA types 06, 07, 08, & 09.

2. File Deletion

The HHA submits a file as "Production" data instead of "Test" data. The State must verify the HHA's claim of "Production" data versus "Test" data. The HHA must send

the following information in writing to the State coordinator to request deletion of a file:

- HHA Name;
- HHA ID;
- Submission Date/Time;
- Submission Batch ID; and
- Reason this data should be removed from the State's database.

The State will then send in writing to the CMS contractor following information to request deletion of a file:

- HHA Name;
- HHA ID;
- Submission Date/Time;
- Submission Batch ID; and
- Reason this data should be removed from the State's database.

The following events will then take place:

The CMS DNS Contractor will create a report from the above listed information. This report will be sent to the State OASIS Coordinator for him/her to verify the accuracy of assessment(s) to be deleted from the State's database.

- The OASIS Coordinator will notify the CMS DNS contractor that the information is accurate and should be deleted from the State's database.
- The CMS DNS contractor will consult with CMS on any questionable deletion requests.
- The CMS DNS contractor will delete the data upon approval from CMS.
- The CMS DNS contractor will keep a log of all deleted data from each State's database.

The deletion request information should be communicated to the CMS DNS contractor by one of the following methods of communication:

The Deletion Request Form directs states to forward the signed form to the CMS

DNS contractor via certified mail to the address on the form.

The deletion request sheets must be submitted to the CMS DNS contractor by the State. Requests received directly from HHA will not be accepted.

NOTE: This information MUST NOT be sent via e-mail due to the confidentiality of the information.

2202.11C - Types of Corrections an HHA Can Make in HAVEN

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

HAVEN offers the following menu of corrections an HHA can make:

1. Assessment was Submitted to the State and was Rejected

The HHA can unlock the assessment, make the necessary changes, and re-submit it. Because of the built-in edit checks, HHAs using the HAVEN software should not expect records to be rejected by the OASIS System for this reason. Note that the following examples are provided for illustration purposes to troubleshoot HAVEN-like software, but **cannot** occur in HAVEN.

EXAMPLE 1: The HHA Agency ID field in one or more assessment records does not match the HHA Agency ID in the header record of the submission file. The entire submission file is rejected and no data is loaded into the state database.

EXAMPLE 2: The patient's last name was missing from the assessment file (data record). The HHA may have inadvertently left this field blank. The OASIS System must have the patient's last name. The data record in this example would be rejected and no data from this record would be loaded into the state database.

In these examples, the HHA would make the necessary corrections and re-submit the record. Since the OASIS System never accepted the original assessment, the correction number field IS NOT incremented in this situation. HHAs may still receive a warning if submission/timing guidelines have been exceeded.

2. Assessment was Submitted to the State and was Accepted. Correction to Key Fields is Necessary

With the implementation of the OASIS System update, this option will display in HAVEN but will no longer be available and is disabled in the HAVEN software. To correct an assessment with key field errors, first inactivate the assessment, then create a new assessment for re-submission, as applicable. See correction type 4 below.

3. Assessment was Submitted to the State and was Accepted. Correction to Non-Key Fields is Necessary

If an HHA determines that a correction(s) must be made to non-key fields only (i.e.,

any fields in the OASIS data set not contained in the key fields listed above), the HHA should re-open the assessment, revise the targeted non-key fields, and re-lock and re-submit the corrected record. The lock date changes to reflect the date the correction was made.

NOTE: "CORRECTION_NUM" is a counter field contained in the programming of the HAVEN software used to track corrections made to an assessment record. The counter field is set to 00 when an assessment record is initially locked. The counter field is incremented in this case. Both the original assessment and the corrected assessment will be stored in the state database.

4. Assessment was Submitted to the State and was Accepted. Inactivation of the Assessment is Necessary

This is an option in HAVEN that allows HHAs to correct key field errors by inactivating the assessment(s) containing key field errors and re-submitting a new, corrected assessment. Unlike making non-key field changes, as described in correction type 3 above, the HHA does not simply unlock the assessment record, make the necessary key field changes, re-lock the record, and re-submit it. Instead, the HHA is taken directly to the assessment in question where it can be viewed in a read-only format. While in read-only mode, when the HHA confirms that the assessment should be inactivated, HAVEN will ask the HHA to commit to this selection. The correction number field on the HAVEN Management screen displays an "X" and the assessment status is set to Export Ready." The "value of '99'" indicates that this assessment has been inactivated.

When the HHA selects this correction type, a copy of the original assessment record is created. To re-submit the assessment with the necessary corrections, the HHA first exports the assessment that is being inactivated. From the HAVEN Management screen, the HHA then selects the inactivated record in question and clicks on the "Correct Assessment" button. A pop-up box will appear asking if the HHA wants to create a new assessment containing data from the inactivated assessment. When the HHA clicks on the "OK" button, a copy of the original assessment appears. The HHA makes the necessary changes and re-submits the assessment. The correction number for this assessment is reset to 00.

2202.11D - Documentation of Corrected Assessments
(Rev. 1, 05-21-04)

When a comprehensive assessment is corrected, the HHA must maintain the original assessment record as well as all subsequent corrected assessments in the patient's clinical record in accordance with current clinical record requirements at 42 CFR 484. If maintained electronically, the HHA must be capable of retrieving and reproducing a hard copy of these assessments upon request. It is acceptable to have multiple corrected assessments for an OASIS assessment, as long as the OASIS and the clinical record are documented in accordance with the clinical record requirements at 42 CFR 484.

2202.11E - Clinical Implications of Corrected Assessment Records
(Rev. 1, 05-21-04)

When corrections are made to an assessment already submitted to the OASIS State System, the HHA must determine if there is an impact on the patient's current care plan. If there is an impact, in addition to the correction made to the assessment, the HHA must make corresponding changes to the current care plan. If there are any other records where the correction has an impact, for example, the Home Health Resource Group, the Plan of Treatment (CMS Form-485), or the Request for Anticipated Payment, the agency should make corresponding changes to that record, as applicable. The agency should establish a procedure to review the impact of any corrections made to assessment records and make corresponding changes to other records that are affected.

2202.11F - Regarding Corrections in Lieu of Required Assessments
(Rev. 1, 05-21-04)

Collection and submission of information on SOC, ROC, Follow-up, Other Follow-up, transfer, and discharge assessments are required by the comprehensive assessment requirements at 42 CFR 484. The correction process described here does not preclude the need for accurate patient assessment at the required time points.

The inactivation of an assessment and subsequent correction and re-submission of a new assessment, or a correction to a non-key field cannot be used in lieu of the appropriate OASIS assessment for documenting an unanticipated change in patient condition that was not envisioned in the original plan of care. If there is an unexpected change in the patient's clinical condition due to a major decline or improvement in health status that warrants a change in plan of treatment, the appropriate OASIS assessment is expected to document the change, i.e., the ROC or Other Follow-up assessment, as appropriate. This is in keeping with the regulation at 42 CFR 484.20(b) for accuracy of encoded OASIS data that states, "The encoded OASIS data must accurately reflect the patient's status at the time of assessment." The HHA should have one document for the patient's assessment, care planning, and payment purposes.

2202.11G - Timeliness of Corrections
(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

HHAs are urged to make corrections and/or submit inactivations as quickly as possible after errors are identified so the state system will be as current and accurate as possible prior to HHA submission of the RAP. This also affects the data used to calculate the HHA's OBQI and OBQM reports.

2202.11H - Multiple Corrections in a Record
(Rev. 1, 05-21-04)

Correcting assessments with key field errors can only be done by inactivating the incorrect assessments and replacing them with the corrected assessments, as previously described above. Correcting assessments with non-key field errors can only be done by re-opening

the assessment, revising the targeted non-key fields, re-locking and re-submitting the assessment, as previously described above. “CORRECTION_NUM” (the counter field) is implemented in non-key field changes. For more specific information concerning the process of correction and inactivation, refer to the OASIS data specification notes on the OASIS web site.

See below for a flow chart depicting the most common situations necessitating corrections

2202.12 - OASIS State System

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

The purpose of the OASIS State System is to provide computerized storage, access, and analysis of the OASIS data on patients in HHAs across the nation. The OASIS State System is intended to create a standard, nationwide system for connecting HHAs to their respective SAs for the purpose of electronic interchange of data, reports, and other information. The automated OASIS system is a critical component of SA and CMS operations. It is a key part of a fully integrated system of clinical data, facility demographics, survey findings, and SA operations information. The OASIS State System also provides the means for transmission of assessment data to CMS for validating payments under prospective payment for HHAs.

The OASIS State System implementation involved a CMS-funded installation of standardized computer hardware and data management software at each SA to allow electronic transfer of OASIS data elements from all HHAs to the State. The data management software:

Validates the basic accuracy of the data and rejects submission files (batches) with fatal file errors, such as a missing or invalid agency ID, incorrect record length, or missing headers or trailers;

Validates individual assessment records and rejects those records with fatal record errors;

Stores and reports non-fatal or warning errors on records that are accepted by the database; and

Builds a database of OASIS information for all applicable patients of each HHA in the State.

In accordance with the regulations, HHAs will collect SOC, ROC, follow-up, discharge to the community, transfer to an inpatient facility (with or without discharge), and death at home OASIS data on all patients (except those under 18; those receiving maternity services; and patients receiving only housekeeping or chore services) under the care of the HHA as of July 19, 1999, as applicable. The requirements for OASIS collection, encoding, and transmission apply to all Medicare and Medicaid patients, including Medicare and Medicaid HMO/Managed Care patients (with the exception of those listed above) receiving skilled services. The applicability of the comprehensive assessment and reporting regulations to patients receiving personal care only services, regardless of payer

source, has been delayed until further notice. In addition, the collection, encoding and transmission requirement for non-Medicare and non-Medicaid patients receiving skilled care is also temporarily suspended until further notice. Until collection and submission of non-Medicare/non-Medicaid patient assessments is required, HHAs must meet all other requirements of the comprehensive assessment regulation including conducting SOC comprehensive assessments and updates at the required time points on all non-Medicare and non-Medicaid patients receiving skilled services, although the OASIS data items are not required. This means that only the requirement to collect, encode and transmit OASIS data is delayed. The completion of the comprehensive assessment and updates at the required time points is required in order to ensure quality of care for all patients and to encourage the use of OASIS as the basis for care planning.

Effective August 24, 1999, and at least monthly thereafter, HHAs should transmit to the SA all applicable OASIS data collected and encoded from July 19, 1999, and monthly thereafter. Monthly transmissions should include all OASIS data encoded in the previous month.

OASIS activities will provide enhanced analytical capabilities at the SAs; electronic transmission from the State databases to a national repository; integration with performance indicators for quality oversight and survey planning by the SA; a basis for maintaining prospective payment of HHAs; research directed at improving quality of care; feedback to providers; and dissemination of information to purchasers, beneficiaries, and others.

2202.12A - System Description

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

The CMS has provided each State with an OASIS State System composed of standardized hardware and software platforms scaled to meet each State's anticipated processing volumes, and a standardized operating system. The hardware is comprised of a communications server, database server, the local area network, and other peripheral devices.

The OASIS State System deployed to each State was specifically engineered and purchased to fulfill the OASIS requirements of §484 and §488, as well as to incorporate additional CMS provider assessment processes as they become effective, and operational support of Medicare and Medicaid Survey and Certification pursuant to §1864 of the Act. The system was designed with an emphasis on flexibility and integration, so that additional software components could be easily added to provide the States with new related functionality (such as outcome measures and expanded analytical reports), as well as applications that support future assessment processes for other provider types, and new capabilities to support survey and certification operations. Since each State's OASIS system was specifically sized to accommodate these planned functions, the SA should not add other non-CMS prescribed applications or databases to it.

2202.12B - Administration Requirements

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

The OASIS State System in each State is part of a comprehensive, Quality Improvement and Evaluation System that will not only fulfill OASIS administration requirements, but also grow to support other assessment-based programs; quality and performance indicators; and new, integrated survey and certification data systems. The State should use the OASIS State System for editing, storing, and processing OASIS data to support CMS' OASIS operating requirements within the State and to transmit the required OASIS data to the CMS OASIS repository. As noted above, the State may not add additional software applications to the OASIS system without a specific directive from CMS.

The States are directly responsible for fulfilling requirements to operate the OASIS State System. However, the State may enter into an agreement with the State Medicaid agency, another State component, or a private contractor to perform day-to-day operations of the system.

The State must obtain RO approval prior to entering into an agreement with another agency**.** Such agreements should address the following provisions:

1. Meets confidentiality requirements: Federal Privacy Act, 5 U.S.C. §522a; HIAA of 1996; other applicable Federal data acts; §1902(a)(7) of the Act; applicable State standards; and industry security standards;

2. Gives the SA real-time access to the system to fully support all OASIS-driven functions which will be required of the survey agency (e.g., quality indicator reporting, survey targeting, etc.), or if a contractor is performing analysis for SA contract, provides the details on how this is to be conducted;

3. Complies with the need for high capacity, fault-tolerant network connections to ensure reliable support for the SAs, CMS' national database, and any other daily operations (e.g. Intermediary Medical Case Review, Office of the Inspector General or Department of Justice Fraud and Abuse activities), which will be affected by this system. Assures hardware will be properly maintained and upgraded as necessary to meet any future CMS or SA requirements. Assures adequate backup of all data;

4. Includes SA responsibilities for reporting OASIS data to a central repository at CMS. Designates responsibilities for edits and "cleanness" of data:

   - Designates responsibilities for generating and communicating facility error reports.

   - Describes what kinds of communication will be established, e.g., a State-specific Internet and/or Intranet web pages, newsletters, etc., their content, and who will produce/maintain/distribute these communications.

   If there is a separate database, designates who is responsible for operating and maintaining the CMS-provided equipment and who will assure the viability of the

CMS database;

5. Lists responsibilities of contractor and/or State for training and support operations: Includes at least who will provide facility and OASIS software vendor startup training, and on-going customer/facility support/troubleshooting; provide internal training and daily user support within the SA; work with program staff to integrate the OASIS system into SA functions; train SA staff on aspects of analytical system (e.g., ASPEN upgrades and "performance measure/quality indicator" linked reports); handle System Operations - functions associated with transmission logging, error tracking and resolution, system archival, and process reporting; and designate who is responsible for determining facility transmission schedules;

6. Delineates how State will fund the monthly line charges associated with installation, maintenance, and transmission of the OASIS data from the facilities to the contractor and between the contractor and State, e.g., built into contract costs or is an outside ongoing cost to the SA; and

7. Specifies whether it is the contractor's or the SA's responsibility for systems maintenance for commercial "off-the-shelf" OASIS hardware and software components.

NOTE: Standardized OASIS software components that are developed and distributed by CMS will be maintained and upgraded centrally by CMS.

Under any such arrangement, the State must be guaranteed real-time, priority access to this system to fully support all OASIS functions. All CMS privacy and confidentiality requirements must be met. Off-site operation of the OASIS State System will require high capacity, fault-tolerant network connections to ensure reliable support for the State's daily operations that will be affected by this system. The State also must use the OASIS State System for reporting OASIS data to the CMS central repository.

To promote national consistency in OASIS system operations and troubleshooting, each State should designate one individual as the OASIS automation project coordinator. This person is CMS' key contact within each State for managing OASIS State System issues and must be familiar with the use of the OASIS automation and transmission process. Technical knowledge of information systems is useful but far less critical than an understanding of the OASIS processes, good communication and project management skills, and the ability to educate and work with providers and vendors to ensure successful implementation of an automated process for all providers. The State should designate additional staff, including a System Administrator, to manage the technical aspects of running the OASIS State System and support staff to assist in processing corrections, answering routine user questions, assigning passwords, etc.

With respect to systems maintenance, the OASIS State System installed in each State is comprised of commercial, off-the-shelf hardware, and software components that are generally covered under typical umbrella service agreements that the State may already have in place for maintenance of data processing equipment. Those OASIS software

components that are developed and distributed by CMS will be maintained and upgraded centrally by CMS. The State will not be responsible for these software upgrades.

To the extent that the State has developed customized external applications for using information obtained from the OASIS database (e.g., to support Medicaid payment), the costs of developing and maintaining these additional software applications (and any related hardware components) will not be funded through the survey and certification budget.

2202.12C - Validation and Editing Process

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

Each time an HHA accesses the OASIS State System and transmits an assessment file, it performs a series of three levels of validations:

1. Fatal File Errors

   - The first check examines the basic structure and integrity of the submission file. If there are fatal flaws in the file (batch of records), then the entire file is rejected and the HHA is notified of the reason for rejection in the "Initial Feedback Report." In the event that a batch is rejected due to fatal file errors, the HHA will not receive a "Final Validation Report." Fatal file errors are listed in the data specifications, which can be found on the OASIS Web site. Rejected files must be corrected and retransmitted.

2. Fatal Record Errors

   - If the file structure is acceptable, then each record in the file is examined individually for fatal record errors. These errors may cause an individual assessment within a submission to be rejected. Assessments that have fatal records are not stored in the database. The HHA is informed of fatal record errors on the "Final Validation Report." OASIS data specifications outline the valid data requirements and are posted on the OASIS Web site.

   The Initial Feedback and Final Validation reports are available shortly following the submission of a file.

3. Non-Fatal or Warning Errors

   If there are no fatal record errors, the record is loaded into the State database and the record is further examined for non-fatal errors. Any non-fatal errors are reported to the facility in the "Final Validation Report." Non-fatal errors include missing or questionable data of a non-critical nature, record sequencing, field consistency errors, invalid value, and range errors.

The Initial Feedback Report is available immediately following the submission of a file.

The HHA should obtain this report before logging off to ensure the submission has been processed. Since the Final Validation Report is not available for up to 48 hours after the Initial Feedback Report, the HHA may, based on experience, choose to obtain this report on a subsequent log on.

The validations and edits described above fulfill all of CMS' editing requirements under §488.68. Also, States may not modify any aspect of the CMS OASIS standard system, including these validations and edits, the Standard Record Layout, and the software code and specifications on which the system is based.

States that use OASIS data for Medicaid payment may require additional assessment information not required by CMS' OASIS system. Some States may impose additional edits on Medicaid assessments. However, a State may not interfere with, modify, or delay the transmission of records meeting CMS edit standards from a Medicare-certified or Medicaid-approved agency to the CMS OASIS standard system. Furthermore, the State may not impose any requirements that modify the clinical accuracy of CMS prescribed OASIS records, reports, or calculations.

2202.12D - Reports

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

The OASIS State System provides reports to both the State and the provider. These reports, which focus on errors in OASIS submissions, are particularly key to working with agencies to ensure successful transmission of OASIS data. Refer to the State OASIS Administration Manual available on the QTSO Web site (http://www.qtso.com/) for information about specific reports provided. Monthly validation of OASIS submission is highly recommended for both states and providers as OASIS is required for payment, pay for reporting, and medical review.

2202.12E - Replication to the CMS Repository

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

Each State's OASIS database will be transmitted to the CMS central repository at least monthly using a data replication process initiated by CMS. Since the process will be managed by CMS through an automatic polling process, the States will not actually have to transmit the data. However, the State must ensure that the CMS data line established for this purpose is accessible to CMS at all times for testing and monitoring purposes. Actual access to the Oracle assessment data tables may be controlled by the States but in such cases, CMS recommends that a fixed schedule be established with CMS central office.

The OASIS State System and CMS data line meet all industry security standards. However, if the State is concerned about security, it may establish a firewall (an electronic block) to restrict access to the State's portion of the network. Access must not be restricted to the CMS-supplied OASIS System.

2202.12F - System Security
(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

As distinguished from confidentiality and privacy, which primarily focuses on the rules for release of information when it is authorized, security relates to the means by which the information is protected from "unauthorized" access, disclosure, and misuse. As part of the new requirements under §488.68, States must ensure that electronic data in the OASIS State System are protected to the same degree that paper records containing any identifiable data must be safeguarded. Additionally, any printed copies of reports from the system must be maintained in a secure locked area while they are needed and properly disposed of when no longer needed. States must issue a policy that defines and limits the qualifications for an individual to access the OASIS State System. The System Administrator must issue passwords and user identifications in strict adherence to those requirements. State personnel who receive passwords must be aware of the requirements of the State's security policies and those of the System of Records and the Privacy Act. Passwords must be protected by the System Administrator and those receiving passwords. Passwords must be disabled at the time an individual exits a position requiring OASIS State System access. SAs are likewise reminded of the secure nature of passwords for the HHAs and must use due process to ensure the security of those passwords.

State personnel should not leave the OASIS State System in a logged-in status when leaving the area. If possible, the system hardware should be located in an enclosed area, preferably with a door having interior hinges that can be locked. Keys or a combination lock should be available to only a minimum group of individuals with need for access to the system.

In addition to the specific guidance above, the safeguards must provide a level of security at least equivalent to that required by the Office of Management and Budget Circular A-130 (revised), Appendix III, Security of Federal Automated Information Resources.

2202.12G - Security of Transmission
(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

OASIS data is encoded and transmitted from HHAs to SAs via the CMSnet, a private communications network CMS purchased to ensure the security of OASIS and MDS transmissions to the State. This system replaces the previous process of direct dial-up by public telephone lines to the SA and reflects the latest technology available for securing the privacy of data during transmission. Standard industry authentication is employed at each SA. Further security is provided at the SA by isolation of the receiving communications server from the actual storage site at the State (the MDS/OASIS Database Server). This serves effectively as a security firewall. Transmission of OASIS data from the SAs to CMS occurs via the CMS Virtual Private Network (VPN), which allows only authorized CMS staff access within this secure CMS infrastructure.

The CMS has determined that the transmission of OASIS data through the process described above is fully compliant with all current Federal, Department of Health and Human Services, and CMS information system's security requirements. The applicable

Federal guidelines include The Computer Security Act of 1987, Federal Information Processing Standards promulgated by the National Institute of Standards and Technology pursuant to the Computer Security Act of 1987, the Office of Management and Budget Circular A-130 (revised), and Appendix III, Security of Federal Automated Information Resources.

Per CMS policy, in the CMS Information Systems Security Policy, Standards and Guidelines Handbook, it is a violation of the CMS Security policy to send via email or fax: patient personally identifiable information, IP addresses, and both ID and password in the same document. CMS Security policy prohibits saving the login information in the Internet browser or sharing the personal login ID or the password with anyone else.

2202.12H - Provider Relations
(Rev. 1, 05-21-04)

With CMS technical support and guidance, the States work closely with the provider community and their OASIS software vendors in providing information on specific requirements related to the submission of OASIS assessments to the OASIS State System.

The CMS expects that some vendors will provide primary support to HHAs in terms of OASIS encoding and transmission to the State repository. The State, however, must work with HHAs and software vendors in educating them about this process. The States must also provide training and technical assistance in interpretation of OASIS reports provided to HHAs.

2202.13 - Protection of the Confidentiality of OASIS Data
(Rev. 1, 05-21-04)

2202.13A - OASIS System of Records
(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

The OASIS database is operated and maintained by States or CMS contractors as a Federal database and, as such, is subject to the requirements of the Federal Privacy Act. In general, the only records subject to the Privacy Act are records that are maintained in a system of records (SOR). The idea of a “system of records” is unique to the Privacy Act and requires explanation.

The Act defines a “record” to include most personal information maintained by an agency about an individual. A record contains individually identifiable information, including but not limited to information about education, financial transactions, medical history, criminal history, or employment history. A SOR is a group of records from which information is actually retrieved by name, social security number, or other identifying symbol assigned to an individual.

The text of the SOR notice for the OASIS database describes the legal requirements regarding privacy and disclosure of information by CMS or the State. The assigned identifying number for this system is: System No. 09-70-0522.

The CMS established a new SOR, published June 18, 1999, in the "Federal Register" (64 FR 32992) containing data on the physical, mental, functional, and psychosocial status of patients receiving the services of HHAs that are approved to participate in the Medicare and/or Medicaid programs. The purpose of the system is to aid in the administration of the survey and certification of Medicare/Medicaid HHAs and to study the effectiveness and quality of care given by those agencies. This system also supports regulatory, reimbursement, policy, and research functions, and enables CMS to provide HHAs with outcome data for providers' internal quality improvement activities.

The OASIS SOR was modified and published on December 27, 2001, (66 FR 66903) to allow a new routine use authorizing disclosure to national accrediting organizations that have been approved by CMS for deeming authority for Medicare requirements for home health services. This SOR notice replaces the SOR notice published June 18, 1999. The SOR was again updated November 13, 2007.

The HHA SOR contains individually identifiable clinical assessment information (OASIS records) for all Medicare/Medicaid patients receiving the services of a Medicare and/or Medicaid approved HHA, except prepartum and postpartum patients; patients under 18 years of age; patients receiving only housekeeping services and/or chore services exclusively; and, until sometime in the future, patients receiving only personal care services. The CMS established the system in accordance with the principles and requirements of the Privacy Act.

2202.13B - Protection of Confidentiality Under the Privacy Act of 1974

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

OASIS data are generally protected under the provisions of the Privacy Act of 1974. The Privacy Act of 1974 protects the confidentiality of person-specific records that are maintained by the Federal Government and retrieved by a unique indicator. It contains 12 conditions of disclosure under which these records may be released without the written consent of the individual.

The system notice for the OASIS repository (HHA OASIS) was originally published in the "Federal Register" on June 18, 1999, and modified on December 27, 2001 and November 13, 2007. The system notice contains a listing of the prescribed limited circumstances under which person-specific records contained in that system may be released. These circumstances are called routine uses. Routine uses must be compatible with the purpose for which the records are collected and maintained. The OASIS system notice now contains nine routine uses.

Requests submitted to CMS for release of OASIS data are forwarded to the appropriate data release authority. The authority to release data from the OASIS national repository is limited to the System Manager and his or her designees. The OASIS System Manager is the Director of the Survey and Certification Group at CMS, and as such has the sole authority to grant or deny a request for access to, or disclosure of data contained in the HHA OASIS system of records. It is the responsibility of the data release authority to

review these requests for adherence to Privacy Act requirements. Release of data from any system is discretionary.

Release of data from the OASIS repository follows CMS policy and procedure for data release. It is CMS policy that each requestor of Privacy Act protected data must sign a CMS approved Data Use Agreement (DUA). A DUA is not required by the Privacy Act, however; it is one safeguard CMS has instituted in order to protect the confidentiality of identifiable data. DUAs are an integral part of the data use approval process. The agreements delineate the confidentiality requirements of the Privacy Act and CMS' data use policies. The agreement serves as both a means of informing data users of these requirements and a means of obtaining their agreement to abide by these requirements. Additionally, the agreements serve as a control mechanism through which CMS can track the location of its data and the reason for the release of the data. CMS' Office of Information Systems carries the functional responsibility to control guidelines and policies for the language in the agreements and coordinates the requests for release of data.

2202.14 - SA and RO Roles and Responsibilities
(Rev. 1, 05-21-04)

2202.14A - State
(Rev. 1, 05-21-04)

The CMS expects the SA to play a key role in providing the educational and technical resources to HHAs in each State concerning OASIS. States must designate an OASIS Automation Coordinator and OASIS Educational Coordinator to function as resources for the HHAs in each State. These positions are funded by CMS through the Medicare Survey and Certification program.

Each State Automation Coordinator must have the ability, through education, training, or experience, to provide for the statewide administration of the OASIS project. The State Automation Coordinator provides systems operations and technical support for the HHAs, vendors, and SA staff. The State OASIS Educational Coordinator must be a member of any professional discipline operating in the home health environment, that is, a social worker, registered nurse, occupational therapist, or physical therapist. Together, the functions of these two positions include providing training and educational support to HHAs in the administration of OASIS for:

- Integrating the OASIS items into the HHA assessment process;
- Answering questions on the clinical aspects of OASIS;
- Training HHAs on the OASIS data set administration;
- Providing information about hardware and software requirements for HHAs to consider when automating OASIS;
- Training HHAs on submission of OASIS data to the State and interpreting

validation reports, including providing support for transmission of test data during start-up, supporting callers requesting technical assistance, providing passwords to HHAs, and answering questions about computer edits and reports;

- Submit an annual training report of the state-wide OASIS training and other activities in the Home Health Training Worksheet available in Casper reports of the QIES system by October 15 following each Federal Fiscal Year.

- Using the outcome reports generated by the OASIS data;

- Using OASIS data in survey tasks;

- Training other SA staff, as applicable;

- Providing information from OASIS to determine prospective payment rates for HHA patients; and

- Participating in training updates on OASIS and related home health issues.

2202.14B - Regional Office

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

ROs also have OASIS coordinators for the implementation updates and automation of OASIS. Designated RO staff provides information about OASIS in the region, act as a resource to the provider and a consultant to the SA. They also administer survey and certification funds, and other aspects of the OASIS project. At least one RO staff person, knowledgeable about home health survey and certification issues, and/or knowledgeable about MDS automation coordination should be assigned to these OASIS related roles. ROs must provide the States with the program guidance and technical assistance critical to the successful implementation of OASIS and ensure that the States have the necessary resources to accomplish these goals.

The following activities are performed by the RO:

1. Budget Process

   The RO reviews each SA's budget request and the required OASIS Implementation Plans in accordance with the SCG Budget instructions. The RO must monitor for a reasonable and prudent expenditure of funds to ensure that States receive a fair and reasonable allocation. The RO must monitor Quarterly Expenditure Reports against the States' allocation.

2. Review State Implementation Plans

   The RO annually reviews all State OASIS Implementation Plans to ensure States have reasonable plans for assisting HHAs with the technical information, training, and assistance needed to comply with requirements for OASIS submission,

accuracy, privacy, and security. The RO must assess whether States are monitoring HHA compliance with the OASIS requirements.

3. Review Contracts and Agreements

   The RO ensures that the SA has executed an agreement with any other entity if that other entity is operating the OASIS system on behalf of the SA. The RO must use the criteria in §2202.12.B in performing this review.

4. Provide Training and Technical Assistance

   The RO supports CO in training and technical assistance to the States in OASIS and ASPEN requirements and supports OASIS continuing education and program requirements.

5. Perform Focused Reviews/Federal Surveys

   The RO uses the OASIS Repository and outcome data to select HHAs for focused reviews, and in preparation for Federal surveys.

6. Take Enforcement Action.

   The RO processes and carries out enforcement actions for non-compliance with OASIS requirements (as reported by SAs).

2202.15 - OASIS Education and Training
(Rev. 1, 05-21-04)

2202.15A - State
(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

The OASIS Educational and Automation Coordinators (OEC/OAC) participate in various training programs concerning OASIS, monthly All State teleconferences to discuss OASIS issues, and meetings for OASIS updates and other matters related to home health services, as necessary. State support is provided by CMS central office, ROs, the OASIS Web site, and clinical and technical Help Desks supported by CMS contractors. The State OACs and OECs are considered the subject matter experts who provide training to State Agency staff and act as a resource to providers.

The OASIS Education Coordinators (by state) can be found at:- http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/EducationCoord.html.

The OASIS Automation Coordinators (by state) can be found at: - http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/AutomationCoord.html.

2202.15B - RO
(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

The RO OASIS Coordinators participate in regularly scheduled teleconferences with central office to discuss issues concerning updates and maintaining OASIS and other related survey issues. RO staff participates in periodic meetings for OASIS updates and other matters related to home health services as scheduled.

2202.15C - HHAs
(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

All HHAs, both existing and prospective, are trained on the implementation and automation of OASIS by each State's OASIS Educational and Automation Coordinators. HHAs with clinical, technical and regulations-related questions should contact the State OASIS Educational or Automation Coordinator about OASIS. A current list of the State OASIS Educational Coordinators is found on the OASIS Web site. Support is also available for HHAs via the OASIS Help Desk. The Help Desk can be accessed toll-free by telephone on (877) 201-4721 between the hours of 7:00 a.m. and 7:00 p.m. Central Time and by electronic mail at HAVEN_help@IMFC.org.

The SA provides support to HHAs by providing OASIS presentations at meetings sponsored by the SA, HHA provider associations, or other entities.

Updates to existing software and training manuals which support OASIS updates, HAVEN, and the OASIS State System, are distributed via the OASIS and QTSO Web site.

2202.16 - Fax Transmission of OASIS or Other Patient Identifiable Information
(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

OASIS assessment data is personal information about home health recipients that HHAs are required to collect and keep confidential in accordance with federal law. The use of electronic means of communication is acceptable in HHAs, if appropriate safeguards are in place. The fax machine provides a fast and inexpensive method to send and receive patient specific information, such as patient referrals and physician orders. However, the use of fax transmission can open up the possibility that confidential patient information can be transmitted or handled in a manner that is not secure and does not protect the patient's confidential health information. For example, the use of an incorrect fax number can allow the material being transmitted to persons who are not legally authorized to have this information. CMS takes its responsibility seriously to protect patient specific information once it has been transmitted to the State, and CMS expects HHAs to provide the same protections to OASIS data while it is maintained at the HHA.

SAs must follow Federal requirements for systems that retain "Federal data" e.g., MDS data, OASIS data. Additional information on information security (IS) can be found on the CMS Information Security web pages at http://www.cms.gov/Research-Statistics-Data-and-

Systems/CMS-Information-Technology/InformationSecurity/index.html?redirect=/informationsecurity in the CMS Policy for the Information Security Program (PISP) and the CMS IS Acceptable Risk Safeguards (ARS) found under "Policies" and "Standards."

The home health CoP at §484.11, Release of Patient Identifiable OASIS information, requires that HHAs and agents acting on behalf of the HHA in accordance with a written contract must ensure the confidentiality of all patient identifiable information contained in the clinical record, including OASIS data, and may not release patient identifiable information to the public.

It is the responsibility of the HHA to make sure that it has a written contract providing its agent with the legal authority to encode and transmit OASIS assessment data. The contract should also ensure that the agent holds all OASIS data confidential. Each HHA that uses fax transmission of OASIS information should develop its own policies and procedures to assure confidentiality of patient information, as well as, comply with legal, regulatory and accreditation requirements. It is also the responsibility of the HHA to make sure that OASIS assessment data is transmitted to its agent by a secure method.

If the HHA chooses to use facsimile transmission of OASIS data, guidelines for use of facsimile transmission of OASIS data are provided below:

- The HHA or agent should place fax machines in a secure area and limit access to them.

- The HHA should identify one person in a department or unit to monitor incoming documents on a fax machine, or to deliver the document information directly into a secured data base system.

- The HHA should outline appropriate written policies that safeguard that transmitted OASIS information is sent to the appropriate person and verify the correct facsimile number to which the OASIS data is being transmitted. This should include:

    (a) Use of the of a cover sheet, either electronic or hard copy, accompanying the faxed information that specifies that the OASIS information is confidential and limits its use to the terms of the written contract;

    (b) That the person who is the legal authority for the receipt of the OASIS information is prohibited from disclosing this information to any other party, any may use the data only for the purposes outlined in the written contract; and

    (c) The HHA should contact the agent to verify the correct fax number to use prior to faxing.

The HHA should develop and enforce procedures to be followed in the case of a

misdirected transmission. This should include:

(a) A notice on the cover sheet that prohibits the disclosure, copying, or distribution of the information by the unintentional receiver of the fax;

(b) A notice to the unintentional receiver of the fax to notify the sender immediately if they have received this information in error to arrange for the return of the information; and
(c) The name and phone number of the sender to contact.

HHAs shall only use or disclose patient identifiable records as permitted or required by law.

State survey agencies should follow the CMS guidelines when sending and receiving requests to correct errors to the OASIS data base.

2202.17 - Change of Ownership, Merger, and Termination Procedures Affecting HHAs and OASIS Requirements

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

It is imperative that the Medicare CCN be accurately reported on the OASIS assessments in all reports, including when HHAs undergo change of ownership, merger, or termination.

Change of Ownership - Mergers

In accordance with §489.18 and §3210, the merger of a provider corporation into another corporation constitutes a change of ownership. In the case of the merger of Agency A into Agency B, Agency A's provider agreement and its associated CCN are terminated. Agency B retains its existing provider agreement and CCN. Agency A should provide the OASIS discharge comprehensive assessment for each discharged patient prior to or at the effective date of the merger. The surviving HHA (Agency B) should provide a Start of Care (SOC) comprehensive assessment for all persons it admits after the merger at the next skilled visit after the official merger date. The SOC assessment will allow eligibility for the home health benefit to be verified and care planning for the individual to proceed under Agency B. Subsequently, the assessments for all individuals being accepted for care by Agency B will be linked to the correct provider number to enable the agency to engage in quality improvement efforts with accurate OBQI reports.

In accordance with §489.18 and §3210, when there is a permissible change in ownership under §424.550(b)(2), as described below and the new owner does not reject automatic assignment of the existing provider agreement under §489.18(c), the new owner is subject to all the terms and conditions under which the existing agreement was issued, including compliance with the comprehensive assessment of patients condition of participation. The CCN remains the same if the new HHA owner accepts assignment of the existing provider agreement. The new owner is responsible for continuing to complete updates to the comprehensive assessment at the next scheduled time points.

Change of Ownership without Assignment

In accordance with §489.18 and §3210, when there is change of ownership and the new owner rejects this automatic assignment of the provider agreement, the provider agreement and provider number of the former owner should be terminated.

The HHA that is terminating its provider agreement and provider number should provide an OASIS discharge comprehensive assessment for each patient subject to OASIS standards prior to the effective date of the termination, according to §484. The new HHA will not be able to participate in the Medicare program without going through the same process as any new provider, which includes an initial survey. The HHA should meet all the Federal requirements, including applicable OASIS requirements as specified in the regulations, for all persons it accepts for care in order to participate in the Medicare program. This means that the HHA should provide a new SOC comprehensive assessment at the first skilled visit once it becomes Medicare-approved. In addition, updates to the comprehensive assessment should be provided at the other OASIS time points, in accordance with §484, for all patients of the former owner it accepts for care.

NOTE: The "Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2011; Changes in Certification Requirements for Home Health Agencies and Hospices; Final Rule"(75 FR 70372) (also referred to as CMS-1510-F) published on November 17, 2010, revised certain policies related to the prohibition of the sale or the transfer of HHA billing privileges at §424.550(b)(1), defined "change in majority ownership" at §424.502, and provided several exceptions to the new "36-month rule." Specifically, the final rule provided that, effective January 1, 2011, and in accordance with §424.550(b)(1), if there is a change in majority ownership of an HHA by sale (including asset sales, stock transfers, mergers, and consolidations) within 36 months after the effective date of the HHA's initial enrollment in Medicare or within 36 months after the HHA's most recent change in majority ownership, the provider agreement and Medicare billing privileges do **not** convey to the new owner.

Section §424.502 defines the term "Change in Majority Ownership" as a transaction in which an individual or organization acquires more than a 50 percent direct ownership interest in an HHA during the 36 months following the HHA's initial enrollment into the Medicare program or the 36 months following the HHA's most recent change in majority ownership (including asset sales, stock transfers, mergers, and consolidations). This includes an individual or organization that acquires majority ownership in an HHA through the cumulative effect of asset sales, stock transfers, consolidations, or mergers during the 36-month period after Medicare billing privileges are conveyed or the 36-month period following the HHA's most recent change in majority ownership.

If the CMS RO or SA receives an inquiry from the provider regarding procedures for a change in majority ownership pursuant to §424.550(b) (1), it should refer the provider to its Medicare Administrative Contractor (MAC). The MAC will review the applicable time frames, exceptions and any other pertinent enrollment requirements, and will determine if the facility has had a majority ownership change within 36 months of its

initial certification or within 36 months of another majority ownership change.

If the proposed HHA change of ownership meets the revised HHA change in majority ownership definition, it must:

- Enroll in the Medicare program as a new (initial) HHA under the provisions of §424.510;
- Obtain a State survey or an accreditation from an approved accreditation organization with deeming authority; and
- Sign a new Medicare provider agreement and receive a newly assigned CMS Certification Number (CCN).

CMS will deactivate the HHA's old Medicare billing number if the sale has already occurred.

Scheduling of an initial certification survey is initiated by a recommendation from the MAC to the RO/SA. The SAs and ROs will follow the current established processes and policies for initial certification. The initial surveys required under the change in majority ownership guidelines will be considered Tier IV as per CMS's Mission Priority Document (MPD). The HHA may utilize an approved AO for an initial survey if it is seeking deemed status through accreditation. It is the responsibility of the HHA to arrange the initial Medicare survey with the AO.

Upon successful completion of the enrollment and survey process, the new HHA will have a new effective date of Medicare participation and a new CCN.

Questions from the provider community about the definitions for a change in majority ownership and specifics regarding participation dates, exceptions, etc., should be directed to the applicable MAC.

An existing HHA that has engaged in a transaction that meets the definition of change in majority ownership is considered to have voluntarily terminated its participation under its original provider agreement. The requirements for a provider/supplier to terminate voluntarily from participation in the Medicare program are set forth at §489.52. The RO should follow the usual procedure regarding voluntary termination, using the date of the ownership change as determined by the MAC as the effective date of voluntary termination.

There are a four allowable exceptions to the sale or transfer prohibition at §424.550(b)(2). Specifically, the provisions of §424.550(b)(1) do not apply if:

- The HHA submitted two consecutive years of full cost reports (which are not low utilization or no utilization cost reports);
- The HHA parent company is undergoing an internal corporate restructuring, such as a merger or consolidation;
- The owners of an existing HHA are changing the HHA's existing business structure and the owners remain the same; or

- An individual owner of an HHA dies.

Note: §424.550(b)(1) does not apply to "indirect" changes in majority ownership (e.g., changes to the ownership of a holding company that owns and operates HHAs through subsidiaries).

Voluntary Terminations

In accordance with §489.52 and §2005 and §3046, a Medicare approved HHA may voluntarily terminate its provider agreement by filing a written notice of its intention to the State Agency who, in turn, notifies the RO. The provider/supplier must also submit a Form CMS-855A or CMS-855B to voluntarily terminate its Medicare billing privileges. .

NOTE: According to Pub. 100-08, chapter 10, section 7.3: In the event the HHA notifies the MAC of its intent to voluntarily terminate, the MAC shall notify the State and RO. This notification can be made via letter, e-mail, or fax, no later than 3 business days after the contractor has finished processing the termination.

CMS recommends that an HHA provide a discharge comprehensive assessment for each patient prior to the effective date of the termination of its provider agreement.

The former HHA that meets the 2010 revised HHA CHOW definition is considered to have voluntarily terminated the original provider agreement. The State should follow usual procedures regarding voluntary termination, using the date of the CHOW as the effective date of voluntary termination. Electronic communication with the MAC should occur between all interested parties.

Involuntary Terminations

The RO may terminate the provider agreement with an HHA, in accordance with §489.53. Revocation of billing privileges in the Medicare program may be initiated by the MAC at §424.535, which results in termination of the provider agreement. When revocation of billing privileges also results in the termination of a corresponding provider agreement, the provider may appeal CMS's decision under §498, where a final decision applies to both the billing privileges and the provider agreement. See §424.545.

CMS will work with the HHA on a case-by-case basis to provide for the safe and orderly transfer of patients to another Medicare-approved HHA if appropriate.

Deactivation of billing privileges

Under §424.540, a provider or supplier who does not submit any Medicare claims for 12 consecutive calendar months will have its Medicare billing privileges deactivated. The 12 month period begins on the 1st day of the 1st month without claims submission through the last day of the 12th month without a submitted claim. Deactivated agencies are not terminated and are still required to be surveyed every 36 months by the SA or AO, if deemed.

Effective January 1, 2010, if an HHA's billing privileges are deactivated, the HHA must also undergo a Medicare survey in order for its billing privileges to be reactivated. This applies to all applications for reactivation that were received after December 31, 2009.

In order for its billing privileges to be reactivated, a HHA must first submit a Form CMS-855 update (re-activation application) to the MAC. The MAC will conduct its preliminary review of the application and either deny the application or notify the RO, AO or SA that a survey may be scheduled. The MAC will notify the provider that the preliminary review is complete and that the SA has been notified.

Once the RO/SA receives notification from the MAC, surveys of deactivated HHAs are scheduled as a low survey priority. In circumstances of demonstrated access to care issues, the RO may change the survey priority and determine if an earlier recertification survey is indicated.
If an HHA chooses to have a deemed status survey by an AO, it is the responsibility of the HHA to arrange the Medicare recertification or initial survey with the AO. The AO shall perform a recertification survey for existing clients when billing privileges have been deactivated and the agency has subsequently requested reactivation. In the event the HHA wishes to use the AO to conduct a reactivation survey when it formerly was under the jurisdiction of the SA, the AO would conduct this as an initial survey. The AO must notify the RO of the survey findings and the deeming recommendation. The RO retains the responsibility to notify the MAC that the agency passed the requirements of the Medicare survey.

A standard survey is conducted and entered into the ASPEN system as a recertification survey along with a note that this is an early recertification due to a request for reactivation of Medicare billing. The SA must notify the RO of the survey activity. If the survey finds condition level non-compliance, routine enforcement procedures should be followed. If the survey finds substantial compliance, the RO should forward Form CMS-2007 to the MAC with the date the provider was determined to be in compliance with the CoPs in the remarks section. The HHA will retain its existing CMS CCN.

2202.18 - Wound Ostomy Continence Nurses Society (WOCN) and the National Pressure Ulcer Advisory Panel (NPUAP) OASIS Guidance

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

The CMS collaborates with clinical wound care experts from the WOCN and the NPUAP to clarify OASIS wound items. The clarifications are intended to be helpful to home health agency (HHA) clinicians as they complete their patient assessments. For more information about the WOCN guidelines and for answers to questions about the WOCN guidelines, please contact the WOCN web site at http://www.wocn.org.

HHA clinicians are encouraged to use the WOCN and the NPUAP guidance to assist with clinical assessments of patient wounds. The WOCN OASIS Guidance is located at: http://www.wocn.org/pdfs/GuidanceOASIS-C.pdf (http://www.wocn.org) and the NPUAP website is located at http://www.npuap.org/.

2202.19 - OASIS Collection on Private Pay (Non-Medicare/Non-Medicaid) Patients

(Rev. 1, 05-21-04)

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 includes a provision regarding the collection of OASIS data for non-Medicare/non-Medicaid (private pay) patients. Specifically, section 704 of this Act temporarily suspends the requirement that Medicare-approved HHAs collect OASIS data on non-Medicare/non-Medicaid patients, effective December 8, 2003.

2210 - ASCs - Citations and Description
(Rev. 1, 05-21-04)

Section 1832(a)(2)(F) of the Social Security Act (the Act) provides that, as an adjunct to outpatient surgical services, ASC facility services can be paid under Part B of the Medicare program. Though it is a supplier, an ASC must be certified and approved to enter into a written agreement with CMS. The Conditions for Coverage of ASC services are found in 42 CFR 416. Interpretive guidelines and surveyor procedures are in Appendix L.

Participation as an ASC is limited to any distinct entity that operates exclusively for purposes of providing surgical services to patients not requiring hospitalization (i.e., an inpatient stay in a hospital). The regulatory definition of an ASC (42 CFR 416.2) does not allow the ASC and another entity to mix functions and operations in a common space during concurrent or overlapping hours of operations. Our current regulations and policy do not allow an entity to function both as an ASC and an Independent Diagnostic Testing Facility (IDTF), mixing unrelated functions and operations in a common space during concurrent or overlapping hours of operation. That is, the two facilities must be separated by time (different hours of operation) or the other entity may operate in the ASCs space when the space is not operating in that space.

An exception to this rule is when there is a need for imaging services during the course of a procedure in progress at an ASC, the IDTF sharing the space with the ASC (but a different time), may conduct the required service outside of its normal business hours, as needed, and receive Medicare payment for those services. In this situation, our regulations and regulations and policy allow the IDTF to bill and receive Medicare payment for imaging and guidance services (such as angiography, venography, fluoroscopy, and ultrasonic needle guidance) **that are reasonable and necessary and directly related to the performance of a surgical procedure and furnished in conjunction with a surgical procedure despite** being conducted during the ASC's designated hours.

The operating room(s) and recovery room(s) are to be used only for patients having surgery. The ASC must also have a separate recovery room and waiting area. (See 42 CFR 416.44(a)(2)).

An ASC may be either hospital-operated or independent. The hospital-operated ASC must be a separately identified entity. It must be physically and administratively distinct from other operations of the hospital and be able to identify its costs separately from other hospital costs. A hospital ASC's agreement is made effective prospectively at the start of the hospital's next cost reporting year. (See 42 CFR 416.30(f)(1).)

The ASC may not perform a surgical procedure on a Medicare beneficiary when, before surgery, an overnight hospital stay is anticipated. There may, however, arise unanticipated medical circumstances that warrant a beneficiary's hospitalization after an

ASC surgical procedure. The ASC must have procedures for the immediate transfer of these patients to a hospital (42 CFR 416.41). Such situations should be infrequent.

ASC covered procedures (see 42 CFR 416.65) are those that generally do not exceed 90 minutes in length and do not require more than four hours recovery or convalescent time. Therefore, ASC patients generally do not require extended care as a result of ASC procedures. An unanticipated medical circumstance may arise that would require an ASC patient to stay in an overnight health care setting. Such situations should also be infrequent. When extended care in a non-hospital health care setting is anticipated as a result of a particular procedure, that procedure would not be a covered ASC procedure for beneficiaries.

The SA follows standard procedures for identifying interested ASCs and certifying them. If the ASC operates other activities as part of the same enterprise, the SA forwards a request for certification, Form CMS-377, (Exhibit 64) with a Certification and Transmittal, Form CMS-1539, to the RO, together with any evidence covering the activities operated. Copies of the ASC Health Insurance Benefits Agreement, Form CMS-370 (Exhibit 65) are signed and processed in the same manner as provider agreements.

Rural Health Clinics (RHCs)

2240 - RHCs - Citations and Description

(Rev. 1, 05-21-04)

The statutory basis for RHCs is found in §1861(aa) of the Act. The Conditions for Certification are in 42 CFR 491, Subpart A. Appendix G contains interpretive guidelines and surveyor procedures. An RHC is a facility located in a rural area designated as a shortage area and is neither a rehabilitation agency nor a facility primarily for the care and treatment of mental diseases. It meets all other requirements of the RHC regulations at 42 CFR 491, Subpart A. A clinic located on an island may be eligible to be certified as an RHC even though it does not have a physician assistant, nurse practitioner, or certified nurse-midwife. (See §6213 of OBRA 1989.)

2242 - Conditions to Be Assessed Prior to Scheduling RHC Survey

(Rev. 1, 05-21-04)

2242A - General

(Rev. 139, Issued: 04-24-15, Effective: 04-24-15, Implementation: 04-24-15)

Applicants seeking initial certification as an RHC must, among other requirements, satisfy certain location and staffing requirements in order to participate in Medicare. In order to facilitate an efficient survey and certification process for applicants, State Survey Agencies and CMS, CMS requires an RHC applicant to complete and submit Form CMS-29, Verification of Clinic Data – Rural Health Clinic Program, as part of its application for certification. To make efficient use of survey resources, State Survey Agencies (SAs) make a preliminary assessment of the information contained on the Form CMS-29 prior to conducting a survey, to avoid conducting a survey of an ineligible location. Likewise SAs conduct a preliminary assessment of the information contained on the Form CMS-29 prior to forwarding a certification packet to the RO when the RHC applicant is seeking to participate via deemed status accreditation. However, since only the CMS RO may make a determination whether the RHC applicant has satisfied all Federal requirements, including the location and staffing requirements, the SA must not notify the applicant of the results of the SA's preliminary assessment of the Form CMS-29.

The SA or an accrediting organization (AO) may not conduct a survey before receiving a positive recommendation from the Medicare Administrative Contractor (MAC), issued after the MAC has completed its review of the RHC applicant's Form CMS-855A application to enroll in Medicare. An AO must receive a copy of the MAC's notice to the applicant that it has concluded its review before conducting an accreditation survey.

CMS makes RHC location determinations only after an RHC applicant has submitted an application to enroll in Medicare and is open and operating at the site identified in the application. CMS does not provide advance or preliminary determinations about whether a location satisfies the RHC criteria, even if interested parties request one. SAs also may

not issue any preliminary or final assessments about a location's potential eligibility for RHC status.

2242A1 - Location of Clinic

(Rev. 139, Issued: 04-24-15, Effective: 04-24-15, Implementation: 04-24-15)

Subpart A of 42 CFR Part 491 sets forth the conditions that RHCs must meet in order to qualify for certification under Medicare. Question I on Form CMS-29 identifies the location of the clinic and defines location as "the location at which health services are furnished."
In accordance with 42 CFR 491.5, the clinic must be located in a rural area that is designated as a shortage area.

- A rural area is defined in 42 CFR 491.2 as an area that is not delineated as an "urbanized area" by the US Census Bureau. An "urban cluster" is not considered an urbanized area. CMS relies upon the information in the US Census Bureau's American FactFinder tool, http://factfinder2.census.gov/faces/nav/jsf/pages/index.xhtml, when determining whether a location falls within a rural area. Note that once a RHC is certified for Medicare participation, it may continue to participate as an RHC even if the US Census Bureau subsequently changes the classification of its location to an urbanized area.

- A shortage area is a defined geographic area designated by the Health Resources and Services Administration (HRSA) on behalf of the Secretary as having either a shortage of personal health services or an area or population group with a shortage of primary medical care manpower. HRSA may also designate at the request of a State governor specified areas of a State as having a shortage of personal health services. CMS uses data from HRSA's Data Warehouse, http://www.hrsa.gov/shortage/find.html, supplemented as needed by information obtained via telephone or e-mail from HRSA, when determining whether a location falls within a shortage area.

SAs may use these same on-line tools when conducting their preliminary assessments of an RHC applicant's location prior to conducting a survey, but the results of their assessments are not considered determinations by CMS. AOs may also use these tools when deciding whether to accept an application for RHC accreditation and conduct an accreditation survey. However, SAs and AOs are not authorized to provide notice to the RHC applicant of the results of their assessments. Further, the fact that the SA, or an AO with a CMS-approved Medicare RHC accreditation program, conducts a survey of the RHC applicant does not constitute a determination by CMS that the applicant's location satisfies the regulatory criteria. Only the CMS RO may make such a determination and notify the applicant whether or not it has been determined to meet participation requirements.

Relocating an Existing RHC

An existing Medicare-certified RHC that has relocated must submit a CMS-855A

updating the location information to the appropriate MAC within 90 days after it relocates. (See section 15.10.1 of the Medicare Program Integrity Manual, CMS Pub. 100-08). CMS also does not provide advance determinations on the location eligibility of a potential relocation site. Rural and shortage area location determinations are only made after the relocation has occurred and the CMS-855A has been submitted to the appropriate MAC. The RHC must also submit to the SA a Form CMS-29 reflecting its new location at the same time that it submits the CMS-855A update to the MAC. The SA forwards this information to the RO, which reviews it to determine whether the RHC at the new location continues to meet the location requirements. If it does not, the RO will issue a termination notice to the RHC. If the new location does continue to meet the RHC requirements, the RO does not need to take any further action, beyond documenting its determination in the RHC's certification file. However, based on the information on the Form CMS-29, the RO also has the discretion to require an on-site survey of the RHC at the new location.

If the RHC is only changing suites within the same building, CMS would not consider this a relocation. However, the RHC must still report the change of information to the MAC using the CMS-855A.

2242A2 - Medical Direction

(Rev. 1, 05-21-04)

Question II on Form CMS-29 asks for the name and address of the physician(s) providing the clinic's medical direction. The physician(s) providing medical direction must be a member of the clinic's staff or under agreement with the clinic to carry out the responsibilities required of a physician. If performed in the clinic, the time spent in this medical direction must be included in the answer to question III.A.

2242A3 - Physician Assistant, Nurse Practitioner, and/or Certified Nurse Midwife Staff

(Rev. 139, Issued: 04-24-15, Effective: 04-24-15, Implementation: 04-24-15)

Question III.B. and/or III.C. on Form CMS-29 indicates whether the clinic's staff includes a physician assistant, nurse practitioner, and/or certified nurse-midwife. A nurse practitioner, a physician assistant, or certified nurse-midwife must be available to furnish patient care services at least 50 percent of the time the clinic operates. (See Appendix G.) The SA contacts the clinic for clarification if the combined full-time equivalent entries in question III.B. and C. (and/or D., if D. is used to indicate a nurse-midwife) do not equal 50 percent of the clinic's scheduled hours of operation. In computing the full-time equivalents, the SA uses only the time personnel are present in the clinic or are providing RHC services away from the clinic site. The results of the SA's preliminary assessment of the staffing information on the Form CMS- 29 do not constitute a determination by CMS, and the SA may not provide notice to the applicant of the results of its assessment. Likewise, any information or advice provided by an AO to the applicant about meeting the basic staffing eligibility requirements does not constitute a determination by CMS.

The SA (or AO) may proceed to conduct a survey of the RHC applicant based on the

results of its preliminary assessment of the applicant's staffing information, but the fact that the SA or AO conducted a survey does not constitute a determination by CMS that the RHC applicant meets the basic staffing requirements.

An RHC which is already certified and participating in Medicare may request a temporary waiver of these staffing requirements for a one-year period, if it demonstrates that it has been unable to hire a physician assistant, nurse-practitioner, or a certified nurse-midwife in the previous 90-day period. However, staffing waivers are not available to RHC applicants seeking initial enrollment in the Medicare program.

A subsequent request for a waiver cannot be made less than 6 months after the expiration date of any previous waiver of staffing requirements for the facility.

2242B - Clinic Is Determined Ineligible

(Rev. 139, Issued: 04-24-15, Effective: 04-24-15, Implementation: 04-24-15)

If the SA's preliminary assessment of the Form CMS-29 suggests that the RHC applicant's location does not satisfy the RHC eligibility requirements, the SA must notify the RO of this, forwarding the Form CMS-29. The RO will independently assess the location requirements, and if it concurs with the SA, the RO will issue a denial of initial certification to the applicant based on its determination regarding the applicant's location.

Likewise, if the SA's preliminary assessment of the Form CMS-29 suggests that the applicant does not have the minimum required physician assistant, nurse practitioner and/or certified nurse/midwife staff, the SA must notify the RO of this, forwarding the Form CMS-29. The RO will independently assess the staffing information contained on the Form CMS- 29, and if it concurs with the SA, the RO will issue a denial of initial certification to the applicant based on its determination regarding the applicant's self-reported staffing information.

2242D - Identifying Clinic as Provider-Based

(Rev. 139, Issued: 04-24-15, Effective: 04-24-15, Implementation: 04-24-15)

If the RHC applicant submits a Form CMS-29 indicating that it is a provider-based entity of a critical access hospital (CAH) or eligible hospital, the SA confirms the accuracy of the CAH's or hospital's CMS Certification Number (CCN) entered on the form. After conducting a survey and/or receiving notice of an AO's recommendation of RHC deemed status for the applicant, the SA forwards the Form CMS-29 and other certification documentation to the RO for review and a certification determination. If the RHC meets all Federal requirements for certification, and has indicated on its Form CMS-29 that it is provider-based to a hospital or CAH, the RO will issue a Medicare RHC agreement with a provider-based RHC CCN.

Issuance of a Medicare provider agreement with a provider-based CCN to a RHC does not constitute a CMS provider-based determination as provided for in §413.65(b). Seeking such a provider-based determination is voluntary, and neither the SA nor the RO may require RHC applicants and their affiliated hospitals/CAHs to seek such a

determination as a condition to being issued a provider-based RHC CCN.

However, when CMS issues a provider-based RHC CCN, the letter approving the RHC's provider agreement and issuing the CCN must contain the following disclaimer language: "Issuance of a provider-based RHC CCN does **not** constitute a CMS provider-based determination."

2242E - Compliance With Civil Rights Statutes

(Rev. 1, 05-21-04)

An RHC that only received Federal funds through Medicare Part B is not required to comply with the various civil rights statutes enforced by the Department of Health and Human Services' (DHHS) Office for Civil Rights. However, if the RHC participates in the Medicaid program or receives any other financial assistance such as grants from DHHS, it must comply with all applicable civil rights statutes. RHCs are not subject to the pre-grant review process required of participants in Medicare Part A.

2242F - Laboratory Services Provided in RHCs

(Rev. 1, 05-21-04)

An RHC must provide primary health care, including laboratory services to its patients. The RHC's laboratory services are subject to the Clinical Laboratory Improvement Amendments (CLIA).

2244 - Preparing for RHC Survey

(Rev. 1, 05-21-04)

Prior to the survey, in addition to reviewing the information and references needed for surveys generally, the SA reviews:

- Listings of formal educational programs for physician assistants, nurse practitioners, and certified nurse midwives; and

- A list of formal educational programs supported under HRSA grants to prepare RNs to perform in an expanded role in the delivery of primary care and any other educational programs that meet the requirements of the regulation.

2246 - Clinic's Request to Provide Visiting Nurse Services

(Rev. 1, 05-21-04)

An approved RHC may also seek approval to provide covered visiting nurse services. An RN, LPN, or licensed vocational nurse must furnish these services.

When a request is received, the SA determines if a shortage of HHAs exists in the area. Refer to 42 CFR Part 405.2417 and consults with the RO, as appropriate. If there is an existing HHA furnishing services in the RHC area, the SA contacts the HHA for a statement of its ability or inability to adequately furnish nursing services in the area. In addition, the SA obtains information from the local or State health planning organization.

If there is not a shortage of home health services for the area, the SA notifies the RO. In such cases, approval to furnish visiting nursing services to homebound patients will not be granted, and the RHC must refer its homebound patients to the HHA serving the area.

If there is a shortage of home health services, the SA notifies the RO and evaluates the qualifications of RHC personnel who are responsible for the delivery of nursing services. This evaluation must include compliance with applicable State licensure/certification requirements for RNs, LPNs, or licensed vocational nurses who provide services for the clinic.

2248 - Clinic's Request for Waiver of Staffing Requirements

(Rev. 1, 05-21-04)

As provided by §1861(aa)(7) of the Act, the Secretary of HHS is required to grant a 1-year waiver to RHCs for staffing requirements that the clinic employ a nurse practitioner, physician assistant, or certified nurse midwife, or that such disciplines furnish services 50 percent of the time that the clinic operates if:

- The facility requests a waiver;
- The facility demonstrates that it has been unable, despite reasonable efforts, to hire a physician assistant, nurse practitioner, or certified nurse midwife in the previous 90-day period; and
- The facility is not making the request less than 6 months after the date of the expiration of any previous such waiver for the facility.

The waiver is applicable to participating RHCs. The SA is responsible for recommending approval or disapproval of the requested waiver to the RO within 30 days of receiving it. The waiver shall be deemed granted unless the waiver request is denied by the RO within **60 days** after the date the SA received the request. In such situations the effective date of the 1-year waiver is the **61st day** after the date the request is received by the SA. The SA uses the date the RO approves the waiver as the effective date of the 1-year waiver period.

2248A - Applying Waiver to Applicants

(Rev. 1, 05-21-04)

The initial packet of information sent to RHC applicants by the SA should include a statement that the applicant cannot request a waiver of the mid-level requirement on initial

application. In §4205(c) of the BBA, the Congress amended, effective January 1, 1998, §1861(aa)(7)(B) of the Act to restrict further our authority to waive the requirement that each RHC must hire a physician assistant, nurse practitioner, or certified nurse midwife. A waiver may now be granted only to a participating RHC. That is, the waiver cannot be granted before the clinic has been determined by us to meet all the requirements for Medicare participation as an RHC and is actually participating as an RHC.

2248B - Applying Waiver to Participating RHCs

(Rev. 1, 05-21-04)

A participating RHC may request a waiver either when it loses its nurse practitioner, physician assistant, or certified nurse-midwife, or when it fails to meet the 50 percent staffing requirement regarding these disciplines.

Some RHCs will probably experience an unexpected loss of staff and therefore will not be able to demonstrate any effort to hire staff in the previous 90-day period. The SA should advise an RHC that it must comply with the staffing requirement within 90 days from the date it informed the SA it no longer met the staffing requirements or be terminated unless a waiver request is submitted by the facility and approved by the RO at the end of the 90-day period.

2248C - Documentation Demonstrating Efforts to Meet Staffing Requirements

(Rev. 1, 05-21-04)

An RHC must submit written documentation to the SA demonstrating its reasonable efforts to hire the required staff. This documentation should evidence ongoing activities throughout the 90-day time period prior to making a waiver request. The following types of documentation would be acceptable:

- Copies of reports of telephone contacts with potential hires, professional schools and organizations, recruiting services, etc.;
- Information about trips to professional meetings, educational institutions, and health care facilities for recruiting purposes;
- Copies of advertisements for recruiting hires; and
- Results of personal interviews with potential hires.

2248D - Monitoring Waivers

(Rev. 1, 05-21-04)

The SA monitors the expiration dates of waivers. When the expiration date of an RHC's

waiver is imminent, the SA must contact the RHC to determine whether the RHC will be in compliance with 42 CFR Part 491.8 as of the expiration date of the waiver.

If it is determined that the RHC will not be in compliance with 42 CFR Part 491.8 as of the expiration date of the waiver, the SA notifies the RHC that it will be terminated from the Medicare program. The RHC should be given notice of the termination at least 15 days before the effective date of the termination date. The termination date cannot be earlier than the day after the expiration date of the waiver.

If the RHC provides evidence that it has hired the required staff, but the staff will not be available at the clinic until after the expiration date of the waiver, the SA initiates termination action pursuant to §3012. The SA informs the RHC that when it meets the staffing requirement it should notify you immediately.

2248E - Notification

(Rev. 1, 05-21-04)

Both the SA and the ROs should notify an RHC when an RHC's waiver has been approved and include an explanation of the above termination procedures for expired waivers.

2249 - RO Notification of RHC Initial Certification Approval

(Rev. 139, Issued: 04-24-15, Effective: 04-24-15, Implementation: 04-24-15)

The SA forwards to the RO its survey report or the AO's notice of accreditation and recommendation of deemed status, along with any other supporting documents required in the RHC certification packet. The RO reviews all documentation to determine whether the applicant is or is not in compliance with all RHC requirements. The RO notifies an applicant of its approval or denial of certification in writing. If the applicant is approved, the RO countersigns, dates and issues the Form 1561A, Health Insurance Benefits Agreement, Rural Health Clinic, along with a cover letter indicating the RHC's CCN and the effective date of the Agreement. See §2784 which governs how the RO determines the effective date of participation.

- The RO sends a copy of Form CMS-2007 to the Medicare Administrative Contractor (MAC) and another to the State Medicaid Agency (SMA) that has billing jurisdiction for RHCs.

- The RO sends a copy of the letter issuing the clinic's agreement to the Regional Health Administrator, HRSA, so that appropriate notification may be given to components of the PHS engaged in program support for rural health service activity.

The RO adds the following paragraph to the letter accepting the RHC's agreement:

> Your participation as an RHC under the Medicare program will also be

accepted as certification as an RHC under the Medicaid program. If you need information about payment for RHC services under the State plan for medical assistance, contact (name, address, and telephone number of appropriate SMA).

If a provider-based CCN is being issued, the approval letter must contain the following explicit language: "Issuance of a provider-based RHC CCN does **not** constitute a CMS provider-based determination."

Community Mental Health Centers

2250 - Community Mental Health Centers (CMHC) - Citations and Descriptions

(Rev. 197, Issued: 01-10-20, Effective: 01-10-20, Implementation: 01-10-20)

NOTE: Recognition of marriages: Every psychiatric hospital/facility is expected to recognize all lawful marriages and spouses for purposes of compliance with the Conditions of Participation and regulatory requirements. In this guidance, and in every instance where the following terms appear:

- "Spouse" means an individual who is married to another individual as a result of a marriage that was lawful where entered into, including an individual married to an individual of the same-sex.

- "Marriage" means a marriage that was lawful where entered into, including a marriage of two individuals of the same sex;

- "Family" includes, but is not limited to, an individual's "spouse" (see above); and,

- "Relative," when used as a noun, includes, but is not limited to an individual's "spouse" (see above).

Furthermore, wherever the text of a regulation or associated guidance includes a reference to a patient's "representative," "surrogate," "support person," "next-of-kin," or similar term in such a manner as would normally implicitly or explicitly include a spousal relationship, the terms are to be interpreted as indicated above.

2250A - Citations and Definitions

(Rev. 197, Issued: 01-10-20, Effective: 01-10-20, Implementation: 01-10-20)

Citations

Section 4162 of P.L. 101-508 (OBRA 1990), amended §1861(ff)(3)(A) and §1832(a)(2)(J) of the Act to include CMHCs as entities that are authorized to provide partial hospitalization services under Part B of the Medicare program, effective October 1, 1991. Applicable regulations are found at 42 CFR Chapter IV, Parts 400, 410, 424, 485 and 489. The Conditions of Participation (CoPs) were published on October 29, 2013 and were effective on October 29, 2014.

Definitions

Community Mental Health Center (CMHC) is as defined in §410.2: "an entity that- (1) Provides outpatient services, including specialized outpatient services for children, the elderly, individuals who are chronically mentally ill, and clients of its mental health service area who have been discharged from inpatient treatment at a mental health

facility; (2). Provides 24-hour-a-day emergency care services; (3) Provides day treatment or other partial hospitalization services, or psychosocial rehabilitation services; (4) Provides screening for patients being considered for admission to State mental health facilities to determine the appropriateness of this admission; (5) Meets applicable licensing or certification requirements for CMHCs in the State in which it is located; and (6) Provides at least 40 percent of its services to individuals who are not eligible for benefits under title XVIII of the Social Security Act."

Active treatment plan means an individualized client plan that focuses on the provision of care and treatment services that address the client's physical, psychological, psychosocial, emotional, and therapeutic needs and goals as identified in the comprehensive assessment.

Comprehensive assessment means a thorough evaluation of the client's physical, physiological, psychosocial, emotional, and therapeutic needs related to the diagnosis under which care is being furnished by the CMHC.
Initial evaluation means an immediate care and support assessment of the client's physical, psychosocial (including a screen for harm to self or others), and therapeutic needs related to the psychiatric illness and related conditions for which care is being furnished by the CMHC.

Representative means an individual who has the authority under State law to authorize or terminate medical care on behalf of a client who is mentally or physically incapacitated. This includes a legal guardian.

Restraint means (1) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a client to move his or her arms, legs, body, or head freely, not including devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a client for the purpose of conducting routine physical examinations or tests, or to protect the client from falling out of bed, or to permit the client to participate in activities without the risk of physical harm (this does not include a client being physically escorted); or (2) A drug or medication when it is used as a restriction to manage the client's behavior or restrict the client's freedom of movement, and which is not a standard treatment or dosage for the client's condition.

Partial Hospitalization Services (PHS) is as defined in §410.2:"Partial hospitalization services means a distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting and furnishes the services as described in § 410.43." Per §410.43 "(a) Partial hospitalization services are services that—(1) Are reasonable and necessary for the diagnosis or active treatment of the individual's condition; (2) Are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization;(3) Are furnished in accordance with a physician certification and plan of care as specified under § 424.24(e) of this chapter; and (4) Include any of the following: (i) Individual and group therapy with physicians or psychologists or other mental health professionals to the extent authorized under State

law. (ii) Occupational therapy requiring the skills of a qualified occupational therapist, provided by an occupational therapist, or under appropriate supervision of a qualified occupational therapist by an occupational therapy assistant as specified in part 484 of this chapter. (iii) Services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients. (iv) Drugs and biologicals furnished for therapeutic purposes, subject to the limitations specified in § 410.29. (v) Individualized activity therapies that are not primarily recreational or diversionary. (vi) Family counseling, the primary purpose of which is treatment of the individual's condition. (vii) Patient training and education, to the extent the training and educational activities are closely and clearly related to the individual's care and treatment. (viii) Diagnostic services. (b) The following services are separately covered and not paid as partial hospitalization services: (1) Physician services that meet the requirements of §415.102(a) of this chapter for payment on a fee schedule basis. (2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act. (3) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act. (4) Qualified psychologist services, as defined in section 1861(ii) of the Act. (5) Services furnished to SNF residents as defined in § 411.15(p) of this chapter. (c) Partial hospitalization programs are intended for patients who—(1) Require a minimum of 20 hours per week of therapeutic services as evidenced in their plan of care; (2) Are likely to benefit from a coordinated program of services and require more than isolated sessions of outpatient treatment; (3) Do not require 24-hour care; (4) Have an adequate support system while not actively engaged in the program; (5) Have a mental health diagnosis; (6) Are not judged to be dangerous to self or others; and (7) Have the cognitive and emotional ability to participate in the active treatment process and can tolerate the intensity of the partial hospitalization program."

Day Treatment Services generally include person-centered, culturally and linguistically appropriate, comprehensive, coordinated, structured treatment services and activities. A day treatment program consists of a scheduled series of structured, face-to-face therapeutic sessions organized at various levels of intensity and frequency in order to assist the persons served in achieving the goals identified in their person-centered plans. Day treatment programs are offered four or more days per week, typically with support available in the evenings and on weekends. A day treatment program may prevent or minimize the need for a more intensive level of treatment. It may also function as a step-down from inpatient care or partial hospitalization or, as transitional care following an inpatient or partial hospitalization stay to facilitate return to the community.

Psychosocial Rehabilitation Services (PSR) are activities aimed at reintegrating the individual back into society by improving their functioning and ability to comply with rules and expectations of the community and are consistent with the identified goals or objectives of the client's active treatment plan. This includes the fullest possible integration of the client as an active and productive member of his or her family, community, and/or culture with the least amount of structured professional intervention. Services may be provided individually or in a group setting.

Seclusion "means the involuntary confinement of a client alone in a room or an area from which the client is physically prevented from leaving."

Children are defined by Medicare as an unmarried person younger than 22 years old. Surveyors should also be aware of their State law for defining a child, based on where the CMHC is located.

Elderly refers to an individual who is aged 65 years and older.

2250B - Special Requirements

(Rev. 197, Issued: 01-10-20, Effective: 01-10-20, Implementation: 01-10-20)

A CMHC is required to submit a certification statement, provided by an independent licensed professional, to certify that the CMHC client population meets the 40 percent requirement as specified in 42 CFR §485.918(b)(1)(v)(A) and 42 CFR §485.918(b)(1)(v)(B). The certification statement is required upon initial application to enroll in the Medicare program and as part of provider enrollment revalidation. The statements are submitted to the applicable Medicare Administrative Contractor. Medicare enrollment may be denied or revoked in instances where the CMHC fails to provide the certification statement as required. The CMHC and individuals furnishing services on its behalf must meet applicable State licensure requirements.

2250C - Partial Hospitalization Services Provided by CMHCs or by Others Under Arrangements With the CMHC

(Rev. 197, Issued: 01-10-20, Effective: 01-10-20, Implementation: 01-10-20)

Per section 1866(e)(2) of the Act CMHCs are recognized as Medicare providers only with respect to providing partial hospitalization services and under regulations at 42 CFR §489.2(c)(2) CMHCs may only enter into provider agreements under Medicare to furnish partial hospitalization services. If during the course of a survey it is determined that the CMHC does not provide partial hospitalization services, the surveyor should document this finding in the CMS-2567 “Statement of Deficiencies and Plan of Correction” under Tag 000 “Initial Comments.” The survey should be completed, despite this finding. The surveyor should include in their documentation all information collected to confirm that the provider is not providing PHS, including documentation from records reviewed and interviews.

Even if the CMHC is found to be in compliance with the CoP in §485.918 Organization, Governance, Administration of Services, and Partial Hospitalization Services, the CMHC may not enter into, or continue, a provider agreement with CMS unless the CMHC chooses to provide partial hospitalization services. If the CMHC does not choose to either provide partial hospitalization services, or to voluntarily terminate its Medicare provider agreement, CMS may exercise its authority to terminate the provider agreement pursuant to §489.53.

In order for a CMHC to demonstrate that they are providing Partial Hospitalization Services, the following program service requirements must be met pursuant to §410.43:

1) Physician approved (ideally a psychiatrist) certification or active treatment plans for clients;

2) Both individual and group therapy services facilitated by approved mental health professionals to the extent authorized under State law;

3) Occupational therapy services to the extent authorized under State law;

4) Services provided by social workers, psychiatric nurses and other staff trained to work with psychiatric clients;

5) Drugs and biologicals furnished for therapeutic purposes;

6) Individual therapy services not primarily for recreational or diversionary reasons (examples: Games, outings, gardening, computers, gentle exercise, music, arts and crafts);

7) Family counseling, primarily focused on or addressing the clients psychiatric condition;

8) Training and education services that are directly related to the clients individual active treatment plan; and

9) Diagnostic services (example: psychological testing).

2251 - Certification Process

(Rev. 197, Issued: 01-10-20, Effective: 01-10-20, Implementation: 01-10-20)

2251A – Request to Participate

(Rev. 197, Issued: 01-10-20, Effective: 01-10-20, Implementation: 01-10-20)

The CMHC notifies the State Survey Agency (SA) that it wishes to participate. The SA ensures that the CMHC submits a CMS-855A to the Medicare Administrative Contractor (MAC) and forwards information to the applicant concerning the procedure for Office of Civil Rights clearance. Once the MAC has completed its review, including a review of the facility certification statement that at least 40% of the CMHC's items and services are provided to non- eligible individuals, it will forward an approval recommendation notice to the appropriate CMS Regional Office (RO) and the SA. The SA will schedule an initial survey for the CMHC according to the CMS Mission and Priority Document (MPD).

2251B – Initial Survey/Certification-SA Role

(Rev. 197, Issued: 01-10-20, Effective: 01-10-20, Implementation: 01-10-20)

The SA evaluates whether the applicant meets the CoPs and applicable licensing requirements in the State through an on-site survey. Include within the survey process,

the requirements as stated in section 2250C of the SOM. A CMHC may be certified with Standard level deficiencies as long as an acceptable plan of correction is submitted. However, a CMHC may not be certified with a Condition level deficiency or if it does not provide PHS. The SA will forward its recommendation for certification or denial of certification to the RO. The SA will process the certification packet pursuant to applicable instructions in §§2760-2776.

2251C – Initial Certification- RO Role

(Rev. 197, Issued: 01-10-20, Effective: 01-10-20, Implementation: 01-10-20)

The RO will make a determination on the CMHC's request to be a participant in the Medicare program. The RO will evaluate the information and recommendation received from the SA regarding a CMHC's initial certification application including whether or not PHS are being provided; either agree or disagree with the SA recommendation for initial certification or denial based upon provider agreement requirements; and notify the applicant of the its decision. The RO will forward a CMS-2007 to the MAC whether the applicant is approved or denied for certification. If approved, a CCN and provider agreement are issued.

2251D - Facility Alleges it is Provider-Based

(Rev. 197, Issued: 01-10-20, Effective: 01-10-20, Implementation: 01-10-20)

A hospital may provide partial hospitalization services either through its outpatient department or through a hospital based CMHC. The hospital's ability to bill for partial hospitalization through its outpatient departments became effective December 22, 1987, under §1861(ff) of the Act. Hospital outpatient departments do not need to qualify as CMHCs to initially provide, or continue to provide, partial hospitalization services. The hospital may also elect to operate a certified facility as a component of its hospital.

Although the statute does not preclude CMS' approval of hospital-based CMHCs, an entity, for the purposes of providing partial hospitalization services, can qualify under Medicare either as a hospital outpatient department or a CMHC that is hospital- based. An entity does not have the option to qualify as both a hospital outpatient department and a hospital-based CMHC to provide partial hospitalization services. Allegations of provider-based, whether alleged initially by the applying CMHC, or subsequent to CMS approval as a CMHC, will be developed using the guidelines contained in §2004.

2251E – Voluntary Termination

(Rev. 197, Issued: 01-10-20, Effective: 01-10-20, Implementation: 01-10-20)

A Medicare participating CMHC may voluntarily terminate its provider agreement at any time. The SA will follow the guidance in SOM §§3046, 3047, and 3048 in processing the termination.

2251F - Involuntary Termination

(Rev. 197, Issued: 01-10-20, Effective: 01-10-20, Implementation: 01-10-20)

A CMHC's provider agreement will be involuntarily terminated if the CMHC is not in compliance with the CoPs or does not provide PHS. The SA will follow the guidance in SOM §§3005, 3005A, 3005B and 3005D in processing the termination. All CMHCs must comply with the CoPs.

Critical Access Hospitals (CAHS)

2254 - CAHS (Critical Access Hospitals)

(Rev. 1, 05-21-04)

2254A - Statutory Citation

(Rev. 1, 05-21-04)

Section 4201 of the Balanced Budget Act of 1997, Public Law 105-33, amended §1820 of the Social Security Act and created the Medicare Rural Hospital Flexibility Program (MRHFP). The program allows for the creation of critical access hospitals and is designed to promote rural health planning, network development, and improve access to health services for rural residents of the State. The program is available in any State having rural facilities and which chooses to set up such a program and submits an acceptable State plan to CMS.

2254B - Regulatory Citation

(Rev. 1, 05-21-04)

The Conditions of Participation (CoPs) for Critical Access Hospitals are found in the Code of Federal Regulations at 42 CFR Part 485 subpart F.

2254C - Submission of a State Plan

(Rev. 1, 05-21-04)

States who are interested in establishing CAHS must submit an application to the Regional Administrator of the CMS Regional Office responsible for oversight of Medicare and Medicaid in the State. An official of the State must sign the application. The application must express the State's interest in developing a MRHFP. There are no Federal forms and no set format for the submission of the State plan. The State plan should designate facilities in the State that qualify for critical access hospital status. There is no statutory or regulatory requirement for CMS to review changes or updates to any State plan subsequent to the initial review and acceptance by CMS.

2254D - Requirements for Critical Access Hospitals

(Rev. 1, 05-21-04)

A critical access hospital is a facility that is designated as a CAH by the State in which it is located and meets the following criteria:

- Meets the Conditions of Participation found at 42 CFR Part 485 subpart F;
- Is a rural public, non-profit or for-profit hospital; or is a hospital that was closed within the previous ten years; or is a rural health clinic that was downsized from a hospital;
- Is a facility located in a State that has established a State plan with CMS for the Medicare Rural Hospital Flexibility Program;
- Is located more than a 35-mile drive from any other hospital or CAH (in mountainous terrain or in areas with only secondary roads available, the mileage criterion is 15 miles); **or** is certified by the State in the State plan as being a **necessary provider** of health care services to residents in the area;
- Makes available 24-hour emergency care services 7 days per week;
- Provides not more than 15 beds for acute (hospital level) inpatient care. An exception to the 15-bed requirement is made for swing-bed facilities, which are allowed to have up to 25 inpatient beds that can be used interchangeably for acute or SNF-level care, provided that not more than 15 beds are used at any one time for acute care;
- Provides an annual average length of stay of 96 hours per patient for acute care patients;

NOTE: An exception has been made by CMS for hospice admissions to a CAH. The hospice may contract with a CAH to provide the hospice hospital benefit. Reimbursement from Medicare is made to the hospice. The CAH may dedicate beds to the hospice but the beds must be counted as part of the allowable number of CAH beds. The hospice patient does not contribute to the 96-hour annual average length of stay computation. The hospice patient can be admitted to the CAH for any care involved in their treatment plan or for respite care. The CAH negotiates reimbursement through an agreement with the hospice.

2255 - SA Procedures for CAH Approval

(Rev. 1, 05-21-04)

A CAH must be surveyed for compliance with the CoPs in 42 CFR Part 485 subpart F, and compliance with the specific CAH SNF requirements specified by 42 CFR 485.645(d)

if it has or is requesting swing-bed approval.

2255A - CAH Applications

(Rev. 1, 05-21-04)

When a facility contacts the SA to apply for Medicare participation as a CAH, the SA sends a letter to the CAH, see (Exhibit 134) "Transmitting Materials to Critical Access Hospitals."

A current Medicare provider who is requesting a change of status to a CAH sends an amended Form CMS-855A to the FI with specific information required by the FI.

Within 30 days, the intermediary will notify the SA indicating if the Form CMS-855A was approved or not approved. The State survey agency verifies that the facility has been properly designated as a CAH by the State government entity responsible for CAH designation prior to forwarding the application to the RO.

2255B - Pre-Survey Activity

(Rev. 1, 05-21-04)

The SA follows the procedures outlines in Appendix W, Survey Protocol for CAH Providers. The SA verifies requirements in the CAH CoPs in 42 CFR 485.608, 485.610, and 485.612 from facility files and any other documentation available at its office. If the prospective CAH has swing-bed approval, the SA determines that the swing-bed approval is current.

2255C - Arranging a CAH Survey

(Rev. 1, 05-21-04)

After the RO has authorized a survey, the SA follows the procedures outlined in Appendix W, Survey Protocol for CAH Providers. All CAH surveys are unannounced surveys.

2255D - Onsite Survey Activity

(Rev. 1, 05-21-04)

The SA follows the guidelines for the survey process in Appendix W.

2255E - Preparing a Statement of Deficiencies

(Rev. 1, 05-21-04)

The SA uses the "Statement of Deficiencies and Plan of Correction," Form CMS-2567, when citing deficiencies, and refers to Exhibit 7A, "Principles of Documentation," for

procedural guidance. The SA sends the completed Form CMS-2567 to the facility. If there are deficiencies cited, the SA sends a letter, see Exhibit 151, "Request for a Plan of Correction Following an Initial CAH Survey." If there are swing-bed deficiencies, a separate Form CMS-2567 must be prepared.

2256 - RO Procedures for CAH Approval

(Rev. 1, 05-21-04)

A prospective CAH must be surveyed by the SA and be in compliance with the CoPs for CAHS at 42 CFR Part 485 subpart F, before it can be approved for participation in Medicare as a CAH provider. The change from hospital to CAH is considered a change in status. A new provider agreement is not needed unless there is a change in ownership (CHOW) without the assumption of debt.

2256A - Verification Criteria

(Rev. 143, Issued: 07-31-15, Effective: 07-31-15, Implementation: 07-31-15)

If the provider is a hospital, CAH verification requires that the RO review the facility file to determine if the prospective CAH is in compliance with the hospital CoPs in 42 CFR Part 482 at the time it made application for designation as a CAH (see 42 CFR 485.612). If the provider is a closed hospital or a downsized hospital, it is not necessary that they meet hospital CoPs at the time of application or on conversion.

The RO will reverify compliance with 42 CFR 485.610(a) and (b) and has primary responsibility to verify compliance with 42 CFR 485.610(c) and (d).

NOTE: A hospital applying for CAH certification should **not** be surveyed until after the RO determined that the applicant is compliant with the CAH location and distance requirements. If the survey is conducted prior to the RO making a determination regarding the applicant's compliance with the location and distance requirements, and the RO finds that the applicant is noncompliant, the application must be denied. The applicant may submit a reapplication for CAH certification in connection with the initial enrollment application – using the guidance in Chapter 2 of the SOM, §2005A2.

Rural location

Among other requirements, pursuant to 42 CFR 485.610(b), all CAH applicants and existing CAHs, including necessary provider CAHs, must either be:

- Located in a rural area; or
- Treated as rural in accordance with 42 CFR 412.103

in order to be eligible for CAH designation and certification.

Only the CMS Regional Office makes the determination whether a CAH applicant or existing CAH meets the rural location requirement, following the instructions below.

However, State Survey Agencies (SA) may wish to make informal assessments prior to conducting a survey. If the SA's informal assessment suggests the CAH applicant or existing CAH is not rural, it should consult with the RO before conducting a survey.

- **Located in a rural area – i.e., outside a Metropolitan Statistical Area (MSA)**

Under 42 CFR 485.610(b)(1)(i), a rural area is any area that is outside a MSA, as defined by the Federal Office of Management and Budget (OMB). In making a determination regarding the rural status of a CAH, the CMS RO first consults the latest OMB MSA delineations that have been adopted by CMS.

OMB conducts a comprehensive review of its MSA delineations once a decade and also conducts periodic updates between decennial censuses based on Census Bureau data. When OMB releases revised statistical area delineations, typically CMS adopts the new delineations in the next hospital Inpatient Prospective Payment System (IPPS) rule, which is usually proposed in April of each year, published as a final rule in August and effective on October 1st following the final rule publication date. If an IPPS final rule has been released during a time when OMB has not released revised statistical area delineations, the most recently-released OMB delineations adopted by CMS remain in effect. Accordingly, the RO must consult the MSA delineations used for the purpose of the final IPPS rule that is in effect at the time of:

- The Medicare Administrative Contractor's (MAC) determination that a hospital has submitted a complete application to convert to CAH certification; or
- At the time of the RO's recertification review of an existing CAH.

The most recent final IPPS rule~~s~~ can be found on CMS' Acute Inpatient PPS webpage:

http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html

ROs may use the following instructions to locate the OMB MSA delineations in effect at the applicable time for a rural location determination:

1. Go to the Acute Inpatient PPS webpage noted above.
2. Select the link for the IPPS final rule in effect at the applicable time for the initial applicant or at the time of the recertification decision for an existing CAH. For example, if a CAH is up for recertification and the RO is evaluating the CAH's compliance with the rural location requirement on February 1, 2016, the most recent OMB MSA delineations adopted by CMS would be those effective October 1, 2015 and the RO would select "FY 2016 IPPS Final Rule Home Page" from the list of IPPS rules on the left-hand column. On the other hand, if the RO is evaluating the existing CAH's compliance on September 10, 2015, it would select the FY 2015 IPPS Final Rule Home Page, since the FY 2016 rule would not go into effect until October 1, 2015.

3. Select the link for final rule data files. For example, on the FY 2015 IPPS Final Rule Home Page, select the link titled "FY 2015 Final Rule Data Files."
4. In the Downloads section at the bottom of the page, select the link for the "County to CBSA Crosswalk File."
5. Select the Excel file. For example, for the FY 2015 IPPS final rule, select the file titled "CBSAtoCountycrosswalk_FY15_FR.xlsx."
6. Search for the county in which the CAH is located. If the IPPS rule has adopted revised OMB statistical delineations, the revised information will be found in column "G", which is titled, "New CBSA" (Blanks are Rural)." Column G includes the CBSA code for each county. If the cell is blank, the county is a rural county. If all of Column G is blank, this means that the final IPPS rule did not include adoption of revised OMB statistical delineations, and that the delineations from a prior final rule remain in effect.

- **Even if the existing CAH or CAH applicant is located outside an MSA and therefore is in a rural area, it is also necessary to determine that it is also <u>not</u>:**

  - Located in an area that has been recognized as urban in accordance with 42 CFR 412.64(b), excluding §412.64(b)(3);
  - Classified as an urban hospital in accordance with 42 CFR 412.230(d) (NOTE: 42 CFR 412.230(d) became 412.230(d) in 2001); or
  - Redesignated to an adjacent urban area in accordance with 42 CFR 412.232.

  Financial staff in the RO should be able to provide information on whether the CAH applicant falls in one of the above three categories, since 42 CFR Part 412 are regulations developed primarily for payment purposes.

- **Located within an MSA, but treated as rural**

  Even if the CAH applicant is located in an MSA, it may nevertheless qualify to be "treated" as rural if it is a hospital that has been reclassified as rural in accordance with 42 CFR 412.103, i.e., it was reclassified based on:

  - Being located in a rural census tract of a MSA per the most recent version of the Goldsmith Modification or the Rural-Urban Commuting codes, as determined by the Office of Rural Health in the Health Resources and Services Administration. (See <u>http://www.hrsa.gov/ruralhealth/policy/definition_of_rural.html</u>);

  Or

  - It would qualify as a rural referral center or a sole community hospital if it were located in a rural area;

  Or

- It is located in an area designated under any State law (including State regulation) as a rural area, or has been designated as a rural hospital under State law (including regulation).

Rural reclassifications are handled by the CMS RO Office of Financial Management. RO survey and certification staff should consult with their financial management counterparts to determine whether a reclassification has been made that would permit a CAH applicant or existing CAH to be treated as rural.

In the case of an initial application for CAH status by a hospital, the application must be denied if the hospital applicant is located within an MSA or has not been reclassified in a manner that allows it to be treated as rural. If the applicant subsequently succeeds in being reclassified as rural, it may submit a reapplication for CAH certification in connection with the initial enrollment application – using the guidance in Chapter 2 of the SOM, §2005A2 – on or after the effective date of its reclassification . If the hospital was surveyed for compliance with the CAH CoPs as part of its prior denied application, it must nevertheless be surveyed again; however, this survey does not require an on-site visit if the hospital is otherwise in substantial compliance with the CAH CoPs. (NOTE: This should be a rare occurrence as a hospital applying for CAH certification should **not** be surveyed until the RO has determined that the applicant is in compliance with the CAH location and distance requirements). The effective date of its CAH conversion must be no earlier than the date when the applicant demonstrates compliance with all requirements to be certified as a CAH.

In the case of an existing CAH that is being recertified, the RO first determines whether the CAH is outside of an MSA, using the OMB MSA delineations adopted by CMS and in effect at the time the RO is processing the CAH's recertification. If the CAH is no longer outside an MSA, the RO must consult with the RO Office of Financial Management to determine whether there is a reclassification in effect that permits the CAH to be treated as rural.

If the existing CAH previously was outside an MSA, but is now in an MSA and has not been reclassified as rural, the CAH may continue to retain its CAH status up to two years after the effective date of CMS's adoption of the OMB MSA delineations that changed the CAH's rural status. The CAH is responsible at all times for ensuring that it meets the requirement at §485.610(b) to be considered rural. Therefore, in order to continue participating in the Medicare program, during the two-year grace period the CAH is expected either to successfully be reclassified to be treated as rural or to have completed conversion to a Medicare-certified hospital, including demonstrating compliance with the hospital CoPs at 42 CFR Part 482. Note that a recertification review of the CAH's status and location by the RO is triggered any time:

- An SA conducts a full survey of a CAH, whether for recertification of a non-accredited CAH, for a validation survey of a deemed status CAH, or when following up on a prior complaint survey and the RO requires a full survey; or

- An accrediting organization reaccredits a deemed status CAH and recommends to the RO continued deemed status.

If the recertification review of the CAH takes place more than two years after the effective date of the CMS adoption of revised OMB MSA delineations that resulted in the CAH's loss of rural status and the CAH has not been reclassified to be treated as rural, the CAH is substantially noncompliant with the CAH Status and Location CoP (§485.610) and the RO takes action to terminate the CAH's Medicare agreement.

Examples:

- Example 1: The RO is conducting a recertification review of a CAH in January, 2016. When CMS initially certified the CAH, it determined that the CAH was located outside of an MSA. However, for the purposes of this example, the OMB MSA delineations that were adopted by CMS and effective October 1, 2014 resulted in the CAH being located within an MSA. The CAH had a maximum of two years – up to and including October 1, 2016 - to retain its CAH certification status. However, the CAH did not seek reclassification to be treated as rural. After conducting its January 2016 review, the RO would notify the CAH that it no longer satisfies the CAH rural status requirement and could remain certified as a CAH only until October 1, 2016. The CAH would then have 10 months to either be reclassified as rural or to complete conversion to CMS-certified hospital status in order to avoid termination of its Medicare agreement.

- Example 2: The CAH in Example 1 was not reviewed for recertification until January 2017, a date more than two years after the effective date of its changed MSA status. Additionally, the CAH had not been reclassified as rural and had not converted to hospital certification. In this situation, the CMS RO would determine that the CAH does not satisfy the CAH rural status requirement and would take action to terminate the CAH's Medicare agreement.

- Example 3: For the purposes of this example only, revised OMB MSA delineations were released in May 2014, proposed for adoption by CMS as part of the IPPS rule in April 2015, adopted by CMS August 8, 2015, and became effective October 1, 2015. Furthermore, a MAC determined that an initial CAH applicant's application was complete and could be recommended to the RO and SA for approval as of June 5, 2015, contingent upon the CAH being certified by CMS. Also the CAH applicant was recommended for deemed status by a CMS-approved Medicare CAH accreditation program, with an August 15, 2015 accreditation effective date. In this case, the RO would use the OMB MSA delineations that CMS had most recently adopted as of June 5, 2015, i.e., those adopted by CMS effective October 1, 2014, in making its determination about rural status, and found that the CAH was outside an MSA and certified it as a CAH effective August 15, 2015. The RO does this even though OMB released more recent delineations in May 2014 and CMS has already adopted a rule incorporating the later OMB MSA delineations. Since the adoption of the later delineations is not effective until October 1, 2015, the RO must use the MSA delineations previously adopted by CMS and applicable on June 5, 2015.

- Example 4: Finally, using the CAH in Example 3, the CAH is now located inside an MSA based on revised OMB MSA delineations adopted by CMS effective October 1, 2015. As a result, the CAH no longer meets the rural location requirement as of October 1, 2015, but may retain its CAH status until October 1, 2017. Note that in this case the CAH is not due for reaccreditation and recertification until August 2018, which is after the end of the grace period. If the CAH has neither been successfully reclassified as rural nor converted to a hospital by October 1, 2017, the RO would take action to terminate the CAH's Medicare agreement.

In all of the above examples, the CAH has primary responsibility for monitoring changes in its rural status resulting from CMS's adopted revised OMB MSA delineations, and taking appropriate action if it loses its rural status on the basis of the revised delineations.

Necessary Provider Status and Rural Reclassification

Necessary provider certification only provides an exemption from the CAH distance requirements relative to other CAHs and hospitals. Necessary provider CAHs are still required to meet the rural location requirement; therefore, if a necessary provider CAH is located within an MSA as a result of a change in the OMB MSA delineations adopted by CMS, it must follow the same procedures noted above as any other CAH.

Location relative to other facilities or necessary provider certifications:

In addition, the regulations at 42 CFR 485.610(c) specify that one of the following 3 minimum driving distances from other facilities requirements must be met:

- 35-Mile Distance: The CAH must be located more than a 35-mile drive from any hospital or other CAH; or

- 15-Mile Distance: In the case of mountainous terrain or in areas with only secondary roads available, the CAH must be located more than a 15-mile drive from any hospital or other CAH; or

- No Distance Requirement: In the case of a CAH that was designated by the State as being a necessary provider of health care services to residents in the area before January 1, 2006, there is no minimum distance requirement.

In determining whether a currently certified CAH or a CAH applicant meets the location requirements at §485.610(c), the proximity of IHS/Tribal hospitals or CAHs and non-IHS/Tribal hospitals or CAHs to each other is not considered.

The following examples clarify how determinations are to be made when IHS or Tribal hospitals or CAHs are in the vicinity of non-IHS or non-Tribal hospitals or CAHs:

- Example 1: Hospital A is seeking CAH certification and is a 10-mile drive from Hospital B, an IHS hospital. Hospital C is the next nearest hospital/CAH and is a 42-

mile drive from Hospital A. The distance to Hospital B is not considered; Hospital A meets the minimum distance to another CAH or hospital requirement.

- Example 2: CAH A is a tribal facility that is being reviewed as part of the recertification process. It is a 17-mile drive from a non-tribal/non-IHS CAH (CAH B). It is also a 75-mile drive from an IHS hospital (Hospital C). The distance to CAH B is not considered; CAH A continues to meet the minimum distance to another CAH or hospital requirement.

- Example 3: Hospital A is a tribal hospital seeking CAH certification and is a 33-mile drive along primary roads to an IHS hospital, Hospital B. It is also a 50-mile drive to Hospital C, a non-IHS/non-tribal hospital. The distance to Hospital B is considered; Hospital A does not meet the minimum distance to another CAH or hospital requirement.

If a CAH is located on an island and the location meets the following characteristics, the CAH is considered to be in compliance with the distance requirements relative to other hospitals and CAHs under §485.610(c):

- The island is entirely surrounded by water;
- The CAH is the only hospital or CAH on the island; and
- The island is not accessible by any roads.

CAHs located on islands that meet the criteria above are still required to comply with the rural location requirement under §485.610(b).

In demonstrating that it meets the standard for more than a 35-mile drive, a CAH applicant must document that there is no driving route from the applicant to any other CAH or hospital that is 35 miles or less in length.

Application of the more than 15-mile drive standard, based on mountainous terrain

Slope and ruggedness of the terrain around the CAH, together with absolute altitude (the distance above sea level), determine many of the fundamental characteristics of mountainous terrain.[1] However, being located at a high elevation does not, in and of itself, constitute "mountainous terrain," nor does being located at the foot of a mountain or where mountains can be viewed. Further, the absolute altitude required to constitute mountainous terrain will vary in different regions. For example, the altitude of the Appalachian Mountains is considerably lower than that of the Rocky Mountains, yet the slope and ruggedness of the terrain in many portions of the Appalachians is mountainous. Furthermore, roads passing through mountainous terrain are characterized by certain typical engineering features. For the purposes of determining a CAH's eligibility for the 15-mile drive standard based on mountainous terrain, the roads on the travel route(s) to hospitals or other CAHs must meet the following criteria:

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[1] United Nations Environment Programme World Conservation Monitoring Centre. (2002). *Mountain Watch.* Retrieved August 11, 2010, from http://www.unep-wcmc.org/mountains/mountain_watch/pdfs/.

- Over 15 miles of the roads on the travel route(s) from the CAH to any hospital or another CAH must be located in a mountain range, identified as such on any official maps or other documents prepared for and issued to the public;

and

- Since being located within a mountain range in and of itself does not mean that the drive to any other hospital or CAH includes travel through "mountainous terrain," the roads on the travel route(s) from the CAH to any other hospital or CAH must have either of the following characteristics:

    - Extensive sections of roads with steep grades (i.e., greater than 5 percent), continuous abrupt and frequent changes in elevation or direction, or any combination of horizontal and vertical alignment that causes heavy vehicles to operate at crawl speeds for significant distances or at frequent intervals.[2] (Horizontal alignment refers to the "straightness" of the roadway, vertical alignment refers to the roadway's "flatness," and crawl speed is the speed at which a truck has no power to accelerate on long, steep grades.[3,4] Thus, roads in mountainous terrain are commonly described as winding and steep);

  or

    - Be considered mountainous terrain by the State Transportation or Highway agency, based on significantly more complicated than usual construction techniques that were originally required to achieve compatibility between the road alignment and surrounding rugged terrain. For example, because the changes in elevation and direction are abrupt in mountainous terrain, roadbeds may require frequent benching, side hill excavations, and embankment fills. [5]

A letter from the State Transportation or Highway agency specific to the travel route(s) in question is required to support the claim of mountainous terrain based on either of these sets of road characteristics.

It is not uncommon for there to be roads (or sections of roads) through mountainous areas that do not meet the criteria for "mountainous terrain." A CAH would qualify for application of the mountainous terrain criterion if there is a combination of mountainous and non-mountainous terrain between it and any other hospital or CAH, so long as there is no route to any hospital or other CAH with 15 or fewer miles of roads in mountainous terrain. When calculating the mountainous terrain travel distance to any hospital/other CAH, subtract the total distance represented by those sections of the travel route that are

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[2] Mannering, F. L., Washburn, S. S., & Kilareski, W. P. (2009). *Principles of Highway Engineering and Traffic Analysis.* Hoboken, NJ: John Wiley and Sons, Inc

[3] *Highway Capacity Manual: 2000 (U. S. Customary Units)* by Transportation Research Board (Dec. 2000). p 23-9.

[4] Donnell, E. T., Ni, Y., Adolini, M., & Elefteriadou, L. (2001). *Speed prediction models on two-lane rural highways.* Transportation Research Record, 1751, 44-55.

[5] *Mannering, F. L., Washburn, S. S., & Kilareski, W. P. (2009). Principles of Highway Engineering and Traffic Analysis. Hoboken, NJ: John Wiley and Sons, Inc.*

not considered "mountainous terrain." For example, if the route to the nearest hospital consisted of 12 miles in mountainous terrain, followed by 5 miles in non-mountainous terrain, followed by 4 miles in mountainous terrain, then the requirement for a total of more than 15 miles would be met (12 miles plus 4 miles – or 21 miles minus 5 miles – yield 16 total miles of mountainous terrain).

Application of the more than 15-mile drive standard, based on secondary roads

To be eligible for the lesser distance standard due to the secondary road criteria under §485.610(c) the CAH must document that there is a drive of more than 15 miles between the CAH and any hospital or other CAH where there are no primary roads. A primary road is:

- Any US highway, including any road:
  - In the National Highway System, as defined in 23 US Code §103(b); or
  - In the Interstate System, as defined in US Code §103(c); or
  - Which is a US-Numbered Highway (also called "US Routes" or "US Highways") as designated by the American Association of the State Highway and Transportation Officials (AASHTO), regardless of whether it is also part of the National Highway System;

  All US highways are readily identified via signage along the roads and on maps by the presence of "US" or "I" above the highway number, with the letters and number appearing on a distinctive, uniform shield background that is called the six point shield, with five points above and one below. Note: Although the National Highway System and the U.S. Numbered Highway system largely overlap, they are not identical. According to the American Association of the State Highway and Transportation Officials (AASHTO), which is responsible for designation of roads in the U.S. Numbered Highway system, the system is intended to facilitate the movement of interstate traffic in two or more States with the use of uniform markings.[6]

  Given the role all US highways are intended to play in interstate commerce, they are, by definition, primary roads.

  OR

  - A numbered State highway with 2 or more lanes each way;

  OR

  - A road shown on a map prepared in accordance with the U.S. Geological Survey's Federal Geographic Data Committee (FGDC) Digital Cartographic Standard for Geologic Map Symbolization as a "primary highway, divided by median strip."

[6] *AASHTO Special Committee on U.S. Route Numbering. Retrieved June 17, 2014, from: http://route.transportation.org/Documents/HO1_Policy_Establ_Develop_USRN.pdf*

A CAH may qualify for application of the "secondary roads" criterion if there is a combination of primary and secondary roads between it and any hospital or other CAH, so long as more than 15 of the total miles from the hospital or other CAH consists of areas in which only secondary roads are available. To apply the secondary roads criterion, measure the total driving distance between the CAH and each hospital or CAH located within a 35-mile drive and subtract the portion of that drive in which primary roads are available. If the result is more than 15 miles for each drive to a hospital or CAH facility, the 15-mile criterion is met.

The RO will review Web-based map servers, such as Google Maps, or NationalAtlas.gov for example, to determine whether the provider meets the requirements of 42 CFR 485.610(c). The RO will also review any documentation the provider may submit to demonstrate that it meets either the mountainous terrain or secondary roads criterion of §485.610(c), but such documentation must satisfy the requirements discussed above. For example, CMS does not consider any issues raised by CAH applicants or other parties concerning the physical features of any specific US highway, or portion thereof, when making a CAH location determination. Therefore, documentation submitted by the applicant indicating that a particular portion of a US highway has numerous curves, or a weight limitation, or narrow shoulders, etc. would not affect the RO's determination that the highway is a primary road.

2256B - Notification

(Rev. 1, 05-21-04)

When the facility is found to be in full compliance with the CoPs in 42 CFR Part 485, Subpart F, or has submitted an acceptable Plan of Correction, the RO notifies the facility in writing by sending letter, see Exhibit 150, "CAH Approval Notification," stating the facility has been approved for participation. A copy of the notice letter is sent to the FI and SA. Do not issue the letter until the facility is in compliance with all the CoPs.

2256C - Effective Dates

(Rev. 1, 05-21-04)

After the RO has reviewed and approved the SA recommendation for Medicare participation, the effective date for participation by a CAH will be one of the following:

- The last date of the initial survey by the SA, provided the prospective CAH is in full compliance with the CAH CoPs on that date; or

- The date that the prospective CAH submits an acceptable plan of correction to the SA.

2256D - RO Processing Complaints Against a CAH

(Rev. 1, 05-21-04)

When the RO or SA receives a complaint against a CAH regarding the CoPs in 42 CFR Part 485 subpart F, including the SNF requirements for a swing-bed CAH, the RO follows the normal complaint process for non-accredited hospitals.

2256E - RO Processing Denials or Terminations of a CAH

(Rev. 1, 05-21-04)

When the RO processes a denial or termination of a CAH, it follows the normal procedures that apply to Medicare-participating hospitals. For CAH denials, the RO uses a letter, see Exhibit 149, "CAH Denial for Medicare Participation Letter"; for CAH terminations use a letter, see Exhibit 152, "CAH Termination Letter."

2256F - Relocation of CAHs With a Grandfathered Necessary Provider Designation

(Rev. 32, Issued: 01-18-08, Effective: 09-07-07, Implementation: 09-07-07)

The intent of the CAH program is to keep hospital-level services in rural communities, thereby ensuring access to care, through provision of reimbursement on a more favorable basis than that available to participating hospitals. Therefore, CAHs are required to satisfy criteria designed to assure that they are located in rural areas and that there are no other hospitals or CAHs close by.

Prior to January 1, 2006, States were able to waive the distance requirement (the requirement that the facility be 35 miles from other hospitals or CAHs) by designating a facility as a necessary provider CAH. Section 405(h)(2)(B) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 changed the statute. As of January 1, 2006, States are no longer permitted to designate a facility as a necessary provider CAH, but existing necessary provider CAHs were grandfathered. The regulations at 42 CFR 485.610(d) specify limits on the ability of a grandfathered CAH to relocate and still retain its grandfathered status. The regulation permits such CAHs to relocate, so long as the CAH remains essentially the same provider and continues to ensure access to care in the same rural service area. Specifically:

> **"§485.610(d) Standard: Relocation of CAHs that have a necessary provider designation.**

A CAH that has a necessary provider designation from the State that was in effect prior to January 1, 2006, and relocates its facility after January 1, 2006, can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the relocated facility meets the requirements as specified in paragraph (d)(1) of this section.

> (1) If a necessary provider CAH relocates its facility and begins providing services in a new location, the CAH can continue to meet the location requirement of

paragraph (c) of this section based on the necessary provider designation only if the CAH is in its new location--

(i) Serves at least 75 percent of the same service area that it served prior to its relocation;

(ii) Provides at least 75 percent of the same services that it provided prior to the relocation; and

(iii)Is staffed by 75 percent of the same staff (including medical staff, contracted staff, and employees) that were on staff at the original location.

(2 If a CAH that has been designated as a necessary provider by the State begins providing services at another location after January 1, 2006, and does not meet the requirements in paragraph (d)(1) of this section, the action will be considered a cessation of business as described in §489.52(b)(3)."

Apply the guidance below in determining whether the regulatory requirements have been met.

General Considerations in Any Relocation

- Burden of Proof: The CAH bears the burden of proof in demonstrating that its relocation satisfies the regulatory standards.

- Basis for Necessary Provider Designation: As explained when the regulation at 42 CFR 610(d) was first published, the CAH is expected to continue to provide services based on the criteria that the State used when initially determining that the CAH was a necessary provider. For example, if the determination was based on the CAH being located in a health professional shortage area (HPSA), then the relocated CAH must continue to be located in a HPSA. (See 70 FR 23453 and 70 FR 47472.) The CAH bears the burden of providing documentation from the State indicating what the original basis of the State's necessary provider determination was, and that the relocation will not have any impact on continued conformity of the CAH to the original decision criteria.

- Renovation or Expansion: Renovation or expansion of a CAH's existing building or addition of building(s) on the existing main campus of the CAH is not considered a relocation (unless a CAH previously undertook a relocation without receiving the necessary RO approval). There is no change to its CAH designation and, therefore, no need for the RO to make any determination on its continued CAH designation.

- All New Facilities: All newly constructed necessary provider CAH facilities are considered relocated facilities. This includes construction of a new facility that replaces the existing CAH main campus, even when on the same site as the

original building. (See 70 FR 47472.) (See discussion at 70 FR 47472.)

- Relocation Without Necessary Provider Designation: If a CAH relocates and meets, at the new location, all of the CoPs found at 42 CFR 485 Subpart F (including location in a rural area as required at §485.610(b) and distance from other hospitals or CAHs as required at §485.610(c)), it will qualify for CAH designation in the same way as would a new CAH. However, if it wishes to retain its grandfathered necessary provider status, then it must also satisfy the requirements at §485.610(d).

- 75 Percent Criteria: The relocated CAH must meet each of the three 75 percent criteria found at 42 CFR 485.610(d) (and explained below) in order to maintain its grandfathered necessary provider designation after relocation. We expect that CAHs will demonstrate in advance of their relocation the likelihood that they will satisfy the criteria. The discussion below focuses on the evaluation of this prospective data. After the relocation is completed, the CAH must submit evidence confirming that it satisfied the criteria.

Listed below are examples of methods necessary provider-designated CAHs could use to meet each of the 75 percent criteria at 42 CFR 485.610(d) (1). The CAHs are free to submit documentation employing different methodologies for each criterion, indicating how they think both the methodology and supporting evidence document comply with the regulatory requirements. The RO will determine whether the methodology employed is supported by the evidence and if the CAH has met the burden of proof necessary to satisfy the regulation. The same methodology should be used by the CAH for both the pre-relocation attestation and the confirmation after relocation is completed.

Relocation Serves 75 Percent of the Same Service Area

The CAH must present documentation showing why the Service Area projected for the relocated CAH will include at least 75 percent of its original service area.

In the absence of special factors that indicate the need for an alternative methodology, in order to meet the statutory and regulatory intent of this provision, CMS will compare the zip code location of populations currently served by the CAH with the populations in the zip codes served by the CAH in its new or proposed new location. Examples of special factors are: (a) Statistical anomalies that may occur when each of one or more zip codes contains less than 5 percent of the total number of individuals served by the CAH, or (b) The presence of major demographic or geographical differences between the old and new location (such as an un-bridged river separating the two locations).

Example of adequate documentation:

Assume that the CAH identifies the zip codes of its patients from the past year, ranked from highest to lowest volume of patients per zip code, and found that it served 200 patients from the following zip codes:

		Patients in New Location		
Zip Code	Current Patients	Example # 1	Example #2	Example #3
Zip code A ……	80 patients ……	70 ……	70 ……	80
Zip code B…….	30 patients……	26…	26 …	30
Zip code C…….	29 patients……	9……	9…	29
Zip code D…….	28 patients …	15…	15	28
Zip code E…….	24 patients……	0……	24 …	24
Zip code F……..	9 patients (4.5%)	30…	0 (Dropped #2)	9
Subtotal (Ex. #1)…	**200**	**150 (75%)**	**144**	
Subtotal (Ex. #2) …	191		144 (75% of 191)	
Subtotal (Ex. #3)	**200**			
Zip code G	20	26	40	
Zip code H	30	30	60	
GRAND TOTAL	200	200	200	300

In example #2, zip code "F" has been dropped at the CAH's request because its percent of the current service area is less than 5 percent.

In example #3, the CAH meets the 75 percent requirement. Even though the number of people served from the original location is only 67 percent of the total to be served in the new location (200/300), 100% of the volume from the zip codes served in the original location will be served in the new location (200/200). The regulation focuses on whether the people in the original location will continue to be served, not whether the CAH services are being expanded.

After the CAH has been in operation at the new location for a reasonable period of time (e.g., 6 months to 1 year), the CAH must submit evidence to confirm that the 75 percent requirement is met as a matter of fact rather than projection.

CMS may lessen the amount of supporting information required in some cases where the circumstances and extent of relocation are very simple. For example, if the CAH documents that the new facility is being built on or adjacent to the current facility's campus, then it would be reasonable for the CAH to argue that the relocated CAH by virtue of its very close proximity to the original CAH could be assumed to serve the same community. For almost all other cases, more evidence will be required. Depending on the characteristics of the community served by the CAH and the availability of other CAHs or hospitals in the region, it is possible that relocations of even a few miles might significantly change the CAH's service area.

Seventy-five Percent of the Same Services

In order to meet the "75 percent of the same services standard," the CAH must demonstrate that at least 75 percent of the total service lines provided by the CAH at its

original location will continue to be offered at its new location, under generally similar terms.

The same services standard under 42 CFR 485.610(d)(ii) does not preclude the CAH from adding additional, new services at the new location. It merely states that the CAH must retain 75 percent of the original services offered at its original location prior to relocation.

CMS examines two dimensions to the "same services" requirement:

- The services lines themselves (e.g., lines of business such as obstetrics), in which we compare the number of such lines retained after relocation compared to the pre-relocation service array; and

- The scope and availability of such services, in which we seek to understand if there are to be any significant reductions in the new location compared to the pre-location services.

There are a variety of ways in which health care services can be categorized. The regulation does not prescribe a particular service classification taxonomy. However, the CAH must present a breakdown of its services that is sufficiently detailed to enable a pre- and post-relocation analysis. For example, a listing that consisted only of "inpatient" and "outpatient" services would be too general to permit meaningful analysis. It would be acceptable for a CAH to use the service categories found in the American Hospital Association annual hospital survey data, but the CAH can also submit an alternative list of services. In the latter case, the RO will determine whether there is sufficient information about the services to make a determination of regulatory compliance. Whatever service classification system the CAH uses to describe the services offered prior to relocation must also be used for the services after relocation.

Example 1:

- The CAH originally offered 14 services:

Outpatient	Inpatient
Emergency department	General medical/surgical services
Primary care	Pediatric medical/surgical services
Pre- & postnatal care	General obstetrics/gynecology
Outpatient surgery	Orthopedics
Counseling services	Distinct Part Unit – Psychiatric*
Well-baby clinic	
Pediatric outpatient services	
Ultrasound	
Mammography	

- After relocation the CAH attests that it will retain 12 of those services

Retained:

Outpatient	Inpatient
Emergency department	General medical/surgical services
Primary care	
Pre & postnatal care	General obstetrics/gynecology
Outpatient Surgery	Orthopedics
Well-baby clinic	
Pediatric outpatient services	
Counseling services	
Ultrasound	
Mammography	

Eliminated:

Outpatient	Inpatient
	Pediatric medical/surgical services
	Distinct Part Unit – Psychiatric*

- The CAH also proposes to add 7 services:

Added:

Outpatient	Inpatient
MRI	
CT Scanner	
Dietician	
Physical rehabilitation	Distinct Part Unit – Rehabilitation*
Chemotherapy	Oncology

- Additionally, the retained services are planned and actually are generally available under the same terms, e.g., the number of inpatient beds or service hours for outpatient clinics are generally the same, etc. In this scenario the CAH demonstrates it will retain over 85 percent of its original services, exceeding the 75 percent regulatory requirement.

*__NOTE__: Although CAH distinct part units are subject to hospital rather than CAH Conditions of Participation, for purposes of determining compliance with the 75 percent same services standard they must be included in the list of services.

Example 2:

- The CAH originally offered 20 different services. If the CAH attests it will drop 6 services, while adding 6 new and different services, it has not

demonstrated it will retain 75 percent of the same services and would not meet the regulatory same service requirement.

Regardless of the number of original services, if the CAH attests it will retain a service, but make it available only 20 percent of the time that it was available at the original location, then that is not the same service. If it is available 50 percent or more of the time than it was available at the original location, then that service can count toward its 75 percent of the same services compliance.

In its attestation the CAH should list all the services offered at the CAH at its original location at the time of the attestation, including an indication of the quantity or hours the outpatient services are available. It should also list the services and their availability planned for the new location.

After the relocation is complete, the CAH must submit confirming evidence that it meets the 75 percent same services standard. The CAH should provide the list of its actual services and their availability.

Seventy five percent of the Same Staff (including medical staff, contracted staff, and direct employees):

In order to meet the "75 percent of the same staff" standard, the CAH must demonstrate that 75 percent of the CAH's staff that were at the CAH prior to relocation remains on staff after the relocation takes place. This includes contracted personnel. For purposes of this requirement, contracted staff includes all personnel who regularly work onsite at the CAH, whether they are directly contracted by the CAH or whether they are employees of a contractor. At the CAH's option, the CAH may exclude from these calculations all contracted employees who work less than halftime on average (or any lesser threshold of time the CAH elects (such as 10 hours per week on average). However, the CAH must consistently apply such a threshold in all calculations.

It is not necessary to calculate the 75 percent for each of the 3 types of staff – medical, contracted, and direct employees – separately. For example, a CAH could retain 50 percent of its medical staff, 40 percent of its contracted staff, but 80 percent of its direct employees, and meet the regulatory standard, so long as the retention rate for these 3 groups combined is 75 percent.

In its attestation, the CAH should provide a list of all staff at the time of the attestation. It must demonstrate how it plans to retain at least 75 percent of its current staff. Staff who are working on a J-1 Visa Waiver Program, National Health Service Corps Federal Loan Repayment Program, or National Health Service Corps State Loan Repayment Program and whose service limits under the terms of those programs will have expired at the time of relocation should not be included when comparing the staff at the old and new locations.

Examples of how a CAH could demonstrate in its attestation that it will meet the 75 percent of the same staff criteria include:

- Attestation from staff that they expect to continue their current employment or contractual relationship with the CAH at the new location; or

- Evidence demonstrating how staff commutes to the CAH would not change significantly from the original location to the new location for at least 75 percent of staff; or

- Evidence of employment arrangements/contracts continuing with at least 75 percent of the same staff.

Those CAHs that have difficulty meeting the 75 percent same staff criterion due to historically high staff turnover and/or vacancy rates, can provide additional documentation explaining the effect of such factors on their ability to satisfy the standard, and whether they could meet the standard if the original staff list is adjusted to reflect historical turnover. The CAH must provide evidence, however, that it is actively attempting to recruit replacements for the same type of staff as those who have left. The documentation must provide evidence that circumstances beyond the CAH's control rather than the relocation of the CAH accounts for the expected greater than 25 percent change in the staff roster. It might not be reasonable to expect a CAH to meet the 75 percent same staff standard if it can provide sufficient evidence that it has, for example, a 25 percent historic rate of staff turnover. In addition, to documenting an historically high turnover rate the CAH should also provide documentation of efforts it is making to reduce turnover, such as evidence of active recruitment efforts, i.e., posting of vacancies, participating in job fairs, and evidence of outreach to professional schools and universities. The CAHs might also indicate whether they believe relocation will benefit the facility by decreasing the staff turnover rate, including evidence to support this assumption.

Letter of Attestation

Prior to the relocation of a CAH with a necessary provider designation, the CAH should submit a letter of intent to the RO. The CAH would be well-advised to send the letter early in the planning stage of its relocation, prior to spending or obligating significant funds and resources. The letter should state that the CAH plans to relocate, i.e., that it plans to build a new replacement facility, and must attest that it will continue to be essentially the same provider serving the same service area, but in a new facility. It is recommended that the CAH administration contact CMS RO Survey and Certification staff prior to preparing the letter of attestation, in order to facilitate communications about the standards that a relocated CAH with a necessary provider designation must meet.

To facilitate efficient review by the RO, the Letter of Attestation should include:

- A copy of the CAH's original necessary provider determination from its State Office of Rural Health;

- Documentation from the State of how the CAH at the relocation site will continue to satisfy the criteria used by the State in the original necessary provider

determination;

- Addresses of both the present location and the future location;
- Documentation that demonstrates how the new facility/location meets the rural location requirement at §485.610(b);
- Documentation showing how the CAH will continue to be essentially the same provider at the new facility/location, in accordance with 485.610(d); and
- Timetable for the relocation.

The RO will evaluate the letter of attestation and documentation provided by the CAH to determine if the planned relocation appears likely to meet the requirements under §485.610. The RO will advise the CAH in writing of any additional information that may be needed. The RO will assess the information provided in the attestation letter and notify the CAH of its preliminary determination. The RO will provide preliminary approval of the relocation if the information provided by the applicant demonstrates that the proposed relocation complies with the regulatory standards at 42 CFR 485.610(b) and (d). A final determination can only be made after the relocation is completed.

Implementation Phase

During the implementation phase, the CAH should notify the RO of any changes to the information submitted in its letter of attestation. The purpose is for the RO to be kept apprised of any changes so that the CAH can be informed if the changes do not comply with the requirements at §485.610(b) and (d).

After the relocation is completed, if the RO determines the CAH meets all of the following criteria:

- Received a preliminary approval for its relocation from the RO;
- No changes have occurred that materially affect its preliminary attestation;
- Holds any required State license at the new location;
- Meets all CoP requirements as determined by an accreditation or SA survey; and
- Submits confirming evidence of compliance with the 75 percent criteria (in the case of same service area criterion, as noted below, the submission of this evidence will need to be submitted at a later point in time as the CAH must see patients to conclusively show compliance with the same service area requirement, but this should not delay continuation of the provider agreement at the new location upon satisfaction of all the other listed criteria);

then the RO makes a final determination that the relocated necessary provider CAH will be permitted to continue Medicare participation under its original provider agreement as a necessary provider CAH.

If the RO determines that the relocated necessary provider CAH does not satisfy the regulatory requirements under §485.610(b) and (d), the CAH will be considered to have ceased business in accordance with §489.52(b)(3) as of the date that it relocated. The RO will take action to terminate the CAH's provider agreement.

2256G - Co-Location of Critical Access Hospital

(Rev. 49, Issued: 06-12-09, Effective/Implementation: 06-12-09)

It is never permissible for a CAH that is not designated as a necessary provider to be co-located with another hospital or CAH because of distance requirements it is required to meet at 42 CFR 485.610(c). However, since States had the ability, up until January 1, 2006, to waive the minimum distance from other hospitals or CAHs requirement for CAHs designated as necessary providers, it was technically possible for a necessary provider CAH (NPCAH) to be co-located with another hospital or CAH, i.e., share the same building or campus as the other facility. Moreover, prior to the enactment of Section 405(g) of Pub. L. 108-173, which permits CAHs to operate distinct part inpatient psychiatric and/or rehabilitation distinct part units, it was understandable that a State Medicare Rural Hospital Flexibility Program (MRHFP) might have allowed co-location of a CAH with a necessary provider designation with the specialized services of a psychiatric and/or a rehabilitation hospital.

However, as of January 1, 2008, CAHs with a necessary provider designation can no longer enter into co-location arrangements with another CAH and/or hospital (72 FR 66878). Necessary provider CAHs that had co-location arrangements in effect prior to January 1, 2008, may continue these arrangements, as long as the type and scope of services offered by the facility co-located with the CAH do not change. An example of a change in type of services would be when a hospital that provides only rehabilitation services chooses to provide general hospital acute care services. An example of a change in scope of services would be when a grandfathered necessary provider CAH is currently co-located with a 20-bed psychiatric hospital and the psychiatric hospital decides to increase the number of beds to 30.

A change of ownership of a CAH participating in a grandfathered co-location arrangement will not be considered to create a new, and therefore prohibited, co-location arrangement, if, and only if, assignment of the existing provider agreement is accepted by the new owner. In all cases where there is a change of ownership of a grandfathered necessary provider CAH and the new owner does not accept assignment of the provider agreement, both the CAH's provider agreement and necessary provider designation are terminated as part of the former owner's provider agreement. If a grandfathered necessary provider CAH's provider agreement is terminated, and the facility seeks a new CAH designation, it would be required to meet all CAH requirements, including the minimum distance from other hospitals or CAHs. It would also be prohibited from entering into any co-location

arrangement with a hospital or another CAH.

A change of ownership by a hospital that is co-located with a necessary provider CAH does not affect the grandfathered co-location arrangement, regardless of whether the hospital's provider agreement is assumed by the new owner or not.

Termination for Noncompliance

Compliance with the co-location requirements of §485.610(e)(1) is determined by the RO. A CAH found out of compliance with the requirement is subject to termination of its Medicare provider agreement under §489.53(a)(3). In such cases the CAH is placed on a 90-day termination track, as outlined in §3012 of the SOM. During this period, the CAH will have the opportunity to come back into compliance and meet all conditions of participation (CoPs). If the CAH corrects the noncompliance situation, by terminating the co-location arrangement that led to the non-compliance during this 90-day period, then the provider agreement is not terminated.

A facility facing termination of its CAH designation as a result of non-compliance with §485.610(e)(1) could also continue to participate in Medicare by converting to a hospital, assuming that the facility satisfies all requirements for participation as a hospital in the Medicare program under the provisions at 42 CFR Part 482. Under this scenario, the CAH would apply to convert back to a hospital and be assigned a new CMS Certification Number (CCN) accordingly.

2256H – Off-Campus CAH Facilities

(Rev. 193, Issued: 09-20-19, Effective: 09-20-19, Implementation: 09-20-19)

Section 42 CFR 485.610(e)(2) requires that if a CAH operates an off-campus provider-based facility as defined in §413.65(a)(2) (except for a rural health clinic (RHC)) or off-campus rehabilitation or psychiatric distinct part unit as defined in §485.647, that was created or acquired on or after January 1, 2008, then the off-campus facility must meet the requirement at 42 CFR 485.610(c) to be more than a 35 mile drive (or a 15 mile drive in the case of mountainous terrain or an area with only secondary roads) from another hospital or CAH. Off-campus CAH facilities that were in existence prior to January 1, 2008, are not subject to this requirement. The drive to another hospital or CAH is calculated from the off-campus facility's location to the main campus of the other hospital or CAH.

If a non-IHS or non-Tribal CAH operates an off-campus provider-based facility, its proximity to an IHS or Tribal CAH or hospital is not considered when determining compliance with these requirements. Similarly, if an IHS or Tribal CAH operates an off-campus provider-based facility, its proximity to a non-IHS or non-Tribal CAH or hospital is not considered when determining compliance.

Definitions related to provider-based status are found at 42 CFR 413.65(a)(2):

"**Campus:** means the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings, but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus."

"**Department of a provider:** means a facility or organization that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A department of a provider comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A department of a provider may not itself be qualified to participate in Medicare as a provider under §489.2 of this chapter, and the Medicare conditions of participation do not apply to a department as an independent entity. For purposes of this part, the term 'department of a provider' does not include an RHC or, except as specified in paragraph (n) of this section, an FQHC."

"Remote location of a hospital: means a facility or organization that is either created by, or acquired by, a hospital that is the main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A remote location of a hospital comprises both the specific physical facility that serves as the site of services for which separate payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. The Medicare conditions of participation do not apply to a remote location of a hospital as an independent entity. For purposes of this part, the term "remote location of a hospital" does not include a satellite facility as defined in §412.22(h)(1) and §412.25(e)(1) of this chapter."

"Provider-based entity: means a provider of health care services, or a RHC as defined in §405.2401(b) of this chapter, that is either created or acquired by the main provider for the purpose of furnishing health care services of a different type from those of the main provider under which the ownership and administrative and financial control of the main provider, in accordance with the provisions of this section. A provider-based entity comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at the facility. A provider-based entity may, by itself, be qualified to participate as a provider under §489.2, and the Medicare conditions of participation do apply to a provider-based entity as an independent entity."

"Provider-based status: means the relationship between a main provider and a provider-based entity or a department of a provider, remote location of a hospital, or a satellite facility, that complies with the provisions of this section."

The CAH off-campus location regulations at §485.610(e)(2) apply to off-campus distinct part units, as defined at §485.647, to departments that are off-campus, to remote locations of CAHs, as defined at §413.65(a)(2), and, on or after October 1, 2010, to off-campus facilities that furnish only clinical diagnostic laboratory tests operating as parts of CAHs. The requirements apply, regardless of whether the CAH is a grandfathered necessary provider CAH or not. However, the regulations also specifically state that they do not apply to RHCs that are provider-based to a CAH.

These regulations also do not apply to the following types of facilities/services owned and operated by a CAH, because such facilities or services generally are not eligible for provider-based status, in accordance with §413.65(a)(1)(ii):

- Ambulatory surgical centers (ASCs);
- Comprehensive outpatient rehabilitation facilities (CORFs);
- Home Health Agencies (HHAs);
- Skilled nursing facilities (SNFs);
- Hospices;
- Independent diagnostic testing facilities furnishing only services paid under a fee schedule, such as facilities that furnish only screening mammography services, facilities that furnish only clinical diagnostic laboratory tests, other than those operating as parts of a CAH, or facilities that furnish only some combination of these services.
- ESRD facilities;
- Departments of providers that perform functions necessary for the successful operation of the CAH, but for which separate CAH payment may not be claimed under Medicare or Medicaid, e.g., laundry, or medical records department; and
- Ambulances.

In the case of Federally Qualified Health Centers (FQHCs), although CMS rules permit them to be provider-based departments of a hospital or CAH, it is unlikely that there are new FQHCs that meet the provider-based criteria, since Health Resources and Services Administration (HRSA) requirements for separate FQHC governance make it unlikely an FQHC could meet provider-based governance requirements. However, there are grandfathered FQHCs that were in operation prior to April 7, 2000, which are permitted to retain their provider-based status.

Provider-based determinations are site-specific and based on the facility's location with respect to the main campus when the attestation is made to the RO. If a CAH relocates an off-campus facility, including off-campus facilities that were in existence or under

development prior to January 1, 2008, and are currently grandfathered, the off-campus facility must comply with the requirements at §485.610(e)(2) and the provider-based rules at §413.65. The CAH will resubmit an attestation to the RO for the new location to determine if it meets all the requirements at the new location.

In addition, if the main campus of the CAH relocates, it may wish to obtain a provider-based determination for all of its off-campus locations. However, this is a voluntary decision on the part of the CAH. There is no need for a new determination of compliance with the CAH location requirements at §485.610(e)(2) when there is no change of location of the off-campus facilities. If the CAH seeks a provider-based determination, the RO conducts the review in the same manner as described below.

Process Requirements

Under the general provider-based rules at §413.65, hospitals and CAHs are not required to seek an advance determination from CMS that their provider-based locations meet the provider-based requirements, but many choose to do so rather than risk the consequences of having erroneously claimed provider-based status for a facility. However, §485.610(e)(2) provides that a CAH can continue to meet the location requirement at §485.610(c) **only if** the off-campus provider-based location or off-campus distinct part unit is located more than a 35 mile drive (or 15 mile drive in the case of mountainous terrain or in areas where only secondary roads are available) from a hospital or another CAH. **Therefore, a CAH should seek an advance determination of compliance with the CAH location requirements for any off-campus provider-based facility established on or after January 1, 2008.**

If a CAH submits a provider-enrollment application (Form CMS-855) to its affiliated Medicare Administrative Contractor (MAC) noting that it is adding a provider-based location, the CAH should also submit documentation noting how it continues to comply with the CAH distance requirements at §485.610(e)(2) to ensure that the CAH will retain its status as a CAH.

The MAC reviews the CAH's Form CMS-855 for addition of a provider-based location and, once completed, forwards the form and any submitted documentation to their CMS affiliated Regional Office (RO) Division of Survey and Certification (DSC) for review of compliance with §485.610(e)(2). If the CAH does not submit documentation noting how it continues to comply with the CAH distance requirements in the provider-enrollment application (Form CMS-855), the CMS RO DSC requests that information from the CAH during their distance review.

The RO DSC reviews the Form CMS-855 and any corresponding documentation from the CAH as well as any information received from the SA for evidence that the **CAH's off-campus provider-based location is more than a 35 mile drive (or 15 miles in the case of mountainous terrain or an area with only secondary roads) from another hospital or CAH.**

If the RO DSC verifies that the CAH **will continue to meet** the §485.610(e)(2) distance requirements with the added provider-based location, the RO DSC issues a tie-in notice and notifies the MAC, the CMS RO Division of Financial Management and Fee for Service Operations (DFMFFSO), and the SA of the tie-in.

However, if the RO DSC review verifies that the CAH's provider-based location **does not meet** the CAH distance requirements at §485.610(e)(2), the RO DSC notifies the CMS Central Office (CO), the MAC, the RO DFMFFSO, and the SA. Once notified of the RO DSC review:

- The MAC does not take further action on the submitted CAH Form CMS-855 to add the provider-based location (under Chapter 15 of the Medicare Program Integrity Manual) until the MAC is notified of the CAH's decision as outlined below.

- The RO DSC informs the CAH that its provider-based location causes the CAH to no longer meet the §485.610(e)(2) distance requirement and offers the CAH the following options (A, B, or C):

  A. **Termination of participation:** By adding the provider-based location, the CAH would be placed on a 90 day termination track (as outlined in Section 3012 of the SOM) or the CAH can voluntarily terminate its participation from the program all together.

  B. **Continued CAH certification:** The CAH may retain its CAH status by terminating the off-campus provider-based location arrangement that led to the non-compliance with the §485.610(e)(2) distance requirements within the 90 day termination period or by physically moving the provider-based location so that the distance requirements are met.

  C. **Conversion:** The CAH may continue to participate in Medicare by converting to a hospital. If the CAH chooses to convert to a hospital, the CAH would need to submit to the MAC another Form CMS-855 to terminate their CAH enrollment along with a separate Form CMS-855 to enroll as a hospital. The effective date of the CAH's hospital certification would coincide with the effective date of termination of CAH status. See Section 2005 of the SOM for the Medicare enrollment process.

Once the RO DSC notifies the MAC of its review that the CAH is in compliance with §485.610(e)(2) distance requirements or, if not in compliance, of the CAH's choice of option A, B, or C (as described above), the MAC then proceeds with sending the Form CMS-855 and its recommendation for approval on the provider-based location to its affiliated RO DFMFFSO for a determination under §413.65.

- The RO DFMFFSO reviews the Form CMS-855 and confers with CMS CO and RO DSC on specific issues as needed.

- The RO DFMFFSO sends the CAH/Hospital (Form CMS-855 applicant) a notice letter with the determination on its request for provider-based location designation, with copies sent to the MAC, RO DSC, and the SA).

The CAH must comply with all applicable requirements at §485.610(e)(2) for the distance requirements and §413.65 for the provider-based rules.

During the review process, CMS RO DFMFFSO also considers additional issues such as the following (this list is provided for informational purposes only; it is not all-inclusive):

- The off-site facility must operate under the same license of the main provider, except in areas where the State requires a separate license for facilities that Medicare would treat as the department of the provider or in areas where State law does not address licensure.

- The clinical services of the off-site facility and the CAH main provider are fully integrated as evidenced by:

    - Professional staff have clinical privileges at the main provider;

    - The main provider maintains the same monitoring and oversight of the off-campus facility as it does for any other department of the provider;

    - The medical director or other similar official of the off-campus facility maintains a reporting relationship with the chief medical officer or other similar official of the main provider and is under the same type of supervision and accountability, and reporting as any other director, medical or otherwise of the main provider;

    - Medical staff committees or other professional committees at the main provider are responsible for medical activities in the off-campus facility and the main provider. This includes quality assurance, utilization review, and the coordination and integration of services, to the extent practical, between the off-campus facility and the main provider;

    - Medical records for patients treated in the off-campus facility are integrated into a unified retrieval system (or cross-referenced) of the main provider; and

    - Inpatient and outpatient services of the off-campus facility and the main provider are integrated, and patients treated at the off-campus facility who require further care have full access to all services of the main provider and are referred where appropriate to the corresponding inpatient or outpatient department of the main provider.

- The financial operations of the off-campus facility are fully integrated within the financial system of the main provider;

- The off-campus facility is held out to the public as part of the main provider. When patients enter the off-campus facility, they are made aware they are entering the main provider and will be billed accordingly;

- The off-campus facility is operated under the ownership (100 percent) and control of the main provider;

- The reporting relationship between the off-campus facility and the main provider must have the same frequency, intensity, and level of accountability that exists between the main provider and one of its existing departments;

- The off-campus facility is located within a 35 mile radius of the main provider. This distance is measured in radial miles or a straight line measurement between the main provider and the provider-based department, remote location, and/or distinct part unit;

- Off-campus outpatient departments must also comply with the following:

    - Physician services furnished in a department of the CAH must be billed with the correct site of service so that appropriate physician and practitioner payment amounts can be made;

    - CAH outpatient departments must comply with all of the terms of the CAH's provider agreement, including the CAH Conditions of Participation at 42 CFR Part 485, Subpart F;

    - Physicians working in departments of the main provider are obligated to comply with the non-discrimination provisions in §489.10(b);

    - CAH outpatient departments must treat all Medicare patients, for billing purposes, as CAH outpatients; and

    - When Medicare beneficiaries are treated in CAH outpatient departments that are located off-campus, the treatment is not required to be provided by the anti-dumping rules in §489.2, unless the off-campus facility meets the EMTALA definition of a dedicated emergency department found at 42 CFR 489.24(b).

Termination for Noncompliance

A CAH that is found to be out of compliance with the off-campus location requirements at §485.610(e)(2) is subject to termination of its Medicare provider agreement. In such cases, the CAH is placed on a 90-day termination track, as outlined in §3012. If the CAH corrects the noncompliance within this 90-day period, by terminating the off-campus provider-based arrangement that led to the non-compliance, then the provider agreement is not terminated.

A facility facing termination of its CAH status as a result of non-compliance with §485.610(e)(2) distance requirements could also continue to participate in Medicare by converting to a hospital, **assuming that the facility satisfies all requirements for participation as a hospital** in the Medicare program under the provisions at 42 CFR Part 482. Under the scenario of a CAH not meeting the CAH distance requirements at §485.610(e)(2), the CAH would have the choice of
A, B, or C –

A. **Termination of Participation:** By adding the provider-based location, the CAH would be placed on a 90 day termination track (as outlined in Section 3012 of the SOM) or the CAH can voluntarily terminate its participation from the program all together.

B. **Continued CAH certification:** The CAH may retain its CAH status by terminating the off-campus provider-based location arrangement that led to the non-compliance with the §485.610(e)(2) distance requirements within the 90 day termination period or by physically move the provider-based location so that the distance requirements are met.

C. **Conversion:** The CAH may continue to participate in Medicare by converting to a hospital. If the CAH chooses to convert to a hospital, the CAH would need to submit to the MAC another Form CMS-855 to terminate their CAH enrollment along with a separate Form CMS-855 to enroll as a hospital. If the CAH fails to comply with the CAH CoPs, and fails to convert and comply to the hospital CoPs, the provider agreement will be terminated. If the CAH applies to convert back to a hospital and meets the hospital CoPs, the effective date of the CAH's hospital certification would coincide with the effective date of termination of CAH status. A new CCN number would be assigned accordingly. See Section 2005 of the SOM for the Medicare enrollment process.

Beginning October 1, 2010, off-campus CAH-owned clinical diagnostic laboratory facilities that do not satisfy the requirements to be provider-based to a CAH, including applicable distance requirements, may continue to participate separately in Medicare as a clinical diagnostic laboratory, but will no longer be considered to be part of the certified CAH.

2257 - CAH Anti-Dumping Requirements

(Rev. 1, 05-21-04)

Medicare participating hospitals must meet the requirements in §1867 of the Act, "Examination and Treatment for Emergency Medical Conditions and Women in Labor," and the applicable provisions of §1866 of the Act. The regulatory requirements are found in 42 CFR 489.24 and 489.20(l),(m),(q) and (r). For purposes of the anti-dumping requirements the term "hospital" includes CAHS. The provisions of §1867 apply to all individuals (not just Medicare beneficiaries) who attempt to gain access to a hospital or a

CAH for emergency care. The SA will investigate any alleged violation by a CAH according to the procedures found in the SOM.

2258 - Advance Directive Requirements for CAHS

(Rev. 1, 05-21-04)

The requirements at 42 CFR 489.100, 489.102, and 489.104, apply advance directive requirements to CAH inpatients, including inpatients receiving SNF level of care in swing-beds. When the SA is conducting a CAH survey, apply the advance directive requirement to all CAH inpatients.

2259 - Procedures for Processing CAH Swing-Bed Applications

(Rev. 1, 05-21-04)

A facility that has been designated as a CAH by the State and certified as a CAH by CMS may apply at any time to participate in the swing-bed program. Application is made using a letter on the provider's letterhead requesting participating for swing-beds. Only CMS can approve an application to participate in the Medicare swing-bed program.

2259A - Definition, Authority and Requirements for CAH Providers of Extended Care Services ("Swing-Beds")

(Rev. 1, 05-21-04)

"Swing-bed" is a reimbursement term that means the care and reimbursement for the care of a patient in a small rural hospital or CAH "swings" from acute care to post hospital skilled nursing care (SNF). A swing-bed hospital means a hospital or CAH participating in Medicare that has an approval from CMS to provide post hospital SNF care and meets the requirements specified in 482.66 for a hospital or 485.645 for a CAH.

Certification to provide swing-beds is an approval separate from the certification to operate as a hospital or CAH. When a survey of swing-beds is completed, any deficiencies and Plans of Correction (PoC) must be documented on a separate Form CMS-2567. If the swing-beds are voluntary terminated or terminated by CMS, that action does not affect the continuing operation of the provider as a hospital or CAH. It terminates the approval to operate and receive reimbursement for the swing-beds.

The swing-beds in a hospital or CAH do not have to be separated from the acute patients although the facility may choose to do so. The patients do not have to move to a different location in the facility when changing from acute care status to swing-bed status unless the facility requires it.

There is no length of stay restriction for a swing-bed patient whether they are in a hospital or a CAH. There is no required discharge to a nursing home and no transfer agreement. Patients may be discharged to a nursing home as part of discharge planning, but it is not

required.

A medical order in the chart by the physician is required to change status from acute care to swing-bed because the patient is being discharge from acute care status and admitted to swing-bed status. This is necessary for reimbursement purposes because the billing and reimbursement change or "swing." Accordingly, the facility is given a sub-provider number for billing swing-bed services.

For Medicare patients, a 3-day qualifying stay in any hospital or CAH is required to prior to admission to a swing-bed and the admission must be for treatment of the same condition. This 3-day qualifying stay only applies to a Medicare patient.

NOTE: The 30-day patient transfer notice requirement at 42 CFR Part 483.12(a)(5) does not apply to swing-bed CAHS.

2259B - Request from a Medicare Participating CAH to add Swing-bed Approval

(Rev. 1, 05-21-04)

The request can be initiated on the provider's letterhead stationery and sent to the SA. Acknowledgement and request for further information can be sent from the SA to the provider in a letter.

2259C - Pre-Survey Activity

(Rev. 1, 05-21-04)

Prior to scheduling a survey, the SA reviews the provider file as well as any other information maintained on the CAH. If the CAH requirements are met and the CAH has begun to provide swing-bed services, the SA schedules a survey. No CAH may receive initial swing-bed approval without an onsite survey of the actual provision of such services. The SA may send a letter to the provider notifying them of a future survey. Prior to survey the SA verifies that the hospital has a valid Medicare provider agreement.

2259D - Certificate Of Need (CON) Approval

(Rev. 1, 05-21-04)

States that have a CON requirement for the initiation or expansion of long-term care services may require a CON for a limited number of beds for LTC use. There is no federal requirement for a CON but CMS will not intervene if there is a state requirement.

2260 - Survey Procedures for Swing-Bed Approval

(Rev. 1, 05-21-04)

The SA surveys any CAH that meets CAH requirements and that has begun to provide post-hospital SNF and NF care services. The SA may choose to use the optional Swing-Bed Survey Report that can be found with Appendix W to record survey findings.

The survey for swing-bed approval may be conducted at the same time as a survey of the CAH CoP at 42 CFR Part 485, although the findings must be documented on a separate Form CMS-2567.

2261 - Post-Survey Procedures for Swing-Bed CAHS

(Rev. 1, 05-21-04)

To receive swing-bed approval, a CAH must be found in compliance with the provisions of 42 CFR Part 485.645 and the specific skilled nursing requirements in 42 CFR 483 that apply to swing-bed CAHS, see Appendix W. If a plan of correction is required following the survey, send a copy of Exhibit 151, "Request for a Plan of Correction Following an Initial CAH Survey," to the provider.

Effective dates for all swing-bed approvals are based on the provisions at 42 CFR 489.13 that state the agreements will be effective on the date the onsite survey is completed if all Federal requirements are met on the date of the survey. If the provider fails to meet any of the requirements, the approval will be effective on the earlier of the following dates:

- The date on which the prospective CAH meets all requirements; or
- The date the prospective CAH submits a correction plan acceptable to CMS.

2262 - RO Approval Procedures for Swing-Bed Approval

(Rev. 1, 05-21-04)

The RO prepares a formal determination and notifies the CAH of its approval or denial. For approvals, see Exhibit 150B,"Approval Notification for Swing-beds in a Hospital," or denials, see Exhibit 149, "CAH Denial for Medicare Participation."

If the provider is found to be in non-compliance after they have started to provide swing-bed services, a termination of the approval can be accomplished through a termination letter, see Exhibit 152, "CAH Termination Letter." Failure to satisfy requirements for swing-bed approval does not affect Medicare approval as a provider of hospital services, but it does withdraw the approval to provide SNF level services at the CAH.

End Stage Renal Disease (ESRD) Facilities

2270 - Medicare and ESRD

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

The Social Security Act (the Act) designates those providers and suppliers that are subject to Federal health care quality standards. Dialysis facilities are so designated under §1881(b)(1) of the Act.

NOTE: The terms ESRD facility and dialysis facility are used interchangeably in this document.

ESRD is that stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplant to maintain life. Section 1802 of the Act provides that any individual entitled to Medicare may obtain health services from any institution, agency, or person qualified to participate in Medicare if that institution, agency, or person undertakes to provide that individual such services.

The ESRD Conditions for Coverage (CfCs) set baseline standards for ESRD facilities to meet when furnishing dialysis services which apply to all patients receiving care from the Medicare-approved facility, not just those who are Medicare beneficiaries. All dialysis patients must receive care that meets or exceeds the CfCs.

2270A – ESRD Conditions for Coverage

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

Social Security Act §1881(b)(1)

Section 1881(b)(1) of the Act requires dialysis facilities to comply with the Conditions for Coverage (CfCs) for End-Stage Renal Disease (ESRD) Facilities in 42 CFR Part 494. These regulations specify the conditions with which facilities must comply to achieve and maintain approval for Medicare reimbursement.

Conditions for Coverage

The current CfCs for ESRD facilities were comprehensively updated through a final rule that was published on April 15, 2008, with an effective date of October 14, 2008 for most of the requirements. The requirement for an isolation room or area for hepatitis B virus positive (HBV+) patients at §494.30 became effective February 9, 2009. Some provisions addressing Life Safety Code (LSC) for ESRD facilities at §494.60 were updated though a final rule (77 FR 29002) that was published May 12, 2012, which became effective on July 16, 2012. The requirement for emergency preparedness at §494.62 became effective November 15, 2016 with an implementation of November 15, 2017.

2270B - ESRD Survey and Certification Communication, Information, Tools

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

In order to foster communication among States Survey Agencies, CMS Regional Offices, and the ESRD community, the following website may be accessed for ESRD information and updates:

CMS Dialysis Survey and Certification web site

The website contains:

- Hyperlinks to the 2008 Final Rule, Conditions for Coverage for End-Stage Renal Disease Facilities and the Interpretive Guidance (IGs);
- Frequently Asked Questions (FAQs) submitted by ESRD surveyors and the public since the implementation of the 2008 CfCs. The FAQs are organized by respective Conditions and V-tags in the IGs and are updated periodically with new questions and answers that are noted in red for easy reference;
- Survey tools and training materials including, but not limited to, the ESRD Core Survey Field Manual, Outline of the ESRD Core Survey Process, ESRD Core Survey Process Triggers, the Measures Assessment Tool (MAT), critical water and dialysate requirements, a list of V-tags and identifiers, information on infection control and requirements for isolation rooms/areas, ESRD personnel requirements including information on organizations that certify dialysis patient care technicians, components of immediate jeopardy, and a list of helpful web sites for ESRD surveyors;
- ESRD program-related survey and certification memoranda; and
- Hyperlinks to ESRD-related web sites within and external to CMS.

2270C – Definitions

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

Dialysis

Dialysis is a process by which waste products are removed from the body by diffusion from one fluid compartment to another across a semi-permeable membrane. There are two types of renal dialysis procedures in common clinical usage: hemodialysis and peritoneal dialysis. Both hemodialysis and peritoneal dialysis are modalities of treatment for ESRD under Medicare and can be performed in a dialysis facility or in the patient's residence.

Hemodialysis

In hemodialysis (HD), blood from the patient's body is passed through blood lines and a hemodialyzer ("artificial kidney") with the use of a hemodialysis machine. Hemodialysis uses osmosis and diffusion to remove waste products and excess fluids. Access to the patient's blood circulation is required. Through exposure to a prescribed solution called dialysate, the patient's blood is cleansed and extra fluid is removed. The cleansed blood is returned to the patient's bloodstream. Hemodialysis is most commonly conducted 3 times a week with each session lasting 3 to 5 hours. It can also be conducted in 4 to 6 shorter sessions per week or in 3 to 6 overnight sessions lasting 6 to 8 hours each. Hemodialysis can be performed in a dialysis facility or at the patient's home.

Peritoneal Dialysis

Peritoneal dialysis (PD) uses the patient's peritoneal membrane as the filter, and direct access to the patient's blood system is not required. A permanent tube (catheter) is surgically placed through the skin into the peritoneal space to allow introduction of a prescribed solution (dialysate). Waste products pass from the patient's blood through the peritoneal membrane into this fluid, which is drained and exchanged for clean solution

periodically. Peritoneal dialysis can be done manually four to five times daily at spaced intervals or may be done using a machine (called a cycler) 7 to10 hours daily, generally overnight. The length of time, number of exchanges, and content of the dialysate is based on the physician's prescription. PD is usually performed in the patient's home but may be performed in-center for ESRD facilities approved for in-center PD.

Intermittent Peritoneal Dialysis (IPD)
Waste products pass from the patient's body through the peritoneal membrane into the peritoneal cavity where the dialysate is introduced and removed periodically by machine. Peritoneal dialysis generally is required for approximately 30 hours a week, either as three 10-hour sessions or less frequent, but longer, sessions.

Continuous Ambulatory Peritoneal Dialysis Coverage (CAPD)
In CAPD, the patient's peritoneal membrane is used as a dialyzer. CAPD does not require machinery or water supplies since the dialysate comes prepackaged in plastic bags ready for use. CAPD requires implantation of an indwelling catheter to provide access to the peritoneum. The patient connects the 2-liter plastic bag of the dialysate to the catheter, and the fluid infuses into the peritoneal cavity. Four to six hours later, the patient drains the fluid into a new drain bag and refills the peritoneal cavity with fresh dialysate. The procedure is accomplished three to five times daily, with the first exchange made upon arising and the last at bedtime. The procedure not only frees the patient from a machine but also allows scheduling flexibility without many of the restrictions associated with other types of dialysis.

Continuous Cycling Peritoneal Dialysis (CCPD)
CCPD uses an automated peritoneal dialysis machine to infuse a prescribed amount of dialysate into the abdomen and drain it, depending on the prescription. The process is repeated for 8 to 10 hours a day, usually at night while the patient sleeps. The last exchange stays in the abdomen during the day. Thus the patient cycles at night, but continuously dialyzes during the day.

2271 - General Requirements for In-center and Home Dialysis Program
(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

In-Center Dialysis:

Approval to provide in-center dialysis includes approval for a specific number of dialysis "stations" for that modality. A dialysis station is an individual patient treatment area that provides sufficient space to accommodate the dialysis equipment and supplies needed for routine care and any emergency care indicated. There must be sufficient separation from other dialysis stations to afford protection from cross-contamination with blood-borne pathogens. A hemodialysis station is equipped with an adjustable chair or bed, a hemodialysis machine, and, depending on the hemodialysis machine being used, access to a purified water source and dialysate concentrates.

Federal regulations do not have space/dimension requirements for in-center dialysis stations or home dialysis training and support areas. Some State regulations may identify

space/dimension and other requirements for each in-center dialysis stations and the home dialysis training and support room/area.

Home Training and Support Program:
Approval to provide home training and support services requires the dialysis facility to provide both home training to the patient and/or their care partner in the modality and ongoing support and monitoring of the patient/care partner, as outlined in 42 CFR §494.100. An approved home training and support program must include both training and support services. A dialysis facility that is approved to provide services to home patients must ensure through its interdisciplinary team that home dialysis services are at least equivalent to those provided to in-facility patients and meet all applicable ESRD CfCs.

There are no requirements for a specification of the number of training stations. The expectation for these services is that there will be sufficient space to provide an appropriate learning environment for each patient and care partner, if applicable. The in-facility home dialysis training and support space must be large enough to accommodate the dialysis equipment, routine and emergency care, to afford patient privacy, and to prevent cross-contamination with pathogens.

In accordance with §494.100(c)(1)(vii), facilities which provide only home dialysis training and support must have a plan/arrangement in place to provide emergency back-up dialysis services when there is an interruption, or anticipated interruption, in a patient's routine home dialysis treatment. Situations that may require back-up dialysis services include, but are not limited to, non-functional equipment, power or water outages, availability of a designated care partner and/or a patient's anticipated travel away from their home.

The home dialysis support services may be provided directly by the ESRD facility or by arrangement with another ESRD facility. If the support services are provided by another ESRD facility, such arrangements should be made at a location as convenient to the patient's home as possible, regardless of facility ownership.

2271A - Dialysis in Nursing Homes
(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

Terms Used in This Guidance
The term "nursing home" in this guidance refers to a Skilled Nursing Facility (SNF) or a Nursing Facility (NF). The term "ESRD facility" refers to the certified end-stage renal disease (ESRD) facility that retains overall responsibility for all the dialysis care and services of the patient.
Overview: Dialysis for Nursing Home Residents
Medicare reimbursement for dialysis services is available to certified ESRD facilities. All dialysis patients must be under the care of a certified ESRD facility to have their outpatient dialysis care and treatments reimbursed by Medicare.
Nursing homes are not required to accommodate dialysis services on-site. Some State regulations may not allow dialysis services to be provided in a nursing home setting, or

may have additional requirements regarding the qualifications of personnel who provide dialysis treatments in a nursing home.

Residents of a nursing home may receive chronic dialysis treatments through two options:

1. **In-Center Dialysis:**
   - Transporting the resident to and from a separately certified ESRD facility that is located off-site of the nursing home for dialysis treatments; or
   - Transporting the resident to and from a separately certified ESRD facility providing in-center dialysis located within the nursing home or proximate to the nursing home building.

2. **Home Dialysis in a Nursing Home**:
   Residents may receive dialysis treatments in the nursing home. These dialysis treatments are administered and supervised by personnel who meet the criteria for training, and competency verification in 42 CFR 494.100(a) and (b) as also stated in this guidance, and are provided through a written agreement between the nursing home and the ESRD facility.

Mitigating risks for residents receiving dialysis treatments in a nursing home include: 1) ensuring only qualified personnel administer, monitor, and supervise the dialysis treatments; 2) monitoring the dialysis patient's status before, during, and after the treatments; and 3) ensuring a safe and sanitary environment for the treatments.

The goal of this guidance is to ensure that an ESRD facility, providing home dialysis services to a nursing home resident under a written agreement with the resident's nursing home, maintains direct responsibility for the dialysis related care and services provided to the nursing home resident(s) consistent with the ESRD Conditions for Coverage (CfC) requirements as well as the terms of an applicable agreement with the nursing home.

ESRD Notification to the State Survey Agency of a New or Additional Contract with a Nursing Home to Provide Dialysis Services On-Site

No additional approval is required from CMS for an ESRD facility to enter into an agreement with a nursing home to provide dialysis services to nursing home residents. However, the ESRD facility must notify its State Survey Agency (SA) of any such agreement(s). This notification is accomplished through submitting a completed Form CMS-3427 End Stage Renal Disease Application and Survey and Certification Report. Only the following applicable fields of the Form CMS-3427 must be completed for this notification:

- Field: (1) #6 Other
- Field: (2) Name of Dialysis Facility
- Field: (3) CCN
- Field: (4) Street Address of Dialysis Facility
- Field: (6) City
- Field: (7) County
- Field: (9) State
- Field: (10) Zip Code
- Field: (12) Telephone Number
- Field: (22) Dialysis in LTC Facility Field:
- Field: (26) How is isolation provided in the nursing home?

Written Agreement between the ESRD Facility and the Long Term Care Facility

The ESRD facility is expected to enter into a written agreement with any individual nursing home for which they will provide dialysis services. The agreement delineates the responsibilities of the ESRD facility and the nursing home regarding the care of the resident before, during, and after dialysis treatments.

The ESRD facility is ultimately responsible for the safe delivery of dialysis to the nursing home resident which would include review of the qualifications, training, competency verification, and monitoring of all personnel who administer dialysis treatments in the nursing home and who provide on-site supervision of dialysis treatments. The ESRD facility is responsible for the quality and safety of the dialysis treatments and the management of the residents' ESRD-related conditions. The ESRD facility is also responsible for providing all equipment necessary for the resident's dialysis treatment and for the maintenance of such equipment.

The nursing home is responsible for providing a safe environment for the dialysis treatments, monitoring the resident before, during, and after dialysis treatments for complications possibly related to dialysis, and provides all non-dialysis related care. Nursing home staff must be prepared to appropriately address and respond to dialysis related complications and provide emergency interventions, as needed. See 42 CFR §483.25(l) and SOM App. PP at tag F698.

Both the ESRD facility and the nursing home are responsible for ensuring the collaboration necessary to provide dialysis care coordination to each nursing home resident receiving dialysis treatments.

The written agreement must be signed by authorized representatives of the Medicare-certified dialysis facility and the nursing home prior to the provision of dialysis care at the nursing home and must:

1. Delineate the lines of authority of each party;
2. Delineate the responsibilities of each party;
3. Describe how coordination between the parties will occur;
4. Describes the accountability for the dialysis services provided;
5. Be consistent with the written policies and procedures of the ESRD facility and the nursing home;
6. Specify the method by which the parties will ensure adherence to the terms of the agreement, communicate as issues arise, and take remedial action when appropriate; and
7. Be reviewed at least annually, and updated as needed.

ESRD Policies and Procedures for Services to Residents Located in a Nursing Home

At a minimum, the ESRD facility, in collaboration with the nursing home, must develop and implement protocols for the delivery of ESRD services that are equivalent to the standards of care provided to dialysis patients receiving treatments in a dialysis facility. The protocols must include requirements set forth at 42 CFR 494.30 and 494.80 through 494.100. These protocols include procedures for infection control, patient assessment, patient plans of care, and care of the dialysis patient at home.

Policies and procedures must be reviewed and updated as necessary to be consistent with the most current standards of practice. Timeframes for re-evaluation of policies and procedures should be determined by each ESRD facility.

Dialysis Supervision and Administration

The ESRD facility providing services to a resident in a nursing home must ensure:

1. Onsite supervision of dialysis by a trained registered nurse (RN) (who has completed a training course approved by the ESRD facility) whenever a resident is receiving hemodialysis (HD) in the nursing home, and by a trained RN or licensed practical/vocational nurse (LPN/LVN) (who has completed a training course approved by the ESRD facility) when a resident is receiving peritoneal dialysis (PD) treatment in the nursing home;
2. Qualified/trained dialysis administering personnel are present in the room and maintain direct visual contact with the resident receiving HD throughout the entire duration of the treatment (the supervising nurse may also be the dialysis administering personnel); and
3. If a situation occurs where the nursing home is unable to provide dialysis treatments due to reasons such as insufficient trained staff and/or supervision, the ESRD facility is notified and provides the dialysis treatments to avoid a delay or cancellation of treatment.

Documentation of training and competency verifications for nursing home staff should be maintained by both the ESRD and nursing home facility.

Hemodialysis Treatment Supervision: Qualifications and Training

The ESRD facility must ensure that a trained supervising RN is constantly present on-site at the nursing home and immediately available to respond to concerns or emergencies that may occur during a resident's hemodialysis treatment. The supervising nurse must be present in the general area where the resident(s) are receiving dialysis and readily available. If the supervising nurse has other nursing duties in the nursing home, these other duties must not hinder or negatively affect his/her ability to respond immediately to the needs of the dialysis patient(s).

Training: RNs who supervise hemodialysis treatments in the nursing home must have successfully completed a training program which:

- Covers, at a minimum, the subjects listed at §494.100 (a)(3)(i)-(viii);
- Is approved by the dialysis facility medical director and governing body;
- Is administered under the direction of a home training nurse meeting the qualifications at §494.140(b)(2); and
- Is equivalent to the ESRD facility training and competency verification for home dialysis patients at §494.100 (a)(3)(i)-(viii) and §494.100(b)(1).

Peritoneal Dialysis Treatment Supervision: Qualifications and Training

The ESRD facility must ensure that a qualified supervising RN/LPN/LVN is constantly present on-site at the nursing home and immediately available to respond to concerns or emergencies that may occur during a resident's PD treatment (i.e. automated PD, continuous ambulatory PD). The supervising nurse must be present in the general area where the resident(s) are receiving dialysis and be readily available. If the supervising nurse has other nursing duties in the nursing home, these other duties must not hinder or negatively affect his/her ability to respond immediately to the needs of the dialysis patient(s).

Training: RNs/LPNs/LVNs who supervise PD treatments in the nursing home must successfully complete a training program that is:

- Specific to PD care and covers, at a minimum, the subjects listed at §494.100 (a)(3)(i)-(viii)
- Approved by the dialysis facility medical director and governing body;
- Administered under the direction of a home dialysis training nurse meeting the qualifications at §494.140(b)(2) and;
- Equivalent to the ESRD facility training and competency verification for home dialysis patients at §494.100 (a)(3)(i)-(viii) and §494.100 (b)(1).

Hemodialysis and Peritoneal Dialysis Administration

Qualifications: The personnel who initiate and discontinue dialysis treatments for HD and PD to nursing home residents must be a RN, LPN or LVN who meets the practice requirements in the State in which he or she is employed. A trained nursing home staff member such as a nurse aide or trained caregiver may monitor the patient for the duration of the patient's treatment, but initiation and discontinuation of HD and PD must only be performed by the supervising nurse.

Training: The dialysis administering personnel, for example RN, LPN/LVN, nurse aide or trained caregiver, must receive adequate training and possess sufficient competency to ensure that the resident on dialysis receives a safe and effective treatment. The training must be:

- Equivalent to the ESRD facility training and competency verification for home dialysis patients at §494.100 (a)(3)(i-viii) and §494.100 (b)(1).
- Approved by the ESRD facility medical director and governing body;
- Administered under the direction of a home dialysis training nurse meeting the qualifications at §494.140(b)(2) and;
- Specific to the dialysis modality. The training program for HD and PD must include at least the subject matter listed at §494.100 (a)(3)(i-viii) .

Ongoing competency for dialysis administering personnel must be verified through visual audits by an ESRD RN who meets the qualifications of home training nurse at §494.140(b)(2) . Frequency for competency verification is determined by the ESRD facility. More frequent competency checks may be warranted if problems in care are identified. For example, a concern of poor clinical outcomes, such as frequent infections, may indicate infection control issues and may be an indicator to review dialysis procedures performed by the nursing home staff and possible re-training.

In-Room Presence

To assure resident safety, the ESRD facility and nursing home must ensure that qualified dialysis administering personnel remain in the room with direct visual contact of the resident and their vascular access throughout the hemodialysis treatment, in accordance with §494.60(c)(4).

Existing Personal Caregiver

If an existing ESRD facility home dialysis (PD or home HD) patient is admitted to a nursing home and that patient has a trained personal caregiver who administered the dialysis treatments at home, that caregiver may be approved by the ESRD facility and the

nursing home to continue to administer the patient's dialysis treatments in the nursing home. The collaborative decision-making process for such situations must be addressed in the written agreement between the ESRD facility and nursing home. If the nursing home and ESRD facility determine that an existing home dialysis caregiver may continue to administer the dialysis in the nursing home, the ESRD facility must assure that the caregiver meets the training requirements at §494.100(a)(3)(i-viii), and the verification of demonstrated competency at §494.100(b)(1). The ESRD facility is responsible for the ongoing monitoring of the competency of the personal caregiver.

Coordination of Care

Communication

The ESRD facility and nursing home must establish procedures for 24/7 communication between the two entities. The ESRD facility must provide to the nursing home an on-call schedule with the names and contact information of physicians and/or ESRD facility RN's to be called for emergencies. There should be written agreement on a communication process to include how communication and responses will be coordinated and documented between the ESRD facility and nursing home staff.

Interdisciplinary Team (IDT) Coordination between ESRD Facility and Nursing Home Staff

The dialysis facility IDT team must coordinate with the nursing home staff for the development and implementation of an individualized care plan based on the patient's assessment. Both the nursing home staff and ESRD facility staff are responsible for monitoring and addressing any medical or non-medical needs that are identified. Any identified barriers or issues that are preventing residents from meeting the established ESRD facility goals identified through a patient assessment and/or defined in the plan of care, should be promptly communicated between the ESRD facility IDT and the nursing home IDT. Any barriers experienced by a dialysis patient will require re-assessment and an updated plan of care by both teams.

Emergency Plans

The dialysis facility maintains overall responsibility to prepare the nursing home to address all emergencies related to the dialysis needs of the resident receiving treatments in the nursing home. The following emergency plans must be clear and communicated to nursing home staff in a manner that allows for the continuity of care and be incorporated into the written agreement between the two entities:

1. **Emergency Staffing**
   When the nursing home staff are functioning as the caregiver for the nursing home resident and providing the dialysis treatment for the resident, it is the responsibility of the nursing home staff to notify the ESRD facility of any delays or interruptions in the provision of the prescribed dialysis treatment. The ESRD facility is responsible for ensuring that a backup plan is in place to ensure the resident receives the treatment.
2. **Emergency Care**
   Nursing Home residents receiving dialysis may have complications which require treatment with emergency medications or equipment. The physician treatment orders for the ESRD patient should include what emergency medications are to be kept on hand.
3. **Equipment Failure**
   The ESRD facility must provide nursing home staff with:

- Adequate and appropriate education for possible equipment failures and risk(s) associated with equipment failures;
- Troubleshooting techniques; and
- Contact information for assistance in resolving issues with equipment failure.

Any equipment that is non-functional must be replaced or restored by the ESRD facility to avoid interruption of a patient's dialysis treatment.

4. **Emergency Supplies**
   Nursing homes should maintain all necessary medication and supply inventories to prevent any delays or interruptions to a resident's prescribed dialysis treatment. The ESRD facility and the nursing home should ensure a reserve of supplies to be available in emergency circumstances. The emergency supply reserve is in excess of the routine supply inventory and generally includes at least five (5) days of emergency supplies for each resident.
   To assist with the inventory, the ESRD facility should provide nursing homes with medications, equipment, and dialysis related supplies through routine deliveries. Plans must be in place for the safe delivery of additional supplies in the event of an emergency.

2271B - Dialysis in Hospitals

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

A department/unit of a hospital (other than a psychiatric hospital) may, as permitted under State law, provide either inpatient or outpatient dialysis services.
In certain situations dialysis services may be provided in a hospital department/unit for non-ESRD patients requiring temporary dialysis or for ESRD patients who are admitted to the hospital for other diagnoses or injuries. These dialysis services are referred to as "acute dialysis." A department /unit of a hospital that provides acute dialysis services must provide those services in compliance with the hospital Conditions of Participation (CoP) and are not subject to the ESRD CfCs.
Hospitals that provide outpatient dialysis services must be certified as a hospital-based ESRD facility.

2272 - ESRD Facility Classification

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

Hospital-Based ESRD Facility
A hospital-based ESRD facility is a separately certified ESRD facility that is an outpatient department of a hospital and that meets the ESRD CfCs at 42 CFR Part 494. A hospital-based ESRD facility is owned and administered by a hospital or critical access hospital (CAH) and is physically located on the hospital campus. If a hospital operates multiple separately certified hospital-based ESRD facilities, each separate ESRD facility must have its own CMS certification number (CCN).
A hospital-based ESRD facility is discussed at 42 CFR §413.174(c) and meets the following criteria:

- The ESRD facility and hospital have a common governing body and are subject to

the bylaws and operating policies of this body. All management authority flows from this governing body which has final administrative responsibility over both entities. The common governing body approves all personnel actions, appoints medical staff, and carries out similar management functions;

- There is a clearly established line of authority between the ESRD facility administrator and the hospital chief executive officer wherein the administrator is under the supervision of the chief executive officer. The ESRD facility administrator reports to the common governing body through the hospital's chief executive officer;
- ESRD facility personnel policies and practices conform to those of the hospital;
- Administrative functions of the ESRD facility (for example, records, billing, laundry, housekeeping, and purchasing) are integrated with those of the hospital; and
- The ESRD facility and hospital are financially integrated, as evidenced by the cost report, which reflects allocation of overhead to the ESRD facility through the required step-down methodology.
- Hospital-based ESRD facilities are assigned CCNs from the 2300-2499 series.

Satellite Renal Dialysis Facility (Hospital-Based)

A satellite renal dialysis facility is a hospital-owned and hospital-administered ESRD facility but is not located on the campus of the hospital. A single hospital may have several satellite renal dialysis facilities. Each satellite facility is separately certified and surveyed; must independently meet the ESRD CfCs from other facilities owned by that hospital; and is assigned its own CCN.

Satellite renal dialysis facilities (Hospital-Based) are assigned CCNs in the 3500-3699 series.

Independent Renal Dialysis Facility

An independent renal dialysis facility is any ESRD facility that does not meet the definition of a hospital-based renal dialysis facility or satellite renal dialysis facility as described in the paragraphs above. An independent renal dialysis facility may be physically located on a hospital campus, but is not owned and/or administered by the hospital.

Independent renal dialysis facilities are assigned CCNs in the 2500-2899 series.

Special Purpose Renal Dialysis Facility (SPRDF) (§494.120)

This type of renal disease facility is temporarily certified to furnish dialysis at special locations on a short-term basis (i.e. up to 8 months in any 12 month period) to a group of dialysis patients who would otherwise be unable to obtain treatment in the geographical area.

The RO must clearly specify the limited nature of the SPRDF certification, the time period covered by the certification, and the automatic termination of payment on the last day of the certification period in its notifications.

The special locations for SPRDF fall into two categories:

Vacation Camps

Vacation camps serve dialysis patients temporarily residing there. A vacation camp SPRDF would allow campers to receive hemodialysis at the camp site, avoiding interruption of the camping experience. Vacation camps may be

approved for the duration of the camp, but up to a maximum of 8 months in any 12-month period.

Emergency Circumstance SPRDFs

These locations are set up to provide dialysis services to those ESRD patients who would otherwise be unable to obtain such services in their geographical area as a result of a natural or man-made disaster or a need for a greater capacity to dialyze patients who may have been evacuated from another location.

The RO may extend the time period in emergency SPRDF approvals, where necessary, beyond the standard eight-month period based upon the termination of the emergency condition.

In emergency situations, the RO should coordinate with the applicable State Health Department to assist the ESRD Network to relocate all patients to permanent facilities prior to the scheduled closing date of the emergency circumstance SPRDF.

Special purpose renal dialysis facilities are assigned CCNs in the 3700-3799 series when owned and administered by a hospital and in the 2900-2999 series for independent facilities.

2273 – Dialysis Modalities and Dialysis Related Services

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

Dialysis is a treatment option for end stage renal disease. Under the Medicare program, ESRD facilities may apply for and be approved to provide a variety of specific dialysis modalities and dialysis-related services. The dialysis modalities and dialysis-related services are listed below.

Dialysis Modalities

In-center Hemodialysis:

Under this modality, in-center hemodialysis patients receive their treatments at the ESRD facility, usually 2-5 times per week for varying lengths of time, generally from 3-5 hours as prescribed by their physician.

In-center Nocturnal Hemodialysis

This modality is a type of in-center hemodialysis where patients receive longer treatments overnight. In-center nocturnal hemodialysis stations usually include a reclining chair or bed to accommodate patient comfort.

In-center Hemodialysis- Self-dialysis

"Self-dialysis" is defined in the ESRD CfCs at 42 CFR 494.10 as "dialysis performed with little or no professional assistance by an ESRD patient or caregiver who has completed an appropriate course of training as specified in § 494.100(a) of this part." Self-dialysis refers to an individual patient's preference for performing self-care in the outpatient dialysis facility setting. In contrast to "home dialysis" which is also defined at §494.10, CMS considers the self-dialysis patient as an in-center dialysis patient (or their personal care partner) who wishes to self-administer most or all of their dialysis treatment without professional help in one of the approved in-center dialysis stations of the certified ESRD facility rather than in their home. There is no separate approval for facilities that offer "self-dialysis" so long as they are approved for in-center dialysis.

The ESRD CfCs include requirements related to the training of self-dialysis patients and/or care partners. The patient or care partner must successfully complete a course of training that covers at least the subject matters listed at § 494.100(a)(3). The training must

be conducted by a qualified self-care/home care dialysis training nurse (who meets the requirements pursuant to § 494.140(b)(2)), be provided by an ESRD facility which is approved to provide home dialysis services (§ 494.100(a)(1)). The facility must verify the competency of the patient/care partner in the administration of the dialysis treatments, and document the verification in the patient's medical record (§ 494.100(b)(1)).

In-center dialysis patients who wish to self-administer a minor portion of their treatments, such as inserting their own needles, or taking their own blood pressures do not meet the definition of "self-dialysis."

In-center Peritoneal Dialysis (PD)

Although PD is primarily a home dialysis therapy, there may be situations when a patient is receiving PD at the dialysis facility on a temporary basis while training for home PD, or prior to switching to hemodialysis. In-center PD generally requires a patient to come to the dialysis facility for PD treatment for eight or more hours per treatment as prescribed by their physician.

Home Hemodialysis Training and Support

The patient and/or care partner is trained to perform routine hemodialysis treatments at the patient's place of residence by a home training nurse who meets the qualifications at 42 CFR 494.140(b)(2). The home dialysis training and support facility staff, inclusive of the interdisciplinary team, provides ongoing monitoring and support services to the patient for their home hemodialysis treatments.

Staff-Assisted Dialysis in the Home

The dialysis facility may provide qualified staff members in the patient's home to assist them in performing their home dialysis treatments. The dialysis staff member functions in the role of the patient's caregiver and monitors the patient throughout the dialysis treatment. The dialysis facility maintains overall responsibility and oversight to ensure appropriate, qualified staff are assigned and trained and provides supervision of staff members as indicated. Employees performing staff assisted dialysis must meet the personnel qualification requirements at §494.140.

In order to provide staff-assisted home dialysis, a dialysis facility must be approved to provide Home Training & Support services. Staff-assisted home dialysis does not require additional approval.

Home Peritoneal Dialysis (PD) Training and Support

The patient and/or designated care partner are trained to perform peritoneal dialysis at the patient's place of residence by a home training nurse who meets the qualifications at 42 CFR 494.140(b)(2). The home dialysis training and support staff, inclusive of the interdisciplinary team, provides ongoing monitoring and support services to the patient for their PD at home. Home PD may include Intermittent Peritoneal Dialysis (IPD), Continuous Ambulatory Peritoneal Dialysis (CAPD), or Continuous Cycling Peritoneal Dialysis (CCPD). A dialysis facility must have an approved Home Training & Support program to offer IPD, CAPD, or CCPD. IPD, CAPD and CCPD do not require additional approval.

Urgent Start Peritoneal Dialysis (PD) in the ESRD Facility

Urgent start peritoneal dialysis is the initiation of peritoneal dialysis as early as two weeks following catheter placement and is an option to avoid central line insertion for patients interested in home dialysis but requiring initiation of dialysis. Urgent start PD allows the facility to support the patient's dialysis related needs until the

patient's catheter is healed and training is completed. Typically, patients will receive peritoneal dialysis treatments in the facility up to five days/week over eight hours. This process usually lasts between two to four weeks and after this period the patient will begin routine home PD independently in their home.
In order to perform urgent PD, the facility must be have an approved in-center PD and Home Training & Support program. No separate approval is required.

Pre-Configured Systems

ESRD CfCs applicable to preconfigured hemodialysis systems are located at 42 CFR 494.40 (e), "Standard: In-center use of preconfigured hemodialysis system. **Follow FDA labeling.**" This requires that the system's FDA approved labeling must be adhered to for machine use and monitoring of the water and dialysate quality. Because this system does not share the same design or configuration of a traditional in-center hemodialysis water system, all the requirements of §494.40 Water and Dialysate Quality will not be applicable. Accordingly, for purposes of surveying water and dialysate quality with preconfigured hemodialysis machines, the surveyor determines whether the facility follows the FDA and manufacturer's labeling for the machine. If that is confirmed, the surveyor may conclude that the preconfigured machine meets the requirements of 42 CFR 494.40(e) and the AAMI requirements at RD52. Maximum levels for contaminants including chlorine, bacteria and endotoxins in water and dialysate recommended by AAMI apply to both traditional in-center hemodialysis water systems and preconfigured systems.

Portable Reverse Osmosis (RO) Systems

A central water treatment and delivery system remains the traditional method for water purification for multiple hemodialysis machines in a dialysis facility. However, improvements in the manufacturing of small portable water treatment devices (i.e. portable reverse osmosis units) have created changes in options for water treatment in small chronic dialysis facilities. The use of portable RO units in small chronic dialysis facilities is an alternative method of delivering AAMI quality water to the point of use (hemodialysis machine), if the portable RO units are appropriately constructed, monitored, and maintained. The portable RO unit must produce the water quality defined in American National Standard Institute (ANSI)/AAMI RD52:2004, as incorporated by reference in 42 CFR 494.40 "Condition: Water and dialysate quality." The portable RO unit must be operated in accordance with manufacturer's directions for use.
Pursuant to §494.40, monitoring of each portable RO unit must include testing for total chlorine before each treatment, monthly microbiological monitoring of cultures and endotoxins, and at least annual testing of chemical quality of the product water. Monitoring must also include daily function monitoring and recording of the portable RO unit for percent rejection and the water quality produced by conductivity or total dissolved solids (TDS). Surveyors should follow the guidance of the ESRD Core Survey process and tools, expanding their review for the above-mentioned specific requirements, when reviewing a facility using portable RO units. During an initial certification survey, the surveyor should confirm that the facility's policies address all of these requirements.

Dialysis-related Services

Dialyzer Reprocessing and Reuse

A hemodialyzer (artificial kidney) is a medical device which may be manufactured for single use, or constructed so that it may be reprocessed and reused for hemodialysis following specific safety guidelines. Reusable hemodialyzers are:

- Assigned to an individual patient;
- Labeled with the patient's unique identifying information;
- Rinsed/cleaned;
- Tested for efficiency;
- Disinfected after each hemodialysis treatment and rinsed, and
- Tested for any residual disinfectant chemicals**.**

The processes for safe and effective dialyzer reprocessing and reuse are established by the AAMI, which are adopted by reference into the ESRD CfCs at 42 CFR 494.50.
Some dialysis facilities opt to transport patient dialyzers to an off-site location for reprocessing. This is known as a centralized reprocessing location. Guidance for review of centralized dialyzer reprocessing is included in SOM section 2284, "Specialized Areas of ESRD Oversight."
Many dialysis facilities do not reuse hemodialyzers. At these facilities, single-use dialyzers are prescribed to individual patients by type and are discarded in a biohazard receptacle after a single hemodialysis session.

2274 - ESRD Survey and Certification Forms

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

2274A - Form CMS-855A: "Medicare Enrollment Application: Institutional Providers

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

The ESRD supplier completes the Form CMS-855A and submits it directly to the applicable Medicare Administrative Contractor (MAC). The MAC will process the Form CMS-855A and will send a copy of any approved application to the SA and the CMS Regional Office. Updates to the Form CMS 855A must be submitted to the MAC when there are changes to the information already submitted.

2274B - Form CMS-3427: "End Stage Renal Disease Application and Survey and Certification Report"

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

In addition to the CMS-855, an ESRD facility must submit the completed Form CMS-3427 for:

- An initial application for participation by prospective ESRD facilities;
- A request to expand or add in-center dialysis stations for approved modalities;
- Change in location/relocation;
- Change in ownership (CHOW);
- For addition or elimination of a dialysis modality/service (s) provided, including:

- In-center hemodialysis
- In-center nocturnal hemodialysis
- In-center peritoneal dialysis
- Home hemodialysis training and support
- Home peritoneal dialysis training and support
- Dialysis in the Nursing Home setting
- Dialyzer reprocessing and reuse

After the completion of a survey or review, the SA must complete and upload Part II of the form and denote the type of survey conducted. Instructions for completing the Form-CMS 3427 are included on the last page of the form.

2274C - Form CMS-670: "Survey Team Composition and Workload Report"

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

The Form CMS-670 is completed by the survey team members for each onsite ESRD survey activity to capture surveyor resources utilized. For instructions on completion of Form CMS-670, refer to the State Operations Manual, Chapter 2, the Certification Process, Section 2705.

2274D - Form CMS-2567: "Statement of Deficiencies and Plan of Correction"

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

The Form CMS-2567:

- Is the official report of survey findings;
- Is the document which is disclosed to the public;
- Details the facility's deficient practices identified during the survey; and
- Contains the facility's plan for correction.

For more general information about the Form-CMS 2567, refer to the State Operations Manual, Chapter 2 the Certification Process, Section 2728. For ESRD surveys, specific instructions regarding documentation on the Form CMS-2567 for the following V-tags are provided:

Use of Tag V000

This tag should be used to document the type of survey conducted (e.g., complaint, initial, revisit).

Additionally, Tag V000 should include an explicit statement indicating the facility's compliance, or level of non-compliance with the CfCs, as result of the survey findings. Finally, Tag V000 may also be used to list a glossary of technical terms and abbreviations. If listed at V000, the terms and abbreviations may be used throughout that CMS-2567 without further explanation.

Use of Tags V100, 101: State and Local Law

The State determines compliance with its State licensure requirements. Tags V100 and V101 may not be used to cite noncompliance with State licensure requirements unless the

state licensure finding has been completely adjudicated and is final, i.e., the finding has been upheld through the State appeals process or has not been appealed and is a final state action.
Do not use V100 or V101 to cite deficiencies related to Occupational Safety & Health Administration (OSHA), the Americans with Disabilities Act (ADA), or the Food and Drug Administration. CMS is not the designated entity to survey for those requirements. Refer concerns in these areas to the applicable CMS Regional Office for referral to and notification of the appropriate oversight entity.

2274E - Form CMS-2567B: "Post Certification Revisit Report"
(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

The Form CMS-2567B is completed by the SA after a revisit survey to document verification of correction of deficiencies cited on the recertification survey.

2274F - Form CMS-1539: "Medicare/Medicaid Certification and Transmittal"
(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

The SA uses Form CMS-1539 to communicate findings to the CMS Regional Office with respect to a facility's compliance with health and safety requirements. Form CMS-1539 is also a transmittal cover sheet for the certification packet. The SA completes Part I of the form and the Regional Office completes Part II. For instructions on completion of Form CMS-1539, refer to the State Operations Manual, Chapter 2 the Certification Process, Section 2762.

2276 - SA Control of Form CMS-3427
(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

The SA date-stamps all Form CMS-3427s ("End Stage Renal Disease Application and Survey and Certification Report") and application-related correspondence received and reviews the forms and documentation for accuracy and completeness.
The SA forwards the original and one copy of Form CMS-3427, Part I, and the related materials to the RO within 3 days, using the "Medicare/Medicaid Certification and Transmittal," Form CMS-1539 to forward their recommendation to the RO.

2278 - ESRD Survey Procedures
(Rev. 1, 05-21-04)

2278A - Facility Withdraws Application Prior to Survey
(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

If the surveyor arrives onsite and the facility states it no longer wishes to be considered for ESRD program participation, the SA requests that the facility immediately submit a statement of voluntary withdrawal electronically to the SA. The surveyor should remain at the facility until the SA receives the request and instructs the surveyor to terminate the

survey.

2278B - Certificate of Need (CON)

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

Each application, except for a SPRDF, must be accompanied by evidence of a CON in all States where it is required by State law.

The SA returns applications that do not include the CON on the basis of an incomplete application, using the model letter in Exhibit 30.

2278C - Initial RO Approval

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

In order to be certified in the Medicare program as an ESRD facility, a facility must:

- Complete Part I of Form CMS-3427A, "End Stage Renal Disease Application and Survey and Certification Report;"
- Have provided care to a minimum of one patient per modality; and
- Be in compliance with all federal requirements including the ESRD Conditions for Coverage
- A certificate of need (CON), where required by State law, must be submitted by the facility unless it is a Special Purpose Renal Dialysis Facility (SPRDF).

The SA forwards its recommendation for certification or for denial of certification to the CMS RO. The RO will forward the final determination to the facility. If the facility is approved for certification, the RO assigns the ESRD facility a CMS Certification Number (CCN) number and sends a Form CMS-2007 (Exhibit 156) to the MAC. The RO completes the certification in ASPEN.

2278D - Expansion or Addition of Services – SA/RO Procedures

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

When a facility submits a request for expansion of services, per form CMS-3427, this generally relates to the addition of dialysis stations. The SA/RO will request and review a facility floor plan, with the proposed additional stations shown, to determine whether there are concerns regarding inadequate space for each station or infection control concerns due to inadequate space. Since there are no square footage requirements for each station, the review must ensure that each station has adequate space to provide for patient privacy and sufficient space for safety such as providing the need for the patient to exit if necessary or for emergency care to be provided if necessary.

If the review confirms there is adequate space for the expansion or addition of services, no on-site review is required. The SA should notify the provider of the approval of the additional stations.

When a facility submits a request for addition of a modality or service through the form CMS-3427:

1. On-site survey must be performed for: (All applicable regulations for the service/modality requested should be reviewed.)
    - Addition of In-center Hemodialysis; (Survey confirms that the facility has provided HD to at least one patient.)
    - Addition of Home Training and Support Modality; (Survey must confirm that the facility has provided home training a support to a minimum of one patient.)
    - Addition of In-Center PD, if no approval for Home Training and Support; and
    - Addition of Reuse
2. On-site survey is not required for the following changes in modalities or services:
    - Addition of In-Center Nocturnal HD; (Provider must provide documentation how the water system will be maintained.)
    - Addition of In-Center PD, if facility already approved for Home Training and Support; and
    - Addition of HD or PD in a Long Term Care Facility, if already approved for Home Training and Support.)

The SA notifies the facility of its decision regarding approval or denial of the expansion or addition. If approval is recommended, the SA forwards a CMS-1539 to the CMS RO with a recommendation. The RO forwards a CMS-2007 (Exhibit 156) to the MAC denoting any changes in services.

2279 - ESRD CMS Certification Numbers

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

The CMS Certification Number (CCN) is assigned to the ESRD facility after all certification requirements have been met. Assignment of the ESRD facility CCN should be in accordance with the guidelines contained in Chapter 2 of the State Operations Manual, section §2779.A.1. The RO forwards Form CMS-2007 to the MAC upon issuance of the CCN.
ESRD facilities and their CCN series are as follows:

- 2300-2499 Hospital-Based Renal Dialysis Facilities
- 2500-2899 Independent Renal Dialysis Facilities
- 2900-2999 Independent Special Purpose Renal Dialysis Facilities
- 3500-3699 Satellite Renal Dialysis Facilities
- 3700-3799 Hospital-Based Special Purpose Renal Dialysis Facilities

2280 - ESRD Survey Activities

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

State Licensure Requirements

An entity applying for certification as an ESRD facility must be in compliance with any applicable State Licensure requirements, in addition to the Federal requirements for each type of survey described below. Although State licensure requirements may include State Certificate of Need (CON) for ESRD facilities, Special Purpose Renal Dialysis Facilities (SPRDFs) may be exempt from CON requirements.

Initial Certification Application and Survey

Application

To request initial certification under Medicare, the applicant must notify the SA of their intent in writing, and submit Form CMS 3427: End Stage Renal Disease Application and Certification Report. The SA will communicate with the applicant regarding all required documents that must submitted for enrollment and certification and inform the applicant that the facility must have provided services to at least one patient for each modality or service for which they are applying. CMS will not accept the transfer of an already trained home dialysis patient or "borrowing" qualified home dialysis staff from another certified ESRD facility for initial approval of a Home Dialysis Training & Support program.

The applicant must also submit Form CMS 855A: Medicare Enrollment Application: Institutional Providers to the Medicare Administrative Contractor (MAC). Once the MAC reviews and approves the CMS-855A, it will notify the SA/RO that a survey may be scheduled.

Prioritization of Initial Surveys

The priority of initial certification surveys of prospective ESRD facilities is specified annually in the Survey and Certification Mission and Priority Document (MPD).

Initial ESRD Certification Survey Process

The ESRD initial survey should follow the ESRD Core Survey Process as discussed in Appendix H of the SOM. The ESRD survey process for initial certification includes a review of all ESRD Standards within the Conditions for Coverage.

Initial Certification Determination

The applicable CMS Regional Office is responsible for the initial certification determination of a new ESRD facility.

Denial of Initial Certification

If the initial certification survey identifies Condition-level non-compliance during an initial survey, the SA must notify the CMS Regional Office of the recommendation for denial of Medicare certification. The State survey team must prepare the Form CMS 2567 detailing the survey findings. The CMS Regional Office reviews the findings and makes the final certification determination and then communicates its decision to the dialysis facility and to the SA, as well as notifies the MAC of the denial via Form CMS-2007.

Reapplication after Initial Certification Denial or Voluntary Withdrawal

In the case of voluntary withdrawal of a request for initial certification or a denial of certification, the facility may reapply in the future. To reapply, the facility must resubmit a new Form CMS-3427 to the SA and a new CMS-855A to the MAC. An initial survey will also be required.

Recertification Survey

Prioritization of Recertification Surveys

Prioritization for recertification surveys of ESRD facilities is specified annually in the CMS Survey and Certification (MPD).

Recertification Survey Process

ESRD recertification surveys should follow the ESRD Core Survey Process as discussed in Appendix H of the SOM.

Revisit Survey

The SA must conduct a revisit survey prior to the termination date for any ESRD survey with findings of Condition-level non-compliance. It is at the discretion of the SA/RO as to whether a revisit is performed when only Standard level deficiencies are identified. The revisit survey is conducted to substantiate that the facility is back in substantial compliance with the applicable ESRD CfCs. The SA schedules a revisit survey after the last date of correction provided in the approved plan of correction. The information reviewed at the revisit is drawn from records and other evidence dated since the original survey. It is the intent of the revisit survey to review compliance with requirements which were cited as being deficient on the prior recertification survey. However, the surveyor(s) is required to cite any deficient practices identified in the course of determining correction of previously cited deficiencies,

Temporary Closures

A temporary closure may occur as a planned event (either voluntary or as the result of survey findings) to allow repair or remodeling, or as an unplanned event due to damage from a natural or man-made disaster. The facility is required to notify the SA in writing of any temporary closure of the facility which extends greater than one day of operation. Prior to reopening, the facility must submit to the SA a description of the changes or modifications to the facility which occurred during the closure and must submit the results of product water quality testing performed after the restart of the water treatment system. This documentation must include chemical analysis, cultures, and endotoxin levels. The SA will make a determination as to whether an on-site review is required based upon the submitted documentation. In situations where the dialysis facility has damages caused by a natural or man-made disaster which affects, or has the potential to affect the structural integrity of the facility, an on-site survey shall be performed prior to re-opening.

The SA must review the facility-submitted information and determine whether the water testing results (if applicable) are within acceptable limits, as detailed in the ESRD CfCs at 42 CFR 494.40(a) (see V177, V178 and V180), and notify the facility administrative personnel whether or not the water testing results are within the requirements of the regulation and may reopen to treat patients.

If, in the course of repair or remodeling during a temporary closure, the facility determines that it is more expedient to relocate, the facility must immediately communicate this request to the SA. The SA must evaluate the request and determine whether the ESRD facility will retain their participation at the new location. The SA would then follow the relocation process described below.

A temporarily closed facility may not retain its Medicare participation indefinitely. At the time of the temporary closure, the facility provides a projected date for resumption of services. The projected time frame for closure must be consistent with the repairs or renovation required. Depending on the duration, closure may be viewed as a cessation of business (voluntary termination of the Medicare CCN). The facility may be asked to submit periodic progress reports to the SA as to whether the projected re-opening remains the same.

Relocation Survey

Generally, a relocation survey is not required when an ESRD facility relocates to a new physical location but is still serving the same patients and employing the same staff, changes its location on a campus or changes its location within the original address. However, the ESRD facility must submit the following information to the SA and an on-site survey may be performed if indicated by the information submitted:

Prior to the move, the ESRD facility must inform the SA how patients will continue to receive dialysis treatments uninterrupted during the relocation.

Immediately upon the relocation the ESRD facility must submit evidence to the SA that water testing was performed and determined to be within acceptable ranges.

The ESRD facility must also submit a revised floor plan to the SA to confirm adequate space for stations.

Criteria for Relocations

If a dialysis facility permanently relocates, it must remain essentially the same operation at its new location. CMS makes the determination that the facility is serving the same patients with the same staff.

Process for Relocations

A dialysis facility must notify the SA prior to its relocation and notify the Medicare contractor (MAC) via a revised CMS-855A within 90 days following the move. The facility must submit a revised Form CMS-3427 to the SA. The facility must immediately inform the SA of any changes to the relocation date.

Prior to the relocation of any patients, the facility must provide reports to the SA demonstrating acceptable results of product water quality testing, including chemical analysis and reports of acceptable results from testing for bacteria and endotoxin at the new location. If additional or replacement dialysis machines will be used in the new location, documentation must be submitted to confirm that baseline dialysate, bacteria and endotoxin have been completed on those machines. The facility must provide a floor plan to confirm sufficient space and privacy for each station. The facility must also attest to compliance with the Life Safety Code requirements. The SA reviews the reports and the floor plan to ensure the results are within acceptable limits, as detailed in the ESRD CfCs at §494.40(a) (see V177, V178 and V180). Once the SA accepts these water and dialysate quality reports and completes any indicated on-site review, the SA notifies the facility that it may open and operate the same number of treatment stations approved at its previous location and relocate its patients. If the facility requests additional stations concurrent with the relocation, see instructions below for Expansions.

In the event that the ESRD facility relocates without notifying the SA and does not submit the above referenced documentation and information to the SA before relocating patients,

the SA should conduct an immediate jeopardy complaint investigation to ensure that water testing has been done appropriately, there is adequate space for the stations, and Life Safety Code requirements are met.
If the ESRD facility requests approval for an additional service or modality simultaneously with a relocation, refer to SOM Section 2278D regarding "Expansions and Change in Services" to determine whether an on-site review is required.

Certification at the New Location

If an ESRD facility relocates to another state, it is considered a voluntary termination and the facility's Medicare CCN is terminated. The relocated facility must seek Medicare participation as an initial applicant in the new State. The ESRD facility would be certified as a new ESRD facility and have a new CCN once it demonstrates compliance with all federal requirements.

If an independent ESRD facility relocates within the same state, the CMS RO will determine if the facility will retain its Medicare agreement and CCN after the relocation, or whether the move will be treated as a cessation of business (voluntary termination) of the first location and an initial certification of a prospective ESRD facility at the new location. The RO will base its decision on whether the ESRD facility continues to serve the original community and utilizes the same staff after the relocation as it served at the previous location.
If a hospital-based ESRD facility relocates to an off-campus location but continues to serve the same community and utilizes the same staff at this new location, its CCN will be retired and the facility will be assigned a new CCN that corresponds to renal satellite facilities. This is not a voluntary termination.

Expansions and Change in Modalities and Services

Expansion: Addition of In-Center Dialysis Stations

When a dialysis facility wishes to increase the number of its approved in-center dialysis stations, it must submit a new Form CMS-3427 ESRD Application and Survey and Certification Report to the applicable SA. The dialysis facility must specify the number of additional stations requested and include: evidence that adequate space is available for the stations in consideration of safety and infection control; and a summary explanation of any building renovations that will be necessary for the addition of stations.

Voluntary elimination of approved modalities/services

When a dialysis facility wishes to discontinue providing an approved dialysis modality or dialyzer reprocessing/reuse, it must file a new Form CMS 3427 reflecting the modalities/service that it plans to provide after the elimination along with a written explanation of the change(s). When received, the SA must review the information and contact the facility with any concerns or additional information required, such as plans for appropriate transition of patients who rely upon the discontinued service.

To assure patient access to care in the community served by the dialysis facility, when a facility wishes to eliminate a dialysis modality, the change should not inconvenience patients. If a facility has one or more patients in their patient census who is using the dialysis modality it plans to eliminate, the facility must:

- Assess each patient who will be affected by the change (§494.80(a));

- Inform the affected patients of the plan to eliminate the modality, and of their options for continuing treatment (e.g. transfer to a facility that offers the modality, switch to a different modality offered by the current facility) (§494.70(a), §494.70(b));

- Include the affected patients in the decision-making process, giving weight to the patient's preferences for their continued care (§494.80(a)(9)); and

- Arrange for orderly transfer of those patients who opt to transfer to another facility. The facility must report to the applicable ESRD Network any patient transfer when the patient(s) feels that he/she was transferred without their consent (involuntary transfer).

The SA must also communicate with the applicable ESRD Network to confirm that the facility gave the affected patients sufficient (30 days) notice that the service was to be discontinued and that the patients are relocated to other ESRD facilities in consideration of patient preferences and with minimal disruption. If the SA identifies concerns with any of the above protections, a deficiency may be cited at §494.70(a) and/or §494.70(b).

Addition of dialysis modalities or services

When a facility wishes to add a dialysis modality or service, it must file a revised Form CMS-3427 with the applicable SA office. Upon receipt of the form, the SA must review the facility file, if available, for current or past quality concerns, the current FY State Outcomes List, and must contact the applicable ESRD Network. The SA should utilize this information to assist with an on-site review, where required. Refer to section 2278D for guidance on addition of dialysis modalities or services. The SA informs the facility that it must have at least one patient on census using each dialysis modality for which it is applying to allow the SA to review care.

For approval of each home dialysis modality for which the facility is applying, there must be at least one patient and/or their caregiver, on census who is in the process of being trained or has been trained by that facility. CMS will not accept the transfer of an already trained home dialysis patient or "borrowing" qualified home dialysis staff from another certified facility. Such a practice does not constitute evidence that the facility meets the requirements to demonstrate that it will continue to provide safe and effective care for these patients on an ongoing basis.

Complaint Survey

When investigating complaint allegations or the circumstances of a self-reported event in an ESRD facility, the ESRD surveyor should use all applicable survey tasks or portions of tasks from the ESRD Core Survey process at Appendix H of this SOM. See Chapter 5 of the SOM for additional instructions on complaint investigations.

Extension of a Complaint Investigation into Recertification Survey

When the findings from a complaint survey are determined to be at Condition-level or the surveyor identifies an Immediate Jeopardy situation, the SA must extend the complaint survey into a full recertification survey.

Change of Ownership (CHOW)

Refer to SOM Section 3210

2281 - Waivers
(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

2281A - Isolation Room Waiver
(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

The ESRD CfCs at §494.30(a)(1)(i) refer to the requirements for the treatment of hemodialysis patients who are positive for hepatitis B (HBV+). Every certified ESRD facility must have the capacity to treat one or more HBV+ patients in an isolation room or isolation area, or have an approved waiver under §494.30(a)(1)(ii).

An **isolation room** is a separate room with walls and a door to contain any spatter of blood, body fluids or other contaminants. The door does not need to remain closed, except as indicated to contain contaminants. The walls do not need to reach the ceiling, but should be a least six feet in height and must fully contact the floor to contain blood spills. The walls must allow for continuous visualization of the patient(s) in the room. Plexiglas (or similar) walls are acceptable.

An **isolation area** is an area or space separated from other dialysis stations by a space equivalent to the width of a hemodialysis station.

Sufficient capacity takes into account the availability of dialysis facilities with isolation rooms in the proximate geographic area. The proximate area must not create an undue hardship on the patient to have to relocate to the proximate facility.

ESRD facilities certified prior to February 9, 2009 may have an isolation area, an isolation room or apply for an isolation room waiver to provide isolation services. In those instances where a patient already being served by the ESRD facility develops the need for isolation, the ESRD facility must have written arrangements in place to affect the safe transfer of the patient to another local ESRD facility which does provide isolation services.

Facilities certified after February 9, 2009 must have either an isolation room or apply for an isolation room waiver to provide isolation services. In those instances where a patient already being served by the ESRD facility develops the need for isolation, the ESRD facility must have written arrangements in place to affect the safe transfer of the patient to another local ESRD facility which does provide isolation services.

Waiver Process
Under §494.30(a)(1)(i), a new or expanding dialysis facility may be eligible for a waiver of the isolation room requirement if isolation rooms for HBV+ patients in other ESRD facilities are available and the available HBV+ isolation rooms sufficiently serve the needs of the HBV+ patients in the geographic area.

The facility must update the CMS-3427 form by completing Field 26 to annotate the waiver request.

The facility must submit a written request for an isolation room waiver to the applicable SA. The written request must include information about the geographical proximity of facilities with isolation rooms and identifies any barriers to accessibility for the patients.

The SA makes a recommendation via Form CMS-1539 to the RO for approval or denial of an isolation room waiver request. Document in the "Remarks" section the request for a waiver of the isolation room requirement. The CMS RO will review the information, make the decision whether to grant the waiver, and inform the facility and the SA of its decision.

Criteria for Consideration of the Isolation Room Waiver:

1) Other facilities in the local area that provide isolation services (review CMS-3427 Forms to verify if the facility provides isolation services);

2) Communications with the ESRD Network regarding geographical availability of isolation services, quality of care concerns involving isolation, etc.;

3) Complaints received by the SA regarding lack of isolation services provided.

2281B - Medical Director Waiver

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

The ESRD CfCs at §494.140(a)(1) require dialysis facilities to have a qualified medical director and specifies the qualification criteria. A qualified medical director must have completed a board-approved training program in nephrology; have 12 months of experience providing care to dialysis patients; be licensed to practice in the State; and be board certified in internal medicine or pediatrics.

If a qualified physician is not available to serve as the medical director of a certified dialysis facility, the ESRD CfCs at §494.140(a)(2), provide that another physician may direct the services subject to the approval of the Secretary.

Waiver Process

Waiver of the medical director requirement is not available for initial certifications.

For existing facilities, if a physician who meets the required qualifications at §494.140(a)(1) is no longer available to serve as medical director of a certified dialysis facility, a facility may request a waiver to appoint another physician to serve as the medical director. This request must be reviewed and approved by CMS.

The facility request for waiver consideration, along with a brief resume of the alternate physician and an explanation as to why a physician who meets the requirements is not available should be submitted to the applicable SA.

The SA forwards the waiver request along with their recommendation for approval or denial via CMS-1539 to the RO. The CMS RO makes the final determination on approval/denial.

Criteria for Consideration of the Medical Director Waiver:

1) Facility ranking on the most recent confidential outcomes list is at or above the national five percent threshold;

2) Lack of qualified providers in the geographical area;

3) Impact of a waiver denial on patient access to care;

4) Candidate's previous experience in the care of dialysis patients;

5) Continuing efforts of the facility to secure a qualified medical director.

Waivers should be reviewed by the RO on an annual basis. The RO requests the facility to submit updated information addressing 1-5 of the considered criteria above for the annual review.

The CMS RO will review the request, make the decision, and inform the facility and the SA of its decision regarding the waiver request.

The current Master list of approved ESRD facility waivers can be found on the CMS Quality Certifications and Oversight Reports (QCOR) web site under "Resources" in the menu bar, and listed under "ESRD Waivers Tracking Worksheets MASTER." (QCOR)

2281C - Life Safety Code Waiver

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

Limited LSC Applicability – Exemption for certain ESRD Facilities
Effective July 16, 2012, pursuant to §494.60 (d)(1), compliance by certified ESRD facilities with the applicable requirements of the 2000 edition of the National Fire Protection Association (NFPA) Life Safety Code 101 is limited to those ESRD facilities that are located adjacent to high hazardous occupancies and those facilities that do not exit to the outside at grade level from the patient treatment area.

"Exit to the Outside at Grade Level from the Patient Treatment Area Level":
The phrase "exit to the outside at grade level from the patient treatment area level" applies to ESRD facilities that are on the ground or grade level of a building where patients do not have to traverse up or down stairways within the building to evacuate to the outside. Accessibility ramps in the exit area that provide an ease of access between the patient treatment level and the outside ground level are not considered stairways. Compliance with the structural requirements of NFPA LSC 101 for ESRD facilities that pose a higher risk for life safety from fire is still required. Such higher risk ESRD facilities include those that do not have a readily available exit to the outside at grade level for swift, unencumbered exit and those facilities that are located adjacent to an "industrial high hazardous" occupancy, as defined by NFPA 101 at section A.3.3.134.8.2, Annex A.

Defining Adjacent to an Industrial High Hazardous Occupancy:
An "industrial high hazardous occupancy" is based upon the definition in the NFPA LSC 101, 2000 Edition at section A.3.2.134.8.2, Annex A as: "occupancies where gasoline and

other flammable liquids are handled, used, or stored under such conditions that involve possible release of flammable vapors; where grain dust, wood, or plastic dusts, aluminum or magnesium dust, or other explosive dusts are produced; where hazardous chemicals or explosives are manufactured, stored, or handled; where cotton or other combustible fibers are processed or handled under conditions that might produce flammable flyings; and where other situations of similar hazard exist." Being adjacent means an ESRD facility shares a common wall, floor, or ceiling with that occupancy.

The ESRD facility administrator may submit an attestation to the applicable SA that the facility meets the requirements for an exemption to compliance with NFPA LSC 101. Those facilities that do not submit an attestation claiming exemption will be considered a non-exempt facility and will continue to be surveyed for compliance with chapters 20 and 21 of the NFPA 101 LSC, 2000 Edition.

2282 - RO Use of Provider Tie-In Notice, Form CMS-2007, for Suppliers of ESRD Program Services (Exhibit 156)

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

Form CMS-2007 serves as the official notice to the MAC of program actions affecting ESRD facilities that supply Medicare program services. The RO must forward a CMS-2007 to the MAC for all initial certifications/denials, voluntary and involuntary terminations, and CHOWs. The addition of a new service or modality must be communicated with the MAC and may be forwarded through either the CMS-2007 or electronic mail.

2283 - Termination Procedures

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

See SOM Chapter 3.

2284 - Specialized Areas of ESRD Oversight

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

2284A - Centralized Dialyzer Reprocessing

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

Centralized dialyzer reprocessing refers to a process of transporting used hemodialyzers from multiple facilities to a central location for reprocessing. When centralized reprocessing services are used, the certified dialysis facility retains responsibility for the dialyzer reprocessing, is expected to actively communicate and coordinate with the centralized reprocessing entity, and incorporate the activities of the centralized reprocessing location into the dialysis facility's Quality Assessment and Performance Improvement (QAPI) oversight of the dialyzer reprocessing/reuse program.

On-site visits to centralized reprocessing sites are done as a part of the survey of any

dialysis facility using a reprocessing site, since there is no separate Federal certification for centralized reprocessing sites. Some States may have licensing requirements for these sites. The ESRD CfC requirements at 42 CFR 494.50 for the dialyzer reprocessing area, reprocessing procedures, environmental control, safety standards, and training of staff are the same for the centralized reprocessing site as for on-site dialyzer reprocessing at the ESRD facility. An on-site review of the reprocessing center must be included in every initial and recertification survey.

When a facility utilizes a central reprocessing service, there must be clear policies to guide the transporting of the dirty (i.e., used) dialyzers to the reprocessing site and returning the reprocessed dialyzers to the dialysis facility for clinical use. The system for transportation of the dirty dialyzers must protect patients' dialyzers from damage and microbiological contamination. Temperature controls must be in place to prevent microbiological growth, container temperatures monitored during transit, and steps taken to prevent cross-contamination between dialyzers during transport (§ 494.50(b)(1) at V319, V331, and V345). Safety checks must be in place to assure that reprocessed dialyzers are returned to the correct ESRD facility for use. Culture and endotoxin testing must be conducted at least monthly at the centralized reprocessing site and results monitored and retained at user dialysis facilities (§ 494.40(a) at V178; § 494.50(b)(1) at V314). User dialysis facilities must include oversight of the centralized reprocessing location outcomes, equipment maintenance, staff competency verifications, and other applicable Reuse Quality Assurance audits in their QAPI program (§ 494.110(a)(2)(vii); § 494.50(b)(1) at V360-368).

Deficiencies Identified at the Centralized Reprocessing Location
During the on-site visit to a centralized reprocessing location, the surveyor obtains a list of the names and CCNs of all Medicare certified dialysis facilities currently using the center. If any deficiencies are cited during the on-site visit at the reprocessing center, the SA must secure corrective action from all ESRD facilities within their jurisdiction. Each ESRD facility, including the ESRD facility under survey, is immediately notified of the findings and the need for a corrective action plan. The SA must contact the affected ESRD facilities not under survey by electronic mail or telephone the day the finding is made. The findings are then cited on a CMS-2567 for all facilities within the SA's jurisdiction that utilize the center. Upon return to the SA, the finding is entered into ACTS as a complaint against all ESRD facilities not under survey and a CMS-2567 is issued to each facility with a plan of correction requested.

The SA notifies the applicable State Health Department of the findings as required by Revised S&C 14-36.

When survey findings at a reprocessing center identify ESRDs from other states utilizing the center, the SA should notify their RO that will in turn notify the other ROs for the affected states and the associated SAs will prepare the CMS-2567s.

2284B - ESRD Services across State Lines
(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

There are instances when a certified dialysis facility will provide home hemodialysis or

home peritoneal dialysis services to patients or nursing home residents who reside within close proximity of state lines (which in some cases may be across the street). No special approval or agreement is required for a dialysis facility to provide home training and support services to patients in a bordering states.

2286 – ESRD Network Participation and Data Submission

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

2286A – ESRD Network Participation

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

There are 18 geographically-defined ESRD Networks (NW) across the United States. Every dialysis facility is located within the service area of an ESRD NW. ESRD facilities must cooperate with their assigned NW and participate in NW activities.

ESRD NWs are contracted by CMS to advance quality improvement in dialysis facilities through monitoring and supporting facility-based participation in quality improvement activities which ensure safe, effective care. CMS expects ESRD NWs to address and attempt to resolve patient grievances and to facilitate clinical data submission and analysis. To ensure the cooperation of dialysis facilities in achieving the CMS goals assigned to ESRD NWs, each facility is required to sign a NW/Facility agreement as part of their initial certification.
CMS expects SAs and ESRD NWs to establish an ongoing relationship focused on the provision of quality care and the advancement of quality improvement in the ESRD facilities. The relationship should include regular communication and coordination between the SA and the ESRD NW regarding routine quality improvement activities as well as ad hoc communication and collaboration as indicated when individual facilities have serious quality concerns that could impact the health and safety of patients.

Surveyors should contact the ESRD Networks prior to beginning a survey to gather facility information, but only after entering the ESRD facility and beginning the survey to ensure the survey remains unannounced. Surveyors should contact the NW before initiation of the facility Environmental “Flash” Tour. Surveyors should inquire whether the NW has information to share regarding quality concerns, patient complaints, involuntary discharges, and/or involuntary transfers. It is important that surveyors observe the protocols designed to ensure that surveys are unannounced and unpredictable, while also gathering information important to the survey process.

2286B - Furnishing Data and Information for ESRD Program Administration (42 CFR 494.180(h))

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

All certified, participating ESRD facilities must furnish data and information to CMS as specified by the Secretary, pertaining to its ESRD patient care activities and costs. The national End-Stage Renal Disease Program Management and Medical Information System (ESRD-PMMIS) collects information from each participating ESRD facility.

2286C – Using ESRD Data
(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

Surveyors are expected to use Dialysis Facility Reports (see below) to inform the ESRD survey process. This report provides aggregate data regarding laboratory values, demographic information, mortality rates, hospitalizations, infections, etc. which may assist the surveyors during the review of patient medical records.

2286C.1 - Dialysis Facility Reports and Outcomes Lists
(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

Each SA and CMS RO assigns a Master Account Holder to control access to the State-specific data which are available on the CMS ESRD Dialysis Facility Reports website. The State Master Account Holder is responsible for accessing the State-specific data at the beginning of each fiscal year. ESRD data reports on this site include:

- A **State Profile**, which provides an overview of the State-specific outcomes and general information such as the number of facilities and number of patients receiving dialysis in the State;
- An **Outcomes List**, which includes all certified dialysis facilities in the State ranked according to selected outcomes, with the facility which has the poorest outcomes listed first;
- A **Dialysis Facility Report (DFR)** for each dialysis facility in the State; and
- An **ESRD Core Survey Pre-survey DFR Extract Report** for each dialysis facility in the State, which lists key data elements to facilitate pre-survey preparation.

Each SA must:

- Review the State profile to determine specific problem areas in each State, including but not limited to failure to meet expectations regarding infection control practices;
- Use the State rank-ordered Outcomes List and the data profiles, in conjunction with other information, to select the facilities to be surveyed;
- Use the facility-specific Dialysis Facility Reports before each survey to inform survey activities; and
- Use the ESRD Core Survey Pre-survey DFR Extract Report to facilitate surveyor review of key facility outcomes and trends for comparison to national benchmarks in preparation for surveys regarding potentially problematic clinical areas in that facility.

The CMS Dialysis Facility Reports web site has a section that is open to the public and a section that is password protected. No password is required to access the list of Master Account Holders and sample reports (Dialysis Facility Report, Supplemental Report, and State/Regional Profile) and guides to those reports. The password protected section of the web site is:

- For surveyors,

- Controlled by Master Account Holders for each State/Region, and
- Contains the Dialysis Facility Report and DFR Extract Report for each dialysis facility; the Outcomes List for each State; and the State/Regional Profiles.

2286C.2 - Dialysis Facility Compare

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

Dialysis Facility Compare is a site intended for public use and includes a tool for locating and comparing dialysis facilities in an area. This site offers information about Medicare-certified dialysis facilities and other resources for patients and family members who want to learn more about chronic kidney disease and dialysis, or to compare the services available in area dialysis facilities, and the quality of care that those facilities provide. Dialysis Facility Compare uses the same data sources as the Dialysis Facility Reports and provides additional information and resources for patients and families.

2287 - ESRD Patient Care Technician (PCT)

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

2287A - PCT Certification

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

Per §494.140(e), PCTs hired prior to October 14, 2008, should have attained their PCT certification by April 15, 2010. PCTs hired after October 14, 2008 must attain the PCT certification within 18 months of their date of hire. CMS counts all PCT work experience, regardless of changes in employer, in determining the 18-month time period allowed for completion of PCT certification. An approved leave of absence (medical/military/other) extends the period by the number of full or partial months of the leave of absence. If a PCT does not work as a PCT in any dialysis facility for 18 months or more, the 18-month time period allowed for completing certification begins anew.

2287B - Definition of a PCT

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

The CMS requirement for PCT certification applies to unlicensed individuals providing direct patient care. PCTs may be described in a variety of terms, including “biomedical technician” and “dialysis assistant.” For purposes of CMS technician certification requirements, a dialysis PCT is any unlicensed staff member who has responsibility for direct patient care. “Direct patient care” is defined as any aspect of healthcare for a patient provided personally by a staff member, including but not limited to collecting data (e.g., vital signs, weights, symptoms since last treatment), setting up the dialysis machine, testing reprocessed dialyzers for the presence or absence of germicide, initiating/terminating treatment, care of the dialysis access, delivering any aspect of the hemodialysis or peritoneal dialysis process, responding to machine alarms, and administering medications as allowed by State practice acts. A person who only reprocesses dialyzers and/or maintains or “takes down” dialysis machines (removes dialyzer and lines from the machine after use) and who has no direct patient care

responsibilities is not considered a PCT by CMS.

2287C - Certification and Additional Requirements
(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

In addition to being certified by a nationally recognized certification organization program, PCTs must meet applicable Federal and State requirements for education, training, and competency to provide patient care in dialysis facilities. This includes any State requirements related to practice standards, certification, credentialing, licensure, or registration.

ESRD CfC requirements at 42 CFR 494.140(e), which became effective on October 14, 2008, requires that the PCT have a high school diploma or equivalency (GED). Recognizing that there were PCTs with extensive experience working in dialysis facilities as of the effective date of the ESRD CfC who may not have verification of a high school diploma or GED, PCTs with greater than four years of PCT work experience in dialysis as of the effective date were permitted to use that work experience in lieu of the requirement for a high school diploma or GED until April 15, 2010. Any PCT applying for certification after April 15, 2010 must have a proof of high school diploma or GED.

CMS also requires that PCTs complete an RN-directed, medical director-approved, job-specific training program which includes the curricula prescribed by the ESRD CfC at 42 CFR §494.140(e)(3) before independently providing care to dialysis patients.

2287D - State and National Certification Programs for PCTs
(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

PCT certification can occur under the aegis of either a State or National PCT certification organization. Usual components of the State and National programs include:

- A qualifying standardized test;
- An independently proctored and protected testing environment;
- Ongoing re-certification.

There are currently three recognized National organizations providing commercially-available PCT certification programs: the Board of Nephrology Examiners for Nursing and Technology (BONENT), the Nephrology Nursing Certifying Commission (NNCC); and the National Nephrology Certification Organization (NNCO).

2288 - Infection Control Considerations
(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

Saline Flush Syringes

Under 42 CFR §494.30(b)(2), ESRD facilities must follow aseptic technique when preparing and administering intravenous medications; including the filling of syringes with sterile saline for use during the dialysis procedure.

Pursuant to current recommendations from the Centers for Disease Control (CDC), ESRD facilities may not fill syringes with saline from the single dose saline bag or IV tubing connected to the patient at the dialysis station. To comply with recommended safe injection practices, the facility may acquire pre-filled syringes or may prepare saline syringes for an individual patient in a clean area away from the patient treatment area. When saline syringes are required for vascular access care or to flush medications, ESRD facilities should obtain syringes pre-filled with sterile saline from a manufacturer, Food and Drug Administration (FDA) registered outsourcing facility, or pharmacy whenever possible. However, when saline syringes must be prepared in an ESRD facility for administration, the following safe injection practices must be followed:

- Fill syringes with sterile saline for an individual patient in a dedicated clean area removed from the patient treatment area. Although not required, a clean room separate from the patient treatment area is the preferred location.
- Prepare syringes for an individual patient as close as possible to the time of administration to prevent compromised sterility or stability.
- Use aseptic technique for disinfection of saline vials prior to entry and follow the suggested standards from the Association for Professionals in Infection Control and Epidemiology (APIC) and the Institute for Safe Medication Practices (ISMP) when preparing saline flushes including:
    - Medication containers labeled single-dose or single-use (e.g., saline bags, single- dose vials, ampules) may not be used to prepare more than one syringe for vascular access care or to flush medications. Any unused saline in the opened single-dose or single-use container must be discarded and may not be stored for future use on the same patient.
    - If multi-dose vials are used to prepare saline flush syringes, they must be dated upon opening and discarded within 28 days unless the manufacturer specifies a different date for that vial. The beyond-use date should never exceed the manufacturer's expiration date.

Cleaning the Dialysis Station

According to current recommendations from the CDC, to prevent cross-contamination between dialysis patients, it is important that the previous patient completely vacate the dialysis station before the ESRD staff begins cleaning and disinfection of the station and set up for the next patient. Surveyors should cite 42 CFR §494.30(a)(4)(ii) if noncompliance with cleaning and disinfection of the dialysis station is identified during the survey. It is important to note that all dialysis patients must be clinically stabilized (i.e., stable blood pressure, vascular access hemostasis) following their dialysis treatments before being moved from the dialysis station. If a patient is not sufficiently stable to be moved from the dialysis station, cleaning and disinfection of the equipment at the station and preparations for the next patient must be delayed until the patient is able to be safely moved outside the station.

Providers of Outpatient Physical Therapy and/ or Outpatient Speech Pathology Services Specified in §§ 485.701-485.729

2290 – Providers of Outpatient Physical Therapy and Speech-Language Pathology Services - Citations

(Rev. 83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

The statutory basis for providers of outpatient physical therapy and outpatient speech-language pathology services is found under § 1861(p) of the Social Security Act. The Conditions of Participation (CoPs) for rehabilitation agencies, clinics (operated by physicians) and public health agencies as providers of outpatient physical therapy and speech-language pathology services, are specified in 42 CFR Part 485, Subpart H. Appendix E of the State Operations Manual (SOM) and sections 2290-2306 of the SOM contain interpretive guidelines for regional offices (ROs), State Agencies (SAs) and accreditation organizations (AOs).

2292 - Types of Organizations, Who May Provide Outpatient Physical Therapy and Speech-Language Pathology Services, Specified in §§ 485.701-485.729

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

There are three types of organizations that may qualify as providers of outpatient physical therapy and speech-language pathology services under 42 CFR Part 485, Subpart H: clinics, public health clinics, and rehabilitation agencies. However, rehabilitation agencies are the only organizations that are currently enrolled as a Medicare provider with a CMS Certification Number (CCN). The general term "organization" is defined as a clinic, rehabilitation agency, or public health agency and is used throughout this chapter and the interpretive guidance to collectively reference these providers of outpatient therapy services (i.e. outpatient physical therapy and speech-language pathology that were formerly referred to as OPTs). Any specific organization, such as a rehabilitation agency, will be noted in the guidance as appropriate for requirements that are specific to that organization alone.

2292A - Rehabilitation Agency

(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

The primary purpose of a rehabilitation agency is to improve or rehabilitate an injury or disability, and to tailor a rehabilitation program to meet the specific rehabilitation needs of each patient referred to the agency. A rehabilitation agency must provide, at a minimum, physical therapy and/or speech language pathology services to address those needs of the patients. Social/vocational services are no longer a requirement.

The rehabilitation agency must be able to provide therapeutic procedures as well as the modalities of heat, cold, water and electricity for physical therapy treatments for the patients it accepts for service at any of its practice locations. The rehabilitation agency must also be able to provide any equipment required by the speech-language pathologist to

treat patients accepted for such service.

As noted above, rehabilitation agencies must provide at least physical therapy and/or speech language pathology services to comply with the CoPs. Occupational therapy is an optional service and cannot be substituted for either of these two services. It may be provided in addition to physical therapy and/or speech-language pathology services.

A rehabilitation agency is no longer required to have a physician on call to furnish necessary medical care in case of an emergency. However, the rehabilitation agency must have policies and procedures in place that instruct its staff regarding the steps to take in an emergency (including notification of the patient's doctor) and appropriate documentation. Refer to 42 CFR 485.711(c).

2292B – Rehabilitation Agency, Clinic and Public Health Agency

(Rev. 150, Issued: 10-30-15, Effective: 10-30-15, Implementation: 10-30-15)

Two person duty requirement: Organizations must always have at least two persons (either of its own personnel or its contracted personnel) on duty on the premises **anytime** rehabilitation treatment is being provided to a patient. The two person requirement does not specify which staff must be on duty (in other words, professional staff or a combination of professional staff and support staff), but the organizations must consider the supervision required of support staff.

This duty requirement can be verified by requesting staff or personnel time cards. The staff time cards can be compared against patient sign-in sheets if there are concerns regarding the two person duty requirement.

Services provided in a patient's residence are exempt from the two person duty requirement. Additionally, services provided in a patient's room within an assisted living facility (ALF) or independent living facility (ILF) may be considered to be a patient's residence and therefore also exempt from the two person on duty requirement. A common or general use area of the facility, such as a hallway, may be considered to be an extension of the patient's room and residence and also exempt from the two person on duty requirement.

This requirement is for the safety of the patients. It is not a new requirement, but is sometimes overlooked, particularly at a rehabilitation agency's extension location(s). Refer to Interpretive Guidance Tag I-118 in Appendix E of the SOM.

Supervision: A physical therapist may not supervise an occupational therapy assistant, nor, may an occupational therapist supervise a physical therapist assistant. Nonprofessional personnel (generally physical and occupational therapy aides) cannot be supervised by anyone other than the qualified physical or occupational therapist while performing patient care activities.

Clinical records: The regulations at §485.721 require clinical records be maintained on **all patients** served by the organization. A copy of the patient's current clinical record

should be kept at the practice location and readily accessible for prompt retrieval. Electronic records are acceptable but should be password or other method protected to maintain security and patient privacy.

Administrator: The administrator (§485.709) is given internal control of the clinic or rehabilitation agency by the governing body. The administrator must assume overall administrative responsibility for the entirety of the organization's operation including extension locations and/or off-premises activities. Furthermore, the administrator must serve as a full time administrator, meaning he can only be responsible for a single Medicare certified organization. It is important to determine whether the administrator can efficiently and effectively serve as administrator if the agency has several extension locations. Also, a competent individual must be available at each extension location to manage the day to day operations of that location on the days when the administrator is not onsite. That individual is responsible for reporting to the administrator.

Governing body: The governing body (§ 485.709) (or designated person so functioning) has the legal responsibility for the overall clinic or rehabilitation agency operations (including conduct and compliance of the clinic or rehabilitation agency) and may be legally responsible for more than one clinic or rehabilitation agency. The governing body's legal responsibility for the overall conduct of the clinic or rehabilitation agency cannot be delegated to any other entity (for example, a parent corporation). The number of individuals who serve on the governing body is determined by the organization/individuals who own the clinic or rehabilitation agency. The name of the owner(s) or corporate officer(s) (for a corporate entity) is fully disclosed to the State Agency. The governing body is expected to meet periodically, consistent with its by-laws.

Contracts: An organization may provide services with direct hire employees (i.e., salaried personnel) and with those employees under arrangement (or contract) (§485.719). The employees hired under contract may provide services wherever the organization provides therapy services.

Rehabilitation agencies may contract to provide outpatient therapy services at assisted living facilities (ALFs). In this instance, the rehabilitation agency has the administrative responsibility and supervisory oversight for the delivery of services in these facilities. In addition, the rehabilitation agency is responsible for maintaining clinical records for therapy services provided to the ALF patients.

In situations when the OPT is seeing patients in an ALF or ILF, where there is no ongoing or permanent presence of the OPT, common areas do not need to be closed off when an individual therapy session extends beyond the patient's room. However, OPTs must afford patients the opportunity for privacy at the patient's request or when clinical situations warrant privacy.

Any space leased, rented, or dedicated for the provision of OPT services, including space within an ALF or ILF that is designated for therapy service, must meet the two person on duty requirement and become a separately certified OPT or become approved as an extension location of a currently certified OPT. Leased or rented space that is dedicated to

therapy services must be closed to non-therapy participants when services are being provided. See Section 3100 for additional guidance for situations and when a location must be approved as an extension site or separately certified.

2292C - Public Health Agency
(Rev. 1, 05-21-04)

An official agency established by a State or local government, the primary function of which is to maintain the health of the population served by providing environmental health services, preventive medical services, and in certain instances, therapeutic services.

2294 - Change of Address
(Rev. 83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

When an existing organization intends to move its Medicare approved primary site or a rehabilitation agency intends to move any of its approved extension locations to a new practice location or the rehabilitation agency desires to add a new practice location , it must first notify CMS within 90 days of the expected move and seek approval from the RO before it can bill Medicare for covered services from the new address. Refer to §424.515 and §424.516

Process:

The organization must submit written notification to the RO regarding its intended move 90 days prior to the intended move. Concurrently, the organization submits a modified Form CMS-855A to its Medicare administrative contractor (MAC) or fiscal intermediary (FI).

The MAC/FI notifies the RO/SA when it has verified the information.

The RO will evaluate all supporting documentation from the MAC/FI and the SA/AO in making its decision to approve or deny the new practice location.

A survey must be completed in the case of a primary site change of address.

The RO will notify the agency in writing of its decision and provide copies to the SA/AO and MAC/FI.

2296 – Medicare Approved Sites of Service Provision
(Rev.83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

A rehabilitation agency must provide services at its approved primary site (the site that was issued the CCN). The organization may apply to CMS for approval of another location near the primary site for the purpose of providing additional access to care. These locations are known as “extension locations” and are defined in 42 CFR 485.703.

The mandatory services to be provided at the primary site are physical therapy and/or

speech-language pathology services. Occupational therapy is an optional service. The extension location must also provide physical therapy and/or speech-language pathology services.

The primary site and extension locations must have sufficient equipment and modalities to demonstrate that it has an adequate therapy program and can appropriately treat the patients that it has accepted for services. The extension location shares administration, supervision, and services with the primary site in a manner that renders it unnecessary for the extension location to independently meet the CoPs.

2298 – Extension Locations for Rehabilitation Agencies

(Rev. 83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

Currently, only rehabilitation agencies are permitted to have extension locations. The clinics operated by physicians and public health clinics are not permitted extension locations. These two providers must provide outpatient therapy services at their Medicare approved location.

An extension location is defined at 42 CFR 485.703 as "a location or site from which a rehabilitation agency provides services within a portion of the total geographic area served by the primary site. The extension location is part of the agency. The extension location should be located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the extension location to independently meet the conditions of participation as a rehabilitation agency."

This means the extension location and the primary location have the same:

- Governing body,
- Administration; and
- Policies and procedures (e.g., housekeeping, infection control). However, it is important that evacuation plans are specific to the building where the services are provided.

The rehabilitation agency may provide a therapeutic service directly at one location while providing it under arrangement at another. A therapeutic service refers to a type of professional discipline (i.e., physical therapy, occupational therapy, speech language pathology, etc.). Therapeutic services do not refer to particular types of treatment modalities (such as ultrasound or other types of physical agents) applied to produce therapeutic changes to biologic tissue.

2298A - Criteria for Extension Location Approval

(Rev. 150, Issued: 10-30-15, Effective: 10-30-15, Implementation: 10-30-15)

It is the CMS RO (not the SA or AO) that has the final authority for approving the request for an extension location. The following criteria should be reviewed and assessed in a decision regarding the approval or denial of extension locations:

- The extension location must have equipment and modalities appropriate for the needs of the patients it accepts for service.

- The administrator and other supervisors at the primary site must be capable of adequate supervision of the staff at all extension locations to include management and overseeing operations of the extension location. The administrator may delegate aspects of administrative operations at extension locations provided the agency has internal policies and procedures ensuring coordinated oversight of all locations. The administrator or his/her designee should be available by telephone, at a minimum, and be able to arrive at the extension location in a reasonable amount of travel time.

  Primary sites are generally able to meet the requirements for supervision and oversight when the extension location being requested is within 30 miles of the primary site. Requests for approval of extension locations beyond 30 miles must include adequate documentation to support the OPT's ability to maintain supervision and oversight of these locations and that the services are being provided to a portion of the total geographic area served by the primary site. An example of evidence supporting this would include, but is not limited to, policies and procedures describing a structured program for supervision and oversight of activities at extension locations. This may include items such as scheduled teleconferences, videoconferencing, and site visits to facilitate administrative and personnel management. Additionally, OPTs may provide a written narrative to the CMS RO further describing their supervision and oversight of extension locations. The oversight program must ensure that the extension locations maintain compliance with all applicable aspects of the CoPs, even though they are not required to independently meet all the CoPs as a rehabilitation agency.

- The extension location must provide the same level of privacy and dignity for its patients as the primary site does.

- For a rehabilitation agency to establish an extension location across State lines, the affected State Survey Agencies must have a signed reciprocal agreement allowing approval of the extension location.

2298B - Extension Location Approval Process

(Rev. 83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

All extension locations must be approved by CMS before any services are provided and billed to Medicare:

- Any proposed extension location, where the rehabilitation agency wishes to provide services for its own patients, must be listed on a modified Form CMS-

855A and submitted to the MAC/FI for verification.

- The MAC/FI notifies the RO and/or the SA after it has verified the information contained on the Form CMS-855A.

- Concurrently, the rehabilitation agency must submit written notification to the RO regarding its intent to open an extension location 90 days prior to opening the new location.

- The RO will evaluate all supporting documentation from the MAC/FI and the SA/AO in making its decision to approve or deny the new extension location.

- The RO will determine whether a survey needs to be conducted and will instruct the SA/AO appropriately.

The RO will notify the rehabilitation agency in writing of its decision to approve or deny the extension location and will provide copies of its decision to the SA/AO and MAC/FI. The **CMS notice** letter includes:

- Approval decision for the added practice (extension) location and the date that the RO determined the added practice location met all appropriate CoPs, or complete reasons for denial if the request was denied:

- The assigned Federal extension location identification number, if approved:

    - **The identification numbers are not used when submitting claims**. Only the NPI is used by the provider to file a claim.

    - NOTE: The RO enters the extension location identification number into the Automated Survey Processing Environment (ASPEN) prior to sending the notice letter to the agency, so that the rehabilitation agency can begin providing services at the new extension location upon receipt of the CMS approval letter.

- The effective date:

    - The effective date of coverage for services provided from the extension location is the date the RO determines that the extension location meets all Federal requirements. This date will be included in the CMS notice letter. The organization should not begin providing services at the newly added practice location until it receives CMS's notice of its decision to approve or deny the new location.

2298C- Survey of Rehabilitation Agency Extension Locations by SAs

(Rev. 83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

The surveyor must evaluate each condition and standard in the CoPs at all surveyed

sites. The surveyor should conduct record reviews, observations and interviews to reach conclusions regarding the agency's compliance with the CoPs for care provided at all practice locations before recommending approval by the RO.

The extension location must meet all applicable CoPs. The approved extension locations will not have their own governing body since each location must share administration, supervision and services with its primary site. However, if there are concerns with the day-to-day operations of the extension location, assess the effectiveness of the governing body. Condition § 485.713 will be surveyed only if the extension location provides physical therapy services. Condition § 485.715 will only be surveyed if speech language pathology services are provided. Condition § 485.717 is applicable only to a rehabilitation agency's own patients.

The surveyor will record results of interviews and record reviews on the survey report, Form CMS-1893 (Outpatient Physical Therapy – Speech Pathology Survey Report), for the surveyed locations. The surveyor completes only one Form CMS-2567(Statement of Deficiencies and Plan of Correction) and one Form CMS-1539(Medicare and Medicaid Certification and Transmittal) for each agency (primary site and extension locations) surveyed. The names of all practice locations (primary and/or extension location) found not to be in compliance with each regulation is to be documented on the Form CMS-2567. On the CMS-1539, the surveyor notes the names of extension locations in "State Agency Remarks." Surveys of all locations must be coordinated; therefore, the surveyor should schedule and complete surveys of all locations within the same time period.

When the surveyor is certifying compliance, findings at all locations are to be considered as a whole. Failure to correct cited deficiencies at any location (extension location or primary site) will jeopardize the certification status of the agency in its entirety. If the agency has deficiencies in only some locations, but they are judged significant enough to warrant termination, the SA may recommend initiation of termination proceedings to the RO. [Refer to SOM Appendix Q or SOM section 3010].

NOTE: For a rehabilitation agency to establish an extension location across State lines, the two States involved must have a signed reciprocal agreement with each other allowing approval of the extension location. Whether the extension location is in the same State as the primary site or in another State, it must conform to all regulatory requirements. An extension location that is situated in a different State should bill under the primary site's provider number.

2298D - Accreditation Organization (AO) Surveys of Rehabilitation Agencies

(Rev. 83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

For organizations seeking certification or recertification through accreditation by an AO with an approved program, the AO surveys the primary site and any proposed or existing extension locations (of a rehabilitation agency) for compliance with the applicable CoPs. After the survey is completed, the AO will recommend to the RO whether a specific primary and any extension locations should be approved or denied as practice locations for

the agency.

If the RO approves the addition of practice locations based upon the recommendations of the AO, the RO will issue identifiers for those locations and will send a notice letter to the rehabilitation agency regarding the RO approval.

The AO may cross state lines to survey an extension location only if there is a reciprocal agreement between the two states. However, the AO should determine whether the extension location in the second state is in close enough proximity to the Medicare certified primary site to be adequately supervised.

The AO can only survey an extension location and recommend approval to CMS if the primary site is already accredited by the AO and has been certified by CMS as a provider through deemed status. If a provider is currently accredited by a CMS-approved AO and has been certified by CMS as a provider through deemed status, it may submit a request to open an extension location by completing and submitting to the MAC/FI a modified Form CMS-855A. The agency must also notify the AO of its intention to open an extension location.

The AO must evaluate each condition and standard in the CoPs at all surveyed sites. The survey should include record reviews, observations and interviews to reach conclusions regarding the agency's compliance with regulations for care provided at all practice locations before recommending approval by the RO.

2300 - Outpatient Physical Therapy and/or Speech-Language Pathology Services at Other Locations such as a Patient's Private Residence, Assisted Living or Independent Living Facility

(Rev. 150, Issued: 10-30-15, Effective: 10-30-15, Implementation: 10-30-15)

In addition to the primary site and any extension locations, the organization may provide therapy services in the patient's private residence or in a patient's room in a SNF/NF, in an assisted living facility, or in an independent living facility. These are services that are provided on an intermittent basis where there is no ongoing or permanent presence of the OPT. Examples of an ongoing or permanent presence may be indicated by a dedicated therapy gym; storing of equipment, supplies, or medical records at the facility; or having OPT staff regularly assigned to work at that facility directing a coordinated and ongoing rehabilitation program at the facility. These situations are examples that would require the OPT to have the other location become separately certified or become approved as an extension location.

The agency must provide an adequate therapy program whenever and wherever it provides services at locations away from the primary site. The agency must have adequate equipment and modalities available, at any location, to treat the patients accepted for service. If the agency is providing services at more than one location each day, the agency must have infection control policies in place that set forth the techniques the agency employees will use at all locations.

The agency is responsible for providing any modality that is designated on the plan of care or requested by the physician. It is not acceptable for agencies to ask patients to sign waivers for modalities that are not available. The agency should refer the patient to another agency if needed services are not available at the agency practice location. The surveyor should see evidence of the referral in the patient's clinical record.

The current plan of care and progress notes must be accessible to service providers anytime that the patient is receiving care in order to promote continuity of care.

Periodically, an organization may wish to use a community facility to provide certain therapeutic services. For example, the organization may want to use a community pool to provide aquatic therapy. The SA or AO shall verify that the community pool meets all applicable State laws (i.e., health and safety, infection control requirements, etc.) governing the use of the community facility. Also the SA or AO shall review the organization's policies and procedures regarding the type of therapy being provided, training for staff, supervision, etc. The pool must be closed to public use during the time the organization is providing therapy to protect the privacy and safety of the patients being treated. The hours of operation and days of the week during which the facility will be used for therapy services, supervision, etc. must be clearly stated in the organization's policies and procedures as well as the contractual agreement between the community pool and the organization. Verify that the organization has a carefully detailed policy regarding specific arrangements for emergency services in the event of a medical emergency at the community location (i.e., is a telephone in close proximity to the qualified professional providing the service, is there a second organization staff person on site, etc.

2302 - CMS -381 Model Letter Requesting Identification of Extension Locations

(Rev. 83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

Form CMS 381 is **no longer required** to be collected by the SA **on an annual basis** as it is overly burdensome for the SAs. The rehabilitation agency must notify both the MAC and CMS of its intent to add a new practice location prior to providing physical therapy and speech-language pathology services at the new location. The agency submits its request on a modified Form CMS-855A. The SA should request the agency to submit the Form CMS 381, in addition to the modified 855A **whenever the agency requests to add a new practice location.** The SA must continue to notify the RO when new practice locations are added to ensure that identifiers are issued to the new practice locations. As indicated previously, a provider cannot provide services at a new practice location until this location has been approved by CMS.

2304 - Operation of an Organization on the Premises of a Supplier/Provider

(Rev. 83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

There is no prohibition against an organization operating on the premises of a supplier (e.g., physician or chiropractor) or another provider as long as they are not operating in the same space at the same time.

At no time can Medicare be billed twice for the same service. For example, a physician and a rehabilitation agency cannot both bill Medicare for therapy services provided by the agency for the same patient.

In addition, the supplier must adhere to sections of the Social Security Act that prohibit suppliers from referring Medicare patients for certain designated health services (DHS) to an entity with which the supplier or a member of the supplier's immediate family has a financial relationship, unless an exception applies.

2306 – When a Rehabilitation Agency's Extension Location Becomes Its Primary Site

(Rev. 83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

The rehabilitation agency, following the conversion of its primary site to a CORF, may select one of its extension locations as its new primary site. The SA notifies the RO via Form CMS-1539 of the new primary location and any existing, approved, extension locations for outpatient physical therapy and/or speech-language pathology services. A new survey must be conducted to certify that the rehabilitation agency's new primary location meets the CoPs. However, any of the rehabilitation agency's other extension locations that have already been approved do not require a survey or re-approval as an extension location to the new primary site.

2308 - Relocations of Providers of Outpatient Physical Therapy and Outpatient Speech-Language Pathology Services Concurrent with CHOWs

(Rev. 83, Issued: 03-15-13, Effective: 03-15-13, Implementation: 03-15-13)

When an agency undergoes a change of ownership (CHOW), the provider agreement is automatically assigned to the new owner unless the new owner rejects assignment of the agreement. Automatic assignment of the existing provider agreement to the new owner means that the new owner is subject to all the terms and conditions under which the existing agreement was issued. In other words, the new owner must accept all assets and liabilities (including, but not limited to, any Medicare payments owed by or due to the provider, adhering to existing plans of correction, and maintaining compliance with health and safety standards, ownership and financial interest disclosure, and civil rights requirements, etc.) of the entity that is being purchased in order to receive the existing Medicare Provider Agreement and the CCN. If the owner accepts assignment, a survey is generally not required.

If the new owner does not accept assignment of the provider agreement, the existing Medicare Provider Agreement and the CCN will be terminated and the new owner must follow the same process as any other prospective provider (i.e., enrolling with the MAC/FI, applying for participation, undergoing Office of Civil Rights (OCR) clearance and an initial survey, having a new effective date of participation assigned, etc.). See SOM section 3210.

A new owner may propose to relocate the organization concurrent with the CHOW. This would be considered as an address change of the existing provider and the new location will be surveyed to ensure that it meets all the applicable CoPs. However, if the relocation is to a site that is located in a different geographic area serving different patients than previously served and employing different personnel to serve those patients, then the new owner must be treated as a new provider in the Medicare program. Refer to SOM section 3210.1B5 if there are questions regarding this process.

Comprehensive Outpatient Rehabilitation Facilities (CORFs)

2360 - CORF - Citations and Description

(Rev. 1, 05-21-04)

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

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

2362 - Scope and Site of Services

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

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

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

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

2364 - CORF'S Relationship With Other Providers or Suppliers

(Rev. 1, 05-21-04)

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

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

2364A - Shared Space With Another Provider or Supplier

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

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

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

2364B - Sharing of Equipment

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

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

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

2364C - Employee Sharing

(Rev. 1, 05-21-04)

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

2366 - Conversion of OPT/OSP to CORF

(Rev. 1, 05-21-04)

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

Suppliers of Portable X-Ray Services

2420 - Suppliers of Portable X-Ray Services - Citations

(Rev. 1, 05-21-04)

The statutory authority for coverage of suppliers of portable x-ray services is found in §1861(s)(3) of the Act. The regulations are found in 42 CFR 486, Subparts A-C. Appendix D contains surveyor and interpretive guidelines.

2422 - Location of Portable X-Ray Service

(Rev. 1, 05-21-04)

Diagnostic x-ray tests (including tests furnished in a place of residence used as the patient's home) must be under the supervision of a physician. The "residence used as the patient's home" can include a SNF or hospital that does not provide x-ray services for its patients and arranges for these services through a portable x-ray supplier, such as a mobile unit. However, to be certified as a portable x-ray supplier, the mobile unit can neither be fixed at any one location nor permanently located in a SNF or a hospital.

Despite the mobility of the services, the base office address of the supplier must be identified as the supplier, and the supplier must be approved in each State in which its operation is based. A post office box number does not suffice.

Portable x-ray suppliers operating across state lines may or may not maintain separate offices in multiple states. Those that operate in states other than where they are based must meet State and local laws of each state in which they operate. The certifying SA in such instances must check whether the other State permits such operation by reciprocal State agreements. Note on the survey report whether the other State has such a requirement, and if so, whether the specific supplier is permitted to operate in the other State.

2424 - Suppliers Using Improperly Labeled or Post-1974 Equipment

(Rev. 1, 05-21-04)

2424A - Labeling Requirements

(Rev. 1, 05-21-04)

Condition 42 CFR Part 486.100 requires portable x-ray suppliers to provide their services in conformity with Federal, State, and local laws. This includes the requirement that the facilities comply with Food and Drug Administration (FDA) performance standards for diagnostic x-ray systems at 21 CFR Subchapter J, Radiological Health. These standards first became effective August l, 1974, and have been amended several times since.

Diagnostic x-ray systems covered by these standards (manufactured August 1, 1974, or later) **must** bear a label or tag indicating that the equipment met the FDA standards at the time of installation in a facility. Systems manufactured before August 1, 1974, are exempt from the standards. However, if new components manufactured after August 1, 1974, are installed in systems manufactured before that date, the new components must meet the standards and be properly labeled. Equipment that does not bear such a label may be either pre-1974 manufactured equipment, which is legal to use without a label, or post-1974 equipment from which the label was removed and which should not be used by the portable x-ray supplier.

2424B - Request for and Review of Labeling Information

(Rev. 1, 05-21-04)

In order to facilitate the process of determining whether portable x-ray equipment meets FDA standards, the SA must request the supplier to submit the following information on all unlabeled equipment prior to the survey or resurvey:

- Name of manufacturer;
- Equipment model number;
- Equipment serial number; and
- Date of manufacture (if available).

The SA checks the information with the State radiation health specialists who perform the equipment surveys. If doubt exists as to whether the equipment used by a particular x-ray supplier meets Federal standards, the SA forwards the case to the RO for HSQB verification with the FDA. The SA must not certify or recertify the supplier of portable x-ray services until questions concerning the equipment's legality are resolved.

Screening Mammography

2460 - Mammography

(Rev. 1, 05-21-04)

The Mammography Quality Standards Act of 1992 (§354 of the Public Health Services Act) requires all facilities providing diagnostic and screening mammography services to have a certificate issued by the Food and Drug Administration (FDA), regardless of their source of reimbursement. Therefore, all mammography suppliers participating in the Medicare program must have a certificate issued by the FDA and do not undergo a Medicare survey. The CMS ROs do not assign a supplier number to mammography suppliers participating in the Medicare program and collect no health and safety data concerning them. Medicare payments are made to mammography suppliers based on the FDA certificate number. (Also see §§1861(jj) and 1834 of the Act.)

Life Safety Code (LSC)

2470 - LSC - Citations and Applicability

(Rev. 1, 05-21-04)

(Also see Chapter 7, §7410)

2470A - Background

(Rev. 1, 05-21-04)

The LSC is a set of fire protection requirements designed to provide a reasonable degree of safety from fire. It covers construction, protection, and operational features designed to provide safety from fire, smoke, and panic. The LSC, which is revised periodically, is a publication of NFPA, which was founded in 1896 to promote the science and improve the methods of fire protection.

The basic requirement for facilities participating in the Medicare and Medicaid programs is compliance with the 2000 edition of the LSC. Facilities with waivers of the health occupancy provisions of the LSC or with an acceptable PoC are considered "in compliance."

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.)

2470C - Citations for Application to ASCs

(Rev. 1, 05-21-04)

ASCs wishing to participate in the Medicare program must comply with the 2000 edition of the LSC, as it applies to ambulatory health care centers regardless of size. The requirements for ASCs are contained in Chapter 20 for new facilities, and in Chapter 21 for existing facilities. ASCs must comply with Chapter 38 and Chapter 39 (Business Occupancies) in certain instances, such as where high-rise buildings must be sprinklered if they contain ASCs.

2470D - Special Application in ICFs/MR

(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.

2472 – Life Safety Code (LSC) Surveys
(Rev. 1, 05-21-04)

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.

2472C - Coordinating LSC Survey
(Rev. 1, 05-21-04)

In most cases, the SA schedules the LSC survey to coincide with the health survey; however, the timing of the LSC is left to the discretion of the SAs. The SA determines whether the LSC survey is to occur before, after, or simultaneously with the health survey. If the health survey and the LSC survey are conducted at different times, data entry into OSCAR must be deferred until both surveys are completed, and the data of the latest segment of the total survey (the health portion or the LSC portion) is used for OSCAR purposes. In order to complete data submissions in a timely manner, input of the life safety code survey data of long term care facilities should take place not later than 60 days after the conclusion of the long term care survey. Most States require an initial LSC survey before admitting patients prior to becoming operational. Regardless of the timing of the LSC survey, the SA should schedule it so that all certification actions are completed timely.

2472D - ASC Surveys
(Rev. 1, 05-21-04)

The SA uses Form CMS-2786U to survey ASCs. The SA lists any LSC deficiencies found during an ASC survey on Form CMS-2567 and requests a PoC as with any LSC survey of a health care facility.

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 Appendix I, 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 Appendix I 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.

2476 - Fire Safety Survey Report - Short Form, Form CMS-2786S
(Rev. 1, 05-21-04)

2476A - Background
(Rev. 1, 05-21-04)

The Fire Safety Survey Report - Short Form (Form CMS-2786C), (see Exhibit 71), was designed as a screening tool for LSC compliance, since it may not be necessary to conduct a **complete** survey of all facilities annually. Some features of a building do not change from year to year, e.g., an 8-foot corridor remains eight feet wide. Other items require periodic testing and maintenance, e.g., sprinkler systems and fire extinguishers. Such testing is easily verified by a check of service records. Verification does not require the level of expertise of a fire protection engineer or fire marshal, and can be capably performed by the SA surveyor.

2476B - When to Use Short Form
(Rev. 1, 05-21-04)

Except as outlined in subsection C, the SA uses Form CMS-2786S to survey non-JCAHO hospitals, SNFs, and NFs for compliance with the LSC.

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.

2476D - Results of LSC Screening Process - SA Review of Completed Form CMS-2786S

(Rev. 1, 05-21-04)

1 - All Items Met - No deficiencies.

2 - Some Items Not Met - If any item is not met the SA forwards the form to the State fire authority who will determine whether a complete survey is necessary.

3 - Complete Survey Recommended - The SA checks this block if there are many deficiencies or if it finds recent construction or renovation. The SA forwards the form to the State fire authority who takes appropriate action.

4 - Submission of Completed Package - When the Short Form is completed, the SA forwards it to the RO as part of the complete certification kit. (Note that OSCAR includes a special field on the crucial data extract (CDE) sheet for use of the Short Form.)

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.

2478 - Application of Fire Safety Evaluation System (FSES)

(Rev. 1, 05-21-04)

2478A - General

(Rev. 1, 05-21-04)

The National Bureau of Standards developed the FSES at the request of DHHS. It is an alternative method of determining compliance with the provisions of the LSC. Facilities that pass the FSES may be certified for participation in the program even though they have repeated deficiencies reflected on Form CMS-2786.

2478B - Application of System

(Rev. 1, 05-21-04)

The State fire authority uses the FSES in conjunction with Form CMS-2786 in facilities where the surveyor or the provider feels that the application of the system is beneficial to the facility. The state may complete the FSES for the facility at the State's option. The State Fire Authority will review and approve any FSES's submitted by the provider.

2478C - Survey Completion
(Rev. 1, 05-21-04)

Whenever an FSES evaluation is conducted by the fire authority, the following is completed:

- Fire Safety Survey Report (Form CMS-2786);
- FSES zone evaluation worksheet for each fire/smoke zone evaluated;
- Copy of FSES table 8 (facility fire safety requirements worksheet); and
- Statement of deficiencies (Form CMS-2567) for LSC and FSES items.

The SA includes all FSES worksheets with the certification kit, even if certification is based on the findings of Form CMS-2786. The SA marks item 7A of the cover sheet of Form CMS-2786 "FSES." FSES files are forwarded by the RO to a specialist for a thorough technical review.

2478D - Certification of Compliance with FSES
(Rev. 1, 05-21-04)

When the fire authority performs an FSES evaluation, a facility may elect to be certified with deficiencies as well as an acceptable PoC in either of two ways:

- If the provider elects to be certified based upon the findings of the Form CMS-2786, it must indicate its proposed correction in the space adjacent to each deficiency recorded on Form CMS-2567; or
- If the provider elects to be certified based on the FSES, it may not be necessary to correct all of the deficiencies found. In this case, the provider is to write: "Not Necessary to Correct - FSES" in the space next to such deficiencies under "Plan of Correction." A facility that achieves a passing score on the FSES or which submits an acceptable PoC under the FSES may be certified based upon the FSES. Once a facility has been certified based upon the FSES, it may continue to be certified on that basis in subsequent certification surveys after completion of the Form CMS-2786.

The SA refers any questions regarding application of the FSES, completion of the zone evaluation worksheet, appropriate documentation of PoCs, or requests for technical

assistance to the LSC contact person in the RO.

2480 - LSC Waivers
(Rev. 1, 05-21-04)

2480A - General
(Rev. 1, 05-21-04)

In some cases, certain provisions of the LSC might not be met, although the facility provides a reasonable degree of fire safety. Exceptions to the LSC are permissible if:

- The waiver would not adversely affect patient health and safety; **and**

- It would impose an unreasonable hardship on the facility to meet specific LSC provisions.

Although compliance with the LSC would generally be easier for a new facility than for an existing building, there may be an occasional situation that would justify the granting of a waiver in new construction. For example, in the course of drawing up building plans, an architect will often discuss prospective design features with State Building Department officials and licensure authorities. It is not unusual for these authorities to grant approval for innovative design features that, while not in strict conformity with the LSC, nevertheless provide an equivalent degree of protection. In such circumstances, a waiver may be appropriate.

When it is not readily practical for an institution to comply fully with all the individual requirements of the LSC, the fire authority evaluates the degree of enforcement necessary to provide a reasonable measure of safety. In making this recommendation, it considers whether the intent of the LSC is met.

2480B - Meeting Intent of LSC
(Rev. 1, 05-21-04)

The requirements of the LSC are directed to a series of factors or areas. These may be classified as follows:

1. **Fire Load -** All materials which might contribute to the fuel aspect of a fire within the building and requirements pertaining to construction, interior finish, draperies, furnishings, and building service equipment;

2. **Fire Containment -** Those elements which tend to restrict the spread of flame, smoke, or fire gases throughout the building, such as corridor wall construction, subdivision of floor areas, and protection for vertical openings;

3. **Fire Extinguishment -** Elements which help to put out the fire as quickly as possible. They include alarm systems, portable extinguishers, sprinkler systems, and special requirements for protection of hazardous areas;

4. **Evacuation -** Those elements which facilitate the removal of occupants from the scene of the fire. They include details of the emergency plan and exiting capability from the building;

5. **Operating Features -** The administrative and operational features such as housekeeping techniques, smoking regulations, and the fire emergency plan which, if not properly implemented, could result in hazardous fire situations;

The following additional considerations should also be evaluated by the fire authority since they may have an important bearing on the safety of patients in facilities which request a waiver:

1. Staffing considerations such as staff-patient ratios, staffing patterns, and scope of staff training to handle fire emergencies;

2. Availability and adequacy of compartment and horizontal exits, such as areas to hold patients during a fire emergency;

3. Location and number of ambulatory and nonambulatory patients;

4. Availability, extent, and type of automatic fire detection and fire extinguishment systems provided in the facility;

5. Means for notifying the fire department in case of fire; and

6. Effectiveness of fire department (e.g. types of equipment available, number of personnel normally responding to a fire call, distance to the nearest fire station, and normal response time of the fire department).

The total fire safety of a building is dependent upon the combined effect of the factors mentioned above. Each building is a unique problem from a fire safety point of view and should be evaluated by the fire authority on its own merits. Not all requirements are of equal importance in all situations.

If it can be established that a particular deficiency does not materially affect the overall level of safety, it is reasonable to hold that the fire safety characteristics of the facility have not been compromised and that the intent of the LSC has been met.

2480C - Elements Considered in Determination of Unreasonable Hardship

(Rev. 1, 05-21-04)

In cases in which patient safety would not be adversely affected by a waiver, consider the following factors in evaluating the issue of unreasonable hardship:

- Estimated cost of the installation;

- Extent and duration of the disruption of normal use of patient areas resulting from construction work;
- Estimated period over which cost would be recovered through reduced insurance premiums and increased payment related to cost;
- Availability of financing; and
- Remaining useful life of the building.

2482 -Technical Bulletins
(Rev. 1, 05-21-04)

A - Technical Codes And Standards Committee Charter and Function

The Technical Codes and Standards Committee was abolished in 1987 because the majority of the bulletins were written prior to publication of the 1981 edition of the LSC and are no longer applicable.

2490 - Compliance With §504 of the Rehabilitation Act of 1973, as Amended
(Rev. 1, 05-21-04)

The American National Standards Institute specifications have been superseded by the HHS Departmental 504 regulations. Enforcement of §504 of the Rehabilitation Act of 1973, as amended by the Rehabilitation Act of 1974, in Federally assisted programs or activities includes a cross-reference to the Uniform Federal Accessibility Standards (UFAS). (See 45 CFR Part 84.) Because some facilities subject to new construction or alteration requirements under §504 are subject to the Architectural Barriers Act, government-wide reference to UFAS diminishes the possibility that recipients of Federal financial assistance will face conflicting enforcement standards. The surveyor has the responsibility to report any suspected noncompliance with 42 CFR Part 504 to the RO via Form CMS-1539. The RO will refer the matter to Office of Civil Rights (OCR) for resolution.

Utilization Review

2496 - Utilization Review (UR)
(Rev. 1, 05-21-04)

2496A - Definition
(Rev. 1, 05-21-04)

Utilization Review is the process by which the care and services provided to Medicare and Medicaid beneficiaries are reviewed for appropriateness, medical necessity, and whether the services meet professionally recognized standards of health care.

2496B - Hospitals
(Rev. 1, 05-21-04)

Utilization Review requirements for Medicare and Medicaid hospitals are contained in §1861(k) of the Act. The Medicare UR regulations for hospitals are contained in 42 CFR 482.30, CoPs - Utilization Review.

Under Medicare, the Quality Improvement Organization (QIO) performs the UR function for hospitals. 42 CFR 466.78 requires that beginning November 15, 1984, every hospital seeking payment for services provided to Medicare beneficiaries maintain a written agreement with a QIO operating in the area in which the hospital is located.

The law and regulations require that a hospital maintain an agreement with the QIO for the QIO to review the admissions, quality, appropriateness, and diagnostic information related to inpatient services for Medicare patients, if there is a QIO with a contract with CMS in the area where the hospital is located. Also, regulations at 42 CFR 476.86 permit the QIO review activities to fulfill the hospital's UR requirements. State survey agencies acting on behalf of CMS are not required to review the UR CoP. QIOs are to review hospital admissions (paid under the Medicare prospective payment system) under the program referred to as the Payment Error Prevention Program (PEPP) for Medicare. The purpose of PEPP is to reduce the occurrence of errors that may result in incorrect payment to hospitals. (The regulations also refer to other, non-hospital groups that could perform UR functions when the QIO does not fulfill this function or if DMS has favored a state's procedures).

The UR requirements under Medicaid are largely determined by those under Medicare. Section 1903(i)(4) of the Act provides that Federal financial participation is not available in a state's expenditures for hospital services unless the institution has in effect a UR plan that meets Medicare requirements. Under the law, if a hospital already has a UR plan in effect for Medicare, that plan serves as the plan required by Medicaid, with the same procedures and the same review committee or group. Therefore, if there is a UR plan that does not include a hospital-based UR committee for Medicare, none should be used for Medicaid.

If a facility does not participate in Medicare, it must meet the Medicaid regulatory

requirements, which 42 CFR 456.501(c) describes as equivalent to the Medicare regulatory UR requirements (with possible alternatives to hospital committee review). In addition, 42 CFR 456.505 of the regulations provides that the Administrator may waive the standard UR plan requirements if the state Medicaid agency applies for a waiver, and demonstrates that it has specific UR procedures in operation that are superior in their effectiveness to those in the Medicaid regulations.

2496C - SMAs
(Rev. 1, 05-21-04)

Section 1902(d) of the Act allows SMAs the option of contracting with a QIO to perform UR functions. A State may be deemed to meet the State plan requirements specified in 42 CFR 456, Subparts C and D, for those services or providers reviewed by such organization under such a contract.

2496D - Background and Scope of Work
(Rev. 1, 05-21-04)

The QIOs were established under the provisions of P.L. 97-248, the Tax Equity and Fiscal Responsibility Act of 1982. The law requires the Secretary to enter into contracts with physician-sponsored or physician-access organizations to review services provided to Medicare beneficiaries to insure that the care they receive is medically necessary, appropriate, and of a quality that meets professionally recognized standards of care. The ultimate goal of the QIO is to improve the quality of care provided to Medicare beneficiaries by utilizing statistical quality control measures to examine variations in both the processes and the outcomes of care.

2496D1 - Extent of PRO Review
(Rev. 1, 05-21-04)

To participate in the Medicare program, every hospital must have an agreement with a QIO to perform utilization and quality review in that institution. Effective October 1, 1987, SNFs, HHAs, and hospital outpatient departments (HOPDs) must have an agreement with a QIO. This agreement allows QIOs to review post-hospital care, such as care provided in a SNF or by an HHA which is given between a hospital admission and readmission occurring within 31 calendar days of discharge. The QIO then responds to beneficiary complaints about the quality of care given by SNFs, HHAs, and hospitals (including HOPDs). QIOs also have agreements with ASCs to review a sample of Medicare surgical records for medical necessity. For hospitals certified as swing-bed providers, the QIO reviews a sample of cases to determine the medical necessity of the stay and the appropriateness of the setting.

42 CFR 488.14 indicates that when a QIO conducts review activities under §1154 of the Act and 42 CFR 466, its activities shall be in lieu of the UR and evaluation activities required of health care institutions under §§1861(e)(6) and 1861(k) of the Act. In addition, any QIO review activity will also be in lieu of survey, compliance, and assistance activities required of SAs under §1864(a) of the Act.

2496D2 - Availability/Disclosure of QIO Information
(Rev. 1, 05-21-04)

As a result of their review activities, PROs have information related to practitioners and institutions that may be helpful to the SA. 42 CFR 476.138(a)(1) provides for disclosure of this information to licensing and certification bodies if it is required by the agency to carry out a function within the jurisdiction of the agency under Federal or State law. A QIO must disclose confidential information upon request, or may do so without a request, to a State or Federal body responsible for professional licensure of a practitioner or an institution.

Information about an institution that does not identify individuals is not confidential information and may be disclosed. However, 42 CFR 476.105(b)(2) requires disclosure to conform with notice of disclosure requirements. In general, a QIO must notify a practitioner or institution of its intent to disclose information to a licensing or certification body and provide the practitioner or institution with a copy of the information it will disclose at least 30 calendar days in advance.

When disclosing the information, the QIO includes any comments submitted by the practitioner or institution if they were received prior to disclosure, or forwards comments separately if received after disclosure. Recipients of confidential QIO information are prohibited from disclosing the information unless specifically provided for in Federal regulation. For example, in accordance with 42 CFR 476.107(e), if the QIO acquires information from a hospital and provides the information to a licensing body that is authorized to acquire the information directly from the hospital, the licensing body may then disclose the information in accordance with the hospital's redisclosure rules.

The SA should work with QIOs to identify and obtain information that will be helpful to it in the survey and certification process. If further information or assistance is needed, including name and address of the area QIO, the SA contacts the RO.

2496E - Action When a QIO Ceases Utilization Review
(Rev. 1, 05-21-04)

The SA instructs hospitals and SNFs to forward a copy of their UR plan to it within 90 days of a QIO's cessation of review activity in that area. If the plan does not meet the requirements, the SA returns it for necessary revisions.

2496F - Including UR in Next Scheduled Resurvey
(Rev. 1, 05-21-04)

The SA conducts a brief review of UR activities during the next regularly scheduled survey of the institution to verify that the UR plan is in place and functioning. For **accredited hospitals** where surveys are not regularly performed, the SA instructs the hospitals to send it copies of the minutes of their UR committee's meetings (or a summary or synopsis of the minutes). The SA reviews the current UR plan against the regulations

themselves (there is no UR Survey Report at the present time) to verify that the plan meets the applicable requirements and reviews the institution's conduct of UR activities against that written plan.

The SA records any UR deficiencies and plans of correction; after all other deficiencies have been recorded on the Form CMS-2567. (These deficiencies will not be recorded in MMACS.)

The SA records the status of the institution's UR compliance in the "Remarks" portion of the Certification and Transmittal, Form CMS-1539, e.g., **name of facility** is in compliance with UR requirements," or "Acceptable Plan of Correction for UR has been submitted."

The Survey Process

(See Chapter 7 for SNFs and NFs)

2700 - Conducting Initial Surveys and Scheduled Resurveys
(Rev. 1, 05-21-04)

2700A - Unannounced Surveys
(Rev. 1, 05-21-04)

It is CMS policy to have unannounced surveys for all providers (including all types of hospitals) and suppliers (other than laboratories). 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. (See §2008 and §7207.)

While the unannounced surveys may result in some minor inconveniences, this policy represents changing public attitudes and expectations toward compliance surveys. If there is any conflict with internal State policies and practices, the SA should discuss the problem with its RO. To enhance the unpredictability of unannounced standard surveys of LTC facilities, special selection criteria are to be incorporated when State agencies are scheduling standard surveys to LTC facilities. (See §7207.)

Exception: Non-LTC facilities other than HHAs may be given advance notice (usually no more than one working day before an impending survey) if all of the following criteria are met:

- The facility is inaccessible via conventional travel means and it is necessary to make special or extraordinary travel arrangements; and

- There is a high probability that the staff essential to the survey process will be absent, or the facility will be closed unless the survey is announced. (See §2008.)

- The announced survey is approved by the RO on a case-by-case basis.

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.)

2700C - Coordinating LSC Surveys
(Rev. 1, 05-21-04)

In most cases, the SA schedules the LSC survey to coincide with the Health survey. However the timing of the LSC survey is left to the discretion of the SAs. The SA determines whether the LSC survey is to occur before, after, or simultaneously with the health survey. If the health survey and the LSC survey are conducted at different times, data entry into OSCAR must be deferred until both surveys are completed, and the data of the latest segment of the total survey (the health portion or the LSC portion) is used for OSCAR purposes. Most States require an initial LSC survey before allowing a provider/supplier to admit patients prior to becoming operational. Regardless of the timing of the LSC survey, the SA should schedule it so that all survey and certification actions are completed timely.

2702 - SA Conducting Unscheduled Surveys
(Rev. 1, 05-21-04)

2702A - Survey Due to Unanticipated Events
(Rev. 1, 05-21-04)

It may be necessary to conduct a complete survey at an earlier date than planned. Possible reasons for this include:

- A complaint about deteriorating standards of care;
- Results of a complaint validation survey of an accredited hospital/find CoP out of compliance;
- Loss of hospital accreditation;
- An employee strike;
- Change of ownership or changes in managerial personnel; or
- A significant change in the type of treatment provided.

The decision to conduct a full survey at an earlier date than originally planned depends upon whether there is a likelihood that the certification (or compliance) status could have changed. Do not announce such surveys. The SA should schedule subsequent surveys based upon the date of this survey. (See §7205 for SNF/NF.)

2702B - Change of Size or Location of Provider Institution
(Rev. 1, 05-21-04)

Changes of size or location do not ordinarily require a special survey. The provider is

expected to continue to uphold the standards of operation detailed in the most recent survey. Only if the relocation raises significant questions as to the provider's ability to maintain standards is a resurvey necessary. However, there may be situations where the relocation is so far removed from the ordinary approved site that you conclude that this is a different provider/supplier, e.g., different employees, services and patients. In such cases, it may be that the relocation constitutes a cessation of business at the providers old location and a voluntary termination on the part of the provider. Such situations should be discussed immediately with the CMS RO. In deciding whether to advance the resurvey, the SA considers the recentness of the last survey, licensure information concerning the new arrangement, and whether a phone contact for indicated information (e.g., staffing changes) will suffice to resolve questions.

The fact that a new site/building is not shown on the most recent LSC survey report does **not** automatically require the date of the full scheduled resurvey to be advanced. However, the SA should ensure that the new location meets the applicable physical environment and LSC requirements. (See §§3202 and 3204.)

2704 - SA Presurvey Preparation
(Rev. 1, 05-21-04)

The SA, in preparation for the survey/resurvey, reviews documents of record including licensure records, fire inspection reports, previous survey reports including LSC and complaints, media reports about the facility, and other publicly available information about the facility (e.g., its own Web site). This information is helpful in determining composition of the survey team and the time required for the survey or resurvey.

If an onsite survey is necessary, the SA schedules the survey in a manner that results in the most efficient and effective use of survey staff and that provides the most comprehensive look at the facility. The survey is to be completed promptly and is not to be interrupted by other activities. Moreover, in the case of SNFs/NFs, **at least ten percent** of standard surveys must begin on weekends or in the evening/early morning hours. Of these ten percent, the standard survey must be conducted on consecutive days, with all surveyors being onsite some or all of those consecutive days. (See §7207 and note.)

The SA reviews the applicable provider/supplier sections of this part to ascertain whether other special preparation is needed prior to survey and the SA develops factors such as this before the survey is conducted.

2705 - SA Survey Team Workload
(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

The Survey Team Composition and Workload Report (also referred to as the "CMS-670" report) is an integral part of the overall survey process. The SA completes this form for all survey and/or resurvey activities as it provides necessary information on resource use applicable to survey activity of all Medicare, Medicaid-only, and dual participating providers and suppliers and CLIA laboratories.

The SA follows these guidelines in completing this report:

- If a survey does not include an onsite visit, do not enter arrival, departure, onsite, and travel dates or times on the 670. Enter all other appropriate fields;

- Include on the 670 the time spent by surveyors-in-training who have a surveyor ID number. However, if the trainee simply observes a survey, exclude his/her time from the form;

- Report only direct, survey-related time on the 670. This includes data entry and supervisory review time. Do **NOT** include general administrative time, such as time spent logging onto the CMS Data Center;

- The Type of Survey and Extent of Survey boxes are not **required** for data entry. However, complete these boxes on the 670 since the information may be helpful;

- On a combined certification/State licensure survey, enter the **total** time (Federal and licensure) spent on various phases of the survey, even if you conduct the certification survey first, followed by the licensure survey (or vice versa);

- Do not complete the 670 for visits conducted solely for licensure purposes;

- Treat multiple complaints investigated at the same time as one complaint survey and enter on one 670;

- If complaints are conducted concurrently with a recertification survey or follow up, report the complaint on a separate 670;

- Include in Column D time spent reviewing complaints in-office as pre-survey preparation hours if a complaint survey is subsequently conducted;

- Prospective Payment System (PPS) surveys are not entered into CASPER. Therefore, do not complete Form CMS-670 for PPS surveys;

- Prepare separate 670s for all health, LSC, complaint investigation, and Federal Monitoring Surveys (FMS);

- In cases where the same surveyor performs both health and LSC activities, time that cannot be specifically attributed to one survey or the other must be equally split between the two 670s (one for health and one for LSC);

- Supervisory review time reported on the 670 is that level of **routine** review normally conducted on all survey reports. It does not include special quality assurance committee review, team leader review, or team review;

- Do not record time spent tracking nurse aide training and competency reviews on the 670;

- In computing travel time, report the **lesser** of time spent in travel from either the surveyor's home to site or office to site;

- Enter on the 670 under the appropriate surveyor ID number the time supervisors spend participating in a survey (conducting reviews, exit conferences, etc.);

- Assign SA consultants identification numbers in the event that they participate in surveys. Their time should be included on the 670 if they participate;

- If more than 10 surveyors participate in a survey, use continuation forms to input survey data into the system. The CASPER system has been reconfigured to accept up to 990 surveyors.

- If errors are made in data entry, change the information by accessing ASPEN

- For supervisors who review a CHOW in house, **DO NOT** enter the time in ASPEN, unless a survey is conducted in conjunction with the CHOW;

- Do not enter QIO staff on the 670 since they are not part of the survey staff;

- Use the 670 only for collecting time spent preparing for, conducting, and finalizing a survey of a facility. Do not capture time spent in hearings after a survey has been completed on the 670; and

- Record travel to a patient's home as well as time spent in the patient's home on an HHA survey as onsite time, not travel time.

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 §7201 for SNF/NF.)

2708 - Facility Refuses to Allow Survey

(Rev. 1, 05-21-04)

Court decisions, both Federal and State, hold that the acceptance of the Medicare or Medicaid agreement or State licensure is implied consent by the institution to permit authorized officials to make unannounced visits. Refusal of access can be a basis for termination of participation in Medicare or Medicaid. (See 42 CFR 489.53.) If access is refused, the SA surveyor documents the identity (name and title) of the individual refusing admission and the reason. The SA indicates what action the State intends to take in relation to licensure (if a licensure visit was involved), or in relation to Medicaid if a Medicaid-only provider/supplier. The SA submits this documentation immediately to the RO or the SMA, as appropriate.

The SA calls to the attention of the provider/supplier that 42 CFR 1001.1301 permits the Office of Inspector General (OIG) to exclude a facility from the Medicare and Medicaid programs if, upon reasonable request, it fails to grant immediate access to CMS or the SA. The exclusion may be in effect up to a period equal to the sum of the length of the period during which immediate access was not granted plus an additional 90 days. The RO makes the referral to the OIG. (See §§1864(c) and 1128(b)(12) of the Act and 42 CFR 488.6(c) and 489.53(a)(4).)

2710 - Reviewing Forms at Beginning of Survey
(Rev. 1, 05-21-04)

Request to Establish Eligibility

One of the purposes of the "Request to Establish Eligibility" (or the equivalent application form such as Form CMS-671, Form CMS-3070G, or Form CMS-1572) is to obtain and maintain statistical information. At each resurvey, the provider or supplier completes the appropriate request to update the one completed at the previous survey.

If the form does not contain a specific field to indicate initial survey or a resurvey, enter the word "Resurvey" on the upper right corner of the form.

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.

2713 - During Survey
(Rev. 1, 05-21-04)

2713A - Accompanying Surveyors
(Rev. 1, 05-21-04)

The surveyors may allow, or refuse to allow, facility personnel to accompany them during a survey. Each case is at the SA and the surveyor's discretion and is to be worked out with facility management. Facility personnel may be helpful. They may answer questions or point out certain concerns to the survey team, thus making the entire process easier. Conversely, facility personnel may hinder the surveyor, argue about observed problems, and make the survey more difficult. This is not to be tolerated. The surveyors may refuse to allow facility staff to accompany the team if such behavior occurs. The surveyors should make a decision based on the circumstances at the time of the survey. However, the surveyors will always conduct interviews with patients/residents in strict privacy and with prior permission of the individuals.

2713B - Physical Contact With Patients/Residents
(Rev. 1, 05-21-04)

A surveyor is not to touch or examine a patient by himself or herself. However, in certain circumstances it is permissible and necessary to determine the physical condition of patients. For example, if the surveyor believes that blankets or clothing are hiding bedsores, bruises, or incontinence, they may remove the coverings and make a determination based on observation. Surveyor's must obtain the patient's (or representative's) permission prior to making any examination. A surveyor should request that a staff member of the facility interact with the individual as necessary. The health and dignity of the patient is always of paramount concern. A surveyor must respect an individual's refusal to be observed.

2714 - Interviewing Key Personnel
(Rev. 1, 05-21-04)

At the institution, the surveyors will usually meet with the administrator (or director) or supervisors of various departments or services to outline the survey plan. (In many instances one person assumes these roles.) The surveyors obtain information from them and other staff. During the introductory meeting with the administrator, the surveyor alerts him/her that if the facility is planning to record the exit conference, a copy of the tape must be made available to the team at the conclusion of the conference. This can be accomplished by using two recorders. A surveyor is not to accept a promise that a copy will be mailed at a later date.

The surveyor interviews the Administrator (or Director) first since he/she is the key person in the institution. There are elements related to each condition that the surveyor might need to discuss with the administrator. He/she will be able to direct the surveyor to other staff persons to interview relative to specific standards and other requirements. However, contacts are not limited solely to the key person. Even if the administrator feels that he/she can answer most of the questions, the facts must be verified through review of source documents and interviews. The SA investigation must be complete enough to document whether the standards are met and the provider is in compliance with the related condition(s) or in substantial compliance with the requirement for SNFs/NFs.

While interviews with the Administrator or DON must necessarily be in depth, the survey must not disrupt the facility by protracted interviews of all the staff. A surveyor should use a few well-phrased questions to elicit the desired information. For example, to determine if a staff member is aware of disaster procedures and his/her role in such events, simply ask, “If you smelled smoke, what would you do?”

The surveyor should direct questions to the appropriate personnel. For example, if administration of medications is restricted to certain staff, the surveyor questions the personnel charged with this responsibility.

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.

2715 - Interviewing Residents Using the LTC Survey Process
(Rev. 1, 05-21-04)

The surveyors interview residents, family members, or legal guardians to evaluate their impressions about the care being provided by the facility. Residents, members of their family, or legal guardians have the right to refuse to be interviewed. Surveyors must respect the confidentiality of information provided by residents or members of their families. Staff personnel should not accompany the surveyors during resident interviews unless their presence is requested by the resident being interviewed, the family, or guardian. During the interviews surveyors should refrain from moving or handling residents. This is to be done by a member of the facility staff. (See Appendix P.)

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.)

2718 - Assistance in Surveying Psychiatric Hospitals
(Rev. 1, 05-21-04)

2718A - Use of CMS Surveyors
(Rev. 1, 05-21-04)

To participate in Medicare and Medicaid, a psychiatric hospital must meet the special medical records and special staffing requirements. (See 42 CFR 482.61 and 482.62.) Surveys to determine whether these requirements are met are to be performed by board-certified psychiatrists and Masters-prepared psychiatric nurses, and, if necessary, Masters-prepared psychiatric social workers. If the SA does not have qualified psychiatric personnel to conduct the surveys, CMS strongly encourages using the services of specialist surveyors who are under contract with CMS. All State-owned and operated psychiatric hospitals are to be surveyed by CMS contract specialist surveyors to the extent possible, depending on availability and the scope of the program. The SA submits annual requests for survey assistance for the subsequent year to the RO in July. Provide the following information for each hospital:

- Name and address of the hospital to be surveyed;
- Number of beds in the certified component (call the hospital and verify whether the number of beds in previous records is still accurate);
- Identification of the distinct part, if the entire institution is not a psychiatric hospital;
- JCAHO status (i.e., accredited, non-accredited, in appeal);
- Date of last survey;
- Name and telephone number of the SA person responsible for coordinating the survey (a SA surveyor should accompany the CMS psychiatric surveyors during the survey, if possible); and
- Whether the institution is privately or publicly owned.

Upon receipt of the SA request, the RO forwards a copy to CO. The SA and the RO will receive a memo confirming the dates of scheduled surveys and the names of the surveyors that will participate.

In the interest of timely scheduling of complaint and revisit surveys of psychiatric hospitals, the RO should initiate requests by telephone to CO.

2718B - CO Responsibility
(Rev. 1, 05-21-04)

CMS CO contracts with an independent contractor to handle the scheduling of the surveys, e.g., notifying SA and RO of dates of survey by letter, names of CMS surveyors, and hotel accommodations.

2718C - Survey Responsibility
(Rev. 1, 05-21-04)

CMS surveyors are responsible for the opening conference, the survey of the two special Conditions, 42 CFR 482.61 and 482.62, and the exit conference. They discuss their findings at the exit conference. Following this, the surveyors' involvement in the survey process ceases. For further clarification regarding the surveyor's findings, contact the RO.

CMS surveyors forward the Psychiatric Hospital Survey Report (Form CMS-724), and all necessary documentation for recertifications, follow-up visits, and initial certifications to CO.

The completed report is sent by the CMS mental health surveyors to CO within 10 working days after the survey for review of appropriateness and completeness of documentation. In turn, CO mails the completed report to the RO for their determination of compliance or noncompliance along with an informational copy to the SA. The termination process for psychiatric hospitals using CMS mental health surveyors is consistent with the 90-day timeframe for other providers.

However, due to the additional administrative process of sending the survey findings to CO, day 1 of the 90-day termination timeframe begins on the **date of receipt** of the completed psychiatric survey report in the RO.

When CMS surveyors find either of the two psychiatric special conditions out of compliance, they will telephone the findings to CO. CO will telephone the RO.

2718D - RO Responsibility
(Rev. 1, 05-21-04)

The RO acts as a liaison between the SA and CO for activities other than those described above. On an annual basis the RO obtains SA requests for psychiatric hospital survey assistance and forwards them to CO. During the year, the RO monitors development of statements of deficiencies and PoCs and SA revisit activities for psychiatric hospital surveys not performed by CMS surveyors. The RO is also responsible for determining whether the provider has made a credible allegation of compliance and for requesting revisits to be made by the CMS surveyors via CO.

If the RO has any questions or problems arising regarding any aspect of the surveys (e.g., scheduling of surveys, interpretation of survey findings), it contacts the CO project officer responsible for the psychiatric survey program. The ROs and SAs do not contact CMS mental health surveyors directly.

In most cases, if CMS surveyors cite deficiencies that result in a termination action being initiated, the CMS surveyors will perform revisit(s) if the provider makes a credible allegation of compliance. (See §3016.) The CO project officer will notify the RO if the SA is to perform the revisit.

2720 - Completing the Survey Report
(Rev. 1, 05-21-04)

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.

2720B - Specific Items to Consider When Completing SRF

(Rev. 1, 05-21-04)

When using a traditional "check-list style" SRF, surveyors should support all checks in "Yes" boxes by such statements, charts, or findings as they consider appropriate (e.g., the number and type of records examined [personnel, medical], the existence and addresses of any multiple sites, special staffing information, hours of operation, the extent of compliance with related requirements).

Include comments when:

- The "Explanatory Statements" section on the SRF requires them;
- The "Yes" or "Met" represents an apparent inconsistency with other findings. For example, two or more Requirements or Standards are marked "No," yet the covering Standard or Condition is marked "Yes";
- A "No" has been changed to a "Yes." (Have the change initialed and dated by the individual who made the change); or
- In your judgment, additional information is needed to reflect the degree of compliance.

Support "Nos" or "Not Mets" by the following:

- A full description of the deficiency;
- Where appropriate, charts, diagrams, and other documentation to clarify the description;
- A statement regarding the degree of hazard to health and safety or the effect on the quality of care, and how the deficiency relates to other factors and standards; or
- If the deficiency is significant and the covering Standard or Condition is marked "Yes," the reasoning or judgment used in checking the "Yes."

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.

2720D - Completing HHA and SNF/NF Survey Reports
(Rev. 1, 05-21-04)

The survey reports for HHAs, SNFs, and NFs are no longer the traditional "check-list style" SRFs. Rather, the HHA, SNF, and NF survey reports consist of a variety of forms and worksheets used to record information in accordance with outcome-oriented survey protocols. Surveyors complete all required forms and worksheets as instructed in the protocols.

2722 - Preparation for Exit Conference (Excluding SNFs and NFs)
(Rev. 1, 05-21-04)

Surveyors hold a pre-exit survey team conference at the conclusion of the survey prior to the exit conference and come to an agreed judgment on the severity of any deficiencies and whether their number, character, and combination interfere with the delivery of adequate care, and create hazards to patients' health and safety. Deficiencies found in more than one CoP or Standard may be cumulative and interrelated and result in general or across-the-board inadequacies in patient care as to constitute hazards to patients. This would be the basis for a finding of noncompliance. Surveyors use the following criteria, in part, to make a judgment as to the significance of a deficiency:

- A deficiency exists if a particular requirement is not in compliance; and

- A deficiency is significant if it affects the ability of the institution to provide adequate care, or which adversely affects the health and safety of patients. A Standard or an individual requirement (within a CoP) not in compliance may or may not be a significant deficiency.

2723 - Citing Deficiencies in SNFs and NFs
(Rev. 1, 05-21-04)

Refer to Appendix P for instructions.

2724 - Exit Conference
(Rev. 154, Issued: 06-10-16, Effective: 06-10-16, Implementation: 06-10-16)

Subsequent to the pre-exit conference held to allow team members to exchange and formulate survey findings, the surveyors conduct an exit conference ("an exit") with the entity's administrator, designee, and other invited staff. The purpose of the exit conference is to informally communicate preliminary survey team findings and provide an opportunity for the interchange of information, especially if there are differences of opinion. Although it is CMS' general policy to conduct an exit conference as a courtesy

to the provider and to promote timely remediation of quality of care or safety problems, be aware of situations that would justify refusal to continue an exit conference. For example:

- If the provider is represented by counsel (all participants in the exit conference should identify themselves), surveyors may refuse to continue the conference if the entity's attorney attempts to turn it into a evidentiary hearing; or

- Any time the provider creates an environment that is hostile, overly intimidating, or inconsistent with the informal and preliminary nature of an exit conference, surveyors may refuse to conduct or continue the conference.

Additionally, as discussed in §2714, if the entity wishes to audio tape the conference, it must tape the entire meeting and provide the surveyors with a copy of the tape at the conclusion of the conference. Videotaping is also permitted if it is not disruptive to the conference, if a copy is provided at the conclusion of the conference. It is at the sole discretion of the surveyor(s) to determine if videotaping is permitted.

It is critical that the surveyors establish and maintain control throughout the exit conference. Surveyors should present their findings but refrain from arguing with the provider. Be mindful that providers are likely to react defensively to surveyor findings. The provider has a right to disagree with the findings and present arguments to refute them. Surveyors should be receptive to such disagreements. If the provider presents information to negate any of the findings, surveyors should indicate their willingness to reevaluate the findings before leaving the facility. The survey team's reasonableness demonstrates their fairness and professionalism. The degree of receptivity displayed by providers during the exit conference often depends upon the attitudes and survey style of the survey team.

If the LSC survey is conducted independently of the health survey, the fire authority conducts a separate exit conference.

The following guidelines are helpful to surveyors in performing an exit conference:

2724A - Introductory Remarks

(Rev. 154, Issued: 06-10-16, Effective: 06-10-16, Implementation: 06-10-16)

Introduce yourself to those present. Restate why the survey was conducted. Express the team's appreciation for anything the provider has done to facilitate the survey. Explain that the exit conference is an informal meeting given as a courtesy to the provider to discuss preliminary survey findings and thereby assist the provider or supplier in developing an acceptable PoC, if appropriate and required. The tone of the exit conference should be professional and constructive. It is important to communicate that the findings are preliminary and could change following State and CMS supervisory review. Indicate that official findings are presented in writing on Form CMS-2567 and will be forwarded to the provider within 10 working days. Indicate that the provider will, in turn, have 10 calendar days to submit a PoC. (See §2728.)

2724B - Ground Rules
(Rev. 154, Issued: 06-10-16, Effective: 06-10-16, Implementation: 06-10-16)

Explain how you will conduct the exit conference and how the team's findings will be presented; for example, each surveyor may present a portion of the total findings. Inform the provider that where there are disagreements between the team and the provider about the findings that cannot be resolved during the conference or before the team leaves the facility, the provider will have the opportunity to submit additional evidence to the State, and/or the RO through the Plan of Correction process. (See §2728.B. concerning provider attempts to refute survey findings on the Form CMS-2567.)

2724C - Presentation of Findings
(Rev. 154, Issued: 06-10-16, Effective: 06-10-16, Implementation: 06-10-16)

In presenting preliminary findings, avoid reading your findings or only referring to them by their data tag number. Explain why the findings are a violation of Medicare or Medicaid requirements in enough detail to assist the provider in expediting the provider's correction of any deficiencies ahead of the formal receipt of the Form CMS-2567.

Non-Long Term Care Providers/Suppliers
For non-long term care, if the provider/supplier asks for the specific regulatory basis for a finding of noncompliance, the surveyors should generally provide the regulatory grouping to the extent that the team is not still deliberating which part of the regulation is most pertinent. However, the survey team should avoid identifying the specific tags, as the tag codes often identify the Condition- or Standard-level classification for most non-LTC deficiencies. Additionally, such specific details should wait for supervisory review.

Long Term Care Providers
For long term care providers (nursing homes and ICF-IIDs), CMS has invested considerable effort to add to the SOM more explanations and resource material under many deficiency tag codes that can be of particular use to a facility in understanding relevant deficiencies and preparing remedial action. If the provider asks for the specific regulatory basis or the specific tag code, the surveyors should generally provide this information (except as noted below), but must always caution the facility that such coding classifications are preliminary and are provided only to help the provider gain more insight into the issues through the information provided in the interpretive guidance. If the facility does not specifically ask for the regulatory basis or tag, the survey team may use its own judgment in determining whether this additional information would provide additional insight for the facility.
However, if the survey team is still deliberating as to which tags will be most pertinent, the survey team must not speculate at the exit conference as to the specific tag coding that will be applied. For example, the team may still be deliberating as to whether the finding was a care planning deficiency or staff training deficiency. Similarly, the team may believe that additional consultation should occur with other State personnel (e.g., a pharmacist) before a specific tag number is assigned to the deficiency finding. In these cases the survey team should describe the general area of non-compliance without identifying a specific tag code. This is a judgement to be made by the survey team onsite,

so in preparation for the exit conference the team should deliberate as to the degree of detail that will be appropriate to describe at the exit. This is a survey-specific decision based on the evidence gathered. As described below, states must follow the federal process. State licensure laws do not override the procedures outlined in the federal survey process. States are not permitted to have blanket policies that require surveyors to always provide certain information during the Exit conference that differs from the policy described in this section.

Under no circumstances, however, would the surveyors provide the Scope and Severity of a given deficiency finding (unless there has been a finding of Immediate Jeopardy), as such finer degree of possible detail should await supervisory review. Instead, survey teams may describe the general seriousness (e.g., harm) or urgency that, in the preliminary view of the survey team, a particular deficiency may pose to the well-being of residents. If a provider asks whether the noncompliance is isolated, pattern, or widespread, the surveyor should respond with the facts (i.e., noncompliance was found affecting X number of residents).

Clinical Laboratories (CLIA)
For laboratories, given the complexity of the regulations and nature of the survey, the surveyors must d indicate to the laboratory that the specific regulatory reference will be found in the CMS-2567 report that will be issued. The laboratory is informed that the information discussed in the exit interview is preliminary and the lab management will have an opportunity at the exit interview to talk, in general, about the issues that were found.

Life Safety Code
For life safety code surveys, the survey team may follow the procedures for either non-LTC or LTC, depending on the degree to which, in the judgement of the team, the tag codes are important in helping the provider/supplier to understand the nature and location of the deficiency, and the corrective actions that would be necessary. Facility representatives are typically invited to accompany life safety surveyors during building tours, to improve familiarity with preliminary findings and exit conference proceedings.

For all provider types, under no circumstances should you make general statements such as, “Overall the facility is very good.” Stick to the facts. Do not rank requirements. Treat requirements as equally as possible. Cite problems that clearly violate regulatory requirements. The surveyors must not make statements such as, “The condition was not met,” or “The standard was not met.”

2724D - Closure

(Rev. 154, Issued: 06-10-16, Effective: 06-10-16, Implementation: 06-10-16)

When you have completed the exit conference, explain the process to the provider. Inform the provider that the State and/or RO will send a formal statement of deficiencies. 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.

2726 - Summary of SA Certification Actions Performed After Survey
(Rev. 1, 05-21-04)

Following are summaries of eight SA steps of the post-survey certification process:

1. Prepare survey documents for eventual public disclosure.

2. Send Form CMS-2567 to the provider/supplier, requesting a PoC if appropriate. A PoC is required for all deficiencies except as noted in §2728.B.

3. If extensive documentation is required for adverse action, gather the necessary additional evidence. Only achievement of compliance stops termination action. A PoC may not be required when termination action is recommended because the PoC cannot substitute for Condition-level noncompliance. Review and evaluate the PoC to:

    - Ascertain whether compliance is likely to be achieved in a time acceptable to you or the RO, as appropriate; and

    - Help structure the revisit after a credible allegation of compliance is received.

4. Consider waivers of requirements (if explicitly allowed) that may be appropriate. Prepare recommendations accordingly or, in the case of Medicaid-only waivers, prepare determinations granting or denying waivers.

5. Certify compliance or noncompliance.

6. Assemble all required documentation for transmission to the RO or, in a Medicaid-only case, to the SMA.

7. If necessary, schedule a revisit to verify the provider's follow-through on acceptable PoCs. Schedule future surveys for the next certification interval, taking into account the provider's accreditation status if applicable, the anticipated

duration of waivers, and, as required by OBRA '87, flexible survey cycles for SNFs, NFs, and HHAs.

8. Be prepared to modify the revisit schedule for unexpected changes or requested changes in providers' coverage status or for subsequent changes in compliance status.

2727 - Limitations on Technical Assistance Afforded by Surveyors
(Rev. 154, Issued: 06-10-16, Effective: 06-10-16, Implementation: 06-10-16)

SAs are encouraged to communicate with providers and their associations. Discussions of program requirements and the survey process can result in a better understanding of the process by all parties involved. Further, §§1819(g)(1)(B) and 1919(g)(1)(B) of the Act mandate that the State conduct periodic educational programs for staff and residents (and their representatives) of SNFs and NFs in order to present current regulations, procedures, and policies. (See §1010.D.)

When deficiencies are found during the survey process, the surveyor provides an explanation to the provider concerning the deficiency in specific terms as described in §2724C to help the provider understand why the requirement is not met. Frequently, the explanation will embody the action needed to correct the problem. In situations where there may be several possible causes for the deficiency, it is not the surveyor's responsibility to delve into the facility's policies and procedures to determine the root cause of the deficiency or to sift through various alternatives to suggest an acceptable remedy. For example, if a provider was cited for maintaining incomplete clinical records, specify what is missing - not why it is missing or what process is best for ensuring that the records will be complete in the future.

2728 - Statement of Deficiencies and Plan of Correction, Form CMS-2567
(Rev. 1, 05-21-04)

Form CMS-2567 (see Exhibit 7) serves several of the following important functions:

- It is the basic document disclosed to the public about the entity's deficiencies and what is being done to remedy them;
- It documents the specific deficiencies cited;
- It documents any promises made by the provider/supplier, i.e., the provider/supplier's plans for correction and timeframes; and
- It provides an opportunity for the provider to refute survey findings and furnish documentation that requirements are met.

The fire authority performing a LSC survey usually completes a separate Form CMS-2567. However, Form CMS-2567 for the LSC and health surveys may either be

combined or processed separately.

When there are no deficiencies (including LSC if applicable), the SA indicates that the entity is in compliance with **all** requirements. Refer to Principle #1 in Appendix 7A, for specific guidance on preparing this statement.

The SA mails the provider/supplier a copy of Form CMS-2567 within **10 working days** after the survey. If there are deficiencies, the SA allows the provider/supplier **10 calendar days** to complete and return the PoC. Requirements pertaining to submittal of the PoC can be found in subsection B.

2728A - Statement of Deficiencies
(Rev. 1, 05-21-04)

The surveyor prepares Form CMS-2567 using the instructions provided in Appendix 7A. For each Requirement not met, the surveyor makes a citation that includes the following:

- The prefix and data tag number;
- The deficiency that contains the CFR or LSC reference, the Requirement that is not met, and an explicit statement that the Requirement is "not met"; and
- The evidence to support the deficiency.

If the ASPEN computer database program is used to generate Form CMS-2567s, the statement of deficiencies will automatically be generated in the general format required by, Appendix 7A and will simply require the surveyor to enter the evidence to support the deficiency. If ASPEN is not used, the surveyor lists all deficiencies in the left column of Form CMS-2567 preceded by the data prefix tag. The data prefix tag is printed to the left of the regulatory paragraph on each survey report. If a waiver is requested, the surveyor places an asterisk to the left of any deficiency for which the waiver is recommended.

In instances where the facility is in substantial compliance but a deficiency exists and the only data tag on the survey form is for the Condition (e.g., ASCs), the surveyor lists the deficiencies, states that no Condition-level deficiency exists, and does not use a data prefix tag.

NOTE: This practice is not allowed in cases where there are prefix data tags for Standards and/or elements below the Condition level. (Requirement for SNFs/NFs.)

Surveyors must express deficiencies clearly and concisely with a regulatory citation for each. For examples of proper deficiency citations, refer to Exhibit 7A, "Principles of Documentation."

2728B - PoC
(Rev. 1, 05-21-04)

Regulations in 42 CFR 488.28(a) allow certification of providers/suppliers (other than SNFs and NFs) with deficiencies at the Standard level "only if the facility has submitted an acceptable PoC for achieving compliance within a reasonable period of time acceptable to the Secretary." Failure to submit a PoC could result in termination of the provider agreement as authorized by 42 CFR 488.28(a), 488.456(b)(1)(ii), and 489.53(a)(1). After a PoC is submitted, the surveying entity makes the determination of the appropriateness of the PoC. (See §7500 for SNFs/NFs.)

This "reasonable period of time" (to achieve compliance) is **generally** no longer than 60 calendar days. Of course, the correction date for a specific deficiency may be less or greater than 60 calendar days after the survey depending on the circumstances of the deficiency. The SA should not accept dates for correction routinely for 60 calendar days when the deficiency can reasonably be corrected well before 60 calendar days. On the other hand, a provider may reasonably require more time than 60 calendar days to correct some deficiencies, i.e., those requiring construction, or other deficiencies where correction is clearly beyond the control of the provider/supplier. (See 42 CFR 488.28(b) for further guidance on correction dates.)

The provider/supplier cited with deficiencies has the following three options:

- Accept the deficiencies stated on Form CMS-2567 and submit a PoC;
- Record objections to the cited deficiencies on Form CMS-2567 **and** submit a PoC; or
- Record objections to cited deficiencies on Form CMS-2567, do not submit a PoC, and provide convincing arguments and documented evidence that the deficiencies are invalid.

An acceptable plan of correction must contain the following elements:

- The plan of correcting the specific deficiency. The plan should address the processes that lead to the deficiency cited;
- The procedure for implementing the acceptable plan of correction for the specific deficiency cited;
- The monitoring procedure to ensure that the plan of correction is effective and that specific deficiency cited remains corrected and/or in compliance with the regulatory requirements;
- The title of the person responsible for implementing the acceptable plan of correction.

NOTE: The option to record objections pertains only to the opportunity to refute the accuracy of the findings incorporating the deficiency. Providers/suppliers may not refute the professional judgment of the surveyor regarding the level, extent, scope, or

severity of the deficiency. The surveying agency will consider evidence arguing the existence of a deficiency, but will not consider documentation that argues the seriousness of the deficiency.

If a provider attempts to refute the deficiencies, the SA reviews the documentation submitted by the provider. If the provider provides the SA with indisputable documented evidence that the deficiencies that are the basis for noncompliance are invalid, the SA revises Form CMS-2567 to reflect compliance with the CoPs/requirements, and certify the provider/supplier upon receipt of an acceptable PoC for any remaining deficiencies.

In all three options, the provider or supplier response to the deficiency is entered on the right side of Form CMS-2567, opposite the deficiency. The PoC must include the provider/supplier's planned action to correct the deficiency and the expected completion date. (See §7500 for further documentation for SNFs/NFs.) PoCs must be specific and realistic, stating exactly how the deficiency was or will be corrected. The PoC must be signed and dated by the administrator or other authorized official. Additional documentation may be attached to Form CMS-2567, if necessary. If a deficiency has been corrected since the survey, this should be indicated on the form along with the approximate date of correction.

If the administrator requests additional time to develop the plan, the SA asks that it be completed as precisely as present information permits, and that it be followed with a more specific plan as early as possible. The SA advises the administrator to return the PoC to them promptly. Also, the SA informs the administrator that, except for SNFs and NFs, the law requires that Form CMS-2567 must be made available for disclosure to the public within 90 calendar days of the last day of the survey. (See 42 CFR 401.133.) For SNFs and NFs, §§1819(g)(5) and 1919(g)(5) of the Act require disclosure of Form CMS-2567 to the public within 14 calendar days after it is made available to the provider. In addition, the SA advises that a future contact will be made to determine that the corrections have been made as agreed.

The provider/supplier should retain a copy of Form CMS-2567 and return the original copy to the SA within 10 calendar days of receipt. If a multi-copied Form CMS-2567 is used, the provider retains the fifth copy and returns all other copies to the SA.

As indicated above, the provider/supplier may attempt to refute the deficiency(ies) on Form CMS-2567. If so, the SA tries to resolve the disagreement and document the resolution. If the provider/supplier has attempted to refute a deficiency or deficiencies without submitting a PoC, but has not provided the SA with **documented evidence** that successfully refutes the validity of the deficiency, the SA notifies the provider/supplier in writing that its arguments are rejected and the reasons for the rejection. The SA advises the provider/supplier that failure to submit an acceptable PoC may result in recommendations to terminate its participation. If the provider then refuses to submit an acceptable PoC, the SA recommends termination to the RO (or the SMA for title XIX only providers) via a Form CMS-1539. The SA includes in the termination packet all pertinent documentation and correspondence related to the survey in question.

NOTE: In the event of noncompliance with the CoPs or requirements for SNFs and NFs, a "credible allegation of compliance" is required before a revisit is conducted. (See §3014.)

It is not acceptable under any circumstances for a provider or supplier to allude in any way to another provider or to malign an individual on a publicly disclosable Form CMS-2567. When this occurs, such statements must be removed and an amended PoC obtained by the SA.

2728C - Review of PoCs by SA
(Rev. 1, 05-21-04)

The SA reviews the provider or supplier's PoC for appropriateness, legibility, and completeness. If the PoC is not properly completed or if there is a question about it, the SA contacts the provider or supplier representative to obtain clarification or an appropriate modification of the plan. (See §2728.E.) If multi-copied Forms CMS-2567 are used, the SA retains the fourth copy of Form CMS-2567 in the SA file and associate the remaining copies with the certification packet.

2728D - Modifications of PoCs
(Rev. 1, 05-21-04)

The provider or supplier may submit evidence of correction or a modified PoC to the SA at any time. The SA retains a copy of the material in the certification file and forwards the original to the RO or SMA, as appropriate. If the modification does not change the certification, it is not necessary to report verification of the corrections until after the next scheduled resurvey or revisit.

2728E - Rejection of Unacceptable PoCs
(Rev. 1, 05-21-04)

If the SA finds that a PoC is not acceptable, it rejects it and seeks an acceptable one from the provider in writing. Generally, changes to the PoC must be made by the provider/supplier. The SA does not amend a PoC without the provider's concurrence. Changes to a PoC must be signed by the provider/supplier. However, if the adjustments required to the PoC are minor in nature (e.g., the provider failed to include a date for one of several deficiencies), the SA may contact the provider by telephone, make the necessary adjustments on Form CMS-2567, and then submit the change to the provider.

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."

2732 - Follow-Up on PoCS
(Rev. 1, 05-21-04)

2732A - Post-Survey Revisit
(Rev. 1, 05-21-04)

The SA follows up on all deficiencies cited in PoCs. In some cases, the cited deficiencies may be of a nature that a mail or telephone contact will suffice in lieu of an onsite visit (e.g., the facility agreed to amend its bylaws or written policies). A mail or telephone contact is acceptable as long as the SA has no reason to question the validity of the reported corrections. However, an onsite visit is generally required for deficiencies concerning quality of care. Because the LTC survey process focuses on the care of the resident, revisits are almost always necessary to ascertain whether the deficiencies have indeed been corrected. (See Appendix P for further instructions about follow-up surveys in SNFs and NFs.) If documentation or onsite verification is warranted, the SA obtains appropriate verification before reporting a deficiency as corrected. The revisit (or the mail or telephone contact) requires that the SA complete a Post-Certification Revisit Report (Form CMS-2567B).

2732B - Form CMS-2567B (See Exhibit 8)
(Rev. 1, 05-21-04)

At the time of the follow-up visit to verify corrections of deficiencies previously cited on Form CMS-2567 and/or when corrections are verifiable by telephone contact or mail, the SA completes Form CMS-2567B for the corrections that have been completed. The SA enters:

1. Provider or supplier identification information;

2. Date of the revisit or date of verification;

3. Prefix tag;

4. Corresponding regulatory reference cited on the original Form CMS-2567; and

5. Date the correction was accomplished.

If possible, the revisit is to be conducted by a member(s) of the survey team who cited the original findings. The SA has the completed form initialed by the reviewing official and signed by the surveyor and retains the fourth copy for its provider file, mails a copy to the provider or supplier, and forwards a copy to the RO or SMA, as appropriate.

If, at the time of the revisit, some deficiencies have not been corrected, the SA completes another Form CMS-2567 summarizing the deficiencies not corrected by data prefix tag number. The SA asks the provider or supplier to provide a revised PoC with new completion dates. The SA annotate under the heading "Statement of Deficiencies and Plan of Correction," "Summary of Deficiencies Not Corrected on a Follow-Up Visit," and enters the date of the revisit beneath the date of the survey.

The SA associates the fourth copy of the revised Form CMS-2567 with Form CMS-2567B, retains a copy for its provider file, sends a copy to the provider or supplier, and forwards the remaining copies to the RO or SMA, as appropriate. The SA considers whether the uncorrected deficiencies affect the ability of the provider or supplier to meet the CoPs or Requirements. If they do, the SA documents noncompliance and initiates a termination action.

2732C - Notifying Governing Bodies of Continuing Deficiencies
(Rev. 1, 05-21-04)

Generally, the SA deals directly with the administrator or director on a routine basis. However, the SA may notify the governing body if an administrator or director has been ineffective in correcting deficiencies. If the SA does so, it advises the administrator or director.

2734 - SA Evaluation of Compliance
(Rev. 1, 05-21-04)

A qualified surveyor (see §4009) who participated on the survey is expected to coordinate the survey team's compilation of all information required to complete the certification and is responsible for completing all official reports of survey findings. Survey findings, per se, are not certifications. However, they determine the type of the certification recommendation made. The SA director or his/her designee makes certifications. Thus, compliance with program requirements is an official finding made by or for the SA director.

2734A - Conditions for Certifying Compliance
(Rev. 1, 05-21-04)

1 - Medicare, Medicaid and CLIA Participants

A participating provider cannot participate in a program, and a supplier's service cannot

be covered, unless it is in compliance with each of the applicable CoPs, Conditions of Coverage, or substantially in compliance with the requirements for SNFs/NFs.

2 - Certifying Compliance Based on Acceptable PoC

Certifying compliance based on an acceptable PoC indicates that the CoPs, or Conditions of Coverage are substantially met, the provider has submitted an acceptable PoC and/or request for an approvable waiver, if needed, and is able to furnish adequate care which does not jeopardize the health and safety of patients and residents during the time period that the corrections are taking place. (See §7300 for SNFs/NFs.)

If the provider/supplier submits a PoC and/or a request for an approvable waiver, the SA evaluates whether the corrective action will result in compliance within a timeframe acceptable to CMS or the SA, which is usually 60 calendar days. (See §2728 for acceptable PoCs.) The PoC may include the provider's/supplier's objections to the cited deficiencies.

A health or LSC waiver is granted only in accordance with the regulations on the premise that patient/resident health and safety are adequately safeguarded.

2734B - Certifying Noncompliance
(Rev. 1, 05-21-04)

The SA certifies noncompliance based on a provider or supplier's:

- Failure to meet the CoPs, Conditions of Coverage, or substantially meet the Requirements for SNFs and NFs; or

- Inability or refusal to submit an acceptable PoC for any other unmet requirement.

Following a certification of noncompliance, the SA follows the procedures for denial, termination, or denial of payment in §§3000-3040 or Chapter VII for SNFs/NFs.

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 Appendix P for SNFs and NFs, Appendix B for HHAs, and Appendix J 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).

2760 - Forwarding *SA* Certification to RO

(Rev. 201, Issued: 06-19-20, Effective: 06-19-20, Implementation: 07-27-20)

Only CMS makes the determination to approve or deny a provider or *supplier (except for FQHCs) for participation in* the *Medicare program. The SA transmittal of its findings* is *a recommendation to the RO or MAC for the certification action.* The SA certification *is used* as the primary item of evidence to support decisions to approve or *deny* Medicare provider participation or coverage of *provider or* supplier services. The SA sends the entire certification packet to the RO *or MAC for* any action other than a routine periodic recertification. In routine recertifications, the SA inputs the data into the *national data* system and, as appropriate, forwards an abbreviated packet of documents to the RO *and MAC*.

The SA completes the appropriate *provider worksheet* to distill essential information from the survey report for input into the *national data* system. Each *provider worksheet* is identified by the same form number as the corresponding survey report. The alpha prefix tag number assigned to each survey report data item is listed on the appropriate *provider worksheet*.

The SA completes all pertinent documentation relating to certification actions for each provider/supplier or action category and forwards it to the RO *or MAC* (or *State Medicaid Administrator* (SMA), as appropriate) no later than **45 calendar days** after the exit interview.

2762 - Medicare/Medicaid Certification and Transmittal, Form CMS-1539

(Rev. 1, 05-21-04)

2762A - Purpose of Form CMS-1539

(Rev. 201, Issued: 06-19-20, Effective: 06-19-20, Implementation: 07-27-20)

The SA uses Form CMS-1539 to certify findings to the RO*, MACs* or *State Medicaid Agency (*SMA*)* with respect to a facility's compliance with *Conditions of Participation, Conditions for Coverage, Conditions for Certification, or Nursing Home R*equirements. Form CMS-1539 is also a transmittal cover sheet for the certification packet. (See Exhibit 9.)

Together with the SA certification file, Form CMS-1539 constitutes the primary record of the determination to approve a provider or supplier. It may be used with supporting documentation in any appellate action. It is essential, therefore, that the SA completes each item fully and accurately. *Each new certification action requires a separate Form CMS-1539.*

The Form CMS-1539 also exists as an electronic form and is more frequently used than the paper version of the form. The Form CMS-1539 is used to process updates to a provider/supplier's information in the national data system.

2762B - Definitions of Terms Used on Form CMS-1539
(Rev. 1, 05-21-04)

1 - Facility

For Form CMS-1539 purposes, facility means the provider entity or the business establishment of a provider or supplier that is subject to certification and approval in order for the provider or supplier's services to be approved for payment. If a provider operates separate provider institutions or a supplier operates separate businesses, they are regarded as separate facilities for Form CMS-1539 purposes. A LTC facility with a SNF and a NF distinct part is one facility, even though the distinct parts are separately certified for Medicare and Medicaid. Although an agency, such as an HHA with subunits, is one facility, the subunits must be separately certified. "One enterprise; one facility; one certification" is NOT always the rule. Rather, the way CMS assigns provider identification numbers determines how many certifications the SA prepares for any given institution. (See §2764.)

2 - Certified Beds

The Medicare/Medicaid program does not actually "certify" beds. This term means counted beds in the certified provider or supplier facility or in the certified component. A count of facility beds may differ depending on whether the count is used for licensure, eligibility for Medicare payment formulas, eligibility for waivers, or other purposes. For Form CMS-1539, all the following are **excluded** from "certified beds": pediatric visitors, newborn nursery cribs, maternity labor and delivery beds, intensive therapy beds which a patient occupies for only a short time (such as in radiation therapy units), and temporary extra beds. The following are **included**: designated bed locations (even though an actual bed is not in evidence) and beds which a patient occupies for an extensive period of time in special care units such as cancer treatment units as well as all routine inpatient beds.

3 - Dually-Participating

Simultaneous participation of an institution, in the Medicare and Medicaid programs.

4 - Distinct Part

The term "distinct part" refers to a portion of an institution or institutional complex (e.g., a nursing home or a hospital) that is certified to provide SNF and/or NF services. A distinct part must be physically distinguishable from the larger institution and fiscally separate for cost reporting purposes. An institution or institutional complex can only be certified with one distinct part SNF and/or one distinct part NF. Multiple certifications within the same institution or institutional complex are strictly prohibited. The distinct part must consist of all beds within the designated area. The distinct part can be a wing, separate building, a floor, a hallway, or one side of a corridor. The beds in the certified distinct part area must be physically separate from (that is, not commingled with) the beds of the institution or institutional complex in which it is located. However, the distinct part need not be confined to a single location within the institution or institutional complex's physical

plant. It may, for example, consist of several floors or wards in a single building or floors or wards that are located throughout several different buildings within the institutional complex. In each case, however, all residents of the distinct part would have to be located in units that are physically separate from those units housing other patients of the institution or institutional complex. Where an institution or institutional complex owns and operates a distinct part SNF and/or NF, that distinct part SNF and/or NF is a single distinct part even if it is operated at various locations throughout the institution or institutional complex. The aggregate of the SNF and/or NF locations represents a single distinct part subprovider, not multiple subproviders, and must be assigned a single provider number.

5 - Fully Participating

Participation of an institution in its entirety either in the Medicare or Medicaid program, or both.

2762C - Distributing Form CMS-1539

(Rev. 1, 05-21-04)

The SA completes the five copies of Form CMS-1539. Copies are transmitted as follows:

1. First copy (white) - to the RO.

2. Second copy (yellow) - to the RO for a Medicare-only or a dually-participating facility, or the SMA for a Medicaid-only facility or any facility with a Medicaid-only distinct part.

3. Third copy (pink) - retain for SA files.

4. Fourth copy (green) - a convenience copy that the SA may use for cross filing.

5. Fifth copy (blue) - to the SMA. In the case of a Medicaid-only facility or Medicaid-only distinct part, the SMA is to transmit this copy to the RO by to indicate the issuance of a provider agreement.

If Form CMS-1539 is computer generated, copies are distributed the same as above.

2762D - Amended Certifications

(Rev. 201, Issued: 06-19-20, Effective: 06-19-20, Implementation: 07-27-20)

Should the additional information requested via the Regional Office Request for Additional Information (Form CMS-1666, see §2776) result in any changes in the certification, the SA prepares a new Form CMS-1539 incorporating the additional documentation and any resulting changes in the certification. The SA draws a line through the original Form CMS-1539 and note at the top of this form, "See amended certification dated _____." The SA forwards Form CMS-1539 to the RO *or MAC* indicating in Item 16 that "this certification is amending the certification dated_____."

2764 - SA Completion Instructions for Certification and Transmittal, Form CMS-1539*, 1-32*

(Rev. 201, Issued: 06-19-20, Effective: 06-19-20, Implementation: 07-27-20)

The main purpose of Form CMS-1539 is to transmit the SA's certification that a facility meets or does not meet the requirements for participation. The SA completes all applicable parts of the form for Medicare/Medicaid providers/suppliers. The SA completes items 1-32 as follows:
Except for the signatures, the SA types *(includes keyboard entry)* all *applicable* 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)).

Item 1 - Medicare/Medicaid Provider No
Leave this item blank on all initial certifications. *CMS* assigns the *CCN* for all new providers and suppliers.

CCNs 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 *(SNF or NF)* with Distinct Parts

One CCN 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 - Distinct Part *SNF/NF* of Hospitals *or CAHs*

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

CCN are assigned in the following fashion:

1 - Hospital *or CAH* with Distinct-Part SNF

Two *CCNs* are assigned, one for the hospital*/CAH* and one for the SNF. Prepare separate Forms CMS-1539 for certification actions regarding each provider.

2 - Hospital or CAH with Distinct-Part NF

Two *CCNs* are assigned, one for the hospital*/CAH* and one for the NF. Prepare

separate Forms CMS-1539 for certification actions regarding each provider.

3 - Hospital or CAH with Distinct-Part SNF/NF

C -Hospitals *or CAHs with Swing-Bed Approval*

One CCN is assigned, *however* the *single CCN* for the hospital *or CAH is modified to address the hospital's or CAH's* swing-bed *approval. A letter `U' or `Z' in the third space of the CCN is used to identify swing-bed approval designation for a short-term hospital or CAH* (See SOM section 2779C). Prepare one Form CMS-1539.

EXAMPLE: *21-0101 – Is ABC Hospital's (Short-Term Hospital) CCN*

- *21U101 – Is ABC Hospital's modified CCN for its swing-bed approval*

EXAMPLE*: 21-1301 –Is XYZ CAH's CCN*

- *21-Z301 is XYZ CAH's modified CCN for its swing-bed approval*

D –*Hospital or CAH I*PPS Excluded *Rehabilitation or Psychiatric Units*

Hospitals *or CAHs* with psychiatric and/or rehabilitation units that are excluded from the *I*PPS are assigned *one CCN but will have their CCN modified by adding an alpha identifier in the third space to identify their IPPS excluded rehabilitation unit and/or psychiatric unit. IPPS excluded units in CAHs are called "distinct part units (DPU)". (See SOM section 2779C and 2779C1)* 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 *facility properties screen of the national data system automatically generates* the name, *physical* address, city, State, and zip code of the facility. 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:

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.

Code 2 (Recertification)

The SA selects this code when conducting a recertification survey.

Code 3 (Termination or retirement of CCN)

The SA selects this code for involuntary termination, voluntary termination/withdrawal, or change in status requiring a new *CCN. Examples of a change in status includes:*

- *When a hospital converts to a CAH,*
- *When a CAH converts to a hospital,*
- *When a short-term hospital reclassifies to become an IPPS-excluded hospital,*
- *When an IPPS-excluded hospital reclassifies to become another classification of hospital (Short-term hospital or IPPS-excluded hospital), or*
- *When a hospital undergoes a CHOW and then is combined with another hospital the new owner already owns.*

Code 4 (CHOW)

The SA selects this code for a CHOW situation.

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).

Code 6 (Complaints)

The SA selects this code for an onsite complaint investigation.

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 *or CAH* meets the criteria for hospitals *or CAHs* operating with *swing-beds or IPPS-excluded units*; and

3. Onsite visit to verify that an HHA's satellite meets the branch criteria.

Code 8 (Full Survey After Complaint)

The SA selects this code for when a full survey after a complaint investigation is completed in the complaint system.

Code 9 (Other)

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, and the reason for completing Form CMS-1539.

Item 5 - CHOW Date

When Item 4 is marked CHOW (code 4), the SA *is unable to* enter the date the change occurred (e.g., 060782) in Item 5. *CMS will enter the date the change occurred.*

Item 6 - Survey Date

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

Item 7 - Provider/Supplier Category

In the block provided, the code that is most descriptive of the facility identified on the form is *taken. The SA does not manually* enter *a* code.

Item 8 - Accreditation Status

The SA *does not manually enter accreditation status on this form. It is taken from the information already entered into the deemed tab of the certification kit and populated on the form.*

Item 9 *(L35)* - Fiscal Year Ending Date

The *MAC or CMS PEOG, when applicable,* enters the ending date (month and day) of the provider's/supplier's fiscal year (e.g., 0630).

Item 10 - State Agency Certification

A - In Compliance With Program Requirements

If "A" is entered in the first block and the facility is not in full compliance with the program requirements, all conditional aspects are coded in the blocks following "A." For example, the SA enters A126 when a hospital is in compliance with the program

requirements based on an acceptable PoC, recommended waivers for technical personnel, and limited scope of service.

NOTE: A1 applies to all provider/suppliers with an acceptable PoC.
A2 and A6 apply to hospitals only.
A3 applies to hospitals, SNFs, and NFs only.
A4 is no longer applicable.
A8 and A9 apply to all LTC facilities.
A5 applies to all facilities that undergo a fire safety survey.
A7 no longer applies to SNFs.

B - Not in Compliance With Program Requirements (Termination Development)

If "B" is entered in the first block, the documentation supporting the termination action must accompany Form CMS-1539 and be referenced in Item 16 of Remarks. Item "B" is also selected when an accredited hospital is not in compliance with one or more of the CoPs surveyed during the sample validation survey or complaint investigation.

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

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.

D - Resurvey Does Not Find Significant Progress
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 *no longer* required for ICFs/IID. The SA *does not need to* insert the recommended beginning (FROM) and ending (TO) dates of the TLA.

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 (*CCN*) 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 (CMS Certification 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 *(see 42 CFR 424, Subpart G)* 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 *or recommendations for approval or disapproval. The SA should list the names of the surveyor and the SA approval in this space.*

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 Deemed Status Accreditation	§2005B
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. *CCN*

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

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
| 0 | 1 | (Hospital)	3 0 0	3 0 0

14.
LTC Certified Bed Breakdown

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

EXAMPLE 2: ***A total of*** **250 bed*s are in the combined*** **hospital** ***and DP SNF/NF***

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 separate hospital and SNF/NF providers.

1. *CCN*

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

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
| 0|1 |(Hospital)	2 0 0	2 0 0

14.
LTC Certified Bed Breakdown

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

1. *CCN*

| X | X | 5 | 0 | 0 | 0 | (SNF/NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
| 0|2|(SNF/NF)	5 0	5 0

14.
LTC Certified Bed Breakdown

SNF	SNF/NF	NF	ICF/IID
	50		

EXAMPLE 3: ***A Total of* 400 bed*s are in the* hospital *and the DP NF***

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

NOTE: Prepare two Forms CMS-1539 for hospital and LTC components.

1. *CCN*

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

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS

|0 |1 |(Hospital) 3 0 0 3 0 0
14.
LTC Certified Bed Breakdown

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

1. *CCN*

| X | X |A,E, or F | 0 | 0 | 0 | (Title 19 NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
|1 |0 | (NF Distinct Part)	1 0 0	1 0 0

14.
LTC Certified Bed Breakdown

| SNF | SNF/NF | NF | ICF/IID |
100

EXAMPLE 4: 44 bed hospital *with* swing-bed *approval*

1. *CCN*

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

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
| 0| 1| (Hospital)	4 4	4 4

14.
LTC Certified Bed Breakdown

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

EXAMPLE 5: 100 bed nursing home (free-standing)

Beds are distributed as follows:
60 beds certified for Medicaid
40 beds not participating in either Medicare or Medicaid

1. *CCN*

(NF6: 75 Medicaid NF CCN| X | X |A, E, or F| 0 | 0 | 0 | (NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
| 1| 0 |(| (NF) 6 0	7 5	7 51 0 0

14.
LTC Certified Bed Breakdown

SNF	SNF/NF	NF	ICF/IID
		60	

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

1. *CCN*

SNF	SNF/NF	NF	ICF/IID
		75	

EXAMPLE 7: 150 bed SNF/NF and NF

Beds are distributed as follows:
100 beds SNF/NF
50 NF beds

1. *CCN*

| X | X | 5 | 0 | 0 | 0 | (Title 18 & 19 SNF/NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
|0 |3 |(SNF/NF)	1 5 0	1 5 0

14.
LTC Certified Bed Breakdown

SNF	SNF/NF	NF	ICF/IID
	100	50	

EXAMPLE 8: 100 SNF/NF facility

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. *CCN*

| X| X | 5 | 0 | 0 | 0 | (18/19 SNF/NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
| 0| 2| (SNF/NF Dually-Participating)	1 0 0	1 0 0

14.
LTC Certified Bed Breakdown

SNF	SNF/NF	NF	ICF/IID
	100		

EXAMPLE #9: 125 bed SNF/NF facility

Beds are distributed as follows:
100 beds - Title 19 NF
25 beds - Title 18/19 SNF/NF DP
See Example #8 Note.

1. *CCN*

| X | X | 5 | 0 | 0 | 0 | (18/19 SNF/NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
| 0 | 3|(SNF/NF)	1 2 5	1 2 5

14.
LTC Certified Bed Breakdown

SNF	SNF/NF	NF	ICF/IID
	25	100	

EXAMPLE 10: 150 bed Medicaid-only NF

Beds are distributed as follows:
125 beds - Title 19 NF
25 beds - not participating in Medicare or Medicaid

1. *CCN*

| X | X |A, E, or F | 0 | 0 | 0 | (Title 19 NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
| 1 | 0| (NF)	1 5 0	1 2 5

14.
LTC Certified Bed Breakdown

SNF	SNF/NF	NF	ICF/IID
		125	

EXAMPLE 11: 140 bed NF (free-standing)

1. *CCN*

| X | X |A, E or F | 0 | 0 | 0 | (NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
| 1| 0| (NF)	1 4 0	1 4 0

14.
LTC Certified Bed Breakdown

SNF	SNF/NF	NF	ICF/IID
		140	

EXAMPLE #12 - 30 bed ICF/IID (free-standing)

1. *CCN*

| X | X | G | 0 | 0 | 0 | (ICF/IID)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
| 1| 1| (IMR)	3 0	3 0

14.
LTC Certified Bed Breakdown

SNF	SNF/NF	NF	ICF/IID
			30

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

Beds are distributed as follows:
30 beds - Title 19 NF
20 beds - Title 19 ICF/IID

NOTE: Prepare two Forms CMS-1539 identifying the NF and ICF/IID components.

1. *CCN*

| X | X |A, E, or F | 0 | 0 | 0 | (NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
| 1|0 | (NF)	3 0	3 0

14.
LTC Certified Bed Breakdown

SNF	SNF/NF	NF	ICF/IID
		30	

1. *CCN*

| X | X | G | 0 | 0 | 0 | (ICF/IID) 2 0 2 0

14.
LTC Certified Bed Breakdown

SNF	SNF/NF	NF	ICF/IID
			20

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 *MAC, when applicable* or *State Medicaid Agency (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 SA representative's signature on this document represents the adjudicative decision of the SA on the qualifications of the institution to participate in the Medicaid program.

Item 19 - Determination of Eligibility

Enter code 1 or 2 in this block of the SA's findings and certifications. 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 Office for Civil Rights (OCR) clearance, enter code 1 in the available block if the OCR requirements are met. If not in compliance with Title VI of the Civil Rights Act of 1964, as implemented by 45 CFR part 80, enter code 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 code 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 recommended effective date at block L24. The effective date of participation is established pursuant to 42 CFR 489.13 for Medicare and 42 CFR 431.108 for Medicaid.

Items 23-25 - ICF/IID Certification Period ("LTC Agreements")

When an ICF/IID is found not to be 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 (Conditions of Participation, Conditions for Coverage, Conditions for Certification, or Nursing Home Requirements).

Code 6 - Select this code when a provider fails to meet the terms of their agreement.

***NOTE**: If code 5 or 6 is selected, then the National Practitioner Data Bank (NPDB) appeal status box is generated in the national data system. The options to select are:*
1 – No appeal, termination final
2 – Appeal in progress
3 – All appeals exhausted, termination final

3 - Other

Code 7 - Select this code when you terminate a currently assigned CCN. 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*
- *An ASC, ESRD, or RHC elects to participate as free-standing instead of hospital-based and vice versa.*

In any of the above instances, CMS terminates the existing CCN (complete Items 26 and 28) and assigns the new CCN. (See §1060.A.)

Item 27 - Intermediate Sanctions (ICF/IID Only)

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

1 - Suspension of Admissions

*Enter the date in Item 27A that payments for new admissions in the ICF/IID will be denied. In addition, mark Item 10 with "B" (not in compliance with program requirements). Mark Item 19 "1" (facility is 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 "1" (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" (facility is 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 with "1" (facility is eligible to participate).

NOTE: *Pursuant to 42 CFR 442.119(a), the denial of payment for new admissions is to be rescinded if the facility has corrected deficiencies or can document it is making good faith efforts to achieve compliance with the conditions of participation. Good faith efforts 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 noncompliance deficiencies are not corrected by the 11th month following the initial month of denial, the ICF/IID's provider agreement must be terminated pursuant to 42 CFR 442.119.

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 – MAC Number

Enter the five-digit number assigned to the MAC 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 or MAC 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 or MAC.

Item 32 - Determination Approval

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

2764A - In Compliance With Program Requirements
(Rev. 1, 05-21-04)

If "A" is entered in the first block and the facility is not in full compliance with the program requirements, all conditional aspects are coded in the blocks following "A." For example, the SA enters A126 when a hospital is in compliance with the program requirements based on an acceptable PoC, recommended waivers for technical personnel, and limited scope of service.

NOTE: A1 applies to all provider/suppliers with an acceptable PoC.
A2 and A6 apply to hospitals only.
A3 applies to hospitals, SNFs, and NFs only.
A4 is no longer applicable.
A8 and A9 apply to all LTC facilities.
A5 applies to all facilities that undergo a fire safety survey.
A7 no longer applies to SNFs.

2764B - Not in Compliance With Program Requirements (Termination Development)
(Rev. 1, 05-21-04)

If “B” is entered in the first block, the documentation supporting the termination action must accompany Form CMS-1539 and be referenced in Item 16 of Remarks. Item “B” is also selected when an accredited hospital is not in compliance with one or more of the CoPs surveyed during the sample validation survey or complaint investigation.

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

Remarks	SOM Reference
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. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
| 0 | 1 | (Hospital)	3 0 0	3 0 0

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

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
| 0|1 |(Hospital)	2 0 0	2 0 0

14.
LTC Certified Bed Breakdown

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

1. Provider Number

| X | X | 5 | 0 | 0 | 0 | (SNF/NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
| 0|2|(SNF/NF)	5 0	5 0

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 components.

1. Provider Number

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

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
|0 |1 |(Hospital)	3 0 0	3 0 0

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	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
|1 |0 | (NF Distinct Part)	1 0 0	1 0 0

14.
LTC Certified Bed Breakdown

SNF	SNF/NF	NF	ICF/IID
		100	

EXAMPLE 4: 44 bed hospital swing-bed facility

1. Provider Number

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

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
| 0| 1| (Hospital)	4 4	4 4

14.
LTC Certified Bed Breakdown

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

EXAMPLE 5: 100 bed nursing home (free-standing)

Beds are distributed as follows:
60 beds certified for Medicaid
40 beds not participating in either Medicare or Medicaid

1. Provider Number

| X | X |A,E, or F| 0 | 0 | 0 | (NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
| 1| 0 | (NF)	1 0 0	6 0

14.
LTC Certified Bed Breakdown

SNF	SNF/NF	NF	ICF/IID
		60	

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

1. Provider Number

| X | X |A, E or F| 0 | 0 | 0 | (Title 19 NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
|1 |0 |(NF)	7 5	7 5

14.
LTC Certified Bed Breakdown

SNF	SNF/NF	NF	ICF/IID
		75	

EXAMPLE 7: 150 bed SNF/NF and NF

Beds are distributed as follows:
100 beds SNF/NF
50 NF beds

1. Provider Number

| X | X | 5 | 0 | 0 | 0 | (Title 18 & 19 SNF/NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
|0 |3 |(SNF/NF)	1 5 0	1 5 0

14.
LTC Certified Bed Breakdown

SNF	SNF/NF	NF	ICF/IID
	100	50	

EXAMPLE 8: 100 SNF/NF facility

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	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
| 0| 2| (SNF/NF Dually-Participating)	1 0 0	1 0 0

14.
LTC Certified Bed Breakdown

SNF	SNF/NF	NF	ICF/IID
	100		

EXAMPLE #9: 125 bed SNF/NF facility

Beds are distributed as follows:
100 beds - Title 19 NF
25 beds - Title 18/19 SNF/NF DP
See Example #8 Note.

1. Provider Number

| X | X | 5 | 0 | 0 | 0 | (18/19 SNF/NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
| 0 | 3|(SNF/NF)	1 2 5	1 2 5

14.
LTC Certified Bed Breakdown

SNF	SNF/NF	NF	ICF/IID
	25	100	

EXAMPLE 10: 150 bed Medicaid-only NF

Beds are distributed as follows:
125 beds - Title 19 NF
25 beds - not participating in Medicare or Medicaid

1. Provider Number

| X | X |A, E, or F | 0 | 0 | 0 | (Title 19 NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
| 1 | 0| (NF)	1 5 0	1 2 5

14.
LTC Certified Bed Breakdown

SNF	SNF/NF	NF	ICF/IID
		125	

EXAMPLE 11: 140 bed NF (free-standing)

1. Provider Number

| X | X |A, E or F | 0 | 0 | 0 | (NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
| 1| 0| (NF)	1 4 0	1 4 0

14.
LTC Certified Bed Breakdown

SNF	SNF/NF	NF	ICF/IID
		140	

EXAMPLE #12 - 30 bed ICF/IID (free-standing)

1. Provider Number

| X | X | G | 0 | 0 | 0 | (ICF/IID)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
| 1| 1| (IMR)	3 0	3 0

14.
LTC Certified Bed Breakdown

SNF	SNF/NF	NF	ICF/IID
			30

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

Beds are distributed as follows:
30 beds - Title 19 NF
20 beds - Title 19 ICF/IID

NOTE: Prepare two Forms CMS-1539 identifying the NF and ICF/IID components.

1. Provider Number

| X | X |A,E,or F | 0 | 0 | 0 | (NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
| 1|0 | (NF)	3 0	3 0

14.
LTC Certified Bed Breakdown

SNF	SNF/NF	NF	ICF/IID
		30	

1. Provider Number

| X | X | G | 0 | 0 | 0 | (IMR)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
| 1| 1| (ICF/IID)	2 0	2 0

14.
LTC Certified Bed Breakdown

SNF	SNF/NF	NF	ICF/IID
			20

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.

2765 - *MAC* Tie-In Activities

(Rev. 201, Issued: 06-19-20, Effective: 06-19-20, Implementation: 07-27-20)

The SA maintains a list of the *MACs* available to serve providers in the area. The SA includes this list in the initial mailing kit sent to new provider candidates. This list contains the *MACs*' names, addresses, telephone numbers, and service areas. It also indicates that *MAC* elections are subject to approval by the RO and that questions regarding *MAC* selection should be addressed to the RO. The RO furnishes updated lists to the SA when the availability of *MAC* changes.

2766 - Spell of Illness Supplement, Form CMS-1539A (Exhibit 10)

(Rev. 1, 05-21-04)

2766A - Form(s) to Use

(Rev. 1, 05-21-04)

The SA completes both a Form CMS-1539 and a Spell of Illness Supplement, Form CMS-1539A, in making §§1861(e)(1) and 1819(a)(1) (formerly 1861(j)(1)) certifications. The SA forwards the forms to the RO for determination, maintenance of listings, and notification to intermediaries and other interested parties.

For convenience, a single Form CMS-1539A may include certifications for all areas of an institution when there is more than one part.

Situation - Hospital being approved for participation, contains part rendering non-hospital services.

Action - The SA checks Item 14(c) (1 or 2) on Form CMS-1539 and prepares §1819(a)(1) certification(s) on Form CMS-1539A. If "Does not meet §1819(a)(1)" is checked on Form CMS-1539A, add: "or (e)(1)."

Situation - Hospital being denied or terminated and fails to meet §1861(e)(1) definition; entire facility meets (or does not meet) §1819(a)(1) definition.

Action - The SA checks Item 14(b)(2) and Item 14(c)(1) or (3) on Form CMS-1539 and explains in Item 17.

Situation - Hospital fails to meet §1861(e)(1) definition; **part of facility meets and part does not meet** §1819(a)(1) definition.

Action - The SA checks Items 14(b)(1) or (2) and 14(c)(1) and (2) on Form CMS-1539, and provides explanation in Item 17. The SA prepares §1819(a)(1) certification(s) on Form CMS-1539A. If "Does not meet §1819(a)(1)" is checked, add "or (e)(1)."

Situation - Hospital not participating and no termination involvement; contains part rendering non-hospital services.

Action - The SA prepares §1819(a)(1) certification(s) on Form CMS-1539A. If "Does not meet §1819(a)(1)" is checked, add or (e)(1).

Situation - Distinct part SNF being approved for participation.

Action - The SA checks Item 14(c)(1) of Form CMS-1539 and prepares Form CMS-1539A.

Situation - SNF does not meet one or more Conditions; entire **facility** meets (or does not meet) §1819(a)(1) definition.

Action - The SA checks Item 14(c)(1) and (2) on Form CMS-1539; prepares Form CMS-1539A.

Situation - SNF does not meet one or more Conditions; **part of facility meets and part does not meet** §1819(a)(1) definition.

Action - The SA checks Item 14(c)(1) and (2) on Form CMS-1539; provides explanation in Item 17; prepares Form CMS-1539A.

Situation - Nursing facility with no SNF and no termination involvement.

Action - Prepare Form CMS-1539 and Form CMS-1539A.

2766B - Items on Form CMS-1539A
(Rev. 1, 05-21-04)

Item 2 - In addition to the name and address of the facility, the SA identifies the part of the facility the spell of illness certification refers to; e.g., first and second floors of the West Building, or rooms numbered 23-31 of the East Wing of the Tower Building.

Items 3-7 - Self-explanatory.

Item 8 - Number of beds, and number of beds occupied. These items pertain to the number of beds within the part of the institution identified in Item 1.

2772 - Packet of Documentation Attached to Certification and Transmittal by SA
(Rev. 1, 05-21-04)

Direct Data Entry instructions identify those packets that must be sent to the RO or SMA by the SA. For those packets that must be sent, the SA refers to Exhibit 63 for a complete listing of forms and other materials to be sent to the RO or SMA as attachments to Form CMS-1539 or Form CMS-1540. The SA assembles the materials in the order listed in the exhibit.

2774 - Routing of Medicaid-only Certifications
(Rev. 1, 05-21-04)

While Medicaid is a State-administered program, the RO has responsibility for monitoring all Medicaid certification actions. After the SMA takes required actions, it forwards appropriate certification materials to the RO as required by the Direct Data Entry program.

The RO reviews the packets for completeness, acceptability of PoC, and appropriateness of compliance decisions. Since the review is post-certification, feedback is provided to the SA on a case-by-case basis, as appropriate. Medicaid provider agreements are subject to CMS review. In the event prescribed forms, regulations, and procedures were not followed, CMS could disallow FFP in Medicaid payments to the SMA for the involved facilities, i.e., old look behind.

2776 - RO Requests for Additional Information
(Rev. 1, 05-21-04)

The Regional Office Request for Additional Information or Other Action (Form CMS-1666) (see Exhibit 15) provides the RO a means of requesting further information or additional action from the SA at any stage of processing a certification action or providing technical assistance. The SA uses the reverse side of the form to reply and to summarize additional development. If the RO does not request a specific due date, the SA forwards its response (or an interim response) within 20 calendar days of receipt of the request. The SA keeps a copy of Form CMS-1666 in the provider/supplier file for its records.

Form CMS-1666 may be used for a myriad of reasons, such as requesting information or providing technical assistance. It may also be used to request certain actions, such as surveys, or to inform States of processing errors. In preparing Form CMS-1666, the RO completes the self-explanatory portions of the form, (e.g., the addressee, facility name, and provider number) and provides relevant section numbers in the manuals, if appropriate. The RO may include suggestions for the desired action along with a requested response date. The original is sent to the SA, and a copy is filed inside the folder until the completed original is returned.

The RO maintains a log or file of requests to the SA for additional information (i.e., Form CMS-1666s, letters, documented telephone contact reports) which reflects the date of each request, the requested information, the requested response date, and the date the RO received the reply.

2777 - RO Review of SA Certifications
(Rev. 1, 05-21-04)

2777A - Medicaid-Only Certifications
(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

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, which is submitted to the applicable Regional Office of Civil Rights) to the SA for entry into the ASPEN system. Before the initial certification is entered into the ASPEN system, the SA assigns a CCN to the NF, hospital or ICF/IID. The ASPEN system screens the facility's current compliance record for Conditions of Participation (CoPs), Requirements (for NFs), and other RO flags.

2777B - State-Operated Medicaid NFs
(Rev. 1, 05-21-04)

These facilities are certified by the CMS RO.

2777C - Medicare Certifications
(Rev. 1, 05-21-04)

The SA must certify participating providers and suppliers of services and forward the certification to the RO within 45 days after the survey. The RO reviews all initial SA certifications when received. The SA enters routine recertification cases into the OSCAR system. The OSCAR system screens the facilities' current certification compliance records for CoPs, Requirements for SNFs, and other RO flags that are out of compliance. If there is a deficiency in one or more of these requirements, the OSCAR system may notify the SA to forward the case to the RO for additional review. The SA retains unflagged certification documents. Exhibit 164 is a suggested checklist that the RO certification specialist may use as a guide to review certification kits received from the SA. The RO modifies the checklist to suit changing needs or variances.

2777D - Change in Certification
(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

2777D1 - Medicaid NF and Medicaid Distinct Part NF Providers Seeking

to Participate as Medicare SNF providers

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

When Medicaid NF and Medicaid distinct part NF providers wish to participate as Medicare SNF providers, the SA sends the most recent survey information obtained during the latest Medicaid survey along with other documentation required for an initial Medicare certification of a SNF (Exhibit 63) to the RO for official determination of whether to approve the facility and enter into a provider agreement. If these documents provide adequate evidence that the facility is in compliance with the requirements governing program participation, the RO notifies the provider of the effective date of Medicare participation. The effective date is the date requested by the provider, but cannot be earlier than the date the request is filed with the RO or the SA.

The requesting facility must sign a Medicare provider agreement, which will be in effect concurrently with its present Medicaid agreement. The facility will be surveyed for both programs at the end of the current period of Medicaid certification.

A facility may increase its Medicare distinct part by converting Medicaid NF beds to Medicaid/Medicare SNF/NF beds without a survey. In expanding a distinct part, providers must adhere to distinct part organizational requirements and accounting principles.

2777D2 – Medicare- and Medicaid-Participating Hospitals Seeking to Become Medicaid-Only Hospitals

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

When a hospital that dually participates in Medicare and Medicaid wishes to voluntarily terminate its Medicare provider agreement, but continue to participate in Medicaid only, it must provide written notification to the SA and submit a completed Form CMS-855A to the MAC as required in Chapter 15, Section 10 of the Program Integrity Manual, Publication 100-08. In terms of survey and certification, voluntary terminations of the Medicare provider agreement will be processed in accordance with SOM Section 3046. A Non-deemed hospital will be surveyed at the time it ordinarily would have been subject to a recertification survey had it continued to participate in Medicare. In the case of a deemed hospital, it will be surveyed by its CMS-approved AO when its current accreditation is due for renewal.

2777D3 - Medicaid-Only Hospitals Seeking to Participate in Medicare and Medicaid

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

When a Medicaid-only hospital wishes to participate in both Medicare and Medicaid, it must submit a Form CMS-855A to the MAC. After receipt of the MAC's recommendation to approve the hospital's enrollment in Medicare, the SA sends the survey findings from the most recent Medicaid survey and its certification of Medicare CoP compliance or noncompliance based on that survey, along with other documentation required for an initial Medicare certification (see Exhibit 63), to the RO. The RO determines whether or

not to approve the hospital for Medicare participation and enter into a provider agreement.

In the case of a Medicaid-only deemed hospital, after receipt of the MAC's recommendation for approval, the hospital must notify its CMS-approved AO of its application to change its status from a Medicaid-only hospital to a Medicare- and Medicaid (dually)–participating hospital. The hospital must request the AO to send the most recent survey report to the RO. The RO determines whether or not to approve the hospital for Medicare participation and enter into a provider agreement.

The RO has the option of requiring a new full, standard survey if it has concerns based on the most recent Medicaid survey findings.

- If the RO determines there is substantial compliance with Medicare participation requirements based on the most recent Medicaid survey, it determines the effective date in accordance with 42 CFR 489.13, retires the previously issued Medicaid-only hospital CCN number and issues a Medicare CCN along with the signed Medicare provider agreement. The Medicare participation effective date may be the date requested by the provider, but cannot be earlier than the date the CMS 855A was approved by the Medicare Administrative Contractor (MAC) or, if there are other applicable federal requirements, the date on which all federal requirements were met. See Section 2780 concerning the effective date of the Medicare agreement.

  The Medicare provider agreement is in effect concurrently with the Medicaid agreement. The facility will be surveyed for both programs at the end of the current period of Medicaid certification. In the case of Medicaid-only deemed hospitals, when the AO surveys the hospital when the accreditation is due for renewal, it follows the standard process for notifying CMS of accreditation and recommendation of continued Medicare deemed status.

- If the RO requires a new full, standard survey and that survey indicates substantial compliance, the RO determines the effective date in accordance with 42 CFR 489.13. The Medicare participation effective date cannot be earlier than the date the survey was completed or, if applicable, the date an acceptable plan of correction was received. See Section 2780 concerning the effective date of the Medicare agreement.

If the survey indicates noncompliance, the RO denies the hospital's Medicare certification application. See Section 2005A2 for the process related to a denial. The SA must also advise the State Medicaid Agency of the substantial noncompliance.

2778 - Objectives of RO Certification Review

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

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 the case of hospitals that participate in both Medicare and Medicaid or Medicaid-only or of Critical Access Hospitals (CAHs), the RO must ensure the completion of the Hospital/CAH database worksheet (Exhibit 286) by the SA for all certifications, including initial certifications, regardless of whether the survey was conducted by the SA or AO. The survey kit will not upload without completion in ASPEN of the worksheet.

In Medicaid-only cases, the SA certifies its determination as to the provider's compliance with the participation requirements. With the exception of PRTFs, the SMA must accept certification determinations as final and may not enter into a provider agreement with a NF, HHA, hospital 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, HHA, hospital 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 CASPER system accumulates data on the ability of providers and suppliers to meet program participation requirements at the time of the survey. CASPER 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.

2779 - RO Assignment of CMS Certification Numbers

(Rev. 29, Issued: 04-20-07; Effective/Implementation Dates: 10-01-2007)

2779A - Numbering System for CMS Certification Numbers (CCN)

(Rev. 152, Issued: 03-25-16, Effective: 04-04-16, Implementation: 04-04-16)

Effective in 2007, the CCN replaced the term Medicare Provider Number, Medicare Identification Number or OSCAR Number. The CCN is used to verify Medicare/Medicaid certification for survey and certification, assessment-related activities and communications. Additionally, CMS data systems use the CCN to identify each individual provider or supplier that has or currently does participate in Medicare and/or Medicaid. The RO, not the SA or MAC, assigns the CCN and maintains adequate controls.

2779A1 – CCN for Medicare Providers

(Rev. 198, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

The CCN for providers and suppliers paid under Medicare Part A have 6 digits. The first 2 digits identify the State in which the provider is located. The last 4 digits identify the type of facility.

Following is a list of all State Codes:

Alabama	01	New Hampshire	30
Alaska	02	New Jersey	31, 83
Arizona	03, 00	New Mexico	32, 96
Arkansas	04, 89	New York	33, 57
California	05, 55, 75, 92	North Carolina	34, 86
Colorado	06, 91	North Dakota	35
Connecticut	07, 81	Ohio	36, 72
Delaware	08	Oklahoma	37, 90
District of Columbia	09	Oregon	38, 93
Florida	10, 68, 69	Pennsylvania	39, 73
Georgia	11, 85	Puerto Rico	40, 84
Hawaii	12	Rhode Island	41
Idaho	13, 54	South Carolina	42, 87
Illinois	14, 78	South Dakota	43
Indiana	15	Tennessee	44, 88
Iowa	16, 76	Texas	45, 67, 74, 97
Kansas	17, 70	Utah	46
Kentucky	18	Vermont	47
Louisiana	19, 71, 95	Virgin Islands	48

Maine	20	Virginia	49
Maryland	21, 80	Washington	50, 94
Massachusetts	22, 82	West Virginia	51, 58
Michigan	23	Wisconsin	52
Minnesota	24, 77	Wyoming	53
Mississippi	25	Canada	56
Missouri	26, 79	Mexico	59
Montana	27	American Samoa	64
Nebraska	28	Guam	65
Nevada	29	Commonwealth of the Northern Marianas Islands	66
		Foreign Countries (exceptions: Canada and Mexico)	99

New State codes must <u>only</u> be used when all of the existing assigned numbers have been assigned within each of the CCN ranges available for a facility type.

Assign the last 4 digits, which identify the facility type, sequentially from within the appropriate CCN range. In a State that has more than one State code and/or a facility type that has more than one CCN range available, ensure that all the numbers available in one CCN range have been assigned before implementing the use of a new State code or numbers in a new CCN range.

For example: You are assigning a CCN to a new Community Mental Health Center (CMHC) in Florida. Florida has three State Codes: 10, 68 and 69 and three number ranges for CMHCs: 1400-1499, 4600-4799, and 4900-4999. You have been using State Code 68 and the CCN range 4900-4999 for CMHC in Florida, and you last assigned 4999 in that State to a CMHC. Given this information, consider the following scenarios:

- Scenario 1. Review the CCN records for Florida to determine if all the numbers in CCN range 4600-4799 were assigned. It is determined that all those numbers were previously assigned in Florida. Therefore, look to CMHC CCN range 1400-1499 as those numbers have not been assigned in Florida; assign 681400 as the CCN for the new CMHC that is being processed.

- Scenario 2. Review the CCN records for Florida to determine if all the numbers in CCN range 4600-4799 were previously assigned in Florida. It is determined that some, but not all, of the numbers in that CCN range were assigned. The last number in that range that was assigned was 4701. Assign 684702 as the CCN for the new CMHC that is being processed.

- Scenario 3. Review the CCN records for Florida to determine if all the numbers in CCN range 4600-4799 were previously assigned in Florida. It is determined that all the numbers in that range were previously assigned in Florida. It is then determined after a review of the CCN records that all of the numbers in CCN range 1400-1499 were previously assigned in Florida. Look to see if all three CMHC CCN ranges for

State Code 10 have been assigned. It is determined that all three CCN ranges have been previously assigned. Then look to State Code 69. You find that no CCN for CMHC in Florida has been assigned under State Code 69. The new CCN that will be assigned to the new Florida CMHC will be 691400 because is the first CCN range under State Code 69 listed for CMHCs. However, if it is determined that one of the CMHC CCN ranges under State Code 69 has been previously assigned, begin with the next available number in that CCN range.

NOTE: Once the remaining pool of two digit State numeric codes are exhausted, CMS will implement a two digit alpha-numeric code system for State Codes. For example: A0, A1, A2,… B0, B1, B2,…, Z8, and finally Z9). This numbering system will provide a pool of 260 new State Codes for future use.

Use the following CCN ranges for the facility types indicated:

0001-0879	Short-term (General and Specialty) Hospitals
0880-0899	Reserved for hospitals participating in ORD demonstration project
0900-0999	Multiple Hospital Component in a Medical Complex (Numbers Retired)
1000-1199	Federally Qualified Health Centers (also CCN range 1800-1989)
1200-1224	Alcohol/Drug Hospitals (Numbers Retired)
1225-1299	Medical Assistance Facilities
1300-1399	Critical Access Hospitals
1400-1499	Continuation of Community Mental Health Centers (also CCN ranges 4600-4799 and 4900-4999)
1500-1799	Hospices
1800-1989	Federally Qualified Health Centers (also CCN range 1000-1199)
1990-1999	Religious Non-medical Health Care Institutions (formerly Christian Science Sanatoria (Hospital Services)
2000-2299	Long-Term Care Hospitals (Excluded from IPPS)
2300-2499	Hospital-based Renal Dialysis Facilities
2500-2899	Independent Renal Dialysis Facilities
2900-2999	Independent Special Purpose Renal Dialysis Facility 1/
3000-3024	Formerly Tuberculosis Hospitals (Numbers Retired)
3025-3099	Rehabilitation Hospitals (Excluded from IPPS)
3100-3199	Home Health Agencies (also CCN ranges 7000-8499 and 9000-9799)
3200-3299	Continuation of Comprehensive Outpatient Rehabilitation Facilities (also CCN ranges 4500-4599 and 4800-4899)
3300-3399	Children's Hospitals (Excluded from IPPS)

3400-3499	Continuation of Rural Health Clinics (Provider-based) (also CCN ranges 3975-3999 and 8500-8899)
3500-3699	Hospital-based Satellite Renal Dialysis Facilities
3700-3799	Hospital-based Special Purpose Renal Dialysis Facility 1/
3800-3974	Rural Health Clinics (Free-standing) (also CCN range 8900-8999)
3975-3999	Rural Health Clinics (Provider-based) (also CCN ranges 3400-3499 and 8500-8899)
4000-4499	Psychiatric Hospitals (Excluded from IPPS)
4500-4599	Comprehensive Outpatient Rehabilitation Facilities (also CCN ranges 3200-3299 and 4800-4899)
4600-4799	Community Mental Health Centers (also CCN ranges 1400-1499 and 4900-4999)
4800-4899	Continuation of Comprehensive Outpatient Rehabilitation Facilities (also CCN ranges 3200-3299 and 4500-4599)
4900-4999	Continuation of Community Mental Health Centers (also CCN ranges 1400-1499 and 4600-4799)
5000-6499	Skilled Nursing Facilities
6500-6989	Outpatient Physical Therapy Services
6990-6999	Numbers Reserved (formerly Christian Science Sanatoria (Skilled Nursing Services)
7000-8499	Continuation of Home Health Agencies (also CCN ranges 3100-3199 and 9000-9799)
8500-8899	Continuation of Rural Health Clinics (Provider-based) (also CCN ranges 3400-3499 and 3975-3999)
8900-8999	Continuation of Rural Health Clinics (Free-standing) (also CCN range 3800-3974)
9000-9799	Continuation of Home Health Agencies (also CCN ranges 3100-3199 and 7000-8499)
9800-9899	Transplant Centers
9900-9999	Reserved for Future Use
1/	Special Purpose Renal Dialysis Facilities (SPRDFs – these facilities will be assigned the same CCN whenever they are recertified)

NOTE: Religious Nonmedical Health Care Institutions (RNHCI) are not certified by SAs. The CCN for RNHCIs are assigned by the Boston CMS RO.

EXCEPTION - Organ procurement organizations (OPOs) are assigned a 6-digit alphanumeric CCN. The first 2 digits identify the State Code. The third digit is the alpha character "P." The remaining 3 digits are the unique facility identifier.

EXCEPTION- As of the cost reporting period beginning on or after October 1, 2019, an IPPS-excluded hospital is no longer precluded from having an IPPS-excluded psychiatric and/or rehabilitation unit. See section 2779C and 2779C1 for additional CCN numbering

detail. Note: An IPPS-excluded hospital may not have an IPPS-excluded unit of the same type (psychiatric or rehabilitation) as the hospital (for example, an Inpatient Rehabilitation Facility (IRF) may not have an IRF unit).

2779A2 – CCN for Suppliers

(Rev. 198, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

Suppliers that are paid by Part B carriers have a 10-digit alphanumeric CCN. The first 2 digits identify the State in which the supplier is located. (See list of State Codes under subsection 2779A1.) The third digit is an alpha character that identifies the type of facility. The remaining 7 digits are the unique facility identifier. (Exception: CLIA numbers will continue to be used for fee and certificate issuance.)

The RO assigns the following alpha-characters in the third position as indicated:

C - Ambulatory Surgical Centers
D - Clinical Laboratory Improvement Amendments of 1988 (CLIA) Laboratories
X - Portable X-Ray Facilities

(**Exception**: CLIA numbers are system generated by the database that maintains the CLIA application.)

The last 7 digits of the CCN for the above suppliers will be within the number series 0000001-9999999.

Examples:

ASC	10C0001062
CLIA	45D0634589
Portable X-Ray	21X0009807

2779B – CMS Certification Numbers for Medicaid Providers

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

For certification purposes, title XIX-only providers are identified by a 6-digit alphanumeric CCN. The first 2 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 3 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-J099	Medicaid-Only Short-term acute care hospitals
J100-J199	Medicaid-Only Children's Hospitals
J200-J299	Medicaid-Only Children's Psychiatric Hospitals
J300-J399	Medicaid-Only Psychiatric Hospitals
J400-J499	Medicaid-Only Rehabilitation Hospitals
J500-J599	Medicaid-Only Long-term Hospitals
J600-J999	Reserved for future use

2779C - Special Numbering System for Units of Hospitals That Are Excluded From the Inpatient Prospective Payment System (IPPS) and Hospitals and CAHs with Swing-Bed Approval

(Rev. 198, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

An alpha character in the third position of a hospital's or CAH's CCN identifies either its swing-bed approval or its status as an IPPS-excluded rehabilitation or psychiatric unit. The first 2 digits identify the State in which the provider is located. The third position (which is alpha) identifies the type of unit or swing-bed designation. **The last 3 digits must be exactly the same as the last 3 digits of the CCN of the hospital or CAH operating the unit(s), unless as noted below in Section 2779C1.**

NOTE: As of the cost reporting period beginning on or after October 1, 2019, an IPPS-excluded hospital is no longer precluded from having an IPPS-excluded psychiatric and/or rehabilitation unit (see Section 2779C1 for CCN numbering).

The RO assigns the following alpha-characters in the third position as indicated:

M - Psychiatric Unit of a CAH
R - Rehabilitation Unit of a CAH
S - Psychiatric Unit of a Short-Term, Cancer, Children's, LTCH, or

Rehabilitation Hospital
T - Rehabilitation Unit of a Short-Term, Cancer, Children's, LTCH, or Psychiatric Hospital
U - Swing-Bed Approval for Short-Term Hospitals
W- Swing-Bed Approval for Long-Term Care Hospitals
Z - Swing-Bed Approval for CAHs

EXAMPLE: 21-0101 - ABC Hospital (Short-Term Hospital)

- 21-T101 - ABC Hospital's IPPS-excluded Rehabilitation Unit
- 21-S101 – ABC Hospital's IPPS-excluded Psychiatric Unit
- 21-U101- ABC Hospital's Swing-bed Approval
- **NOTE:** If it meets the applicable requirements, an acute care hospital or a CAH could have swing-bed approval, an IPPS-excluded rehabilitation unit, and/ or an IPPS-excluded psychiatric unit.

2779C1- Special Numbering System for IPPS-Excluded Hospitals with IPPS-Excluded Units

(Rev. 198, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

If an IPPS-excluded hospital also has an IPPS-excluded unit, the fourth position within the CCN requires an additional alpha-character to identify the IPPS-excluded unit type. Note: No special fourth position alpha character is needed for cancer hospitals.

The RO assigns the following alpha-characters in the fourth position as indicated in the table below. Note: This table does not apply to CAHs.

Parent IPPS-Excluded Hospital	Psychiatric Unit Range	Rehab Unit Range
LTCH XX-2000 through XX-2299		
XX-2000 through XX-2099	XX-SA00 through XX-SA99	XX-TA00 through XX-TA99
XX-2100 through XX-2199	XX-SB00 through XX-SB99	XX-TB00 through XX-TB99
XX-2200 through XX-2299	XX-SC00 through XX-SC99	XX-TC00 through XX-TC99
Rehabilitation Hospital XX-3025 through XX-3099	XX-SD00 through XX-SD99	Not Applicable
Children's Hospital XX-3300 through XX-3399	XX-SE00 through XX-SC99	XX-TE00 through XX-TE99

Psychiatric Hospital XX-4000 through XX-4499	Not Applicable	
XX-4000 through XX-4099		XX-TF00 through XX-TF99
XX-4100 through XX-4199		XX-TG00 through XX-TG99
XX-4200 through XX-4299		XX-TH00 through XX-TH99
XX-4300 through XX-4399		XX-TJ00 through XX-TJ99
XX-4400 through XX-4499		XX-TK00 through XX-TK99

NOTE: An IPPS-excluded hospital may not have an IPPS-excluded unit of the same type (psychiatric or rehabilitation) as the hospital (for example, an Inpatient Rehabilitation Facility (IRF) may not have an IRF unit).

EXAMPLE: 21-2026 - XYZ Hospital (IPPS-excluded Long Term Care Hospital)

- 21-SA26 - XYZ Long Term Care Hospital's IPPS-excluded Psychiatric Unit
- 21-TA26 – XYZ Long Term Care Hospital's IPPS-excluded Rehabilitation Unit

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 TYPE	18 or 18/19 SNF	19 NF	ICF/IID
CCN	XX-5000	XX-A000 or XX-E000	XX-G000

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

FACILITY TYPE	18/19 SNF/NF Dually participating	18 SNF or 18/19 Dually participating with SNF or NF DP	18 or 18/19 Dually participating with SNF or NF DP
CCN	XX-5000	XX-5000	XX-5000

FACILITY TYPE	19 NF	19 NF With ICF/IID DP
CCN	XX-A000	XX-A000 or XX-E000 or XX-G000*

***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.

2779E - Assigning Emergency Hospital CMS Certification Numbers (Non-Participating Hospitals)

(Rev. 29, Issued: 04-20-07; Effective/Implementation Dates: 10-01-2007)

The CCN for emergency hospitals is a 6-position alphanumeric code. The first 2 digits are the State code. The third, fourth, and fifth digits represent a sequence number. The first emergency number in a State would contain the sequence number 001. In the sixth position use the letter "E" for non-Federal emergency hospitals, or "F" for Federal emergency hospitals. For example, the 34th emergency hospital issued a CCN in Maryland would have the number "21-034E." The RO assigns the CCN in strict numerical sequence without regard to the Federal or non-Federal status. If a terminated facility again qualifies as an emergency hospital, the RO issues a new CCN. For a non-participating hospital that is now fully participating, see subsection I.

2779F - Merger of Facilities or CHOW

(Rev. 29, Issued: 04-20-07; Effective/Implementation Dates: 10-01-2007)

The RO does not change the CCN merely because the institution has been sold, or has changed ownership or its form of business organization. If 2 or more pre-existing provider enterprises have merged, but continue to operate as separate facilities, each will

have a separate provider agreement and will keep its original number. This is true even though the merged-but-separate facilities may adopt a common name.

However, if the merged facilities operate as a single institution, it must submit a single cost report, which necessitates a single provider agreement/CCN.

When the RO assigns a single CCN, the notices of utilization mailed to beneficiaries will not identify which component rendered the service but will show the name of the organization to which the CCN is assigned (which may be entirely different from the name of the component). To avoid misunderstanding on the part of beneficiaries, CMS must approve, in advance, some method devised by the provider for informing its Medicare patients as to the designation on the notices of utilization. The RO uses the CCN previously assigned to the larger of the merging facilities or, in the case of the merger of 2 provider corporations, uses the CCN of the surviving corporation and retires the other number or numbers.

These principles also apply if providers merge with previous non-providers. In a merger of corporations where the non-provider corporation is the surviving corporation and the facilities will use a common number, retain the original number.

This rule does not, however, preclude retention of a separate number for a distinct part SNF, or for a distinct part of a psychiatric hospital.

2779G - Notification of Change in CMS Certification Numbers
(Rev. 29, Issued: 04-20-07; Effective/Implementation Dates: 10-01-2007)

To notify the intermediary of a correction of a CCN, or the assignment of any number different from that initially sent to a hospital, the RO prepares a CMS-2007. Follow the procedure in §2783 noting in Item V of CMS-2007 the reason for the number change.

2779H - Retirement of CMS Certification Numbers
(Rev. 29, Issued: 04-20-07; Effective/Implementation Dates: 10-01-2007)

The CCN will be classified as **retired** in these situations:

- The provider agreement is terminated;

  EXCEPTION: Where a terminated facility is subsequently reinstated as a provider of services **fully retroactive** to the day of its termination, the RO reassigns the original CCN as there has been no break in the period of participation. When this occurs, show “reinstated with no break in participation,” in item 24 of Form CMS-1539:

- An erroneous assignment that is **used** by the facility is subsequently replaced by the RO with a correct number; or

- A non-participating hospital or SNF now meets the requirements and wishes to

participate. The RO assigns a new number and retires the old number.

2779I - Control of CMS Certification Numbers
(Rev. 29, Issued: 04-20-07; Effective/Implementation Dates: 10-01-2007)

The RO may give responsibility for assigning the CCN to one person, with sufficient alternates so that a trained person will always be available. This control may be maintained electronically or manually. The following is a suggested manual control:

Prepare a loose-leaf ledger for the numbers with a tab divider for each State. Maintain separate pages for each type of provider, including non-participating emergency hospitals, and make entries in strict numerical sequence.

2779J - ESRD CMS Certification Numbers
(Rev. 29, Issued: 04-20-07; Effective/Implementation Dates: 10-01-2007)

It is important for both reimbursement and survey purposes to assign the ESRD facility the correct CCN in accordance with the guidelines contained in §2779.A.1.
ESRD facilities and their CCN are as follows:

0001-0879	Short Term (General and Specialty) Hospitals
2000-2299	Long Term Hospitals
2300-2499	Chronic Renal Disease Facilities (Hospital-Based)
2500-2899	Non-Hospital Renal Disease Treatment Centers
2900-2999	Independent Special Purpose Renal Disease Facilities
3300-3399	Children's Hospitals
3500-3699	Renal Disease Treatment Centers (Hospital Satellites)
3700-3799	Hospital-Based Special Purpose Renal Dialysis Facilities

1 - Hospital-Based Renal Dialysis Facilities, 2300-2499

The CMS is required to make determinations concerning hospital-based and independent ESRD facilities to determine their proper reimbursement in accordance with §1881(b)(7), 42 CFR 413.174, and §2287. Please note that in accordance with 42 CFR 413.174(d)(3). The physical location of an ESRD facility on the premises of a hospital is not considered when determining if the ESRD facility is hospital-based. In accordance with 42 CFR 413.174, hospital corporate control is a critical factor in determining whether an ESRD facility is hospital-based. Hospitals may have a lease arrangement for the management of a hospital-based ESRD facility by a non-hospital manager.

ESRD CCN 2300-2499, for Hospital-Based Renal Dialysis Facilities are used for ESRD facilities that have been determined by the CMS to be hospital-owned, hospital-administered ESRD facilities physically located on the hospital's premises as opposed to independent ESRD facilities and Hospital-Based Renal Disease Satellite Facilities. The satellites are hospital-based, but are physically located off the hospital's premises.

2 - Hospital-Based Renal Dialysis Satellite Facilities, 3500-3699

ESRD CCN 3500-3699 for Hospital-Based Renal Dialysis Satellite Facilities are used for those ESRD facilities that are hospital-owned and hospital administered, but that are not located on the hospital's premises. This is why they are referred to as hospital-based satellites. In determining whether such a satellite facility is hospital-based, use the same criteria as you would in making a hospital-based determination under the 2300-2499 series, except that you would assign a 3500-3699 number to such a facility because it is off the premises of the hospital to which it is based. The word premises per se is not defined in the statute, regulations, or in the SOM, but there is a definition of "furnishes on the premises" at 42 CFR 405.2102 that states "the ESRD facility furnishes services on its main premises; or its other premises that are: (a) contiguous with or in immediate proximity to the main premises, and under the direction of the same professional staff and governing body as the main premises, or (b) approved on a time-limited basis as a special purpose renal dialysis facility." Thus, in addition to the regulations, which should assist you in determining whether the facility is an integral part of the hospital, you may use the "furnishes on the premises" definition to distinguish between a hospital-based entity under the 2300-2499 series as opposed to an entity under the 3500-3699 number series. Also, we do not believe that these satellites will be furnishing inpatient dialysis services. The CMS will make or approve the determination that a particular ESRD facility meets the requirements to be hospital-based, and if it is off the hospital's premises, a hospital-based satellite.

It is conceivable that a hospital-based ESRD facility could have a 2300-2499 number assigned to the location on the hospital's premises, and one or more 3500-3699 numbers for those locations (satellites) off the premises (each satellite is given a separate 3500-3699 number). If an ESRD facility that is assigned a 2300-2499 number moves off the hospital's premises and is determined to be a satellite, it should receive a number in the 3500-3699 series. However, if a satellite changes its address but is still considered off the hospital's premises, it should retain the 3500-3699 number it was originally issued rather than being issued a new 3500-3699 number. Any questions concerning billing should be referred to the RO financial component or the fiscal intermediary as you determine appropriate.

NOTE: In determining whether an entity is hospital-based for reimbursement purposes, the requirements at §2287 must be met.

3 - Hospital-Based Special Purpose Renal Dialysis Facilities, 3700-3799

In order to be classified as a Hospital-Based Special Purpose Renal Dialysis Facility and issued a number under the 3700-3799 series, an ESRD facility must be determined to be hospital-based, and meet the definition at 42 CFR 405.2102, and the requirements at 42 CFR 405.2164 for such a facility. A facility under this category should bill Medicare under the CCN of the hospital to which it is based. There should be very few of these facilities.

4 - Independent Renal Dialysis Facilities, 2500-2899

Independent Renal Dialysis Facilities, issued a number under the 2500-2899 series, are independent ESRD facilities. These facilities do not meet the definition of hospital-based irrespective of whether they are located on or off the hospital's premises. A determination of independent, as opposed to hospital-based, will be based on the statutory and regulatory provisions and manual instructions. Independent facilities bill under their own numbers. ESRD facilities located at skilled nursing facilities will be determined to be independent.

5 - Independent Special Purpose Renal Dialysis Facilities, 2900-2999

The same requirements that apply to a Hospital-Based Special Purpose Renal Dialysis Facility apply to a facility of the same type which is independent except that the independent facility by virtue of its independent status, bills under its own number which is in the 2900-2999 series.

6 - Other

When an ESRD facility proposes to change from hospital-based to independent or vice-versa, an onsite survey is not necessary unless there is a physical relocation of the facility. However, a determination as to the proper facility definition and if necessary, the changing of the number designation, must be made in accordance with the guidance described here and in §2287. If an ESRD facility proposes to add a location that has not been previously surveyed, an onsite inspection would be required. In the absence of an onsite survey and certification, the proposed facility has no authority to bill Medicare for ESRD services provided at the proposed site. (See §3222.) There are some instances when an ESRD facility's CCN requires a change as a result of an action taken by the ESRD facility. If a hospital-based facility converts to an independent ESRD facility or if an independent ESRD facility converts to a hospital-based ESRD facility, there must be a CCN change. Satellite ESRD facilities must be hospital owned and are considered hospital-based. A hospital may have more than one ESRD satellite facility.

The CCN of the ESRD facility may remain the same in the following situations:

- A hospital-based ESRD facility retains ownership of the facility but contracts with another entity for management of the facility;

- The hospital closes the dialysis facility but retains its transplant program. The CMS terminates the outpatient dialysis services but retains the ESRD CCN for the still active transplant program;

- The hospital closes the transplant program but retains the ESRD facility. In such case, CMS terminates the transplant program but keeps the ESRD CCN active for the dialysis program;

- The ESRD facility is purchased by another ESRD facility of the same type. For example, independent by independent or hospital-based by hospital-based; and

- The geographic location of the ESRD facility is changed within the same state. A recertification survey is always required when a dialysis facility relocates within a state. If a geographic location is changed to another state, the ESRD facility at the old location must be terminated and the relocated ESRD facility must qualify as a new applicant with a new identification number in the state to which it moved.

Information contained in Medicare approval letters of ESRD facilities that are issued numbers under the above categories is essential in central office for data collection and program information purposes. Therefore, please send a copy of all Medicare approval letters issued in your region to:

Centers for Medicare & Medicaid Services
Office of Clinical Standards and Quality
Information Systems Group
7500 Security Boulevard
Mail Stop S3-02-01
Baltimore, Maryland 21244-1850.

You should also send to the Office of Clinical Standards and Quality (OCSQ) notices of any numbers that are terminated or changed (e.g., hospital-based to independent or vice-versa) for whatever reasons. In addition, it would be helpful if all ESRD facility notices, including those sent to the fiscal intermediary, contain the CCN of the ESRD facility to which the notice applies (numbers of both the ESRD facility and the hospital to which it is based, when applicable). You should apprise the appropriate ESRD network of the information mentioned above at the same time that you notify OCSQ. A Form CMS-855A must be completed by the ESRD facility when there is a change, addition, or deletion affecting an ESRD facility. You should follow the instructions for issuing a "Provider Tie-In Notice," Form CMS-2000, when an ESRD facility is being added, deleted, or changed. This is particularly important because fiscal intermediaries often cross regional boundaries.

NOTE: The RO refers **all** Forms CMS-1539 that report changes in provider status to its data entry section for input into the ASPEN data system.

When ROs send correspondence concerning certification to ESRD facilities, the following information should always appear:

- The assigned CCN with caption;
- CMS cross reference CCN with caption (if applicable);
- Medicare approval date;
- Number of stations;
- Services offered;

- Name of facility;
- Facility's physical location address;
- Facility's mailing address;
- Facility's type or status (hospital-based/independent/satellite);
- Facility contact for ESRD network;
- Facility ownership (corporation/partnership/sole proprietorship/etc.; and
- RO contact (name and phone number).

EXAMPLE

Maryland
Short-Term Hospitals

CCN	Name and Address of Provider	Date # Assigned
21-0001	Calvert Hospital 101 Chase Street Baltimore, Maryland	4/10/66
21-0002	Red River Hospital 401 River Road Baltimore, Maryland	4/11/66

2779K – HHA Branch CMS Certification Numbers

(Rev. 29, Issued: 04-20-07; Effective/Implementation Dates: 10-01-2007)

HHA Branches are identified by the assignment of a 10-digit alpha-numeric number. Each branch is numbered with the same CCN as the parent or subunit with 2 modifications: (1) The letter "Q" will be in the third position between the state code and the 4-digit provider designation; and (2) three additional digits are added to the end of the number. The last 3 digits are a one-up number for each consecutive branch. These digits allow the capability of assigning up to 999 branches to one parent or subunit HHA. The branch CCN will be used only once. In the event that an HHA branch closes, its unique branch CCN is terminated and will not be reused to identify another branch of that HHA or subunit.

Example: ABC Home Health Agency has three branches. Its CCN is 017001. ABC's three branches would be assigned the numbers 01Q7001001, 01Q7001002, and 01Q7001003.

2779L – Outpatient Physical Therapy (OPT) Extension CMS

Certification Numbers
(Rev. 29, Issued: 04-20-07; Effective/Implementation Dates: 10-01-2007)

OPT extensions are identified by the assignment of a 10-digit alpha-numeric number.

Each extension is numbered with the same CCN as the parent with two modifications: (1) The letter "P" will be in the third position between the state code and the 4-digit provider designation; and (2) three additional digits are added to the end of the number. The last 3 digits are a one-up sequence number for each extension number starting with 001. These digits allow the capability of assigning up to 999 extensions to one OPT. The extension CCN will be used only once. In the event that an OPT extension closes, its unique extension identification number is terminated and will not be reused to identify another extension of that OPT.

OPT extension CCN are not used for reimbursement purposes.

Example: Vibrant Physical Therapy has three extensions. Its CCN is 556599. Vibrant's three extensions would be assigned the numbers 55P6599001, 55P6599002, and 55P6599003.

2780 - Effective Date of Provider Agreement, Form CMS-1561, and Supplier Approval
(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

The effective date of participation in the Medicare program, i.e., of the provider agreement or supplier approval issued by the RO, may not be earlier than the date on which the provider or supplier meets all Federal requirements. See Section 2008D for discussion of Federal requirements. While the on-site initial certification survey is often the final Federal requirement that is met, this is not always the case. For example, when the applicant has not submitted required Office of Civil Rights documentation prior to the survey, the determination of compliance with the requirements of the Office of Civil Rights may be the final requirement that is met and thus be the effective date of the provider agreement or supplier approval. Another example may be if the MAC verification inadvertently occurred after the onsite survey was conducted or, for HHAs, when the second MAC review requires additional information for verification of the information, then the effective date would be on that date.

2780A - Compliance with All Federal Requirements
(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

The agreement is effective on the date the onsite survey is completed if, on the date of the survey the entity not only meets all Federal health and safety standards, i.e., the CoPs, CfCs or Requirements (for SNFs), but also has met all other applicable Federal requirements for Medicare participation.

2780B - All Health and Safety Standards Are Not Met on the Day of the

Survey
(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

If on the initial certification survey the provider or supplier does not meet all applicable health and safety standards, then, assuming all other Federal requirements have been met, the effective date of the Medicare agreement would be:

- For SNFs, the date the SNF has been found to be in substantial compliance with the requirements for participation, and, if applicable, has submitted an approvable waiver request. (See 42 CFR 488.301.)

- For non-long term care providers/suppliers, the date when the provider/supplier has:

    - Met all applicable conditions, i.e., has no deficiency citations; **or**

    - Has been found to be in substantial compliance, but has standard-level deficiencies and the SA or AO has received an acceptable plan of correction (POC) and/or CMS receives an approvable waiver request. If a provider or supplier submits both a POC and an approvable waiver request, the later of the dates of the two submissions would be the effective date.

- Effective dates of Medicare participation for NFs requesting to participate in the Medicare program as SNFs can be any date during the certification period as long as the provider is in substantial compliance with all requirements and if applicable, have an approved waiver.

- For Medicaid-only facilities, the SA determines whether the PoC is acceptable and whether waiver requests for ICFs/IID are approvable. LSC waivers for Medicaid NFs require the RO's approval.

Retroactive SA certifications of compliance with health and safety standards or AO accreditation decisions prior to the survey end date are not permitted under any circumstances.

2781 - RO Countersigning Provider Agreement
(Rev. 1, 05-21-04)

After determining that all title XVIII and appropriate civil rights requirements are met, the RO signs the Health Insurance Benefits Agreement (Form CMS-1561).

Before countersigning the provider agreement the RO must be certain that the name on line 2 of the agreement after the term "Social Security Act" does, in fact, include both the true name of the provider entrepreneur and the trade name of the entity, rather than only the trade name.

For example, a partnership of several persons doing business as East Care Home Health Services completes the second line of the agreement to read: "Robert Johnson, Louis

Miller, and Paul Allen, ptrs., East Care Home Health Services;" the ABC Corporation, using the trade name Community General Hospital, completes the agreement to read: "ABC Corporation d/b/a Community General Hospital." In the case of sole proprietorship, the agreement will read: "John Smith d/b/a Mercy Hospital."

The business name on the agreement should ordinarily conform to the name on all official (i.e., IRS) correspondence/forms concerning payroll withholding taxes, such as the SS-4, W-3, S-l, or 941 forms. The instructions on the SS-4 (Application for Employer Identification Number) clearly differentiate between the true or entrepreneurial name and the trade name. If a question arises regarding an owner's name as it appears on the provider agreement, the RO should refer to the above documents.

2782 - RO Notice of Acceptance
(Rev. 1, 05-21-04)

The RO transmits a letter of acceptance (Exhibit 165) to the provider and encloses a copy of the completed Form CMS-1561. The RO includes in the letter the following notation: "The (name of intermediary) has been authorized to serve as your fiscal intermediary." This is the official notice to the provider of its designated intermediary. In all acceptance notices for hospitals, the RO should state that the agreement applies to the entire hospital, or identify the distinct part (including PPS-excluded psychiatric or rehabilitation units covered by the agreement) or portions of the hospital covered and not covered in the case of a general hospital complex.

In the case of a new hospital the notice must clearly establish the provider numbers which apply to each part of the institution. If a request to establish a PPS-excluded psychiatric or rehabilitation unit or swing-bed approval is refused, the RO must be sure that the refusal is reflected in the Notice of Acceptance.

The provider number (see §2779) must be imprinted on the agreement, or if more than one provider number is assigned, all numbers must be imprinted on the agreement. The RO furnishes the SA and intermediary with a copy of the provider letter. This will assure that the SA and intermediary understand what action has been taken on distinct parts or excluded units.

2783 - Provider Tie-In Notice (Form CMS-2007)
(Rev. 1, 05-21-04)

2783A – Purpose
(Rev. 201, Issued: 06-19-20, Effective: 06-19-20, Implementation: 07-27-20)

Form CMS-2007 (Exhibit 156) is the official notice to the *MAC* of changes in its list of providers *or suppliers* (additions, deletions, corrections, recertifications, and terminations).

2783B - *CMS* Responsibility for Form CMS-2007 Completion

(Rev. 201, Issued: 06-19-20, Effective: 06-19-20, Implementation: 07-27-20)

The RO completes a Form CMS-2007 each time a provider *or supplier* is added to or deleted from a *MAC's* list of providers *and suppliers* or when current provider-supplier tie-in records require correction and sends it at the time the provider agreement or supplier approval is countersigned by its office. In *involuntary* termination actions, the RO sends it at the same time it issues official notification to the provider *or supplier*.

2783C - *CMS* Completion of Form CMS-2007

(Rev. 201, Issued: 06-19-20, Effective: 06-19-20, Implementation: 07-27-20)

Item I - Identifying Information - This section is self-explanatory. Complete it in all instances.

Item II - New Provider *or Supplier* Certification - *CMS* completes this section when a new provider *or supplier* enters the program or when a participating provider *or supplier* has changed ownership. Items A, C, and D are completed in all cases, and Items E through H for changes in ownership. In item B, *CMS* shows the month and day of the provider's *or supplier's* fiscal year ending date for Medicare cost report purposes *(if it summits cost reports)* if the information is available or is readily obtainable. *CMS* contacts the provider *or supplier* directly or solicits the aid of the *MAC* to determine the provider's *or supplier's Medicare* fiscal year ending date. There should be no delay issuing this notice even if the fiscal year information is not obtainable or is not known at the time of certification.

This procedure assures that *CMS* contacts a responsible official or officer of the provider *or supplier* for this information and allows several days for the provider *or supplier* to respond when it appears the information is currently available. The information is not considered readily available if the provider does not know or will decide at a later date.

Item III - Change of *MAC* – *This* section *is not applicable to t*he RO.

Item IV – Termination -This section is completed when a provider *or supplier* involuntarily ends its participation in the program. *When* the new owner *rejects assignment of the existing Medicare agreement following a change in ownership* it *is treated* as a voluntary termination.

Item V – Remarks –*CMS* uses this section for pertinent information. If the provider is part of a chain, insert the name and address of a parent or controlling organization in this section. If Form CMS-2007 corrects previously furnished information, include an explanation of the change.
If a SNF's participation will end, include an explanation relating to services after termination (see §§3008.1 and 3008.2) in the remarks.

EXAMPLE: An agreement with a participating SNF is involuntarily terminated for cause (e.g., failure to file cost reports), and the effective date of termination is established as

October 15, *2015*. As with all providers, this termination takes effect on *(0001 hours on a 24 hour clock)* October 15, *2015*, and not at the close of *(2400 hours on a 24 hour clock)* October 15, *2015*. Therefore, the remarks should indicate "Termination for cause--payment can continue for up to 30 calendar days of post-hospital skilled nursing care services furnished **on or after** October 15, *2015*, to beneficiaries admitted to the facility **before** October 15, *2015*. Do not make payment for new admissions which occur **on or after** October 15, *2015*."

2783D – Distribution

(Rev. 201, Issued: 06-19-20, Effective: 06-19-20, Implementation: 07-27-20)

Whenever there is a change to Form CMS-2007 (new provider *or supplier*, change in *MAC*, or *involuntary* termination) *CMS* forwards *a* copy to the provider's *or supplier's MAC*.

2784 - Effective Date of Certification of Coverage for Suppliers of Services

(Rev. 1, 05-21-04)

The effective date of certification of coverage is the date the SA survey is completed if the supplier is found in compliance with applicable Conditions for Coverage and all other applicable Federal requirements.

If the supplier is found not to be in compliance with all Conditions for Coverage, and all other applicable requirements on the date the survey is completed, then its effective date will be the earlier of the following dates:

- The date on which the supplier meets all requirements; or
- The date on which the supplier is found to meet all Conditions for Coverage and the supplier submits an acceptable PoC for lower level deficiencies or an approvable waiver request, or both. (See 42 CFR 489.13.)

The effective date is linked to the survey date. The RO ensures that the SA surveys the supplier promptly after notification that the supplier has enrolled and is fully operational. The RO uses Exhibit 166 to notify a supplier of its approval.

Provider agreements and supplier participation are determined in the same fashion. Medicaid has no suppliers; they are all providers.

NOTE: RHCs and ASCs, which are suppliers, are subject to the provisions of category-specific agreements which function like provider agreements. When notifying RHCs or ASCs of initial certification, complete, countersign and enclose the appropriate Health Insurance Benefits Agreement Form, Form CMS-1561A (Exhibit 4B), or Form CMS-370 (Exhibit 65), respectively. An FQHC's attestation statement serves as its benefit agreement.

The RO notifies Part B carriers of the effective dates of coverage for all suppliers.

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.

Organ Procurement Organizations

2810 - Organ Procurement Organizations (OPOs) – Citations - Statutory Authority

(Rev. 111, Issued: 04-11-14, Effective: 04-11-14, Implemetation: 04-11-14)

Section §1138 (b)(1) of the Social Security Act (the Act) authorizes the Secretary to provide payment under Medicare or Medicaid to hospitals/CAHs and transplant centers for the cost of organs procured from organ procurement organizations (OPOs) only if the organization:

- Is a qualified OPO operating under a grant made under **§371(a)** of the Public Health Service Act (PHSA), or has been certified or recertified by the Secretary within the previous four years as meeting the standards to be a qualified OPO;
- Meets applicable requirements of Medicare or Medicaid for OPOs;
- Meets performance-related standards prescribed by the Secretary;
- Is a member of and abides by the rules and requirements of the Organ Procurement and Transplantation Network (OPTN) designated by the Secretary pursuant to **§372** of the PHSA. (The United Network for Organ Sharing (UNOS) operates the OPTN under a contract with the PHS);
- Allocates organs, within its service area and nationally, in accordance with medical criteria and the policies of the OPTN; and
- Is designated or re-designated by the Secretary as an OPO under **§1138** of the Act.

To be designated as the OPO for a service area, an organization must at the time of application and throughout the period of designation meet these statutory requirements. Further, the Act requires that the Secretary may not designate more than one OPO for each service area, as described in **§371 (b)(1)(E**) of the PHSA and §1138 (b)(2) of the Act.

2810.1 - Definitions

(Rev. 111, Issued: 04-11-14, Effective: 04-11-14, Implemetation: 04-11-14)

Certification means a CMS determination that an OPO meets the requirements for certification at **42 CFR 486.303.**

Decertification means a CMS determination that an OPO no longer meets the requirements for certification at **42 CFR 486.303.**

Designation means CMS assignment of a geographic service area to an OPO. Once an OPO is certified and assigned a geographic service area, organ procurement costs of the OPO are eligible for Medicare and Medicaid payment under **Section 1138(b)(1)(F)** of the

Act.

Open area means an OPO service area for which CMS has notified the public that it is accepting applications for designation.

Organ Procurement Organization (OPO) means an organization that performs or coordinates the procurement, preservation, and transport of organs and maintains a system for locating prospective beneficiaries for available organs.

Re-certification cycle means the 4-year cycle during which an OPO is certified.

Transplant Hospital means a hospital that provides organ transplants and other medical and surgical specialty services required for the care of transplant patients. There may be one or more types of organ **transplant centers** operating within the same transplant hospital.

Urgent need occurs when an OPO is non-compliant with one or more conditions for coverage and this has caused, or is likely to cause, serious injury, harm, impairment, or death to a potential or actual donor or an organ recipient.

2811 - OPO Requirements for Certification

(Rev. 111, Issued: 04-11-14, Effective: 04-11-14, Implemetation: 04-11-14)

42 CFR 486.303 details the following requirements that an OPO must meet in order to be certified by CMS. A qualified OPO:

1. Must have received a grant under **42 U.S.C. 273(a)** or have been certified or re-certified by the Secretary within the previous 4 years as being a qualified OPO;

2. Be a non-profit entity that is exempt from Federal income taxation under section 501 of the Internal Revenue Code of 1986;

3. Have accounting and other fiscal procedures necessary to assure the fiscal stability of the organization, including procedures to obtain payment for kidneys and non-renal organs provided to transplant hospitals;

4. Have an agreement with CMS, as the Secretary's designated representative, to be reimbursed under Title XVIII for the procurement of kidneys;

5. Have been re-certified as an OPO under the Medicare program from January 1, 2002 through December 31, 2005;

6. Have procedures to obtain payment for non-renal organs provided to transplant centers;

7. Agree to enter into an agreement with any hospital or CAH in the OPO's service area, including a transplant hospital that requests an agreement;

8. Meet or have met the conditions for coverage for OPOs, including both the outcome measures and the process performance measures; and

Meet the provisions of Titles XI, XVIII, and XIX of the Act, section 371(b) of the PHSA, and any other applicable Federal regulations.

2812 - OPO Designation Requirements

(Rev. 111, Issued: 04-11-14, Effective: 04-11-14, Implemetation: 04-11-14)

An OPO must be designated by CMS and must enter into an agreement with CMS in order for the OPO to be reimbursed under Medicare and Medicaid for the costs of organ procurement.

42 CFR 486.306(b) and (c) details the requirements that an OPO must meet for service area designation, service area location, and characteristics.

42 CFR 486.308 specifies that CMS designates only one OPO per service area and that the service area is only **open for competition** after the OPO designated for that area is de-certified and all administrative appeals have been completed under §486.314, or the OPO voluntarily withdraws from the program. A designated OPO may only change its service area boundaries as a result of a merger or consolidation with another OPO after advance approval by CMS as noted in §486.310 (a). An OPO must compete for an entire service area according to §486.316(c)(3).

An OPO is normally designated for a 4-year agreement cycle. In the case of a voluntary termination of its agreement, CMS will open the service area for competition to fill the remaining term of the 4-year agreement cycle. A designation period may be longer than the 4-year agreement cycle in instances where CMS requires a longer period of time to select a successor to an OPO that has been de-certified or has voluntarily terminated.

2812.2 - Waivers

(Rev. 111, Issued: 04-11-14, Effective: 04-11-14, Implemetation: 04-11-14)

A certified hospital/CAH must enter into an agreement only with the OPO designated for the service area in which the hospital/CAH is located, unless CMS has granted the hospital/CAH a **waiver** under §486.308(e). A hospital/CAH may request and CMS may grant a waiver allowing the hospital to have an agreement with a designated OPO outside of its service area. To qualify for a waiver, the hospital must submit data to CMS as detailed in **42 CFR 486.308(e)(1) and (2)**. In making a determination on waiver requests, CMS considers the requirement under **42 CFR 486.308 (f)(1)-(4):**

- Cost effectiveness;
- Improvements in quality;
- Changes in a hospital's designated OPO due to changes in the definition of

metropolitan statistical areas, if applicable; and

- The length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO.

A hospital/CAH may continue to operate under its existing agreement with an out-of-area OPO while CMS is processing the waiver request. If the waiver is denied by CMS, the hospital/CAH must enter into an agreement with the OPO designated for its service area within 30 days of notification of the final determination as noted in §486.308(g).

2812.3 – Opening the Donation Service Area (DSA) for Competition from other OPOs (42 CFR 486.316)

(Rev. 179, Issued: 07-06- 18, Effective: 07-06-18, Implantation: 07- 06-18)

The CMS RO opens an OPO's DSA for competition if:

a. CMS terminates or de-certifies the OPO (involuntary termination) during the current certification period due to non-compliance with the Conditions for Coverage;
b. The normal four year certification period has ended and CMS declines to renew its agreement with the OPO under §486.316 (non-renewal of an agreement); or
c. An OPO ceases to operate or CMS has reasonable grounds for anticipating it will cease to operate (voluntary termination by the OPO).

For a voluntary termination including a cessation of business, the RO opens the DSA for competition on the CMS-approved effective date of the termination. For an involuntary termination of an OPO or the non-renewal of an OPO's agreement, the RO will open the area for competition either on the date of the completion of the administrative appeals process which upholds the termination action or once the time to file an appeal has passed and the OPO has declined to do so. A de-certified OPO cannot compete for its open area or any other open area.

Simultaneously with opening the DSA for competition, the RO will request a transition plan from the non-renewed OPO that provides details on how all aspects of the OPO operation will be transmitted, including time frames, to a new OPO (see SOM Section 2812.4(a)-(l) below).

The CMS RO will announce the opening of the DSA in an email to all currently certified OPOs and the Association of Organ Procurement Organizations. The following entities will be copied on the communication:

- The CMS Center for Medicare;
- The CMS Medicare Administrative Contractor for the non-renewed OPO (Form CMS-2007 Provider Tie-In Notice) (required);and
- The Health Resources and Services Administration (HRSA).

The announcement will specify what information must be submitted by any OPO applicant, the deadline for submission of an application (which will be set at 45 calendar days from the date of the announcement), and the expected timeframe for selection of an

applicant (which will generally be 30 calendar days from the application closing date). In the case of involuntary termination or non-renewal of an agreement, CMS may extend the agreement of the de-certified OPO to facilitate transition to a new OPO.

In order to apply for an open DSA, an applicant OPO must meet the following criteria:

a. Be in compliance with two out the three outcome measure requirements at 42 CFR 486.318;
b. Be at or above 100 percent of the mean national rate averaged over the years of the re-certification cycle for the outcome measures at 42 CFR 486.318;
c. Be at least 15 percentage points higher than the donation rate at 42 CFR 486.318 of the OPO currently designated for the service area;
d. Be in compliance with the requirements for certification at 42 CFR 486.303, including the conditions for coverage at 42 CFR 486.320 through 42 CFR 486.348; and
e. Compete for the entire service area.

2812.4 – Application

(Rev. 179, Issued: 07-06- 18, Effective: 07-06-18, Implantation: 07- 06-18)

The applicant must submit the following information to the CMS RO by the deadline set out in the open competition announcement:

- Completed CMS -Form 576A;
- Transition plan that includes timelines for all aspects of the transition including, but not limited to:
    a. Physical location (office);
    b. Policies for community outreach;
    c. Coordination with transplant hospitals in the DSA;
    d. Coordination with donor hospitals in the DSA;
    e. Coordination with tissue and eye banks in the DSA;
    f. Constitution of an Advisory Board;
    g. Governing Body oversight of the successful transition of the DSA;
    h. Plan for staff retention or additions to ensure adequate and trained staff coverage in the open area;
    i. Transfer of donor data;
    j. Name of Medical Officer;
    k. A plan for prompt response to hospital referrals; and
    l. Plan for identifying and addressing the unique challenges of the DSA which impact the performance of the OPO.

2812.5 - Application Review

(Rev. 179, Issued: 07-06- 18, Effective: 07-06-18, Implantation: 07- 06-18)

The applicant OPO must submit its application by the specified deadline to the CMS RO for review. The RO will assemble a panel to review the applications. Each application will be reviewed according to the following criteria at 42 CFR 486.316(d):

a. Compliance with the outcome measures at 42 CFR 486.318;
b. Compliance with 42 CFR 486.320 through 42 CFR 486.348;

c. Contiguity to the open service area; and
d. Success in identifying and overcoming barriers to donation within its own service area and the relevance of those barriers to barriers in the open area. An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

2812.6 - Selection Process

(Rev. 179, Issued: 07-06- 18, Effective: 07-06-18, Implantation: 07- 06-18)

The CMS RO will complete a review of all applications within 30 calendar days of the application closing date. The RO will either make a selection of a successor OPO for the DSA or decline to accept all applications (see below at SOM Section 2812.8). The OPO selected will be notified of this selection in writing by the RO and the DSA will be redesignated to the selected OPO. The following entities will be copied on the communication to the OPO:

- The CMS Center for Medicare;
- The CMS Medicare Administrative Contractor (Form CMS-2007, Provider Tie-In Notice);
- The Association of Organ Procurement Organizations (AOPO); and
- The Health Resources and Services Administration (HRSA).

2812.7 - OPO Transition

(Rev. 179, Issued: 07-06- 18, Effective: 07-06-18, Implantation: 07- 06-18)

The newly designated OPO will submit a monthly summary to the CMS RO to report on its transition activities. The CMS RO will monitor the transition process to ensure successful oversight and management of OPO operations. The RO will conduct a full survey of the newly designated OPO within six months of the transition to determine compliance with the Conditions for Coverage.

2812.8 - No OPO applications for the open DSA

(Rev. 179, Issued: 07-06- 18, Effective: 07-06-18, Implantation: 07- 06-18)

If no OPO applies for an open DSA or if CMS declines to accept all applications, CMS may select a single OPO to take over the entire open DSA or may adjust the service area boundaries of two or more contiguous OPOs to incorporate the open DSA. The RO will make its decision based on the selection criteria at 42 CFR 486.316(d).

2813 – Re-Certification Cycle (42 CFR 486.309)

(Rev. 111, Issued: 04-11-14, Effective: 04-11-14, Implemetation: 04-11-14)

An OPO is considered re-certified if it meets the standards of a qualified OPO within the 4-year period beginning from August 1, 2006 through July 31, 2010; August 1, 2010 through July 31, 2014; August 1, 2014 through July 31, 2018; August 1, 2018 through July 31, 2022; and onwards.

An OPO is surveyed once every four years and its service area is not opened for competition when the OPO:

- Meets all 3 outcome measure requirements at **42 CFR 486.318;** and

- Has been shown by the results of a survey to be in compliance with the certification requirements at **42 CFR 486.303**, including the conditions for coverage at **42 CFR 486.320 through 486.348**.

2814 – Change in Control/Ownership or Service Area (42 CFR 486.310)

(Rev. 111, Issued: 04-11-14, Effective: 04-11-14, Implemetation: 04-11-14)

The applicable CMS RO must be notified **before** a designated OPO implements a change in either ownership or control or in its service area. The OPO must provide information to the CMS RO that is specific to the board structure of the new organization, as well as operating budgets, financial information, and other written documentation the CMS RO determines to be necessary for designation. A designated OPO considering a change in its service area must obtain prior CMS RO approval.

If an OPO's change of ownership or control is of such an extent that it no longer meets the requirements for designation as an OPO, as determined on **Form CMS-576**, CMS may de-certify the OPO and designate its service area an open area. The OPO may appeal such a de-certification under §486.314. The service area is not opened for competition until the conclusion of the administrative appeals process. The OPO must submit a revised **Form CMS-855** (Medicare Enrollment Application) to the FI/MAC with any change of control or ownership.

*** See 2812.3 Open Competition**

When the CMS RO receives notification of a prospective change in control or ownership for a designated OPO, the CMS RO must determine, based upon the documents submitted, that the operation of the OPO will continue uninterrupted and continue to satisfy Medicare and Medicaid requirements during and following the changeover of ownership or control. The CMS RO will review all the documents submitted by the OPO, including its responses to the elements on Form CMS-576. If the RO approves the CHOW/change of control and the OPO proceeds with change of ownership a new CMS Form 576 must be signed by the person designated by the governing body to be responsible for operations. The OPO should show evidence of transition planning to ensure continuity. Confirm with the Fiscal Intermediary/MAC that the OPO has submitted a revised CMS Form-855 and that the information has been accepted.

De-certification (42 CFR 486.312)

2815 – De-certification and Competition:

(Rev. 111, Issued: 04-11-14, Effective: 04-11-14, Implemetation: 04-11-14)

If an OPO does not meet all 3 outcome measures as outlined in **42 CFR 486.318** or if it has been shown by survey to be out of compliance with the requirements described in **42 CFR 486.320 through 486. 348**, the OPO is de-certified. If the OPO does not appeal the de-certification, or if the OPO appeals and the reconsideration official and the CMS hearing officer uphold the de-certification, the OPO's service area is opened for competition from other OPOs. The OPO that has been de-certified is not permitted to compete for its open area or any other open service area.

2817 - Voluntary Termination of an Agreement:
(Rev. 111, Issued: 04-11-14, Effective: 04-11-14, Implemetation: 04-11-14)

The OPO must submit to the applicable CMS RO a written notice of its intention to terminate its agreement and include a stated proposed effective date. CMS has the option to agree to the proposed effective date or set another termination date no later than six months from the OPO requested date, or set a different date less than six months after the proposed effective date if it determines a different date would not disrupt services in that area. If CMS determines that the OPO has ceased providing services to its donation service area, then that cessation of services is considered a voluntary termination by the OPO, with the effective date to be determined by CMS.

After approval from CMS of the date for voluntary termination, the OPO must provide public notice of its voluntary termination in local newspapers within three (3) business days <u>from the approval date</u>. The notice should include the date the OPO will cease operations and services, a list of hospitals and CAHs in the OPOs service area, and the OPO telephone contact numbers for inquiries. The OPO must provide the CMS RO with copies of each public notice within **seven (7) business days** of CMS's approval of voluntary termination. No further payments under Title XVIII or XIX of the Act will be made with respect to costs attributable to the OPO on or after the effective date of de-certification.

*** See also 2812.3 Open Competition**

2818 - Involuntary Termination and Non-renewal of an Agreement:
(Rev. 111, Issued: 04-11-14, Effective: 04-11-14, Implemetation: 04-11-14)

During the term of an OPO agreement, CMS may terminate an agreement with an OPO at any time the OPO no longer meets the requirements for certification at **42 CFR 486.303**. Additionally, CMS will not voluntarily renew its agreement with an OPO if the OPO fails to meet the requirements for certification at §486.318, based on findings from the most recent re-certification cycle, or the other requirements for certification at §486.303. If CMS determines that the OPO is out of compliance with one or more Conditions for Coverage and the OPO does not implement an approved plan of correction that re-establishes compliance prior to the end of a designated period of time, CMS will begin the process of de-certification. CMS may also immediately terminate an agreement in cases of urgent need as defined in **42 CFR 486.302**. CMS will decertify the OPO as of the effective date of the involuntary termination or as of the ending date of the agreement in the case of non-renewals.

*** See also 2812.3 Open Competition**

Except in cases of urgent need, CMS will give the OPO written notice of the intent to de-certify at least **90 days** before the effective date of de-certification. CMS provides public notice of the effective date of de-certification in local newspapers in the OPO's service area. The notice will state the reasons for de-certification and the effective date. No further payments under Title XVIII or XIX of the Act will be made with respect to costs attributable to the OPO on or after the effective date of the de-certification. In cases of urgent need**,** follow the procedures found in **Appendix Q: Immediate Jeopardy**.

2819 - Appeals (§486.314)

(Rev. 111, Issued: 04-11-14, Effective: 04-11-14, Implemetation: 04-11-14)

Involuntary Termination/Non-Renewal of Agreement:

An OPO may appeal an involuntary termination or non-renewal of an agreement on substantive and procedural grounds. CMS sends a notice of initial de-certification determination to the OPO which contains the reasons for the determination, the effect of the determination, and the OPO's right to seek reconsideration. The notice letter informing the OPO of de-certification and impending termination must include the appropriate appeal rights as well as instructions on how to file a request for reconsideration.

Reconsideration of a De-certification:

An OPO has **15 business days** from receipt of CMS' notice of de-certification to seek reconsideration from CMS if it is dissatisfied with the de-certification determination. The OPO reconsideration request must state the issues or findings of fact with which the OPO disagrees, the reasons for disagreement and factual support for each finding with which they disagree, and the reasons for disagreement. The OPO may submit factual support for each findings with which they disagree as well as additional information and arguments as to why it should not be decertified. CMS then evaluates the submitted information to determine if the de-certification decision is upheld or reversed. An OPO must seek reconsideration before it is entitled to seek a hearing before a hearing officer. If the OPO does not request reconsideration from CMS, or fails to submit its request timely to CMS, the OPO has no right to further administrative review and the de-certification is final.

CMS Reconsideration Determination:

A written reconsidered determination is made by CMS within **10 business days** of the request for reconsideration. This determination will affirm, reverse or modify the initial de-certification determination and the findings on which it was based and will determine whether the submitted documentation and information was sufficient to support a change in the initial decision. If the determination decision is reversed or modified, CMS notifies the OPO in writing with a revised Form **CMS-2567** to reflect the revised findings. If the decision is not reversed or modified, but is affirmed, CMS notifies the OPO in writing of

the decision, including what materials CMS reviewed and why the submitted documentation did not justify a reversal or modification in the initial decision to de-certify. Additionally, CMS informs the OPO that it will not be eligible to compete for the current service area or any other service area opened for competition. CMS will augment the administrative record to include any additional materials submitted by the OPO and a copy of the reconsideration decision, and sends the supplemented administrative record to the CMS hearing officer. If the OPO timely seeks further administrative review (hearing), CMS forwards the initial request for reconsideration and all supporting documentation to the hearing officer.

Administrative Hearing:

An OPO that wishes to appeal the reconsideration decision of CMS must file a written hearing request within **forty (40) business days** of the receipt of the notice of CMS reconsideration decision. If a hearing request is not submitted or received timely by CMS, than the OPO has no further right to appeal or other administrative review. The Administrative Appeal Process is handled through the Office of Medicare Hearings and Appeals.

Administrative Record:

The administrative record consists of, but is not limited to, (1) factual findings from the survey(s) on the OPO conditions for coverage; (2) data from outcome measures; (3) rankings of OPOs based on the outcome data; and (4) correspondence between CMS and the affected OPO. The hearing officer sends the administrative record to both parties within ten (10) business days of receipt of the OPO's written request for hearing.

2820 - Outcome Measures/Data Reporting (§486.318, 486.328): NOT REVIEWED ON SITE

(Rev. 111, Issued: 04-11-14, Effective: 04-11-14, Implemetation: 04-11-14)

Data measures as calculated by University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) utilizing the Scientific Registry of Transplant Recipients (SRTR) data and OPTN reporting data are entered into the OPO database for CMS CO/RO review for regulatory compliance.

2821 - Information Management (§486.330):

(Rev. 111, Issued: 04-11-14, Effective: 04-11-14, Implemetation: 04-11-14)

The OPO is required to keep and maintain donor and transplant recipient records in a human readable and reproducible paper or electronic format for a minimum of **seven (7)** years.

Federally Qualified Health Centers

2825 - Federally Qualified Health Centers (FQHCs) - Citations and Description
(Rev. 1, 05-21-04)

2825A - Citations
(Rev. 40, Issued: 03-20-09, Effective: 03-20-09, Implementation: 03-20-09)

Section 4161(a)(2) of OBRA '90 (P.L. 101-508) amended §1861(aa) of the Act and established FQHC services as a benefit under the Medicare program effective October 1, 1991. The statutory requirements that entities must meet to be considered an FQHC for Medicare purposes are at §1861(aa)(4) of the Act. Regulations establishing the FQHC benefit and outlining Conditions for Coverage for FQHCs were published on June 12, 1992, in the "Federal Register" (57 FR 24961) and became effective on the date of publication. These regulations were amended on April 3, 1996 (61 FR 14640). Section 13556 of OBRA 1993 (P.L. 103-66) amended §1861(aa) of the Act by adding outpatient health programs or facilities operated by a tribe or tribal organization under the Indian Self-Determination Act or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act, as entities eligible to participate in Medicare as FQHCs.

2825B - Description
(Rev. 85, Issued: 07-19-13, Effective: 07-19-13, Implementation: 07-19-13)

The Federally Qualified Health Centers (FQHCs) are considered "suppliers" under Part B of Medicare and are paid Part B benefits for FQHC services. For the purpose of Medicare enrollment, an FQHC is defined as an entity that has entered into an agreement with CMS to meet Medicare program requirements under 42 CFR 405.2434, and:

- Is receiving a grant under Section 330 of the Public Health Service (PHS) Act; or
- Is receiving funding under a contract with the recipient of a Section 330 grant, and meets the requirements to receive a grant under §330 of the PHS Act; or
- Is an FQHC "Look-Alike," i.e., the Health Resources and Services Administration (HRSA), has notified the facility it has been determined to meet the requirements for receiving a Section 330 grant, even though it is not actually receiving such a grant; or
- Was treated by CMS as a comprehensive federally funded health center as of January 1, 1990; or
- Is an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act or by an Urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

2826 - RO Approval Process for FQHCs
(Rev. 40, Issued: 03-20-09, Effective: 03-20-09, Implementation: 03-20-09)

2826A - General
(Rev. 40, Issued: 03-20-09, Effective: 03-20-09, Implementation: 03-20-09)

An FQHC seeking to enroll as a Medicare-participating supplier is subject to a filing procedure instead of SA certification or recertification. Under this procedure, the FQHC must attest that it is in compliance with all applicable Medicare regulations. The SA does not conduct a survey to confirm the FQHC's compliance with Medicare's regulations.

FQHCs must remain in substantial compliance with all of the FQHC regulatory requirements specified in 42 CFR Part 405, Subpart X, and in 42 CFR Part 491, with the exception of Section 491.3.

CMS will enter into an agreement with an entity that qualifies to participate as an FQHC when:

- The applicant provides a copy of its Notice of Grant Award by HRSA that verifies the applicant qualifies as an FQHC; the applicant provides a copy of its FQHC Look-Alike Designation Memo from CMS; <u>or</u> the applicant is confirmed as a qualifying tribal or Urban Indian organization outpatient healthcare facility;

- The applicant assures CMS through a self-attestation that it satisfies the regulatory requirements in 42 CFR 405 Subpart X and 42 CFR Part 491, except for Section 491.3;

- The applicant submits a complete Form CMS-855A enrollment application (along with all supporting documentation) to its MAC/FI, and the MAC/FI recommends approval of said application; and

- The entity terminates other Medicare provider agreement(s) it has, unless it assures CMS that it is not using the same space, staff, and resources simultaneously as a physician's office or other type of provider or supplier. For example, an RHC cannot concurrently be approved for Medicare as both an RHC and FQHC.

In accordance with 42 CFR 491.5(a)(3)(iii), if an FQHC provides services in permanent units in more than one location, each such unit must be separately enrolled in the Medicare program. One FQHC permanent unit cannot be provider-based to another FQHC unit. However, mobile units operated by the FQHC do not require separate enrollment, but are considered part of the permanent FQHC unit that operates them.

In general, RO Survey and Certification staff are responsible for reviewing and approving or denying requests for Medicare participation as an FQHC. The RO notifies the FQHC applicant and HRSA's Bureau of Primary Health Care or the Indian Health Service, as appropriate, of approvals or denials. (The only exception to this involves situations where the MAC/FI determines that the applicant does not comply with the enrollment

requirements at 42 CFR 424.500-525, in which case the contractor itself will issue the denial per Pub. 100-08, Chapter 10.) For approvals, the RO shall transmit the Tie-In Notice in accordance with the following instructions:

- A freestanding FQHC undergoing initial enrollment, except for a tribal or Urban Indian FQHC, is to be assigned to the MAC or legacy FI that covers the State where the FQHC is located.

- A tribal or Urban Indian FQHC undergoing initial enrollment is to be assigned to the Jurisdiction 4 MAC.

NOTE: For FQHCs already enrolled in Medicare:

- In the settled MAC environment (i.e., after the transition to MAC contractors has been completed nationwide) all freestanding FQHCs, except for tribal or Urban Indian FQHCs, will be assigned to the MAC that covers the State where the FQHC is located.

- In the settled MAC environment all tribal and Urban Indian FQHCs will be assigned to the Jurisdiction 4 MAC.

- In the interim, all existing FQHCs will remain in their current assignments. FQHCs will be moved to their destination MACs after all 15 A/B MAC contracts have been awarded and implemented. Each move will be dependent on the then-current status of the systems and contractors that support the claims processing, provider enrollment, and cost report audit functions at the department and destination MACs.

It is unlikely that a new FQHC would qualify for provider-based, as opposed to freestanding, status, since HRSA's requirements for governance of an FQHC preclude the FQHC from satisfying CMS' requirements for clinical, financial and administrative integration with the main provider. However, 42 CFR 413.65(n) permits any FQHC or FQHC Look-Alike facility that, since April 7, 1995, furnished only services that were billed as if they were furnished by a department of a provider to continue to do so, regardless of satisfying the criteria for provider-based status, so long as it was qualified as an FQHC (not including tribal/Urban Indian facilities) or FQHC Look-Alike on or before April 7, 2000. A provider-based FQHC is assigned its own CMS Certification Number (CCN), but uses the same fiscal intermediary or MAC, as applicable, as the main provider to which it is provider-based.

The RO reviews FQHC complaints and either refers them to HRSA or the Indian Health Care Service (IHS), as applicable, for investigation or, in the case of credible allegations that allege an FQHC does not meet applicable Medicare requirements, to the SA for investigation. The CMS RO will conduct complaint allegations that an FQHC does not meet applicable Medicare requirements when the FQHC is located on reservation property. (See §2826H.)

The RO may terminate the agreement with an FQHC if it finds that the FQHC no longer meets the Medicare eligibility standards to participate as an FQHC and/or is not in substantial compliance with the Medicare requirements for FQHCs.

2826B - Information to Be Provided to Potential Applicants

(Rev. 40, Issued: 03-20-09, Effective: 03-20-09, Implementation: 03-20-09)

The ROs are to provide potential applicants for enrollment as an FQHC a copy of the document entitled Information on Medicare Participation for FQHCs (Exhibit 179). This document includes information on:

- Obtaining a copy of Form CMS-855A enrollment application from CMS' Web site at http://www.cms.hhs.gov/cmsforms/downloads/cms855a.pdf; and

- Attestation Statement for FQHCs (Exhibit 177)

2826C - 2826C - Request to Participate

(Rev. 85, Issued: 07-19-13, Effective: 07-19-13, Implementation: 07-19-13)

To participate in the Medicare program, applicants seeking initial enrollment as an FQHC must submit a Form CMS-855A application:

- In the case of applicants that are operated by a tribe or tribal organization, to the jurisdiction H A/B MAC; and

- In the case of all other applicants, to the A/B MAC that covers the State where the applicant facility is located. (Previously all FQHC applications and claims were processed by one national fiscal intermediary. This system is being phased out as CMS implements the MAC contracts, and all new FQHC applications are to be assigned to the applicable MAC, as described above. In the case of a new applicant that is a permanent unit owned and operated by an existing FQHC in a different location in the same state, this could mean that each permanent unit would have a different MAC until the transition to MACs has been completed nationwide. However, accommodations have been made for a set of FQHCs that straddle MAC jurisdiction boundaries to continue filing a consolidated cost report.)

Information on enrollment procedures and a list of A/B MACs may be found at:

- http://www.cms.gov/Center/Provider-Type/Federally-Qualified-Health-Centers-FQHC-Center.html?redirect=/center/fqhc.asp

- http://www.cms.gov/medicare-coverage-database/indexes/contacts-part-a-medicare-administrative-contractor-index.aspx?bc=AgAAAAAAAAAA&

The following documents must be included in the application:

- A signed and completed application Form CMS-855A enrollment application;

- Two signed and dated copies of the attestation statement (Exhibit 177). Since FQHCs must sign an agreement stipulating that they will comply with §1861(aa)(4) of the Act and specific FQHC regulations, this statement serves as the Medicare FQHC agreement when it is also signed and dated by the Regional Office.

- HRSA Notice of Grant Award or FQHC Look-Alike Designation that includes an address for the site of the applicant which matches the practice location reported on the Form 855A;

- Form CMS-588 Electronic Funds Transfer (EFT) Authorization Agreement;

- Clinical Laboratory Improvement Act (CLIA) Certificate (if applicable). Facilities that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings is considered a laboratory and must meet CLIA requirements. These facilities must apply and obtain a certificate from the CLIA program that corresponds to the complexity of tests performed. Certain types of laboratories and laboratory tests are NOT subject to meeting CLIA requirements. One example would be facilities which serve only as collection stations. A collection station receives specimens to be forwarded to a laboratory performing diagnostics test. Chapter 6, Section 6002 of the State Operations Manual provides additional details regarding laboratories and laboratory tests NOT subject to CLIA requirements. It is the responsibility of the FQHC applicant to review the CLIA requirements and obtain a CLIA certificate if needed. Neither the MAC/FI nor the Regional Office makes a determination as to whether the FQHC applicant must obtain and submit a CLIA certificate; and

- Copy of State License (if applicable).

2826D - Processing Requests

(Rev. 85, Issued: 07-19-13, Effective: 07-19-13, Implementation: 07-19-13)

The MAC/FI will review the completed Form CMS-855A and other documents submitted by the applicant to ensure that all required information and documentation has been provided, and thus is complete. Upon completion of its review, the MAC/FI will either: (1) forward its recommendation for approval to the RO, or (2) deny the application (with a cc: to the RO on the denial letter). If the MAC recommends approval, it forwards to the RO with its approval letter: a copy of the Form CMS-855A, both original attestation statements, a copy of the HRSA Notice, a copy of the applicant's State license if applicable, and a copy of its CLIA certificate, if applicable.

Upon receipt of a recommendation for approval, the RO verifies that the application package contains all applicable documents listed above. If the RO finds that documents are missing, e.g., there is no attestation, or no copy of a State license but the RO is aware that the State requires a license, the RO contacts the MAC and requests that it resolve the

discrepancy and send a revised recommendation letter. Lack of a copy of a CLIA certificate, however, is not a basis for the RO to contact the MAC.

For outpatient health programs or facilities operated by a tribe or tribal organization or by an Urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act, the RO confirms the applicant's attestation by using the IHS lists of facilities or organizations provided by CO, or by contacting CO or the IHS for applicants not on the list.

Each RO should designate a survey and certification primary point-of-contact (POC) for coordination with HRSA, IHS, and CMS CO.

2826E - RO Assigning Applicants an FQHC CMS Certification Number (CCN)

(Rev. 40, Issued: 03-20-09, Effective: 03-20-09, Implementation: 03-20-09)

The RO assigns each FQHC permanent site that it approves, a CCN using the 1800-1989 series. This includes RHCs converting to FQHCs. The RO retires the CCN of the RHC and notifies the FQHC replacing the RHC of its new CCN.

2826F - Effective Date

(Rev. 85, Issued: 07-19-13, Effective: 07-19-13, Implementation: 07-19-13)

If the RO determines that the FQHC application meets all requirements, the RO signs and dates the applicant's Attestation Statement for Federally Qualified Health Centers (Exhibit 177). The RO uses as the date for its signature, and therefore the effective date of the agreement, the date the MAC's written recommendation for approval indicates the FQHC's application was complete. In accordance with Section 15.4.1.4, chapter 15, of Publication 100-08, the Medicare Program Integrity Manual, "When sending a recommendation for approval letter to the RO for an initial FQHC application, the contractor [MAC] shall indicate in the letter the date on which the FQHC's application was complete. To illustrate, assume that the FQHC submitted an initial application on March 1. Two data elements were missing; the contractor thus requested additional information. The two elements were submitted on March 30. The contractor shall therefore indicate the March 30 date in its letter."

If the completeness date is not included in the written recommendation, the RO requests the MAC to send a revised recommendation letter that provides this information.
If the MAC forwarded an incomplete documentation package to the RO and the MAC determines, when asked to resolve the discrepancy, that the MAC did not receive all required documentation from the FQHC, the MAC must request the additional required documentation from the FQHC and must send the RO a revised recommendation letter reflecting the new date the FQHC's application was determined complete. On the other hand, if the MAC determines that the FQHC submitted all required documentation but the MAC did not forward all of it to the RO, the completeness date in the MAC's original recommendation letter continues to be used as the effective date of the agreement.

2826G - RO Completion of Forms
(Rev. 40, Issued: 03-20-09, Effective: 03-20-09, Implementation: 03-20-09)

The RO completes appropriate blocks of Part I and Part II of Form CMS-1539. Annotate Item 7 by assigning Code 21 for FQHCs.

The RO completes Form CMS-2007 and notifies the appropriate MAC/FI of changes (additions, deletions, and corrections) in their lists of providers. (See §2783.) Although it is increasingly unlikely that a new FQHC will be provider-based, if the FQHC indicates on the Form CMS-855A that it is part of an existing Medicare/Medicaid provider, the RO sends the tie-in-notice to the main provider's MAC/FI.

2826H - Complaint Investigations
(Rev. 40, Issued: 03-20-09, Effective: 03-20-09, Implementation: 03-20-09)

CMS investigates complaints which raise credible allegations of noncompliance by an FQHC with Medicare requirements and health and safety standards found at 42 CFR 405 Subpart X, and 42 CFR 491 Subpart A, except for 42 CFR 491.3. In conducting complaint investigations, SAs (or ROs, in the case of tribal FQHCs) use the instructions in Chapter 5, particularly §§5200 through 5240, and applicable portions of Appendix G of the State Operations Manual to determine whether the FQHC is in substantial compliance with Medicare requirements.

If the FQHC is found not to be in substantial compliance with Medicare requirements, then the RO may initiate termination of the CMS agreement with the FQHC, in accordance with the provisions at 42 CFR 405.2436. The RO will follow the appropriate termination procedures and document and report as required. (See SOM Chapter 3, §§3010-3028 for termination procedures.) If a determination is made to terminate the FQHC's provider agreement, the RO will notify the FQHC in writing of its intention to terminate the agreement at least 15 days before the termination date stated in the notice. An FQHC may appeal CMS' decision to terminate its agreement in accordance with the provisions at 42 CFR Part 498.

CMS refers complaints about FQHCs that do not involve Medicare health and safety standards found at 42 CFR Part 491 Subpart A, to HRSA or the IHS, as applicable.

The IHS investigation referrals are coordinated with RO Native American Contacts (NAC). The HRSA investigation referrals are coordinated with HRSA's Bureau of Primary Care, Division of Policy and Development, Policy Branch.

NOTE: Under the Defense of Marriage Act (DOMA): Every psychiatric hospital/facility is expected to recognize all state-sanctioned marriages and spouses for purposes of compliance with the Conditions of Participation and regulatory requirements, regardless of any laws to the contrary of the state or locality where the hospital/facility is located. In the regulation or this guidance, and in every instance where the following terms appear:

- "spouse" means an individual who is married to another individual as a result of a state-sanctioned marriage, including a same-sex marriage, regardless of whether the state where the facility is located permits such marriages to occur;

- "marriage" means a state-sanctioned marriage, including a same-sex marriage, regardless of whether the state where the facility is located permits such marriages to occur;

- "family" includes, but is not limited to, an individual's "spouse" (see above); and

- "relative," when used as a noun, includes but is not limited to, an individual's "spouse" (see above).

  Furthermore, wherever the text of a regulation or associated guidance includes a reference to a patient's "representative," "surrogate," "support person," "next-of-kin," or similar term in such a manner as would normally implicitly or explicitly include a spousal relationship, the terms are to be interpreted as indicated above.

2830 – Psychiatric Residential Treatment Facilities (PRTF) – Citations and Definitions

(Rev. 132; Issued: 01-16-15, Effective: 01-16-15, Implementation: 01-16-15)

2830A – Citations

Sections 1905(a)(16) and (h) of the Act provide that inpatient psychiatric services for individuals under age 21 include only inpatient services that are provided in an institution (or distinct part thereof) that is a psychiatric hospital as defined in section 1861(f) of the Act or in another inpatient setting that the Secretary has specified in regulations. Additionally, the Children's Health Act of 2000 (Pub. L. 106–310) imposes procedural reporting and training requirements regarding the use of restraints and involuntary seclusion in facilities, specifically including facilities that provide inpatient psychiatric services for children under the age of 21 as defined by sections 1905(a)(16) and (h) of the Act. (42 CFR 483.350(a)).

Condition of Participation (CoP). The Condition of Participation for PRTFs is contained in 42 CFR Part 483, Subpart G: Condition of Participation for the Use of Restraint or Seclusion in Psychiatric Residential Treatment Facilities Providing Inpatient Psychiatric Services for Individuals Under 21. **Appendix N** of this manual contains the Interpretive Guidelines for surveyors.

2830B – Definitions

A Psychiatric Residential Treatment Facility (PRTF) is defined as a facility other than a hospital, that provides psychiatric services, as described in subpart D of part 441 of this chapter, to individuals under age 21, in an inpatient setting. Sections 441.151, in subpart D of 42 CFR indicates that PRTFs must be accredited by the Joint Commission, the Commission on Accreditation of Rehabilitation Facilities (CARF), the Council on Accreditation of Services for Families and Children (COA), or by any other accrediting organization with comparable standards that is recognized by the State. PRTFs, as indicated in §483.374 must also have either a current provider agreement with the State Medicaid agency or if enrolling as a Medicaid provider must execute a provider agreement with the State Medicaid agency.

Inpatient Psychiatric Services for Individuals Under age 21 Benefit. – Inpatient psychiatric services for individuals under 21 is a Medicaid benefit as provided by section 1905(a)(16) of the Social Security Act, the provision of these services is an optional benefit for individual states. Although a state may choose to or not to offer PRTF services in its state plan, the benefit must be provided in all States to those individuals who are determined during the course of an Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) screen to need this type of inpatient psychiatric care. Under the EPSDT provisions at section 1905(r)(5) of the Act, States must provide any service listed in section 1905(a) of the Act that is needed to correct or ameliorate defects and physical and mental conditions discovered by EPSDT screening services, whether or not the service is covered under the State plan.

Condition of Participation for the Use of Restraint and Seclusion. – PRTFs must

comply with the requirements of 42 CFR 483.350, subpart G in order to participate in the Medicaid program. The interpretive guidelines for the Condition of Participation may be found in Appendix N and include discussion of the following eleven standards of the Condition:

- General requirements for psychiatric residential treatment;
- Resident protections;
- Orders for the use of restraint or seclusion;
- Consultation with treatment team physician;
- Monitoring of residents in and/or immediately following restraint or seclusion;
- Requirements for notifying parents or legal guardians;
- Application of time out;
- Post-intervention debriefing;
- Medical treatment for injuries resulting from an emergency safety intervention;
- Facility reporting requirements;
- Facility's responsibility in educating and training its staff.

Emergency safety situation means unanticipated resident behavior that places the resident or others at serious threat of violence or injury if no intervention occurs and that calls for an emergency safety intervention as defined in this section.

Emergency safety intervention means the use of restraint or seclusion as an immediate response to an emergency safety situation.

Minor means a minor as defined under State law and, for the purpose of this as defined in §483.352, includes a resident who has been declared legally incompetent by the applicable State court.

Resident means an individual under age 21(as described in subpart D of §441.151) receiving psychiatric treatment in a PRTF.

Restraint means a "personal restraint," "mechanical restraint"or"drug used as a restraint," as defined in this section.

Seclusion means the involuntary confinement of a resident alone in a room or an area from which the resident is physically prevented from leaving.

Serious injury means, any significant impairment of physical condition of resident as determined by qualified medical personnel. This includes but is not limited to, burns, lacerations, bone fractures, substantial hematoma, and injuries to internal organs, whether self-inflicted or inflicted by someone else.

Staff means individuals who participate in caring for the resident, who have the responsibility for managing a resident's treatment and who are employed by the facility on a full-time, part-time, or contract basis.

Time out means the restriction of a resident for a period of time to a designated area from which the resident is not physically prevented from leaving, for the purpose of providing

the resident an opportunity to regain self-control.

Drug used as a restraint means any medication that is administered to manage a resident's behavior, which may have temporary effect of restricting the resident's freedom of movement; and is not a standard or routine treatment for the resident's medical or psychiatric condition.

2831 – Determination-Making Authority

(Rev. 132; Issued: 01-16-15, Effective: 01-16-15, Implementation: 01-16-15)

2831A – Survey Agency and State Medicaid Agency Interaction

Section 1902(a)(33) of the Act requires that the same State survey agency (SA) that certifies Medicare provider and supplier eligibility also make the determination of eligibility to participate in Medicaid. The law also requires that there be a separately designated single SA responsible for the overall management of the Medicaid program (42 CFR 431.610(b)). Therefore, in each State, a State Medicaid Agency (SMA) is ultimately responsible for Medicaid program administration. Each SMA enters into an interagency agreement with its certifying SA establishing the determination-making function of the SA and providing for the application of Federal certification standards and procedures.

In addition, 42 CFR 431.610(e) and (f) require that the Medicaid State plan must designate the agency that is responsible to ensure that institutions and agencies meet the requirements for participation in the Medicaid program. The SMA must accept the SA's certification decisions as final, but exercise its own determination whether to enter into an agreement with psychiatric residential treatment facilities (PRTFs), while if the SA determines the PRTF is out of compliance, the SMA may not enter into an agreement. The SMA is responsible for reviewing certifications to ensure that the SA adhered to procedural requirements. If the SMA disagrees with the SA's certification, the SMA should first contact the SA to resolve the issue. If the issue is not resolved after contact with the SA, the SMA should present the issue to the applicable CMS-Regional Office (RO). (See discussion in State Medicaid Manual (SMM) §2084.3A).

2831B – Authorization of Certification Expenditures

Authority to approve Medicare certification budgets and expenditures is delegated to the designated CMS Consortium or Regional Administrator(s). Authority to approve or disapprove Federal Financial Participation (FFP) in Medicaid certification expenses is delegated to the CMS Associate Regional Administrators or the Consortium Survey and Certification Officer where an Associate Regional Administrator is not present.

2831C – Look-Behind Authority on State Determinations

The Secretary has authority under §§1902(a)(33), 1919(g)(3), and 1910(b)(1) of the Act cancel approval of all Medicaid facilities that do not meet Federal health or safety requirements. Such a determination is in lieu of, or overrides a determination by the State and is binding on the SMA. Section 1902(a)(33) of the Act gives CMS the authority to

question State determinations regarding Medicaid facilities' compliance with Federal requirements and authorizes CMS to make independent and binding determinations concerning the extent to which individual institutions and agencies meet requirements for participation. CMS has the authority to "look behind" State determinations and, with cause, to make binding determinations. This authority allows CMS to validate State determinations concerning the extent to which individual institutions and agencies meet the requirements for participation (Section 1902 (a)(33)(B) of the Act).

This look behind authority accords CMS the ability to cancel the approval of a facility to participate in the Medicaid program when CMS determines the facility fails to comply substantially with the Conditions of Participation. (See Section 1902 (a)(33)(B) and SMM §2084.3). Also refer to 42 CFR Part 483, Subpart G for PRTF Conditions of Participation.

Another part of CMS's look- behind authority provides that a provider agreement is considered by CMS to be invalid for purposes of providing FFP to the State if the State failed to adhere to federal procedures. For example, the SMA may have issued the provider agreement even though the SA determined that the facility was not in compliance with the COP. In that case, the agreement is void from its inception. This authority is established by Section 1902 (a)(33)(B) of the Act. (See discussion of look behind authority in SMM §2084.3 and SOM §3042).

2831D – Appeals

2831D.1- State Appeals

A State has the right to appeal the Administrator's decision to withhold federal funds for Medicaid programs due to failure to comply with the Federal regulations; as stated in 42 CFR Part 430 Subpart D "(a) This subpart sets forth the rules for hearings to States that appeal a decision to disapprove State plan material (under §430.18) or to withhold Federal funds (under §430.35), because the State plan or State practice in the Medicaid program is not in compliance with Federal requirements. (b) Nothing in this subpart is intended to preclude or limit negotiations between CMS and the State, whether before, during, or after the hearing to resolve the issues that are, or otherwise would be, considered at the hearing. Such negotiations and resolution of issues are not part of the hearing, and are not governed by the rules in this subpart except as expressly provided."

2831D.2 – Facility Appeals

If a Medicaid-only facility requests a hearing, such hearing must be completed either before or within 120 days after the effective date of the adverse action. (See SMM §2040.) Detailed Medicaid appeal procedures are provided by the State. In the case of "look-behind" terminations, CMS notifies the facility of the termination and whether it has a right to request a hearing before a Federal Administrative Law Judge. Although a facility can appeal a look-behind determination that found the facility out of compliance with the conditions of participation, the facility has no right to request for an appeal in cases where CMS disallowed FFP on the grounds of an SA's improper or inappropriate certification of the facility. (See SMM §2084.3E).

2831E – Accreditation

Federal regulations at 42 CFR 441.151(2)(ii) require that PRTFs are to be accredited by the Joint Commission, the COA, the CARF or by any other accrediting organization with comparable standards that is recognized by the State.

2832 – Survey Agency, State Medicaid Agency, and PRTF Responsibilities & Obligations

(Rev. 132; Issued: 01-16-15, Effective: 01-16-15, Implementation: 01-16-15)

2832A – Attestations

State Responsibilities – The SA of the State which is surveying the PRTF inputs the initial attestation information into ASPEN, and continually thereafter.

- PRTF Responsibilities – PRTFs must submit attestation statements to each SMA where they have established a provider agreement.
- Attestation statements are to be submitted annually and are due on July 21st of each fiscal year. However, if July 21st occurs on a weekend or holiday, the attestation is due on the first business day following the weekend or holiday.
- Attestations must include the following information:
  - Facility General Characteristics: name, address, telephone number of the facility, and a State provider identification number;
  - Facility Specific Characteristics:
    - Bed size;
    - Number of individuals currently served within the PRTF who are provided service based on their eligibility for the Medicaid Inpatient Psychiatric Services for Individuals Under age 21 Benefit (Psych under 21);
    - Number of individuals, if any, whose Medicaid Inpatient Psychiatric Services Under 21 Benefit is paid for by any State other than the State of the PRTF identified in this attestation letter; and
    - List all States from which the PRTF has ever received Medicaid payment for the provision of Psych under 21 services.
  - The signature of the facility director;
  - The date the attestation was signed;
  - A statement certifying that the facility currently meets all of the requirements of Part 483, Subpart G governing the use of restraint and seclusion;
  - A statement acknowledging the right of the SA (or its agents) and, if necessary, CMS to conduct an on site survey at any time to validate the facility's compliance with the requirements of the rule, to investigate complaints lodged against the facility, or to investigate serious occurrences;
  - A statement that the facility will submit a new attestation of compliance annually and in the event a new facility director is appointed.

2832B – Plan of Correction (POC)

Regulations at 42 CFR 488.28(a) allow recertification of providers with deficiencies at the Standard or Condition level "only if the facility has submitted an acceptable Plan of Correction (POC) for achieving compliance within a reasonable period of time acceptable to the Secretary." Failure to submit a POC may result in termination of the provider agreement as authorized by §489.53(a)(1). After a POC is submitted, the certifying SMA, or in some cases the CMS Regional Office, makes the determination of the appropriateness of the POC for it to be acceptable.

2832C – Assigning CMS Certification Numbers (CCN)

A CCN code is assigned based on where the PRTF is physically located. Processing of requests for payment is usually keyed to the Federal identification number; however this identification number is for Online Survey, Certification, and Reporting System (OSCAR) tracking purposes only.

The certification numbers for PRTFs will have five digits and one letter. The first two digits identify the State in which the PRTF facility is located. This number is then followed by the letter L and is then followed by three digits and is numbered according to the order in which a facility was identified as a PRTF in their State. All State codes are listed in SOM §2779. For example, a PRTF located in Maryland would have a State code of "21." This would then be followed by the letter "L" and identified with a three digit number. For example, if it was the fourth PRTF identified by the State, the PRTF's CCN would be 21L004. (See SOM §2779B)

2832D – ASPEN Data Input

- The surveying SA has the responsibility of entering the survey data into ASPEN. After the CCN is assigned to the PRTF, the SA is to enter information received from the PRTF annual attestation as well as information from recertification or complaint surveys. It is also the responsibility of the SA to update the information as needed. The SA is to input information from Forms CMS- 1539, CMS- 670, CMS-2567 and if applicable, CMS-2567B.

- The initial input of information from attestation must be done by the SA of the State surveying the PRTF, even if the State in which the PRTF is located does not include the Inpatient Psychiatric Services for Individuals Under 21 Benefit in its State plan.

- Maintaining attestation and survey information is the responsibility of the SA conducting complaint and validation surveys.

2832E – Multi-State Issues & Interagency Relationships

2832E.1 – State-to-State Differences

There are several State-to-State differences in the provision of services for individuals who qualify for the Inpatient Psychiatric Services for Individuals Under 21 Benefit. The following factors determine where an individual receives services and who has surveying

responsibilities.

1. States may or may not have the Inpatient Psychiatric Services for Individuals Under 21 benefit in their State plan.
2. States may or may not have a PRTF within its borders.
3. States have an obligation to provide inpatient psychiatric services for individuals under 21 years of age regardless of whether or not the benefit is in their State plan or a PRTF is within its borders.

A State will either have the Inpatient Psychiatric Services for Individuals Under 21 Benefit in its State Plan or it will not. However, not all States will have a PRTF within its borders that can meet the needs of its Medicaid beneficiaries and thus will have to transfer beneficiaries to another State to receive the needed service.

Occasionally, a SMA may elect to send a patient out of State to receive the Psych Under 21 Benefit, (reference S&C Memo of July 3, 2013: 13-45-PRTF). It is the responsibility of the transferring SMA to ensure that these services are provided in a certified PRTF. In some instances, the facility selected (i.e., receiving facility) is located in a State that does not include PRTF services in its Medicaid State Plan and thus no facilities in that State are certified as PRTFs. If the transferring SMA still wishes to transfer the patient to such a facility, it must make a written agreement for the certification of that facility prior to the patient's transfer.

The initial certification of a PRTF is currently accomplished through an attestation process. The SA, through an agreement with the SMA, conducts surveys (Recertification, Complaint Investigation, and Validation) at least every five (5) years to ensure that the facility remains in compliance with the applicable regulations and the assertions of the attestation. The SA makes a recommendation to the SMA for re-certification or termination. The SMA enters into a written agreement with the PRTF.

If the certifying SMA of one State wishes to have a facility in another State certified as a PRTF, there are three options available for the SMA regarding the survey portion of the certification process:

- The SMA may make a written agreement with the SA of the State in which the facility is located to conduct the surveys of the facility;
- The SMA may make a written agreement with the SA located within their own State to travel to the receiving State to conduct the surveys; or
- The SMA may make a written agreement with any other SA to conduct the surveys of the facility.

SAs in States where the Medicaid State Plan does <u>not</u> include PRTF services may not have trained personnel or may not have the available resources to conduct these PRTF surveys since this is not a routine part of their workload. If the SMA of one State wishes to certify a PRTF in another State and approaches the other State's SA to conduct the survey activity, the other SA may agree if they feel they have the necessary resources or may decline if they feel they do not. They are under no obligation to perform the work for the SMA of another State.

If the SA from the State where the facility is located is not able to perform the survey activity, the SMA seeking survey of the PRTF may enter into a written agreement with any other State SA (including the SA located within in SMA's own State) that has the resources and appropriately trained personnel. The SA that conducts the surveys would then be responsible for inputting the survey information into ASPEN. The SMA requesting the survey will ensure that the survey information is entered into ASPEN and ensure that re-certification surveys are conducted at least once every five (5) years. The SMA requesting the survey has the authority to enforce non-compliance actions.

2832E.2 – Action for Non-Compliance and Termination

The SMA may take termination action against the PRTF if the SA determines the PRTF is not in compliance with the regulation or fails to appropriately report a death incident. If there are conflicting determinations between the SA and the SMA or there are conflicts that arise based on multi-state issues, then the applicable RO must be informed of the decisions. The RO will settle these conflicts before adverse findings are placed into ASPEN. In the case of multi-state issues, if the SA and the SMA are located in two different Regions, the applicable RO is defined as the RO for the state in which the SMA is located. The facility must submit their plan of correction to the SA of the State that conducted the survey.

If the survey findings do not rise to the condition level, but are only standard level deficiencies, it is still the responsibility of the surveying State to send their findings to the certifying SMA and the applicable Regional Office (RO). It is the responsibility of the certifying SMA to review and accept the facility's plan of correction.

2832E.3 – State Agency – Who Can Survey

The SMA identifies which agency is responsible for conducting survey and certification oversight for its PRTFs. Federal regulation requires that the Medicaid "State plan must designate, as the State authority responsible for establishing and maintaining health standards for private or public institutions that provide services to Medicaid beneficiaries, the same State agency that is used by the Secretary to determine qualifications of institutions and suppliers of services to participate in Medicare." (Emphasis added). (See 42 CFR 431.610(b)).

During surveys to determine compliance with the PRTF condition of participation, if findings show that the condition of participation for the PRTF is not met it is the responsibility of the SMA of the State that certified the PRTF to consider termination of the provider agreement. If findings do not rise to the condition level, but are standard level deficiencies, it is still the responsibility of the surveying State to send their findings to the SMA and the applicable RO. Facilities where standard level deficiencies have been found are required to submit a plan of correction to the surveying SA.

2833 – Survey Process

(Rev. 132; Issued: 01-16-15, Effective: 01-16-15, Implementation: 01-16-15)

2833A – Survey Types

2833A.1 – Recertification Surveys

SAs are required to validate the attestation statements for a 20 percent of all PRTFs in their state on an annual basis. Validation requires that the SA review attestation letters, conduct on-site review of PRTFs based on criteria established in 42 CFR 441.151 through 441.156, and determine compliance with federal standards and regulations, as set forth in 42 CFR 483, Subpart G and further discussed in the interpretive guidelines.

2833A.2 – Complaint Surveys

1. Immediate Jeopardy
The SA conducts an investigation of all allegations which may represent an immediate jeopardy situation within 2 working days of complaint receipt.

"Immediate Jeopardy," as defined in 42 CFR 489.3, is a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident. "Serious injury" is defined as any significant impairment of the physical condition of the resident as determined by qualified medical personnel. The term "serious injury" can be equated with "abuse or neglect." Appendix Q lists abuse and neglect as a trigger to call an immediate jeopardy. Refer to appendix Q for complete guidance on immediate jeopardy. To determine if an immediate jeopardy situation is present and ongoing, an assessment of each complaint intake must be made.

Exception – If the SA receives a restraint/seclusion death report, the SA should complete the investigation of this report within 5 working days of receipt of survey authorization from the RO. This investigation involves both on-site and off-site review. The ACTS report should be reviewed to determine facility history.

2. Non-immediate jeopardy
For non-immediate jeopardy situations, the SMA in conjunction with the SA will establish a mechanism by which to prioritize the nature of complaints. The SA should assess facility compliance with the established standards and regulations as provided in 42 CFR part 483 subpart G, (§§483.350 through 483.376) with additional guidance at §§441.150 through 441.156. If a complaint is received by CMS, CMS will notify the appropriate SA, who will then notify the SMA about the complaint, any ongoing investigation, findings, or decision regarding the complaint.

The SMA must report all serious occurrences, as defined in 42 CFR 483.374(b), to its SA and the SA must conduct both recertification and complaint surveys based on regulations established by the 42 CFR 483 subpart G and further discussed within the interpretive guidelines as established in **Appendix N**. The SA will be advised annually in the CMS Mission and Priority Document (MPD) on the expected validation requirements for its State's psychiatric residential treatment facilities.

2833B – Survey Frequency

1. Frequency – The SAs are required to conduct recertification surveys for 20 percent of all PRTFs in the state each year and for all PRTFs within a State within a 5-year period. Complaint surveys do not count towards a State's 20 percent required recertification surveys.

2833C – Survey Procedures

Pre-survey procedures, onsite survey procedures, required CMS forms, and the interpretive guidelines are located in **Appendix N**.

2833C 1 PRE-SURVEY PROCEDURES

Under CMS policy, surveys for all providers and suppliers must be unannounced. While the unannounced surveys may sometimes result in some minor difficulties, this policy and practice represents public attitudes and expectations toward effective compliance with the regulation and survey standards. If there is any conflict with internal State policies and practices, the State survey agency (SA) should discuss the problem with its State Medicaid Agency (SMA).

2833C.2 ON-SITE SURVEY PROCEDURES

2833C.2a ENTRANCE CONFERENCE

The entrance conference sets the tone for the entire survey. The surveyor should be well prepared, courteous, and make requests, not demands. Upon arrival, the surveyor does the following:

- Presents the appropriate identification;
- Introduces other team members who must also furnish appropriate identification;
- Informs the facility's administrator, director, or supervisor of the purpose of the Survey;
- Provides expected duration and time schedule of the survey; and
- Provides the facility with an overview of the survey and explains the process.

During the entrance conference, the surveyors should:

A. Request a listing of all residents at the facility, including their age or date of birth, and who in the past 12 months:

- Have been secluded or restrained;
- Have been placed in time out;
- Received medication for behavior management;
- Have been injured or hospitalized as a result of restraint or seclusion intervention;
- Had a serious occurrence that was reported regardless of whether it is related to a safety intervention. A Serious occurrence as defined in the regulations is a resident's death, serious injury to a resident, or a resident's suicide attempt;

- Was transferred to a hospital for acute care services; and
- Died while in the facility.

B. Inform the facility that the survey process will include:

- A physical onsite tour of the facility;
- Direct observations, and interviews with residents, families/guardians, and personnel involved in the residents' care, (ask that appropriate family and guardians be made aware of potential interviews); and
- Review of relevant program, treatments, and residents records.

C. Establish personnel availability and discuss approximate time frames for survey completion.

D. Provide approximate or expected exit date and time.

E. Ask if there are any locked areas which require a key for entry, and if there are locked areas, how would the surveyor be able to access those areas.

F. Ask the facility to identify which staff will be available for questions/assistance.

G. Provide a list and category of the facility staff the surveyor will need to interview during the course of the survey.

2833C.3. Survey Team Composition

Survey team size and composition will vary according to the size of the facility and the purpose of the survey. Professional disciplines and experience represented on the survey team should reflect the expertise needed to determine compliance with the CoP. All survey team members must meet education and training qualifications as specified in the SOM §4009 and must have successfully completed the CMS Basic PRTF survey training course.

Any SA or federal surveyor who serves on the PRTF survey team must have completed the PRTF basic survey training course successfully.

2833C.4- INFORMATION GATHERING

2833C.4a TASK 1 - REPRESENTATIVE SAMPLE OF RESIDENTS - SELECTION METHODOLOGY

Purpose of the Sample - The purpose of drawing a sample of residents from the facility is to ensure all the regulatory requirements is applied to a proportionate representation of all residents. The sampling methodology outlined below is not intended to create a "statistically valid" sample. The methodology allows for flexibility in sample selection based on the surveyor's observations while on-site at the facility.

The surveyor must conduct interviews and observations of the sampled residents within

the context of the environment in which the resident lives, receives treatment and spends leisure time. Although focus should be on the sampled residents, the behavior and interactions of all other residents and staff within the environment also contributes to the total context.

After the resident sample is collected, additional information about the facility's practices, as well as additional resident information may emerge. Surveyors may add residents to the sample based on observations or incidents that occur during the survey. The reason for adding residents to the sample must be documented. Surveyors must add any resident who is restrained or secluded during the survey to the sample. A resident substitution may be made in the sample only if it is determined that including such a resident in the sample would negatively impact his/her treatment. For example, when interviewing/observing a resident with diagnosis of paranoid schizophrenia, may result in acute exacerbation of psychiatric symptoms. When a substitution is made within the sample, surveyors must ensure that the resident added to the sample meets the same requirements, and is selected from the same age group as the resident he/she is replacing.

Sample Considerations–

- Survey team should not allow the facility to select the resident sample.
- Sample selection should be completed before beginning review of residents or other survey activities.
- Survey team must randomly select sample from the list of all the residents provided by the facility.
- The sample should represent various age groups of the facility residents. The three main age groups are: ages 18 to 21; 9 to 17 and under 9 years.
- The sample should include residents who experienced restraint, seclusion or time-out in the past 12 month (if any); these residents should make up at least 50% of total sample.

Sample Selection:
Follow the guidance below using the appropriate ratio to select and calculate the size of the sample.

Census:	Sample Ratio:
4-8 residents	4 residents
9-16 residents	6 residents
17-50 residents	8 residents
51 or more residents	10 residents

NOTE:

- Due to unique characteristics the PRTF population and the seriousness of the Condition of Participation, surveyors should investigate further when a facility reports they have no current residents who have experienced either an ESI or time out procedure.

To maximize the advantage of an interdisciplinary survey team, the survey team leader assigns each member an equitable number of individuals on whom to focus. Each member of the team shares salient data about findings relative to his or her assigned individuals. Consult with one another, on a regular basis during the survey, to maximize sharing of data, knowledge and competencies.

Documentation – Document the sample on form CMS-807 Surveyor Notes Worksheet - The team leader must ensure that information related to the sample is well documented and includes the following:

1. Summary listing of all resident information comprising the survey sample (including any additions or substitutions to the sample). At a minimum, identify:
   - The record number of each resident chosen to be part of the sample;
   - Any resident-identifier codes used as a reference to protect the resident's confidentiality; and
   - The record number of each death record reviewed.

2. Description of the representative sample selection must include:
   - The number of residents in the sample;
   - The distribution of the individuals in the sample;
   - The number, if any, of the residents added to the sample, including the reason added,e.g., complaint investigation; and
   - The number, if any, of the residents substituted in the sample, including the reason for withdrawing the original resident record.

2833C.4b TASK 2 - RECORD REVIEW OF INDIVIDUALS IN THE SAMPLE

Review each resident's record to determine appropriate compliance with the condition of participation (CoP) for the use of restraint or seclusion, and the regulation requirements in 42 CFR §§ 441.151 through 441.182. The primary purpose of the record review is to determine if the facility is complying with the requirements of:

1) Certification of need for services;
2) Individual plan of care (treatment plan);
3) Documentation of emergency situation and all events surrounding it;
4) Management and outcome of emergency safety intervention; and
5) Health and wellness of the residents.

During record review, surveyors should be alert to instances of intramuscular medication use, safety hold and escort procedures, and any other procedures that could be mislabeled as not being restraints or seclusion. Utilize direct observations, resident interviews and record review to make informed compliance decisions. Ensure that the facility's definitions and perception of seclusion and restraint is in consonance with the definition that is contained in the regulation.

While reviewing the records, pay attention to key requirements such as: compliance with treatment team members' credentials, facility/program accreditation, and trends that may

suggest that seclusion and restraint intervention are being overused or misused. Also look for records of accidents and incidents which may suggest resident's abuse, neglect, bullying or vulnerability to injury. If there is any evidence of physical, verbal, emotional, or sexual abuse; surveyors must follow-up on the status and if required, implement the immediate jeopardy procedure as directed by Chapter 5 and Appendix Q of the SOM.

2833C.4c TASK 3- REVIEW OF OTHER RECORDS

A. Death Records - Review a list of all resident deaths, in the past 12 months. All team members must participate in the record review of residents who have died while at the facility. For death records, refer to form CMS-726, CMS Death Record Review Data Sheet. Evidence should exist of documented contact with appropriate Federal, State and local agencies notifying of the circumstances and demographics surrounding the resident's death and resulting outcomes from investigation by the PRTF and/or any of the appropriate Federal, State or local agencies.

B. Complaint Investigations - If a complaint is being investigated at the time of the survey, include the record(s) of the resident(s) of the complaint as part of the record review. If the resident named in the complaint is still in the facility, add him/her to the sample.

C. Policy and Procedures – Review the facility's policy and procedure documents on restraint, seclusion, and time out interventions. The policy must contain information about management of emergency safety intervention (ESI), and the facility's procedures regarding all the requirements of the CoP.

D. Serious Injury and Occurrence Report– Review all PRTF's serious injury and occurrence reports for at least past twelve months prior to the date of the present survey. Some individual state laws may preclude the facility from sharing detailed records of the incident. In such case, provide PRTFs an option as to whether or not they share these actual reports. In these States, surveyors should request a written summary of these reports. The PRTFs should provide this summary, as well as a copy of or citation to the applicable state law, within one working day of the entrance conference.

2833C.4d TASK 4 - DIRECT RESIDENT OBSERVATIONS

The purpose of direct observation is to determine the existence of effective therapeutic relationship between the facility staff and the residents. Staff must respect the rights of the residents and interact with them in a mutually productive manner. Direct observation also helps to determine how effective staff manages the milieu and efficiency of the application of de-escalation and other behavior management techniques. De-escalation techniques include: limit setting, therapeutic communication, redirection, conflict resolution, active listening techniques, and visualization.

Observe each sampled resident in as many treatment settings (therapy groups, activities, treatment team meetings, other types of meetings, and milieu interactions in the resident's environment) as possible. Visit as many treatment areas as time permits, and observe residents' activities during different time periods, including day and evening hours, if

possible; for team member's convenience or preference. Surveyors must never request the facility to alter a resident's schedule so that the surveyor will not have to work at other than their regular work times in order to observe the resident during the survey. The observation should be conducted for an amount of time sufficient to assess the sampled resident's responses and behaviors as well as staff responses to resident behaviors.

Documentation - If during resident observation the process of documentation will disrupt the activity in progress, the best option is to document after the observation is completed. Form CMS-3070I is an optional form but can be used to record observations if the surveyor so chooses. After observations are completed, compare observation result with the program/individual treatment plan for consistency.

Record the following information for each observation:

- Date and location;
- Beginning and ending times of observation;
- Number of residents present;
- Approximate number of staff present
- What the resident is doing (regardless of whether or not a scheduled therapeutic modality was in progress);
- What the staff is doing;
- The presence of disruptive behavior, and staff's intervention, if any; and,
- Any other pertinent information.

2833C.4e TASK 5 INTERVIEWS

Resident Interviews

Surveyors must interview all sample residents individually. However, an interview may not be conducted with a resident when it is determined by one of the individual plan of care team members, as described in §441.156(c), as being inappropriate for the resident's condition. Staff information and medical record documentation should support the rationale for not interviewing the resident.

When interviewing residents of a PRTF a surveyor should take into consideration the resident's age and psychiatric condition. Interviews with residents consist of questions directed at determining the resident's understanding of the treatment services indicated in their individual care plan and progress towards goals, type and quality of relationship with program staff, and their restraint or seclusion episode. In addition, the resident should be asked to what degree they felt safe while restrained or secluded and if they feel as if staff are working with them to prevent future restraint or seclusion usage.

Also ascertain if the resident felt that the restraint or seclusion was warranted based on their behavior. Interviewing should not take place in the direct presence of staff. However, a resident should be given an opportunity to have a staff member be within visual proximity if the resident so chooses. When an interview is deemed inappropriate by the facility staff, the survey activities for review of that resident will consist of observations, staff interviews, and record reviews. Resident confidentiality must be

respected, but if the surveyor does find a life-threatening situation, that information is shared with the staff. Listed below are suggested processes and questions that a surveyor may use during an interview.

Interview Setting:
Surveyors must respect resident's rights and ensure the setting of the interview is conducive and less restrictive. The surveyor should:

1. Request permission of the resident to talk with him/her individually.
2. Provide the resident with information, such as surveyor name and purpose of the survey.
3. Ensure resident privacy by conducting the interview in an appropriate location (low stimulus, on or off unit depending on resident restrictions, staff visible for surveyor and resident protection, if necessary). Staff should be easily available and may be present in the room, but should not be able to overhear conversation unless the resident makes a request for staff close physical presence.

Suggested Interview Questions:

- Can you tell me why you are in this facility?
- Tell me about your treatment goals?
- Do you think you are making progress towards your treatment? Can you tell me the names of your medications and why you are taking them?
- Do you have the opportunity to talk to members of your treatment team on a regular basis and how responsive are they to your interaction?
- Can you describe to me your experience with the last time you were restrained/ secluded/ in timeout?
- Where was staff located during your restraint/seclusion/ time out?
- Has the treatment team discussed the incident with you? Did you and the team agree on a plan to reduce the frequency of these incidents? Please describe the plan to me.
- Describe to me what incident that led to the restraint/seclusion/time out?

<u>Age Appropriate Adjustments</u> – Surveyors should keep in mind varying age range of residents in the PRTF (toddlers to adolescents or young adults) and adjust their interview approach accordingly for a better result. For example, there are times when kneeling or sitting in a chair may be less intimidating to residents, and more appropriate to begin a conversation. Also the way a question is framed may determine how much information one can elicit, for instance, instead of asking: "Can you tell me why you are in this facility?" The question can be reworded into different series of probing questions to get at a better answer. For example, "Do you like living here?" "Do you know why you are living here?" "Can you tell me about living here?" It is important to note that different facilities and residents may perceive or interpret restraint/seclusion intervention based on their own understanding and frame of reference.

Staff Interviews

Because milieu interaction and therapeutic intervention involve both the staff and the residents, it is also important to interview the staff in order to ascertain their level of

knowledge and understanding of the facility's restraint and seclusion policies and procedures. In order to ensure improved safety, staff must be adequately educated and oriented to their work environment. Staff should also be familiar with resident treatment plans and understand their role in facilitating the residents' attainment of the target treatment goals. Assess for consistent treatment approaches and collaboration among the interdisciplinary treatment team, as well as the outcomes experienced by the residents. Interview the following:

- Treatment team member who has assigned treatment responsibility for each sample resident (case manager, primary therapist, resident care coordinator, advocate); and

- Other staff members who are involved with the resident, either through multidisciplinary treatment assignment (social worker, dance therapist, dietician) or through work assignment (professional and paraprofessional staff members assigned to resident's unit).

During staff interviews, asking the following questions may help to elicit improved cooperation and more information:

- Do you participate in the interdisciplinary treatment team; if yes, what role do you play?
- Did you contribute to treatment plan objectives/goals for sample residents and updates?
- How often is each resident's treatment plan reviewed?
- Can you describe the discharge plans for sample residents?
- Give examples of de-escalation techniques you were taught and how you utilize them when dealing with residents?
- How do you integrate treatment plan goals and objectives that have been developed as a result of seclusion or restraint episodes?
- How do you manage resident's emergency safety situation, and how you determine when to utilize a restraint or seclusion intervention?
- Describe to me, how staff implement, manage, and discontinue time out, restraint or seclusion.
- What behavior typically warrants interventions such as restraint or seclusion?
- Do you feel you are adequately prepared (through education and training) to handle behavioral safety situations and emergencies related to residents' care?

Interviews with Parents and Legal Guardians

Surveyors will make a request to facility/program staff after the entrance conference to give sample residents family/guardian notice of a potential for interview. The interviews with parents and legal guardians should be conducted in addition to interviews with sampled residents. Interviews with parents and legal guardians should be conducted at their convenience with an opportunity for face-to-face interviews when feasible. In cases where parents or legal guardians reside in another state or are unable or unwilling to meet face-to-face, telephone interviews should be conducted. Suggested questions:

- Were you involved in formulation of your family member's treatment plan and

discharge plans?

- Are you aware of the psychiatric medications your family member is taking and/or being prescribed while in treatment?
- Have you been able to communicate with members of your family member's treatment team?
- Do you know your family members treatment diagnosis, and do you understand what it means?
- Were you informed of the facility's policy on restraint and seclusion?
- Was the information presented in a manner that you could understand?
- Did you receive the information regarding the State Protection and Advocacy organization? What type of information should be reported to them?
- Were you contacted after a restraint or seclusion intervention?
- Were you given an opportunity to participate in the debriefing following restraint/seclusion use?

Interviews with Department Heads and/or Facility Administrator

Conduct these interviews near the end of the survey if it is determined that questions were unanswerable by facility staff and interviewing directors or other facility leaders would prove useful to the survey process and the gathering of information. Base the interview on information that was gathered during observations and direct interviews with residents and staff.

Documentation – Use form CMS-807 to record each observation and interview conducted with residents/ parents/ legal guardians and staff. Clearly delineate the documentation as an interview. Include the date and time of each interview and the following information in every recorded entry:

Resident:

- The record number, any resident-identifier codes used as a reference to protect the resident's confidentiality, and the resident's age;
- Dates of restraint, seclusion or time out; and,
- Summary of information obtained.

Parent/ Legal Guardian:

- Relationship to the resident;
- Method of interview (face-to-face or telephone contact); and,
- Summary of information obtained.

Staff/ Management/ Directors:

- Position, title and assignment of staff member;
- Relationship to the resident or reason for interview; and,
- Summary of information obtained.

2833C.4f TASK 6 - VISIT TO EACH AREA OF THE FACILITY SERVING RESIDENTS

Visit all areas in the facility where residents are permitted to spend their time, both structured and unstructured, as these are places where unanticipated behavior may occur that would require emergency interventions. Also examine the area that is used for restraint as well as those devices that the facility uses as a restraint. Other examples of areas to visit are: restrooms, bathrooms, activity areas, visitation areas, therapy rooms, seclusion/time-out room, dining areas, bedrooms, and classrooms. During the visit or tour, converse with residents and staff. Ask open-ended questions in order to confirm observations, obtain additional information, or corroborate information regarding perceived problems. Observe staff interactions with both residents and other staff members for insight into matters such as individual rights and staff responsibilities.

Protocol - After residents in the sample have been assigned to team members, review the facility's map or building layout. Be sure that at least one team member visits each residential and treatment unit prior to completing the survey. The visit or tour can be conducted at any time during the course of the survey. Always obtain permission from the resident before entering his/her room.

2833C.4g TASK 7 – COMPLIANCE DETERMINATION AND PREPARATION FOR EXIT CONFERENCE

Preparation for Exit Conference.—In preparation for an exit conference, the surveyors should hold a pre-exit survey team conference at the conclusion of the survey and prior to the facility exit conference. The survey team leader must ascertain that all survey team members have completed their respective survey tasks before the pre-exit meeting. At this meeting, the surveyors will share their respective findings, and make team decisions regarding compliance with each standard, requirement, and Condition of Participation. Deficiencies found in more than one aspect of the CoP may be cumulative and interrelated and result in general or across-the-board inadequacies in resident care that may constitute actual or potential hazards to residents. The team leader should record the survey team decisions on the CMS-807 as a record of the team's non-compliance determinations. This would be the basis for a finding of noncompliance. All necessary forms must be completed, which may include:

CMS-807 - Surveyor Notes Worksheet
CMS-2567 - Statement of deficiencies and Plan of Correction (Post Survey)
And if applicable
CMS-726 - CMS Death Record Review Data Sheet
Optional
CMS-3070I - Individual Observation Worksheet

General - It is recommended to complete the CMS-2567 as a post survey document. Include in the CMS-2567 all examples of evidence obtained from observations, interviews, and record reviews that contribute to a determination that the facility is deficient in a certain area.

Special Circumstances - If at any time during the survey one or more team members

identify a possible immediate jeopardy, the team should meet immediately to confer. See Appendix Q for the definition of and for guidance regarding determination of immediate jeopardy.

Exit Conference. — Following the survey team meeting to determine compliance, the survey team should conduct an exit conference with the PRTF's administrator, designee, and other invited staff. The purpose of the exit conference is to communicate preliminary survey team findings.

Although it is CMS' general policy to conduct an exit conference, be aware of situations that may justify discontinuation of an exit conference. For example, if the PRTF is represented by a lawyer (all participants in the exit conference should identify themselves), surveyors may refuse to conduct or continue with the exit conference if the facility lawyer tries to turn it into an evidentiary hearing, or the staff creates an environment that is hostile, overly intimidating, or inconsistent with the informal and preliminary nature of an exit conference. Refer to §2724 of the SOM.

2834 – Other Applicable SOM Sections

(Rev. 132; Issued: 01-16-15, Effective: 01-16-15, Implementation: 01-16-15)

The following procedures already established in various Chapters within this manual serve as a basis for direction for the SA.

- SOM §3010: Termination Procedures – Immediate and Serious Threat to Patient Health and Safety (23 Calendar Days).
- SOM §3012: Termination Procedures – Noncompliance with one or more CoPs or Conditions for Coverage and Cited Deficiencies Limit Capacity of Provider/Supplier to Furnish Adequate Level or Quality of Care (90 Calendar Days).
- SOM §3060: Appeals of Adverse Actions for Medicaid Non-State operated NFs (Non-State Operated) and ICF/IIDs (Not Applicable to Federal Termination of Medicaid Facilities)
- SOM §5200 Investigation of Complaints Against Other than Accredited Providers and Suppliers. Although on its face this section applies to non-accredited providers and suppliers, we believe this section is better suited for PRTFS.
- Appendix Q – Guidelines for Determining Immediate Jeopardy – "these guidelines apply to all certified Medicare/Medicaid entities…and to all types of surveys and investigations…"
- SOM §4009 Federal Surveyors Qualification Standards

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R201SOMA	06/19/2020	State Operations Manual (SOM) Chapter 2, The Certification Process	07/27/2020	N/A
R198SOMA	01/17/2020	Revisions to the State Operations Manual (SOM) Chapter 2 and Chapter 3	01/17/2020	N/A
R197SOMA	01/10/2020	Revisions to the State Operating Manual (SOM) Chapter 2; Community Mental Health Center (CMHC)	01/10/2020	N/A
R193SOMA	09/20/2019	Revisions to Medicare State Operations Manual (SOM) Chapter 2	09/20/2019	N/A
R190SOMA	06/14/2019	Updates to the State Operations Manual (SOM) Chapters 2, 3 and 9 to add instructions for Organ Transplant Programs.	06/14/2019	N/A
R188SOMA	04/26/2019	Revisions to the State Operations Manual (SOM 100-07) Chapter 2, The Certification Process, Chapter 3, Additional Program Activities, and Chapter 4, Program Administration and Fiscal Management	04/26/2019	N/A
R184SOMA	10/17/2018	Revisions to State Operations Manual, Chapter 2, Certification Process	10/17/2018	N/A
R181SOMA	09/21/2018	Revisions to State Operations Manual, Chapter 2, Certification Process- Rescinded and replaced by Transmittal 184	09/21/2018	N/A
R179SOMA	07/06/2018	Revisions to the State Operations Manual (SOM) Chapter Two for Organ Procurement Organizations (OPOs)	07/06/2018	N/A
R164SOM	11/04/2016	Revisions to the State Operations Manual (SOM) Chapter 2	11/04/2016	N/A
R154SOM	06/10/2016	Revisions to the State Operations Manual (SOM) Chapter 2	06/10/2016	N/A
R152SOM	03/25/2016	Revisions to the State Operations Manual (SOM) Chapter 2	04/04/2016	N/A
R150SOM	10/30/2015	Revisions to State Operations Manual (SOM), Chapter 2, Clarification of Requirements for Off-Premises Activities and Approval of Extension Locations for Providers of Outpatient Physical Therapy and Speech-Language Pathology Services	10/30/2015	N/A
R146SOM	09/04/2015	State Operations Manual (SOM), Section 2185- Home Health Agencies (HHAs), Change of Address to a Medical Administrative Contractor (MAC) within 90 Days	09/04/2015	N/A

R143SOM	07/31/2015	Revisions to State Operations Manual (SOM) Chapter 2, The Certification Process and Appendix W, Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs	07/31/2015	N/A
R139SOM	04/24/2015	Revisions to the Medicare State Operations Manual (SOM), Chapter 2, Rural Health Clinic Certification	04/24/2015	N/A
R132SOM	01/16/2015	New Additions to State Operating Manual (SOM), Psychiatric Residential Treatment Facilities (PRTF) Chapter 2	01/16/2015	N/A
125SOM	10/31/2014	Revisions to State Operations Manual (SOM) Chapter 2	10/31/2014	N/A
123SOM	10/03/2014	Revisions to State Operations Manual (SOM) Chapters 1, 2 and 3	10/03/2014	N/A
R111SOM	04/11/2014	State Operations Manual (SOM) Chapter 2 Policy Revisions For Organ Procurement Organizations (OPOs)	04/11/2014	N/A
R91SOM	09/27/2013	State Operations Manual (SOM) Chapter 2 Policy and Nomenclature Revisions for Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID)	09/27/2013	N/A
R90SOM	08/30/2013	State Operations Manual, Chapter 2, Section 2256A,CAH Distance Criteria	08/30/2013	N/A
R85SOM	07/19/2013	Federally Qualified Health Center (FQHC) Medicare Participation	07/19/2013	N/A
R83SOM	03/15/2013	Revisions to Appendix E and Chapter 2 sections 2290-2308 of the State Operations Manual (SOM)	03/15/2013	N/A
R82SOM	08/01/2012	CMS Certification Numbers for Medicaid-Only Hospitals and new State Code for Foreign Countries	08/01/2012	N/A
R73SOM	12/02/2011	Revisions to Chapter 2, “The Certification Process”, Sections 2082-2089-“Hospices”	12/02/2011	N/A
R69SOM	12/15/2010	Revisions to Chapter 2, “The Certification Process”, Sections 2080-2089-“Hospices,” and Appendix M, “Guidance to Surveyors, Hospices”	10/01/2010	N/A

R65SOM	10/01/2010	Revisions to Chapter 2, “The Certification Process”, Sections 2080-2089-“Hospices,” and Appendix M, “Guidance to Surveyors, Hospices” - Rescinded and replaced by Transmittal 69	10/01/2010	N/A
R62SOM	07/30/2010	New State Code for Missouri; New CCN for Medicaid -Only Hospitals	01/03/2011	6989
R57SOM	01/29/2010	Revised Chapter 2, “The Certification Process”, Section 2256H	01/29/2010	N/A
R53SOM	10/16/2009	Revising Chapter 2, “The Certification Process”-Ascertaining Compliance With the Office for Civil Rights (OCR) Requirements	10/16/2009	N/A
R49SOM	06/12/2009	New Critical Access Hospital (CAH) Requirements Under 42 CFR 485.610(e) Related to CAH Co-location and CAH Provider-based Locations	06/12/2009	N/A
R43SOM	05/01/2009	Revised Chapter 2, “The Certification Process,” Section 2008A	05/01/2009	N/A
R40SOM	03/20/2009	Revisions to Chapter 2, “The Certification Process”, Sections Relating to Federally Qualified Health Centers, and Exhibits 177 and 179	03/20/2009	N/A
R33SOM	03/21/2008	Update to Chapter 2, “The Certification Process” Sections 2021 and 2022	03/21/2008	N/A
R32SOM	01/18/2008	Revisions to Chapter 2, “Critical Access Hospitals (CAHs) and Appendix W, “Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs”	09/2007	N/A
R29SOM	10/12/2007	New Number Series and State Codes for CMS Certification Numbers (formerly OSCAR Provider Numbers)	10/01/2007	5490
R28SOM	09/07/2007	Revisions to Appendix D, Guidance to Surveyors for Portable X-ray Services	09/07/2007	N/A
R25SOMA	04/20/2007	New Number Series and State Codes for CMS Certification Numbers (formerly OSCAR Provider Numbers) – Replaced by Transmittal 29	10/01/2007	5490
R17SOMA	01/20/2006	Revisions to Chapter 2 The Certification Process	01/20/2006	N/A

R16SOMA	01/10/2006	Revisions to Chapter 2, "The Certification Process," Appendix E--"Providers of Outpatient Physical Therapy or Outpatient Speech Language Pathology (OPT/OSP) Services," and Appendix K--"Comprehensive Outpatient Rehabilitation Facilities"	11/21/2005	N/A
R13SOM	10/21/2005	Revisions to Chapter 2, "The Certification Process," Appendix E-- "Providers of Outpatient Physical Therapy or Outpatient Speech Language Pathology (OPT/OSP) Services," and Appendix K--"Comprehensive Outpatient Rehabilitation Facilities" – Replaced by Transmittal 16	10/21/2005	N/A
R11SOM	08/12/2005	Revised Chapter 2--"The Certification Process," Sections 2180E thru 2200F, and Appendix B--"Interpretive Guidelines: Home Health Agencies"	08/12/2005	N/A
R06SOM	04/29/2005	Expansion of State Codes for OSCAR Provider Numbers	10/03/2005	3844
R03SOM	10/29/2004	Medicare Systems Acceptance of New Provider Numbers for Federally Qualified Health Centers (FQHC)	04/04/2005	3537
R02SOM	08/20/2004	Assignment of Provider Identification Numbers	N/A	3245
R01SOM	05/21/2004	Initial Issuance of Pub 100-07	N/A	N/A