State Operations Manual

Chapter 2 - The Certification Process

(Rev. 2, 08-20-04)

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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. 1, 05-21-04)

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 489.2(b) and 42 CFR 498.2 respectively.

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 42 CFR 498.2.)

Portable x-ray services, rural health clinics (RHCs), 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, as distinguished from other suppliers, e.g., durable medical equipment (DME) suppliers, pharmacies, prosthesis suppliers, for which there are no conditions for coverage, 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 must meet CLIA requirements. Laboratories that participate in Medicare are considered suppliers. Federally Qualified Health Centers (FQHCs) are also recognized as suppliers of services and provide Medicare Part B coverage for outpatient services similar to those provided by RHCs. Suppliers, with the exception of FQHCs, must meet conditions for coverage to participate in Medicare. FQHCs may be located in urban, as well as rural, areas.

To reiterate, 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. 1, 05-21-04)

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 assist the party in attaining compliance as early as possible, since the effective date of participation can be no earlier than the date on which the party meets all the federal requirements; including compliance with the CoPs (CMHCs have no CoPs), conditions for coverage or Requirements for SNFs are met as determined by an initial certification survey, or the date on which the supplier or provider submits an acceptable PoC or an approved waiver request, or both. For SNFs, the effective date is the date the SNF is in compliance with all the requirements for SNFs or the date it is in substantial compliance and submits, if applicable, an approvable waiver

request. (See 42 CFR 442.13 and 489.13(c).) Since there are not any Medicare conditions for CMHCs and FQHCs, the effective date for these entities is the date the RO signs the provider agreement, after determining that all Medicare requirements including enrollment are met.

2003B - Initial Certification "Kits"

(Rev. 1, 05-21-04)

When an entity wishes to participate initially in either or both programs, the provider/supplier must obtain Forms CMS-855A "Medicare Federal Health Care Provider/Supplier Applications that will Bill Medicare Fiscal Intermediaries," or Form CMS-855B "Medicare Federal Health Care Provider/Supplier Applications that will Bill Medicare Carriers." These forms are available for downloading at http://www.cms.hhs.gov/forms/ along with a user's guide providing instructions for downloading and completing the forms. The provider/supplier will complete the application and submit it directly to the fiscal intermediary (FI) or carrier, as appropriate. The CMS Web site referenced above also contains a list of FIs and carriers by state and specialty that can provide further assistance in downloading, completion, and submission of the form. If the provider/supplier needs to select an FI or carrier, it may access this Web site. The providers' FI of preference does not automatically guarantee that it will be assigned to that FI. (See 42 CFR 421 for additional information.)

The FI/carrier will answer any applicant inquiries concerning completion of the enrollment application. Within ten (10) calendar days of receipt of the Form CMS-855A or Form CMS-855B, the FI/carrier will send a copy of the application to the SA or the regional office, as applicable. If the applicant has not contacted the SA when it receives a copy of the enrollment application, then the State will contact the applicant using the phone number listed on the application.

If the FI/carrier verifies the information on the enrollment application, it will provide the SA and relevant RO with a written recommendation for approval of enrollment. **The SA should not perform a survey of a new facility until it has received notice from the FI or carrier that the information provided on the enrollment application has been verified.** A SA may, however, start planning for a state survey upon initial contact with the applicant. Enrollment also applies to providers/suppliers seeking deemed status through their accreditation by a professional organization. Accreditation organizations have agreed not to survey new providers/suppliers until these providers/suppliers show them evidence of enrollment.

The provider/supplier must still contact the SA for Medicare and/or Medicaid certification forms for their provider/supplier type, and respond to questions about survey and certification including the effect of any proposed changes. The SA mails the initial certification materials under cover of the appropriate form letter. (See Exhibits 1A-1F and Exhibit 63.)

Upon receipt, the SA reviews the forms to see that they are properly completed and secures any necessary changes or additional information. It makes sure any required UR plans and SNF transfer agreements are received. If a distinct part of an organization is being considered for participation, the SA reviews the diagram (or floor plan) submitted to make sure the size and location of the distinct part are clearly shown. If the entity indicates that it is requesting provider-based status under the Medicare program, the SA must notify the RO immediately. Distinct Part and Provider-Based are not synonymous terms. The SA works in conjunction with the RO and the intermediary 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 are sent to the RO, along with the Title VI Assurance of Compliance with Civil Rights (Form HHS-690) or the comparable form, the intermediary preference form. In title XIX-only cases, the SA sends the Form HHS-690 or comparable form to the SMA. Determinations concerning provider-based are made by RO Financial Management Personnel and the Intermediary.

The SA refers questions about enrollment (§2005), intermediaries, 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 FI or carrier.

2004 - Provider-Based Designation

(Rev. 1, 05-21-04)

The RO, Division of Financial Management following the instructions in 42 CFR 413.65 and with the assistance the fiscal intermediary, will make determinations regarding provider-based and freestanding designation. These instructions apply to all such designation decisions regarding any provider of services under the Medicare program, and also includes physicians' practices or clinics or other entities that are not themselves providers, but who state they are part of a provider. These decisions are needed to ensure that both provider-based and freestanding entities are paid appropriately.

After reviewing the documentation from the entity that supports its request and the recommendation of the fiscal intermediary, the RO Financial Management Component makes a determination and notifies the provider and its fiscal intermediary in writing of its decision. Distinct part decisions and determinations involving branches, satellites, extension locations, etc. and non-provider based facility members are made by RO survey and certification personnel with assistance from the SA.

The use of the criteria contained in 42 CFR 413.65 making provider-based designations/determinations may result in identification of previous provider-based decisions that would not be in accordance with the criteria above. As a result of the prospective payment system (PPS) some provider-based determinations are no longer necessary (consult with RO Financial Management Personnel in specific situations). Any

facilities or organizations that were "treated" as provider-based both formally and informally in relation to any hospital or CAH on October 2000 will continue to be treated as such until October 1, 2002. Effective October 1, 2002, the RO may re-evaluate and revise a decision made prior to October 1, 2002. If a decision is not questioned after October 1, 2002, it will remain intact. RO Survey and Certification personnel do not make separate provider-based decisions from those made by the RO Financial Management Component. While these decisions may be discussed, the Financial Component decision rules.

Designation Requirements - The requirements at 42 CFR 413.65 apply to provider-based determinations made in conjunction with all initial certification decisions and recertifications, as well as decisions of providers to add new practice locations or expand their existing practice locations, e.g., a Medicare-certified hospital requests to expand in order to add physician practices or clinics under its Medicare provider certification. Only those criteria that apply to the particular type of entity must be met before an entity can be designated as part of a provider for purposes of payment under the Medicare program. When an entity is determined to be provider based it is subject to the Medicare conditions the same as the provider with which it shares a Medicare agreement/number.

2005 - Medicare Health Care Provider/Supplier Enrollment

(Rev. 1, 05-21-04)

The Centers for Medicare & Medicaid Services (CMS) is authorized to collect the information requested on the Forms CMS-855A and CMS-855B (see §2003.B above) 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]. This information must, minimally, clearly identify the provider and its place of business, including all practice sites, and provide all necessary documentation to show it is qualified to perform the services for which it is billing.

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 "Medicare Federal Health Care Provider/Supplier Application for Health Care Providers that will Bill Fiscal Intermediaries" (Form CMS-855A) and "Medicare Federal Health Care Provider/Supplier Application for Health Care Providers that will Bill Carriers" (Form CMS-855B) are the documents used to collect information and documentation to be verified to assure that the applicant is qualified and eligible to participate in the Medicare

program. These forms standardize the enrollment process for all providers and suppliers. The enrollment process is also to be used for providers/suppliers that are accredited or intend to become accredited. At this time, the Form CMS-855A or Form CMS-855B enrollment forms need to be completed for initial certifications, changes of information, and changes of ownership. An applicant will complete the Form CMS-855A or Form CMS-855B application in order for CMS to obtain certain required information before a survey is conducted.

The fiscal intermediary will process the Form CMS-855A and the carrier will process the Form CMS-855B, depending on which contractor is responsible for processing bills or claims for the provider/supplier. The Form CMS-855A or the CMS-855B is available for downloading from the CMS Web site http://www.cms.hhs.gov/forms/ (See §2003). The State survey agency will be responsible for surveying initial applicants following enrollment, and providing the initial certification package. Hospitals, CAHs, ASCs, HHAs and Hospices have the option of establishing compliance through deemed status (42 CFR 488, Subpart A). Providers/suppliers should be informed of the enrollment process so that they do not expect instant Medicare effective dates. Should the applicant have any questions concerning the enrollment form, The FI/Carrier contacts are available from the above Web site. The Medicare enrollment process is not applicable to the Medicaid program. States use their own enrollment process. The provider/supplier should submit the Form CMS-855A or the CMS-855B to the appropriate contractor as follows:

Fiscal Intermediary - The fiscal intermediary should process the Form CMS-855A for hospitals, critical access hospitals, skilled nursing facilities (SNF), skilled nursing facilities/nursing facilities (SNF/NF), outpatient physical therapy/speech language pathology provider (OPT/SP), comprehensive outpatient rehabilitation facilities (CORF), community mental health centers (CMHC), end-stage renal disease facilities (ESRD), and organ procurement organizations (OPO).

Carrier - The carrier should process the Form CMS-855B for portable x-ray suppliers and ambulatory surgical centers (ASC).

Both Fiscal Intermediary and Carrier - Rural health clinics (RHC), federally qualified health centers (FQHC), and clinical laboratories may bill either the intermediary, the carrier or both. These facilities complete either the Form CMS-855A or the CMS-855B.

Specialty Intermediaries - The specialty intermediary/carrier processes the Form CMS-855A for home health agencies (HHA), hospices, independent RHCs, freestanding FQHCs, and Religious Nonmedical Health Care Institutions (See §2005.G for further information on specialty intermediaries.) Indian Health Services, Veterans Administration and a other Federal facilities are not required to enroll. Tribal entities are required to enroll.

2005A - Initial Certifications

(Rev. 1, 05-21-04)

Applicants who want to enroll in the Medicare program should refer to the CMS Web site http://www.cms.hhs.gov/forms/ for copies of the Form CMS-855A or the CMS-855B. (See §2003.) The Form CMS-855A and Form CMS-855B do not replace existing certification applications. Provider specific forms will continue to be used in addition to the Form CMS-855A or CMS-855B. (Forms that are to be sent to a specific provider are listed in Exhibit 63.) The RO will mail out certification packages to applicants applying to become approved as an OPO, FQHC, IHS hospitals, and for CMHC when the SA has no involvement. The applicant will complete all forms in the packet and return them to the FI/carrier. It is important that all application packages be completed by prospective providers as early as possible since the initial clearance of the Form CMS-855A or Form CMS-855B will occur before the on-site survey is conducted or action is taken by the RO to approve those providers/suppliers that do require an on-site survey. The current Medicare effective date rule will not change, meaning that payment will only be retroactive to the [survey or plan of correction] approval date in accordance with 42 CFR 489.13.

When the completed application package is received from the provider/supplier, the FI/carrier should photocopy and log the receipt of the Form CMS-855A or CMS-855B. The RO or SA should direct the provider/supplier to the CMS Web site listed above. A list of fiscal intermediaries and carriers is also available via that Web site. The State survey agency will be responsible for verifying any licensure documents that they have issued and have control over. The SA does not review the Form CMS-855A or CMS-855B for completeness or accuracy, and does not provide guidance in completing the Form CMS-855A or CMS-855B because this will be done by the appropriate intermediary/carrier. The fiscal intermediary/carrier will be responsible for verifying the Form CMS-855A or CMS-855B application information and making an enrollment recommendation prior to the survey. The fiscal intermediary/carrier will notify the State survey agency and the RO of its recommendation for approval or denial of enrollment, or request for additional information within 30 calendar days of receipt of the completed application by the intermediary/carrier. There are three possible actions an intermediary/carrier may take on an enrollment application:

1. Return to provider/supplier for additional information;

2. Recommend approval; or

3. Recommend denial.

2005A1 - Request for Additional Information

(Rev. 1, 05-21-04)

If required information is missing or information provided on the application cannot be verified, the fiscal intermediary/carrier may request additional information directly from the applicant. In most cases, requests for additional information will be made within 30 calendar days of the initial receipt of the application by the intermediary/carrier. The fiscal intermediary/carrier will forward a copy of the request for additional information to, either the RO or State survey agency. The 30-calendar day period for processing an application restarts when the additional information is received by the intermediary/carrier from the applicant.

2005A2 - Approval

(Rev. 1, 05-21-04)

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 State survey agency and the RO of its recommendation for approval of the provider/supplier within 30 calendar days (absent extenuating circumstances) of the receipt of the completed Form CMS-855A or CMS-855B. The notification will be in written form. It will be accompanied by a copy of the completed Form CMS-855A or CMS-855B, if changes were made to the Form CMS-855A or CMS-855B since the State survey agency or RO initially received it. The intermediary/carrier will also enumerate the provider in the National Provider System (NPS) and provide the State survey agency and the RO with the National Provider Identifier (NPI), when the NPS becomes operational.

The State survey agency or RO, when applicable, surveys providers that are subject to an on-site certification survey after it receives the recommendation of approval from the intermediary or carrier, and when the provider is ready to be surveyed. Hospitals, CAHs, ASCs, HHAs, and Hospices have the option of establishing compliance through deemed status (42 CFR 488, Subpart A).

Applicant in Compliance - The surveying agency (State survey agency/RO) surveys the provider/supplier and certifies or recommends Medicare approval if it determines that the provider/supplier is in compliance with the conditions of participation/coverage. The surveying agency forwards the survey results to the RO who will then proceed with the provider or supplier's Medicare approval. The RO will issue a provider agreement and assign a provider number (OSCAR number). The RO will notify the intermediary/carrier of the applicant's approval in the Medicare program by sending the Provider Tie-In Notice (Form CMS-2007), when applicable, and/or a copy of the provider's approval letter that will include the provider number. The RO will send the State survey agency a copy of the applicant's approval letter. Before the above documents are sent to the intermediary/carrier, the RO will look at the completed Form CMS-855A that the intermediary sent with the recommendation of approval. On page one of the Form CMS-

855A if "Both" is checked for the item entitled "Where will applicant be submitting billings?" then the FI will also send a copy of the Form CMS-855A, and the provider's approval letter which includes the provider's identification number to the carrier.

Applicant Not in Compliance - The surveying agency surveys the provider/supplier and certifies that the provider/supplier is not in compliance with the conditions of participation/coverage. The State survey agency forwards the survey results to the RO who will send the provider/supplier a denial letter. The RO will forward a copy of the denial letter to the fiscal intermediary/carrier and to the State agency. Claims will not be paid if the applicant is not approved for both the enrollment and the survey and certification processes.

An applicant may be issued a denial letter for noncompliance with the conditions of participation/coverage. The applicant may correct the deficiencies and reapply for certification. If the State surveys the applicant within three months of the date of the denial letter, then the enrollment process does not have to be repeated. If the State surveys the applicant later than three months from the date of the denial letter, then the applicant will have to submit a new Form CMS-855A or CMS-855B to the intermediary/carrier. The applicant has to repeat the enrollment process if it is surveyed after three months from the date of the denial letter.

2005A3 - Denial

(Rev. 1, 05-21-04)

After a complete review and verification of the information provided on the enrollment form, the carrier must only deny an application and intermediaries can only recommend a denial to the RO for the following reasons:

Denial 1

The applicant and/or any owner, managing/directing employee, parent/joint venture or subsidiary, chain, subcontractor, or group member is/are excluded from Medicare by the Office of the Inspector General (OIG).

The applicant and/or any owner, managing/directing employee, parent/joint venture or subsidiary, chain, subcontractor, or group member is/are excluded from Medicare by virtue of being on the Federal Government's (General Service Administration) "List of Parties Excluded from Federal Procurement and Nonprocurement Programs."

Denial 2

The applicant does not possess a current valid license that is required by Federal, State, or local government in order to furnish health care items or services of the type the applicant purportedly furnishes or intends to furnish to Medicare beneficiaries.

The applicant's license, and any other information or documentation furnished by the applicant with respect to such license, fails to show that such license was issued by a governmental entity having jurisdiction over a practice, service-delivery, or operating location designated by the applicant as a location at or from which the applicant purportedly furnishes or intends to furnish items or services to Medicare beneficiaries or that the applicant's license, if valid only for a specific physical location, is not valid for the physical location specified by the applicant, service-delivery, or operating location at or from which the applicant purportedly furnishes or intends to furnish items or services to Medicare beneficiaries.

Denial 3

The applicant failed to furnish an address sufficient to readily identify the physical business location at or from which the applicant purportedly furnishes or intends to furnish items or services to Medicare beneficiaries; or having furnished such an address, the applicant does not appear (on the basis of extrinsic evidence) to be furnishing items or services otherwise operating from such location; or, if the applicant is an individual practitioner who does not furnish or does not intend to furnish items or services to Medicare beneficiaries at or from a location controlled by the applicant (e.g., a physician practicing exclusively as an employee), such applicant failed to furnish an address sufficient to readily identify the physical location at which the applicant can be personally served with required notice in the event that proves necessary.

Denial 4

The applicant does not meet CMS regulatory requirements for the specialty. (In the denial letter, list appropriate regulation citation.)

Denial 5

The applicant's (i) billing agreement, (ii) billing service contract, or (iii) other agreement that creates or maintains, directly or indirectly, a relationship between the applicant and another entity for the purpose of billing, the sale or purchase or other transfer of accounts receivable, or other financial relationship effecting a transfer - directly or indirectly - of Medicare claims payment, or any other evidence, shows or furnishes substantial evidence that the applicant is violating Medicare rules on assignment or reassignment of claims.

Denial 6

The applicant does not provide a valid SSN/employer identification number for the applicant, owner, partner, managing organization/employee, officer, director, ambulance crewmember, Medical Director, and/or delegated or authorized official.

Denial 7

The applicant does not meet the capitalization requirements. If the carrier determines that the applicant should be denied enrollment or if the FI recommends a denial to the RO because of failure to meet one or more of the above requirements, enter this information in the provider file. Once you complete the process, carriers should inform the applicant of the reason(s) for denial and provide the applicant appeal rights.

Denial 8

The applicant deliberately falsifies, misrepresents, or omits information contained in the application or deliberately alters text on the application form.

Procedure for Denials - A provider/supplier may be denied enrollment by the RO. Intermediaries and carriers do not have the authority to issue a denial letter for certified providers/suppliers, but they may make a recommendation of denial to the RO. The RO issues the denial notice. The recommendation will cite one or more of the reasons for denial which are shown above. When an applicant is denied enrollment, the State survey agency does not conduct a certification survey. The intermediary/carrier will provide any relevant information requested by the RO to assist in issuing the denial letter. The RO prepares a letter notifying the applicant that the application has been denied, the reason(s) for the denial, and informs the applicant of the right to appeal a denial. The RO will forward a copy of the denial letter to the State survey agency and the intermediary/carrier. When denying an application, the RO should use the following language:

> Based upon a consideration of the facts and circumstances, your application to enroll as a provider/supplier in the Medicare program has been denied for the following reason(s):
>
> > [Name(s) of excluded persons or organizations] is/are currently excluded from participating in the Medicare program by the Office of the Inspector General.
> >
> > [Name(s) of excluded persons or organizations] is/are currently excluded from participating in the Medicare program because you are on the Federal Government's (General Service Administration) List of Parties Excluded from Federal Procurement and Nonprocurement Programs.
> >
> > [Name(s) of excluded persons or organizations] does not possess a current valid license that is required by Federal, State, or local government in order to furnish health care items or services of the type the applicant purportedly furnishes or intends to furnish to Medicare beneficiaries.

[Name(s) of excluded persons or organizations] failed to furnish an address sufficient to readily identify the physical business location at or from which the applicant purportedly furnishes or intends to furnish items or services to Medicare beneficiaries; or having furnished such an address, the applicant does not appear (on the basis of extrinsic evidence) to be furnishing items or services otherwise operating from such location; or, if the applicant is an individual practitioner who does not furnish or does not intend to furnish items or services to Medicare beneficiaries at or from a location controlled by the applicant (e.g., a physician practicing exclusively as an employee), such applicant fails to furnish an address sufficient to readily identify the physical location at which the applicant can be personally served with required notice in the event that proves necessary.

[Name(s) of excluded persons or organizations] license, and any other information or documentation furnished by the applicant with respect to such license, fail to show that such license was issued by a governmental entity having jurisdiction over a practice, service-delivery, or operating location designated by the applicant as a location at or from which the applicant purportedly furnishes or intends to furnish items or services to Medicare beneficiaries or that the applicant's license, if valid only for a specific physical location, is not valid for the physical location specified by the applicant, service-delivery, or operating location at or from which the applicant purportedly furnishes or intends to furnish items or services to Medicare beneficiaries.

[Name(s) of excluded persons or organizations] (i) billing agreement, (ii) billing service contract, or (iii) other agreement that creates or maintains, directly or indirectly, a relationship between the applicant and another entity for the purpose of billing, the sale or purchase or other transfer of accounts receivable, or other financial relationship effecting a transfer - directly or indirectly - of Medicare claims payment, or any other evidence, shows or furnishes substantial evidence that the applicant is violating Medicare rules on assignment or reassignment of claims.

You have the right to appeal this decision. Submit a written request to (name and address of designated individual at RO) within 60 calendar days from the date of this notice to appeal this denial."

Exhibit 254 demonstrates a model letter of a notification to an applicant that the Medicare General Enrollment Health Care Provider/Supplier Application has been denied. The RO should use this letter or a reasonable facsimile to notify the applicant. The RO will send the denial letter to the applicant, and forward a copy to the State survey agency and the intermediary/carrier.

Procedure for Appeals - An applicant has the right to appeal a denial decision. To appeal a RO denial, the applicant submits a written request to the RO within 60 calendar days from the date of the denial notice. The applicant may appeal factual issues, i.e., issues where the applicant feels either that the information CMS has relied upon is incorrect, or that CMS has misapplied or misinterpreted accurate information. An example of a fact-based appeal would be if there were ambiguity as to whether the applicant was the actual provider/supplier excluded. The merits of an exclusion by the OIG or the GSA may not be appealed through this process. However, the fact of such exclusion, i.e., whether in fact the applicant is presently excluded, may be appealed.

Applicant Submits Information or Documentation to Appeal Denial - The applicant may submit information or documentation to support an appeal within 60 calendar days from the date of the denial notice. If the applicant submits information or documentation that alleges he/she should not be denied enrollment in the Medicare program within the 60 calendar day appeal deadline, then the RO forwards the information or documentation for review to the intermediary/carrier who made the recommendation for denial. The intermediary/carrier will review the information or documentation and advise the RO.

Applicant Meets Requirements - After a consideration of the information or documentation submitted by the applicant for an appeal, if the intermediary/carrier determines that the applicant meets all requirements for enrollment, the intermediary/carrier will process the Form CMS-855A or CMS-855B and notify the RO for its necessary action. (See §2005.A.2) The RO will notify the State survey agency, and the State survey agency will conduct the certification survey.

Applicant Does Not Meet Requirements - After a consideration of the information or documentation submitted by the applicant for an appeal, if the intermediary/carrier determines that the applicant still does not meet the requirements for enrollment, the intermediary/carrier will notify the RO. The RO will send a second denial letter to advise the applicant that any further appeal will follow the process described in 42 CFR 498.5. The RO will forward a copy of this denial letter to the State survey agency and the intermediary/carrier.

Applicant Does Not Submit Information or Documentation to Appeal Denial - When the applicant does not submit information or documentation that alleges he/she should not be denied enrollment in Medicare within the 60 calendar day appeal time frame, then the denial remains in effect. No further action is necessary.

2005B - Recertification

(Rev. 1, 05-21-04)

[RESERVED]

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. 1, 05-21-04)

If a provider/supplier entered the Medicare program under the Form CMS-855A or CMS-855B process, it may voluntarily terminate from the Medicare program by checking the box entitled "Deactivation of Medicare Billing Number(s)" on the Form CMS-855A or CMS-855B. The provider/supplier should send the Form CMS-855B to the fiscal intermediary/carrier. If the provider/supplier sends the Form CMS-855A or CMS-855B for voluntary termination directly to the intermediary/carrier, then the intermediary/carrier will notify the State survey agency or RO by sending them a copy of the Form CMS-855A or CMS-855B. Voluntary use of the Form CMS-855A or CMS-855B is encouraged for providers/suppliers who were certified without completing the Form CMS-855A or CMS-855B. However, these providers/suppliers may voluntarily terminate by sending a letter on letterhead with an authorized signature.

2005G - Specialty Intermediaries

(Rev. 1, 05-21-04)

Specialty intermediaries process applications and claims for independent RHCs, freestanding FQHCs, Religious Nonmedical Health Care Institutions (RNHCIs), HHAs, and hospices. If a RHC or FQHC is freestanding or independent, then the Form CMS-855A should be sent to the specialty intermediary. If a RHC or FQHC indicates on the Form CMS-855A that it is provider-based, then the FI should forward the application to the parent provider's intermediary if it is a different intermediary. All Religious Nonmedical Health Care Institution applications will be forwarded to the same specialty intermediary. The specialty intermediary will always process hospice and HHA applications since they are involved with provider claims whether the applicant is provider-based or independent. The following is a list of specialty intermediaries for these provider types. Consult your RO to determine which intermediary services your area.

Independent RHC Intermediaries

Veritus, Inc.

Associated Hospital Services of Maine

New Hampshire/Vermont Health Service

TrailBlazer Health Enterprises, LLC (formerly Blue Cross/Blue Shield of Texas)

Riverbend Government Benefits Administrators (formerly Blue Cross/Blue Shield of Tennessee)

Freestanding FQHC Intermediary

Blue Cross/Blue Shield of Wisconsin

Religious Nonmedical Health Care Institutions

Riverbend Government Benefits Administrators

Regional Home Health Intermediaries and Hospice Intermediaries

Blue Cross of Maine

Palmetto Government Benefits Administrator (formerly Blue Cross of South Carolina)

Health Care Service Corporation

Blue Cross/Blue Shield of Wisconsin

Wellmark, Inc. (formerly IASD Health Services Corporation)

Blue Cross of California

2008 - Prioritizing SA Survey Workload - Initial Surveys and Recertifications

(Rev. 1, 05-21-04)

2008A - Early Surveys of New Providers and Suppliers

(Rev. 1, 05-21-04)

New providers/suppliers must be in 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 will directly observe

the provision of care and services to patients, and the effects of that care, to assess whether the care provided meets the needs of individual patients and is in compliance with all the requirements.

When the provider/supplier notifies the SA of full operation, it documents the file with the date of notification. The SA conducts the survey within 90 calendar days of the date of notification of full operation, if possible. (See §2700.)

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.

2008C - New CMHC Applicants

(Rev. 1, 05-21-04)

Although a CMHC does not have CoPs, it must provide the core services described at 1913(c)(1) (formerly 1916(c)(4)) of the Public Health Service Act (PHSA). Thus an applicant CMHC, in addition to enrolling, must reasonably demonstrate to CMS that it is providing the core PHSA services. The RO will not approve an entity as a CMHC until the CMHC has reasonably demonstrated that it has provided each of the core services to a sufficient number of patients. Records that show provision of the core services by the CMHC must be sent to CMS upon request and must be available at the site for which the CMHC is requesting Medicare approval.

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

(Rev. 1, 05-21-04)

If all Federal requirements are not met on the date of the survey, the effective date of participation is the earlier of the date on which the provider or supplier meets all Federal health and safety requirements, or meets all conditions, and submits an acceptable PoC or approvable waiver request(s) for lower level deficiencies. If a SNF or NF does not meet all the requirements, the effective date is the date it is in substantial compliance and submits, if applicable, an approvable waiver request. The effective date for an FQHC's

or CMHC's Medicare participation is the date the RO signs the agreement after determining that all Medicare requirements, including enrollment requirements, are met.

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. 1, 05-21-04)

Prepare a general "master" schedule of surveys for the Federal fiscal year that ensures surveys of each provider/supplier, based on the survey coverage levels approved in the SA annual budget approval. Generally, time resurveys to precede the expiration of an ICF/MR's time-limited agreement (TLA) by 90 to 120 days. Do not conduct the survey more than 120 calendar days before the expiration date of the current TLA agreement or certification since a survey conducted earlier than 120 calendar days is not considered to be current. Resurveys are generally conducted annually, but depending on national initiatives and budget constraints, the cycle may vary. If the SA has reason to believe that a participant is no longer in compliance, it advances the resurvey.

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. 1, 05-21-04)

Before an agreement is executed with a provider to participate in the Medicare program, there must be a determination of compliance with civil rights requirements. The regional OCR makes any necessary investigations and decisions related to compliance with the requirements. If the RO cannot secure an OCR clearance within 15 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 required forms for OCR clearance and forwards the completed forms to the RO upon receipt. The Form HHS-690 is the form currently being used by OCR to obtain information concerning Civil Rights compliance.

Regarding Medicaid-only providers, the States themselves are considered the direct 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, determinations of civil rights compliance of providers are under the authority of OCR and are required 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. 1, 05-21-04)

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/MR (terminated under §1910(b) of the Act by CMS) that the deficiencies that caused the termination will not recur.

2016B - Reasonable Assurance Concept

(Rev. 1, 05-21-04)

A Medicare provider terminated under 42 CFR 489.53 and reinstated under 42 CFR 489.57 or a Medicaid ICF/MR 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/MR 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/MR), 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/MR 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. 1, 05-21-04)

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

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

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

The SA conducts the first of the reasonable assurance surveys as instructed by the RO and submits the results of the survey (this may be submitted on Form CMS-2567) to the RO within 10 working days of the survey. Based on the results of this first survey, the RO determines if the reasons for termination no longer exist, or for SNFs, the deficiencies that caused their termination are at the level of substantial compliance. The

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

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

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

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

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

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

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

The regulation at 42 CFR 489.57 does not apply to a provider's voluntary termination of its agreement under the provisions of the regulation at 42 CFR 489.52. In a scenario similar to the situation described above except that the provider's termination from Medicare was voluntary, CMS (the RO) would still be responsible for the if, when and how of the provider agreement under 42 CFR 489.12. However, the provider's

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

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

2016E - Effective Date of Provider Agreement

(Rev. 1, 05-21-04)

If the provider or supplier has maintained compliance throughout the reasonable assurance period, it can reenter the program. The first day that Medicare payment and Medicaid FFP are available is the date of completion of the second full/standard survey. A SNF must be in substantial compliance (see §§7203.B and 7300.). For other providers/suppliers, if all CoPs are met but there are deficiencies below Condition level, the effective date of the provider agreement is the date on which CMS or the State survey agency receives an acceptable PoC for lower level deficiencies, or an approvable waiver request, or both. (See 42 CFR 489.13.)

2016F - Readmission of ICF/MR After Termination

(Rev. 1, 05-21-04)

Before the SMA readmits an ICF/MR 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.

2022 - Hospitals Accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the American Osteopathic Association (AOA)

(Rev. 1, 05-21-04)

2022A - Notice that Participating Hospital Has Been Accredited

(Rev. 1, 05-21-04)

A hospital accredited by JCAHO or AOA is deemed to meet all CoPs for hospitals (except the requirements for UR, the special Conditions for psychiatric hospitals, 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).

When notified that a participating hospital has been accredited, the SA verifies the accreditation, removes the hospital from future resurvey schedules, and discontinues any follow-up on deficiencies. If Condition-level deficiencies still exist, the SA refers the matter to the RO in accordance with §5120. The SA executes Form CMS-1539 to report the accreditation.

2022B - Recertification

(Rev. 1, 05-21-04)

The SA recertifies the compliance of accredited hospitals on a schedule consistent with the accreditation interval, which may be only every three years. Recertification packets for accredited hospitals are to be sent to the RO.

Prior to the accreditation expiration date for each accredited hospital, the SA should send the following documents to the hospital, with instructions that they must be completed, signed, and returned to the SA immediately following the hospitals accreditation survey. These include – Request to Establish Eligibility – Form CMS-1514. Exhibit 63 has a complete listing of documents to be completed and included in the certification packet.

The SA should track the forms to ensure that all hospitals return them in a timely manner.

The OSCAR/ODIE system should be updated with the current information from the Form CMS-1514, and a Certification & Transmittal (C&T) – Form CMS-1539 – should be generated. The Form CMS-1539 should indicate in the "remarks" section that the C&T is transmitting an accredited hospital recertification, and should also indicate that the OSCAR/ODIE system has been updated. Please indicate if a CHOW package was forwarded to the hospital as a result of the recertification process.

The Forms CMS-1539 and CMS-1514 should then be forwarded to the RO.

Also effective immediately, we are implementing a requirement that the above policy be followed for ALL accredited providers and suppliers that are deemed to meet the CMS certification standards (HHAs, Hospices, CAHs and ASCs). The appropriate Request to Establish Eligibility Form should be forwarded to the RO.

2022C - Notification of Withdrawal or Loss of Accreditation

(Rev. 1, 05-21-04)

Hospitals that lose JCAHO or AOA accreditation or voluntarily discontinue their accreditation are no longer deemed to meet the CoPs. Upon loss of accreditation, the SA schedules a survey and recertifies the institution. The SA completes Form CMS-1539 indicating the date of the scheduled survey in Item 16 and forwards it to the RO as soon as the loss of accreditation is verified.

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 - Accredited Psychiatric Hospitals Not Deemed to Meet Special CoPs

(Rev. 1, 05-21-04)

Psychiatric hospitals participating in Medicare and accredited by AoA or JCAHO under their hospital accreditation programs or under JCAHO's consolidated standards for adult psychiatric facilities are deemed to meet the CoPs for hospitals, with the exception of the special medical record and staffing requirements. Consequently, for a newly applying accredited psychiatric hospital, the effective date can be no sooner than the date established by CMS under 42 CFR 489.13(c)(2). (See §2042). Facilities accredited exclusively under the JCAHO community mental health standards, or under the consolidated standards for child and adolescent psychiatric facilities, or alcoholism and drug abuse facilities are not deemed to meet any of the CoPs.

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 of accredited psychiatric hospitals. Some surveys of these facilities are surveyed by contracting surveyors hired by CMS while others are surveyed by the SA.

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.

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)).

Hospices

2080 - Hospice - Citations and Description

(Rev. 1, 05-21-04)

2080A - Citations

(Rev. 1, 05-21-04)

Section 1861(u) of the Act created hospices as a provider category. Section 1861(dd) of the Act defines hospice care and the hospice program. 42 CFR 418 sets forth the CoPs. 42 CFR Part 418.100 is an additional 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 §1866 of the Act regarding advance directives.

The CMS has a Web site for hospice at http://www.cms.hhs.gov/providers/hospiceps. This site contains recent policy memos, hospice provisions enacted by the Balanced Budget Act (BBA) of 1997, State Operations Manual, §§2080-2087 and Appendix M, Hospice Survey Procedures and Interpretive Guidelines.

Definition

A hospice is a public agency or private organization or a subdivision of either that is primarily engaged in providing care to terminally ill individuals, meets the conditions of participation for hospices, and has a valid Medicare provider agreement. The law governing the provision of Medicare hospice services is found at §1861(dd) of the Act. The law further clarifies that "terminally ill individuals" are individuals having a "medical prognosis that their life expectancy is 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 (§1861(dd)(2)(A)(i)). "Primarily" does not mean "exclusively." This requirement does not preclude provision of non-hospice services to terminally ill individuals who have not been accepted into the hospice program or services to individuals, who are not terminally ill, so 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 coverage for an unlimited number of election periods of hospice care. The periods consist of two 90-day periods, and an unlimited number of 60-day periods.

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. 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.

The hospice must obtain the certification that an individual is terminally ill in accordance with the following procedures.

For the first 90 calendar-day period of hospice coverage, the hospice must obtain, no later than two calendar days after hospice care is initiated (that is, by the end of the third calendar day), certification of the terminal illness by the medical director of the hospice or the physician member of the hospice interdisciplinary group and the individual's attending physician (if the individual has an attending physician). If the written certification is not obtained within two calendar days following the initiation of hospice care, a verbal certification must be made within two calendar days following the initiation of hospice care, with a written certification obtained before billing for hospice care. If these requirements are not met, no payment is made for the days prior to the certification. Instead, payment begins with the day of certification**,** i.e., the date verbal certification is obtained**.** These certifications may be completed up to two weeks before hospice care is elected. The attending physician is a doctor of medicine or osteopathy and 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.

For the subsequent periods, the hospice must obtain, no later than two calendar days after the first day of each period, a verbal certification statement from the medical director of the hospice or the physician member of the hospice's interdisciplinary group. A written certification from the medical director of the hospice or the physician member of the interdisciplinary group must be on file in the beneficiary's record prior to the submission of a claim to the intermediary. The certification must include: (1) the statement that the individual's medical prognosis is that his or her life expectancy is 6 months or less if the terminal illness runs its normal course and (2) the signature(s) of the physician(s). The provider must retain a copy of the certification statement in the patient's clinical record.

2080B - Description

(Rev. 1, 05-21-04)

Hospice care is an approach to caring for terminally ill individuals that stresses palliative care (relief of pain and uncomfortable symptoms), as opposed to curative care. In addition to meeting the patient's medical needs, hospice care addresses the physical, psychosocial, and spiritual needs of the patient, as well as the psychosocial needs of the patient's family/caregiver. The emphasis of the hospice program is on keeping the hospice patient at home with family and friends as long as possible.

Although some hospices are located as a part of a hospital, SNF, and HHA, hospices must meet specific CoPs and be separately certified and approved for Medicare participation. (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.)

Services and Items Provided

Substantially all core services must be provided directly by hospice employees on a routine basis. The following are hospice core services and must be provided directly by hospice employees:

- Nursing care (on a 24-hour basis) provided by or under the supervision of an RN functioning within a medically approved plan of care;
- Medical social services under the direction of a physician; and
- Counseling (including dietary and bereavement counseling) with respect to care of the terminally ill individual and adjustment to death.

A hospice may use contracted staff for core services only under extraordinary circumstances (i.e., to supplement hospice employees in order to meet patients' needs during periods of peak patient load.) If contracting is used, the hospice must continue to maintain professional, financial, and administrative responsibility for the services in accordance with 42 CFR 418.56.

Substantially all hospice core services must be routinely provided directly by hospice employees and cannot be delegated or otherwise furnished under arrangement. For example, nursing services are core services and as such are subject to the core services requirements contained in 42 CFR 418.80. Just because a service is highly specialized, such as managing a peripherally inserted central catheter (PICC) line or other highly specialized nursing services, does not relieve the hospice of this requirement. It is expected that the hospice employ sufficient RNs who have the educational preparation and attainment of clinical competence to manage the ongoing needs of the hospice

patients. For hospices that are unable to hire a sufficient number of nurses directly due to the nursing shortage, CMS has instituted a temporary measure. [1]

Qualifying for an "Extraordinary Circumstance" Exemption

During the time period from October 1, 2002 – September 30, 2004, in order to qualify for an "extraordinary circumstance" exemption, a hospice must notify the state agency 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 state survey agency 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 that it believes it will currently need to employ under contract. Notification may be made prior to September 30, 2004, and should address the following:

- An estimate of the number of patients that it has not been able to admit during the past three 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 advertisements in local newspapers that demonstrate recruitment efforts;

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

    - 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); and

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

- The hospice must also demonstrate that it has a training program in place to assure that contracted staff is trained in the hospice philosophy and the provision of palliative care prior to patient contact.

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[1] CMS has instituted a temporary measure to allow individual hospices to contract for nurses until September 30, 2004, if the hospice can demonstrate that the nursing shortage is creating an extraordinary circumstance that prevents it from hiring an adequate number of nurses.

- The hospice must assure that contracted staff is providing care that is consistent with the hospice philosophy and the patient's plan of care.

- Contracted nurses are used to supplement the hospice nurses employed directly. Contracted nurses 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.

Monitoring the Need for Exemption

The state survey agency 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 patient that is consistent with the plan of care established by the attending physician, the medical director or physician designee and interdisciplinary group.

Role of the Hospice Medical Director

The medical director is required by regulation to assume overall responsibility for the medical component of the hospice's patient care program. In addition, the hospice physician(s), including the physician members of the IDG must also meet the general medical needs of the patient to the extent that these needs are not met by the attending physician. Hospice physician involvement in the plan of care must by evident in the clinical record documentation. Medical directors and physician members of IDG may work "under contract" with the hospice. The requirements at 42 CFR 418.56 and 418.86 are still applicable to hospice, as well as all other responsibilities under the hospice conditions of participation. Hospices retain professional management responsibilities for the services under contract and must ensure that qualified persons furnish them in a safe and effective manner.

Role of the RN Team Coordinator

The hospice is required by 42 CFR 418.68(d) to designate a registered nurse to coordinate the implementation of the plan of care for each patient. The is no requirement that this person work full time – but there must be assurances that the plan of care is coordinated on a 24 hour basis so the patient receives the necessary care and services required in the plan.

Hospice Required Services

Requirement for 24-Hour Services

The hospice is required by the COP at 42 CFR 418.50 to make nursing services, physician services, drugs and biologicals routinely available on a 24-hour basis. They also have to make all other covered services available on a 24-hour basis to the extent necessary to meet the needs of individuals for care that is reasonable and necessary for the palliation and management of terminal illness and related conditions.

In addition to the hospice core services, the following services must also be available when needed and provided by the hospice, either directly or under arrangements made by the hospice to meet the needs of the patient:

- Physical and occupational therapy and speech-language pathology services;
- Home health aide services. A home health aide employed by a hospice, either directly or under a contract, must meet the personnel qualifications specified in 42 CFR 484.4 for "home health aide" and must meet all the training, attitude, competency, and skill requirements for a home health aide working in an HHA, as specified in 42 CFR Part 484.36;
- Homemaker services;
- Medical supplies (including drugs and biologicals on a 24-hour basis) and the use of medical appliances related to the terminal diagnosis;
- Short-term inpatient care (including both respite care and procedures necessary for pain control and acute and chronic symptom management) in a Medicare/Medicaid approved inpatient facility; and
- Continuous home care provided for a period of 8 or more hours in a day during a period of crisis, and only 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 requires a minimum of 8 hours of primarily nursing care within a 24-hour period commencing at midnight and terminating on the following midnight.

Hospices must maintain professional management and financial responsibility for services provided under arrangements, regardless of the location or facility in which such services are furnished.

In addition, the statute stipulates other specific requirements including a limitation on the proportion of inpatient days for hospice patients and a prohibition against discontinuing or diminishing services for Medicare beneficiaries unable to pay for hospice care.

Section 1861(dd)(5) of the Act has been modified to allow 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. Dietary counseling must be provided to hospice patients/families when the hospice patient experiences unmet nutritional needs. This could include patients with dysphasia or other swallowing problems, problematic enteral feedings, unresolved nutritional issues secondary to nausea, vomiting, or the dying process. Dietary counseling must be provided, consistent with accepted standards of practice, by a qualified individual. Qualified individuals may include dietitians as well as nurses and other individuals who are able to address the dietary needs of the patient. 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. Hospices are required to submit evidence to establish "diligent efforts." CMS applies the requirements for the nursing services waiver found at 42 CFR 418.83(a)(3) in determining that a hospice has made diligent efforts. A waiver request will be deemed to be granted unless it is denied within 60 days after it is received by CMS.

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 provider number, it shall be considered to meet those CoPs that are common to both the hospice and the other type of provider.

Review of the Patient Plan of Care by the Interdisciplinary Group (IDG)

Hospices participating in the Medicare program must use an interdisciplinary approach to assessing the medical, physical, social, emotional and spiritual needs of the patient and continue this approach while caring for the patient and family. The regulations at 42 CFR 418.58 require the hospice to have a written plan of care established by the attending physician, the medical director or physician designee and interdisciplinary group (IDG) prior to providing care. The regulations at 42 CFR 418.58 also require that the plan of care be reviewed and updated, at intervals specified in the plan, by the attending physician, the medical director or physician designee and the IDG. These reviews and updates must be completed in such a way as to ensure that the plan of care continues to reflect the patient's condition and meet the needs of the patient and his/her family.

The hospice may chose to develop an initial plan of care at admission that is based on the information obtained, or the priorities identified, during the initial assessment and is consistent with the patient/family's immediate care needs and desires. The hospice nurse

or physician in consultation with the patient's attending physician may develop the initial plan of care, if the patient has an attending physician, and one other member of the IDG. However, the other two members of the IDG must review the initial plan of care and provide their input into the process of establishing the plan of care within two calendar days following the initial assessment. A face-to-face meeting of group members is not required within this 2-day period; input may be provided by telephone.

The attending physician, the medical director or physician designee and the hospice IDG are to work actively together to establish the overall plan of care. This plan of care must include an assessment of the individual's needs, identification of the services to be provided including the management of pain and other uncomfortable symptoms and must state in detail the scope and frequency of services needed to meet the patient's and family needs. The plan of care may include a range of visits and PRN orders for visit frequencies to ensure the most appropriate level of service is provided to the patient. A range of visits is acceptable as long as it continues to meet the identified needs of the patient/family. Ranges that include "0" as a frequency are not allowed. The plan of care should clearly reflect the ongoing interventions of the IDG with the patient's attending physician e.g., telephone contact, verbal orders, progress notes, clinical notes, and plan of care issues.

The hospice physician and IDG are responsible for establishing a system of communication, coordination and integration of services that ensures that the plan of care continues to be reviewed and updated to serve the dying person and his/her family well. It is not permissible for the attending physician to provide the sole guidance for the plan of care or for the hospice medical director to do so. The law and regulations require that it be the combined work of the IDG. Where this may not be the case, CMS would expect the hospice to introduce corrective procedures to ensure the involvement of the whole IDG as soon as feasible after the patient's admission.

Standing orders or routine orders must be individualized (patient specific and not generic) and are not allowed unless they meet this criteria.

There is nothing in the statute or regulation that requires the IDG to meet every time a change is necessary to the plan of care. There are, however, statutory and regulatory requirements for an IDG approach to caring for the hospice patient. What is critical to hospice care is that the IDG identify through its on going assessment when a change is needed to care for a patient and assure that the patient/family receive the care and services necessitated by the change. The hospice must then follow its own system of communication, which has been established by the IDG to ensure that the plan is reviewed and updated by the IDG when any changes are warranted.

For example, the hospice IDG must agree to communicate at appropriate intervals in the plan of care. If a nurse assesses a patient's pain on a Thursday evening and determines that the medication is not effective, the nurse and the physician can make a change to the medication and plan of care and implement the plan immediately. However, the nurse and/or physician must communicate this change in the plan of care to the other IDG members so that the patient receives the benefit of the full IDG's assessment regarding

his/her change in condition. In this way the patient receives the benefit of the entire IDG's assessment of the patient's needs which would include the nurse and physician's assessment and interventions regarding the pain management issue. The IDG can then revise the plan of care as appropriate to address the change in the patient's condition. The IDG should be proactive in developing their plan of care by planning ahead for anticipated patient changes and needs so that decisions can reflect the patient/family preferences rather than be solely a response to a crisis.

2080C - Termination of Hospice Services

(Rev. 1, 05-21-04)

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 or inconvenient, or the State allows for discharge under State requirements. 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. The hospice should neither request nor demand that the patient revoke his/her election.

In most situations, discharge from the hospice will occur as a result of one of the following:

- The beneficiary decides to revoke the hospice benefit;
- The beneficiary moves away from the geographic area that the hospice defines in its policies as its service area;
- The beneficiary's condition improves and he/she is longer considered terminally ill. In this situation, the hospice will be unable to recertify the patient; or
- The beneficiary dies.

The CMS recognizes however, there may be extraordinary circumstances in which a hospice would be unable to continue to provide hospice care to a patient. These extraordinary situations would only include issues where the patient safety or hospice staff safety is compromised. The hospice IDG with input from the attending physician must make every effort to resolve these problems satisfactorily, before it considers discharge an option. All efforts by the hospice to resolve the problem(s) must be documented in detail in the patient's clinical record and the hospice must notify the fiscal intermediary and state survey agency of the circumstances surrounding the impending discharge. The hospice must also consider referrals to other appropriate and/or relevant state/community agencies (i.e., Adult Protective Services) or health care facilities before discharge.

2081 - Hospice - Multiple Locations

(Rev. 1, 05-21-04)

Neither the statute nor the hospice regulations provides for establishing hospice "satellite" offices. Nonetheless, a hospice is not precluded from providing services at more than one location if certain requirements assuring quality of care are met and these locations are approved by the RO. The RO, in order to support CMS' responsibility to protect the Medicare trust fund against excessive and unnecessary costs, will also ensure that the locations promote cost-effective health care. The RO will make a final determination on both quality and cost effectiveness issues with the assistance of the State agency and the fiscal intermediary, if necessary, and will notify all parties of its decision in writing.

To support our concern for quality, CMS requires a hospice that provides services at more than one location, to comply with the following:

- The hospice must be able to exert the supervision and control necessary at each 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;

- Each location must provide the same full range of services that is required of the hospice issued the provider number;

- Each patient must be assigned to a specific IDG responsible for ongoing assessment, planning, monitoring, coordination and provision of care;

- The hospice medical director must assume overall responsibility for the medical component of the hospice's patient care program at all locations;

- Each location must be responsible to the same governing body and central administration that governs the hospice issued the provider number, and the governing body and central administration must be able to adequately manage the location and assure quality of care at the location; and

- All hospice patients' clinical records requested by the surveyor must be available at the hospice site issued the provider number.

If a proposed hospice location does not meet the above criteria for quality and cost effectiveness, it must seek Medicare approval as a separate hospice with its own provider agreement and provider number.

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

2082 - Election of Hospice Benefit by Resident of SNF, NF, ICF/MR, or Non-Certified Facility

(Rev. 1, 05-21-04)

e is no indication in the statute that the term "home" is to be limited for a Hospice patient. A patient's home is where he or she resides. A Hospice may furnish routine or continuous home care to a Medicare beneficiary who resides in a SNF, NF, ICF/MR, or any residence or facility not certified by Medicare or Medicaid. The facility is considered to be the beneficiary's place of residence (the same as a house or apartment), and the patient/resident may elect the Hospice benefit if he/she also meets the Hospice eligibility criteria. The hospice then assumes full responsibility for professional management of the individual's hospice care in accordance with the hospice CoPs and makes any arrangements necessary for inpatient care in a participating Medicare or Medicaid facility.

When a Nursing Facility Resident elects the Hospice Benefit, the Hospice and Nursing Facility should have a written agreement outlining key elements in the relationship before the hospice provides care (42 CFR 418.56). Issues in the agreement should include the following:

- Services to be provided by the Hospice;
- Services to be provided by the Facility;
- Manner and frequency in which the services are coordinated, supervised, documented, and evaluated;
- Identification of the role(s) of the Hospice and the Nursing Facility in the admission process, patient/family assessment, and interdisciplinary group care conferences;
- Qualifications of the personnel providing services;
- Orientation/ongoing education to Hospice staff by Nursing Facility;
- Orientation/ongoing education to Nursing Facility staff by Hospice;
- Applicable state/Federal health & safety regulations and standards of practice;
- Process by which the Hospice & Nursing Facility staff address service issues and complaints;
- Methods and frequency of communication between Hospice and Nursing Facility staff;

- Financing of medications, supplies, and durable medical equipment related to the terminal illness;
- Payment to the Nursing Facility for a Medicaid patient's "room & board" services;
- Resident eligibility, desire, and election of hospice;
- Resident rights and confidentiality;
- Professional management responsibility of the hospice; and
- Liability and insurance.

In entering into the relationship, each provider retains responsibility for the quality and appropriateness of the care it provides. Both providers must comply with applicable conditions/requirements for participation in Medicare/Medicaid.

In addition, the hospice and nursing facility negotiate an agreement on how they will coordinate their services. These issues include, but are not limited to, the following areas:

- Hospice staff access to and communication with nursing facility staff;
- Development of coordinated plan of care;
- Documentation in both respective entities' clinical records or other means to ensure continuity of communication and easy access to ongoing information;
- Role of any hospice vendor in delivering supplies or medications;
- Ordering, renewal, delivery and administration of medications;
- Role of the attending physician and process for obtaining and implementing physician orders;
- Communicating resident change of condition; and
- Change in level of care and transfer from facility.

The hospice and nursing facility review this agreement as appropriate for needed changes and/or improvement in the working relationship between the two entities and/or the care and services provided to residents electing the hospice benefit.

2082A - Compliance With SNF/NF Requirements

(Rev. 1, 05-21-04)

The SNF/NF Requirements are applicable to all of the residents in a SNF/NF facility. Neither the statute nor the regulations setting out SNF/NF requirements exempt hospice patients in a SNF/NF from those regulations. Sections 1819(c)(4) and 1919(c)(4) provide that a SNF or NF must "establish and maintain identical policies and practices" regarding transfer, discharge, and the provision of covered services under Medicare or Medicaid "for all individuals regardless of source of payment."

Sections 1819 and 1919 of the Act set forth requirements for SNFs and NFs to ensure that these facilities provide quality care and services to their residents. Even though the SNF/NF is the hospice patient's residence for purposes of the hospice benefit, the SNF/NF must still comply with all SNF/NF requirements for participation in Medicare or Medicaid.

Responsibility of the Facility

When a Hospice patient resides in a Nursing Facility, the facility staff is the patient/resident's primary caregiver. As the primary caregiver, facility staff provides services in a safe and comfortable environment to meet the needs of the patient/resident. SNF/NF services offered to a patient/resident should be the same whether or not he/she has elected hospice. The patient/resident has the right to refuse any service.

It is the nursing facility's responsibility to assure that the care outlined in the care plan is performed by qualified staff and consistent with acceptable professional standards of practice. Those services include:

- Performing personal care services;
- Assisting with activities of daily living;
- Administering medication;
- Socializing activities;
- Maintaining the cleanliness of a patient's/resident's room; and
- Supervising and assisting in the use of durable medical equipment and prescribed therapies.

The responsibilities of the Nursing Facility also include:

- Notifying the hospice when the resident experiences a change in condition. The nursing facility must continue to meet the requirements for notifying the attending

physician and family of significant change in condition. As part of a coordinated plan of care, procedures will be identified and addressed.

- Facilitating orientation of new staff by the hospice.

- Assessing the patient/resident according the requirements for participation in Medicare/Medicaid. In completing the assessment, the Nursing Facility may consult with the Hospice. The Medicare/Medicaid regulations for completion and submission of RAI/MDS data do not change when the patient/resident elects the Hospice Benefit.

Responsibility of the Hospice

The Hospice provides services in accordance with the Medicare Hospice Regulations (42 CFR 418) based upon the needs of the patient/resident. Services are provided at the same level as those provided a patient residing in his/her home. These include:

- Ongoing assessment, care planning, monitoring, coordination and provision of care by the Hospice IDG;

- Assessment, coordination and provision of any needed General Inpatient or Continuous Care;

- Professional management of the patient's care with input from nursing facility staff;

- Coordination by the hospice RN of the implementation of the plan of care for resident;

- Provision, in a timely manner, of all supplies, medications, and durable medical equipment that are needed for the palliation and management of the terminal illness and related conditions.

- Financial responsibility for all medical supplies, appliances, medications and biologicals related to the terminal illness;

- Determining the appropriate level of care to be given to the patient/resident (routine homecare, inpatient, or continuous care) and making arrangements for any necessary transfers from the nursing facility in consultation with the nursing facility staff.

When the patient/resident elects the Medicare Hospice Benefit, hospice assumes responsibility for the professional management of the patient's/resident's care. Professional management involves the assessment, planning, monitoring, directing and evaluation of the patient's/resident's care across all settings. All hospice services including nursing services, physician services, medical social services, and counseling

must be routinely provided by the hospice and cannot be delegated to the facility unless circumstance requires nursing facility intervention to meet the immediate needs of the patient/resident. Nursing facility staff should notify the hospice of these unplanned interventions.

Coordinated Care Plan

The Facility/Hospice are jointly responsible for developing a coordinated plan of care based upon their assessments and needs of the patient/resident. Input from the patient/resident and their family/significant other is incorporated into the plan. The plan of care must be consistent with the hospice philosophy of care. This coordinated plan of care must identify the care and services, which the SNF/NF and hospice will provide in order to be responsive to the unique needs of the patient/resident and his/her expressed desire for hospice care. The plan of care must include directives for managing pain and other uncomfortable symptoms and be revised and updated as necessary to reflect the individual's current status. The plan of care must be written in accordance with 42 CFR Part 418.58 and include the individual's current medical, physical, psychosocial, family and spiritual needs. The hospice must designate an RN from the hospice to coordinate the implementation of the plan of care. (See 42 CFR 418.68(d).). The coordinated plan of care identifies the discipline and provider to be held responsible/accountable for each intervention. For example, the hospice aide visits on Tuesday and Thursday to bathe the resident. The nursing facility aide bathes the resident on Monday, Wednesday, and Friday. If there is an unanticipated need to change the schedule, notification must be given to the other provider and resident to assure that the resident's needs continue to be met.

The hospice and the SNF/NF must communicate with each other when any changes are indicated to the plan of care, and each provider must be aware of the other's responsibilities in implementing the plan of care. The hospice must approve any changes to the plan of care proposed by the SNF/NF staff prior to implementation. Evidence of this coordinated plan of care must be present in the clinical records of both providers. All aspects of the plan of care should reflect the hospice philosophy.

The providers may develop one common care plan to be utilized by both providers, or two care plans following the documentation policies for each provider. The hospice and nursing facility may continue to utilize their individual processes/forms for care planning. Regardless of the number, when compared, care plans should reflect the identification of:

- A common problem list;
- Palliative interventions;
- Palliative outcomes;
- Responsible discipline; and

- Responsible provider.

The care plans are to be implemented, evaluated, and updated to meet the identified needs of the patient/resident as changes occur.

Procedures are in place to ensure that the patient receives timely medication and treatments for optimal palliation. The hospice provides education to the nursing facility on the hospice resident's pain management regime.

The hospice works with the nursing facility to monitor the effectiveness of treatments related to pain and symptom control. The hospice and nursing facility coordinate care to assure that the patient does not experience a delay in receiving needed drugs and treatment.

The hospice and nursing facility determine a process by which information from the hospice interdisciplinary team and the nursing facility team will be exchanged when developing, and evaluating outcomes of care and updating the plan of care. to assure that the resident receives the necessary care and services. The teams actively seek input from the resident/family on desired goals.

Documentation

Both respective provider's should agree on documentation issues to ensure continuity of communication and easy access to ongoing information. For example, the providers can agree that the nursing facility clinical record will contain a copy of the hospice election form; physician certification of terminal illness; assessments from core team members; current documentation of visits; and plan of care. In addition, the providers need to ensure that hospice documents are accessible to staff caring for the patient/resident. Both providers may document physician orders. Orders are to be signed in accordance with state regulations. Implementation of the plan of care changes resulting from physician orders received by the nursing facility must have **prior** hospice approval.

Provider Survey

If the surveyor of either provider identifies a potential compliance issue related to hospice patients, the respective surveying agency responsible for oversight of the other provider shall be notified.

2082B - Professional Management

(Rev. 1, 05-21-04)

The use of the term "professional management" for a hospice patient who resides in a SNF/NF or ICF/MR or other non-certified facility should have the same meaning to a hospice that it would have if the hospice patient were living in his/her own home. The professional services usually provided by the hospice to the patient in his/her home

should continue to be provided by the hospice to the resident in a SNF, NF, or other place of residence. This includes furnishing any necessary medical services to those patients that the hospice would normally furnish to patients in their homes. In addition, substantially all hospice core services (nursing services, medical social services, and counseling) must be routinely provided directly by hospice employees and cannot be delegated. For example, the hospice may involve the SNF/NF nursing personnel in assisting with the administration of prescribed therapies included in the plan of care only to the extent that the hospice would routinely utilize the services of a hospice patient's family/caregiver in implementing the plan of care. SNF/NF staff that is permitted by the facility and by law may assist in the administration of medication as established by the plan of care developed by the hospice interdisciplinary group (IDG), in coordination with the SNF/NF.

1 - Ordering of Drugs by the SNF/NF Medical Director

The plan of care is developed, reviewed and updated by the hospice medical director or hospice physician and the IDG with the patient's attending physician (who may or may not be the SNF medical director). This team then decides who will order the drugs and treatments contained in the plan of care, for example, hospice physician or attending physician. The hospice makes any necessary financial arrangements for the drugs related to the terminal illness and arranges for their provision either directly or under arrangement with a pharmacy. If they are provided under arrangement with a pharmacy, the hospice will also meet the professional management requirements contained in the CoP at 42 CFR 418.56.

2082C - Provision of Non-Core Services to SNF/NF Residents or Residents of an ICF/MR or Other Non-Certified Facility

(Rev. 1, 05-21-04)

The hospice may arrange to have **non-core** hospice services provided by the patient's residential facility if the hospice assumes professional management responsibility for these services and assures that these services are performed in accordance with the policies of the hospice and the patient's plan of care. (See 42 CFR 418.56.)

2082D - SNF/NF Residents and Dually-Eligible Beneficiaries

(Rev. 1, 05-21-04)

A Medicare beneficiary who resides in a SNF/NF may elect the hospice benefit when the beneficiary pays for the residential care.

A Medicare beneficiary who is also eligible for Medicaid and whose NF care is being paid for by Medicaid may also elect the Medicare hospice benefit if the hospice and the facility have a written agreement under which the hospice takes full responsibility for the professional management of the individual's hospice care and the facility agrees to

provide room and board to the individual. The hospice patient must remain in a Medicaid certified bed while residing in the NF. The State Medicaid Agency pays the hospice the amount determined as payment for room and board while the patient is receiving hospice care, and the hospice pays the facility. Depending on the State Plan, room and board services may include:

- Performing personal care services;
- Assisting with activities of daily living;
- Administering medication;
- Socializing activities;
- Maintaining the cleanliness of a resident's room; and
- Supervising and assisting in the use of DME and prescribed therapies.

In States that offer the Medicaid hospice benefit, and an individual is eligible for Medicare as well as Medicaid, the hospice benefit must be elected or revoked under both programs. Each program must be notified as to the patient's decision.

2083 - Hospice Regulations and Non-Medicare Patients

(Rev. 1, 05-21-04)

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 Part 418.60 - the continuation of care requirement; and

42 CFR Part 418.98(c) - the 80-20 inpatient care limitation.

2084 - Hospice Inpatient Services Furnished Directly or Furnished Under Arrangements

(Rev. 1, 05-21-04)

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. See 42 CFR 418.56, 418.98 and 418.100.

2084A - Hospice Provides Inpatient Care Directly

(Rev. 1, 05-21-04)

If a hospice provides inpatient care directly, either in owned or leased space in another facility, the inpatient location must be surveyed for compliance with 42 CFR Part 418.100. The leased inpatient unit may consist of several beds, a group of beds, or a wing.

2084B - Hospice Provides Inpatient Services Under Arrangements

(Rev. 1, 05-21-04)

When inpatient services are being provided under arrangements with a Medicare participating hospital or SNF, a Medicaid participating NF (for respite care only), or an inpatient unit of another hospice, a separate survey of each site is **not** required. In these cases, the SA reviews the agreement and patient files to assure that standards in 42 CFR 418.100(a) (24-hour nursing service) and (e) (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. This includes hospitals that are accredited by the JCAHO or AOA that are providing inpatient services under arrangements.

2084C - Hospice Provides Inpatient Services in Space Shared with Medicare-Approved Hospital or SNF at Same Location

(Rev. 1, 05-21-04)

When inpatient services are provided at a location also approved as a SNF or hospital (dual or multiple certification), the SA inspects for compliance with 42 CFR Part 418.100(a) and (e).

Applicability of Inpatient Care CoP
42 CFR Part 418.100

Location Where Inpatient Care is Provided	Applicability Of Condition
Hospice inpatient unit	Survey for compliance with 42 CFR Part 418.100.
Medicare-approved hospital or SNF under arrangements with hospice	Survey for compliance with 42 CFR Part 418.100(a) and 418.100(e). Review both the agreement between the contracting parties and patient records to assure that the hospice arrangements are in compliance with the regulations. The institution already meets the remaining requirements of 42 CFR Part 418.100 as a Medicare-approved hospital or SNF. Do not inspect the hospital or SNF.
Hospice dually certified as hospital or SNF and as a hospice	Survey for compliance with 42 CFR Part 418.100(a) and 418.100(e). The institution already meets the remaining requirements of 42 CFR Part 418.100 as a Medicare-approved hospital or SNF.
Medicaid-approved NF (respite care only)	Survey for compliance with 42 CFR Part 418.100(a) and 418.100(e).

2085 - Operation of Hospice Across State Lines

(Rev. 1, 05-21-04)

When a hospice provides services across State lines each respective state agency 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 provider number is based, and its personnel must be qualified in all States in which they provide services. Certification activities within a particular state are completed by the appropriate SA for that state. The involved States should 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 CoPs within their state. The agreement should assure that home visits are conducted to a sample of all patients served by the hospice in all states served by the hospice.

The CMS 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 §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 285 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/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/number is based should take the lead in assuring that the required survey and certification activities are met.

The hospice must receive approval from CMS to provide services across state lines before it can bill Medicare for any covered services provided to these patients.

2086 - Hospice Home Visits

(Rev. 1, 05-21-04)

The SA makes home visits to a sample of hospice patients (regardless of payment source) during a hospice survey, if any of six conditions exist. Refer to Appendix M, Part III, Task 3.B. for complete instructions. (See model consent for hospice home visit form (Exhibit 128).)

2086A - Patient Home Care Benefits in HHA Preparing for Hospice Certification

(Rev. 1, 05-21-04)

A terminally ill patient who does not wish to elect the Medicare hospice benefit, and who meets the eligibility criteria for skilled care under the Medicare home health benefit is eligible to receive home health care under a plan of care established by the patient's physician and the HHA. If the terminally ill patient does not meet the admission criteria for the Medicare home health benefit, the home health services would not be reimbursed under Medicare.

Terminally ill patients who are admitted by the HHA for skilled services are considered HHA patients. These patients may be selected for the clinical record review and home visit during the HHA certification survey. These patients may not be considered hospice patients during a hospice survey.

2087 - Compliance With Advance Directives

(Rev. 1, 05-21-04)

Under §§1866(a)(1)(Q) and 1902(a)(57) of the Act, a hospice is required to be in compliance with all Federal requirements in §§1866(f)(1) and 1902(w) of the Act, respectively, concerning advance directives. Specifically, a hospice must agree to maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care at the hospice and must, at the time of initial receipt of hospice care by the individual from the program:

(1) Provide written information to such individuals concerning:

(i) An individual's rights under State law (whether statutory or recognized by the courts of the State) to make decisions concerning such medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate, at the individual's option, advance directives. Providers are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met. Providers are to update and disseminate amended information as soon as possible, but no later than 90 days from the effective date of the changes to State law; and

(ii) The written policies of the provider or organization respecting the implementation of such rights, including a clear and precise statement of limitation if the provider cannot implement an advance directive on the basis of conscience. At a minimum, a provider's statement of limitation should:

(A) Clarify any differences between institution-wide conscience objections and those that may be raised by individual physicians;

(B) Identify the state legal authority permitting such objection; and

(C) Describe the range of medical conditions or procedures affected by the conscience objection.

(2) Document in a prominent part of the individual's current medical record, or patient care record in the case of an individual in a religious non-medical health care institution, whether or not the individual has executed an advance directive;

(3) Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

(4) Ensure compliance with requirements of State law (whether statutory or recognized by the courts of the State) regarding advance directives. The provider must inform individuals that complaints concerning the advance directive requirements may be filed with the State survey and certification agency;

(5) Provide for education of staff concerning its policies and procedures on advance directives; and

(6) Provide for community education regarding issues concerning advance directives either directly or in concert with other providers and organizations. Separate community education materials may be developed and used, at the discretion of providers. The same written materials do not have to be provided in all settings, but the material should define what constitutes an advance directive, emphasizing that an advance directive is designed to facilitate an incapacitated individual's control over medical treatment, and describe applicable State law concerning

advance directives. A provider must be able to document its community education efforts.

Hospices:

(1) Are not required to provide care that conflicts with an advance directive.

(2) Are not required to implement an advance directive if, as a matter of conscience, the provider cannot implement an advance directive and State law allows any health care provider or any agent of such provider to conscientiously object.

If an adult individual is incapacitated at the time of admission or at the start of care and is unable to receive information (due to the incapacitating conditions or a mental disorder) or articulate whether or not he or she has executed an advance directive, then the provider may give advance directive information to the individual's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law. The hospice is not relieved of its obligation to provide this information to the individual once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.

Compliance with the advance directives requirements is necessary for continued participation in the Medicare and Medicaid programs.

Intermediate Care Facilities

2130 - ICFs/MR – Citations and Description

(Rev. 1, 05-21-04)

2130A - Citations

(Rev. 1, 05-21-04)

An ICF/MR is defined in §1905(d) of the Act. The ICF/MR CoPs appear in 42 CFR Part 483 Subpart I. Regulatory requirements for ICF/MR 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. 1, 05-21-04)

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

The ICF/MR CoPs recognize the developmental, social, and behavioral needs of individuals with mental retardation who live in residential settings by requiring that each individual both require and receive active treatment for the ICF/MR 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.

2134 - Distinct Part ICF/MR

(Rev. 1, 05-21-04)

Neither the law nor Federal regulations define or require ICF/MR services in terms of distinct parts. However, as a State Medicaid program requirement, States may provide for distinct part ICF/MR approvals. Where the SMA elects to define the ICF/MR 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/MR residents in the institution.

2138 - Approval Procedures for ICFs/MR

(Rev. 1, 05-21-04)

2138A - Initial Certification of ICF/MR

(Rev. 1, 05-21-04)

Initial certification of ICFs/MR 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/MR 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/MR. 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/MR 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/MR 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 mental retardation 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. 1, 05-21-04)

When surveying ICFs/MR 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/MR is centrally administered, the SA prepares a certification package for each unit.

2138C - Minimum Size of ICF/MR

(Rev. 1, 05-21-04)

An ICF/MR is defined as a facility that furnishes food, shelter, treatment, or services to 4 or more individuals unrelated to the proprietor. ICFs/MR 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/MR. 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/MR may be separately certified under its own provider number if the living unit meets the criteria for a **freestanding** ICF/MR. 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/MR.

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/MR

(Rev. 1, 05-21-04)

Guidelines for surveying ICFs/MR are located in Appendix J. They provide an interpretation of the ICF/MR 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 mental retardation and related conditions.

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

(Rev. 1, 05-21-04)

To survey ICFs/MR, 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/MR 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/MR of 16 Beds or Less

(Rev. 1, 05-21-04)

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. 1, 05-21-04)

ICFs/MR have time-limited provider agreements. Each successive certification has an effective period lasting 1 year or less (subject to extensions of up to two months (42 CFR Part 442.16)) beginning on the day following the expiration of the current agreement if all requirements are met.

The SA completes a recertification survey once every year in time to sustain an unbroken succession of provider agreements (see §2141 for time-limited certifications).

2139 - Assessment of ICFs/MR Based on CoPs for Active Treatment

(Rev. 1, 05-21-04)

To be certified as a Medicaid provider of ICF/MR 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/MR. 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 the mentally retarded 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. 1, 05-21-04)

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.

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. 1, 05-21-04)

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 mental retardation professional and revised as necessary.

Approximately one-third of the ICF/MR 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/MR Requirements

(Rev. 1, 05-21-04)

2140A - ICF/MR Room Size and Occupancy

(Rev. 1, 05-21-04)

No waivers are available to an ICF/MR 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 mental retardation 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/MR 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 - Time-Limited Certifications - ICFs/MR

(Rev. 1, 05-21-04)

Because ICFs/MR have time-limited agreements (TLAs), the scheduled expiration of the agreement governs the length of time for which the certification is valid.

2141A - Full 12 Months

(Rev. 1, 05-21-04)

Where there are no Standards or Conditions out of compliance, the SMA will execute an unconditional agreement of 12 full calendar months.

2141B - Conditional 12 Month Agreement Subject to Automatic Cancellation Clause

(Rev. 1, 05-21-04)

Where an ICF/MR is in compliance with the CoPs but has deficiencies that must be corrected, the SMA may execute a conditional agreement up to 12 full calendar months, subject to an automatic cancellation clause (i.e., automatic cancellation 60 days after the projected correction date). Unless the corrections have been completed or there is substantial progress in carrying out the PoC, the agreement will be canceled.

This type of certification period is appropriate where, despite the deficiencies, the facility is able to provide an adequate level of care, has responded with an acceptable PoC, and, by its past performance in correcting deficiencies, can reasonably be expected to make the necessary improvements.

To determine **full** calendar months, first determine the effective date of the agreement; except where the effective date is the first day of a month, the count will start with the first month following the month in which the agreement is effective.

An ICF/MR agreement will expire at the close of the last day of its specified term and will not be automatically renewable from term to term. Where the term of an agreement is extended the "close of the last day of the specified term" will be the close of the day to which the agreement has been extended. In the case of an agreement that is automatically canceled, the agreement ends at the close of the predetermined date specified in the automatic cancellation clause.

2141C - Period of Certification Which Expires 60 Days After PoC

(Rev. 1, 05-21-04)

Where an ICF/MR has deficiencies, the SA may recommend a short period of certification that expires two months after the date specified for complete implementation of the PoC. This certification results in subsequent cancellation of the provider agreement unless deficiencies have been corrected by the next survey.

2141D - Extending the Term of ICF/MR TLA

(Rev. 1, 05-21-04)

The SMA may extend the term of an agreement for a single period of two **full** calendar months if:

- The health and safety of the patients are not jeopardized;
- The determination supporting extension is made before the expiration date of the agreement; **and**
- It is necessary to prevent irreparable harm to the facility;
- It is necessary to prevent hardship to the beneficiaries being furnished care by the facility; or
- It is impractical to determine whether the facility is in compliance. This determination must be documented in writing with supporting evidence.

If an agreement is extended, the SMA will notify the ICF/MR by a letter prepared as a supplement to the agreement. The letter should include rationale for the extension and the extension date of the agreement.

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. 1, 05-21-04)

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. Appendix B contains Interpretive Guidelines for surveyors.

2180B - Types of Agencies

(Rev. 1, 05-21-04)

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 include the nonprofit visiting nurse associations and Easter seal societies, as well as nonprofit 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. 1, 05-21-04)

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 service 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 42 CFR Part 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 complied with, as though the HHA was furnishing the services directly.

When hourly or per visit contracts are used, or when services are provided under arrangements, 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 developing 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.

2182 - Organization of HHA

(Rev. 1, 05-21-04)

Parent HHA

The parent HHA is that part of the HHA that develops and maintains administrative control of subunits and/or branch offices. Services are provided by the parent HHA.

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 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 HHA CoPs because it is too far 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 SA completes an HHA Survey and Deficiencies Report (Form CMS-1572 (a), (b), and (e)), Form CMS-2567, and all other applicable documents for the parent organization and each subunit. The SA does not conduct the initial survey of a subunit prior to the initial survey of the parent agency.

Subdivisions

A subdivision is a component of a multi-function health agency, such as the home care department of a hospital or the nursing division of a health department, which independently meets the CoPs for HHAs. A subdivision may have subunits and/or branch offices and, if so, is regarded as a parent agency.

2182.1 - Characteristics Differentiating Branches From Subunits of HHAs

(Rev. 1, 05-21-04)

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 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 services within a portion of the total geographic area served by the parent agency.
>
> Subunit - Semi-autonomous. Is 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 42 CFR Part 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 42 CFR Part 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 should be requested to convert to a subunit.

Subunit - The subunit functions independently of the parent, and consequently, supervision is provided by staff designated by the subunit.

Administrator (See 42 CFR Part 484.4.)

Branch - The administrator of the HHA maintains an ongoing liaison with the branch staff and 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 - Is semi-autonomous and maintains its own administrative staff. Functions as an independent entity.

Supervising Physician or RN (See 42 CFR Part 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.

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

Personnel Policies (See 42 CFR Part 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 42 CFR Part 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 (i.e., branch) does not base its practice at that site. (Example: A 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 42 CFR Part 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 42 CFR Part 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 parent agency's group of professional personnel may also serve as the subunit's group of professional personnel. 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. 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.

Clinical Records (See 42 CFR Part 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 Change From Branch to Subunit

(Rev. 1, 05-21-04)

In most cases, a survey of an existing, previously approved branch that you now determine should be a subunit will not be needed. In such a situation, follow the existing survey and certification rules for issuing a provider agreement and number to the subunit, and use an effective date agreed upon by the CMS RO. However, if you discover a "branch" 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. Note that a subunit may have branches. An onsite survey will also be necessary for any location where the HHA has not provided services to Medicare beneficiaries in the past that the HHA now proposes to operate as a branch, and that CMS determines on the basis of the information provided, is a subunit.

2182.4 - CMS Approval Necessary for Non-Parent Locations

(Rev. 1, 05-21-04)

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.

2182.4A - Notification by HHA to Add Non-Parent Location

(Rev. 1, 05-21-04)

- The notification should include the following information:
- Address and phone number of the branch/subunit;
- Organizational lines under the parent;
- How supervision will occur;
- Services provided directly and under arrangement; and
- Geographic area (counties, cities, zip codes).

The parent HHA should:

- Identify all branch staff and their job descriptions;
- Provide proof of staff qualifications (resume, licensure, aide training, etc.);
- Provide contracts for any services provided under arrangement;
- List any services shared with the HHA parent;
- Define service area and any intention to cross State lines (need a reciprocal agreement between States and RO approval at that time);
- Provide policy for addressing clinical and other emergency situations;
- Provide plans for addressing staff absenteeism;
- Identify any high-tech services provided;
- Identify how staff will coordinate care and services;
- Identify the person who will resolve patient care issues at the branch, and explain how supervision by the HHA parent will occur;
- Attach organizational chart delineating lines of authority, professional and administrative control for the HHA and the branch; and
- Provide certificate of need, if applicable.

2182.4B - SA Considerations in Reviewing a Request for Branch Determination

(Rev. 1, 05-21-04)

The SA should review the HHA's proposal for:

1. HHA's ability to supervise the branch to assure the provision of quality care for the patients served by the branch. The following information should be considered:

    - The HHA's supervising nurse or physician, as required by 42 CFR 484.14(d) must be available by phone or other means of communication during operating hours. The presence of an effective branch supervisor or manager, who is formally appointed by and under the direct supervision of the HHA parent, is permissible;

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

- The HHA parent may use technological means for supervision in conjunction with periodic onsite visits. The HHA parent should be aware of the staffing, patient census and any issues/matters affecting the operation of the branch. The lines of authority and professional and administrative control should be clearly delineated in the HHA's organizational structure and in practice and should be traced to the HHA parent agency;

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

- The HHA must be able to maintain 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 should have 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 must be able to monitor branch activities (clinical and administrative) and the management of services, as well as personnel and administrative issues;

- Depending on the organization, the HHA's administrator, quality improvement personnel, supervisory personnel etc., should conduct periodic onsite visits to the branch to ensure the delivery of quality care;

- The HHA parent provides ongoing in-service training to ensure that all staff is 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; and

- Whether the required group of professional personnel, which reviews the agency's policies, is directed to service delivery throughout the entire agency, including the HHA parent and any branches.

2. The HHA's past compliance history;

3. Relevant State issues and recommendations including a required written reciprocal agreement between the States to assure that at least one of the SAs assumes responsibility for any necessary surveys of the branch in situations in which an HHA provides services across State lines; and

4. A review of the ability of the branch office to meet the regulatory definition of a branch as defined in 42 CFR 484. The regulations require the branch to be within the HHA's geographical service area and close enough to the HHA to share supervision, administration and services on a daily basis. While mileage and travel times are significant factors to consider because they are implicitly referenced in the regulations, each alone should not be the single issue in determining approval or denial of the branch. The following information should be considered:

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

    - The branch and its service area must be 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.

While all of the above factors should be considered when reviewing branch office applications, the focus should be on the ability of the HHA to demonstrate how it can monitor all services provided in its entire service area, including any branch offices, to ensure compliance with the conditions of participation found at 42 CFR 484. The decision to approve a branch should be based on the HHA's ability to adequately supervise the branch to assure that the quality and scope of items and services provided to all patients is of the highest practicable functional capacity for each patient so as to meet their medical, nursing, and rehabilitative needs. If a review of an HHA's branch office application is determined to be insufficient, the disapproval letter should include some discussion of these criteria.

2182.4C - Onsite Monitoring by the SA

(Rev. 1, 05-21-04)

Onsite monitoring of the operations of an approved branch should reveal 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; and

- Patients are receiving appropriate care and services at the branch.

CMS must then determine if the CoPs continue to be met with the inclusion of the additional location. In the absence of notification, 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.

While the HHA may notify the SA of its proposal to establish a non-parent location, and the SA may make a recommendation to the CMS RO in a particular case, it is the CMS RO which has the authority for determining the non-parent's status as a branch or subunit.

The CMS RO will review each HHA's request for a branch office on a case-by-case basis, and consider all the national guidelines. The CMS RO will communicate its final decision in writing to the parent and copy the SA and the regional home health intermediary (RHHI). The approval letter should include notification of the branch approval and the assigned Federal branch ID number. The RO should enter the branch ID number into ASPEN prior to sending the letter to the HHA, so that the branch can begin providing services and collect and submit OASIS data on receipt of the approval letter. Any decision to deny the request for a branch office should include the full range of the reasons supporting the denial. Use the Model Denial Letter, Exhibit 284, as appropriate and copy the SA.

2182.5 - Branch Identification Numbers

(Rev. 1, 05-21-04)

An identification number is assigned to every branch of a parent HHA and subunit, as applicable, effective January 1, 2004. 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 survey results with individual HHA branches. Also, submission of branch identification numbers on Outcome and Assessment Information Set (OASIS) assessments will provide 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.

Each branch is numbered with the same Federally assigned provider number 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 = Medicare Provider number 017001.
- ABC's branches would be assigned the branch identification numbers 01Q7001001, 01Q7001002, and 01Q7001003.
- As directed by the ROs, HHA branch identification numbers will be entered into the Automated Survey Processing Environment (ASPEN) system along with the branch demographic information.

Assignment of Branch Identification Numbers

The Form CMS-1572, which captures survey and deficiency information on every survey, requests branch information at field G17 that includes an 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. As branch identification numbers are assigned, HHAs and their respective branches are informed of their assigned branch identification number(s). A sample letter is attached available at Exhibit 286 for use by the RO or SA to notify HHAs of their branch identification number(s). HHAs will need this information to enter on OASIS item M0016 (Branch ID). HHAs and subunits that do not have branches will not be assigned any branch IDs.

Form CMS 1572 and Assignment of Branch Identification Numbers

ROs are responsible for assigning branch identification numbers according to the RO's existing policies for assignment of provider numbers. The Form CMS-1572, which captures survey and deficiency information on every survey, requests branch information at field G17 that includes an 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. Current branch information is collected on every state agency home health survey.

When future HHA branches are approved, the ROs must assure that all branch locations nationwide are identified, enumerated, and entered into ASPEN prior to sending the approval letter to the HHA. As surveys are conducted, states should verify that the information they have on branch locations is current and accurate.

Branch Identification Numbers and OASIS

As branch identification numbers are assigned, the RO must ensure that HHAs and their respective branches are informed of their assigned branch identification number. At this time the fiscal intermediaries are not in need of branch identification information**.**

HHAs will need this information to complete 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 8 of the OASIS Implementation Manual.

2183 - Separate Entities

(Rev. 1, 05-21-04)

The surveyor must be able to identify the boundaries of the entity seeking certification or recertification. The Medicare CoPs, in accordance with §1861(o)(6) of the Act, are applicable to all individuals served by the HHA and not just 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.

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 entity to which the CoPs do not apply, ask the HHA or its parent organization for information that will allow you to differentiate between it and the HHA. The HHA may be identified as a department, program, or component of the larger organization. Use the following guidelines, on a case-by-case basis, to assist you 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. 1, 05-21-04)

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.

If the State survey agency 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 (42 CFR Part 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 intermediary must be notified about the allegation of separate entities. (See 42 CFR Parts 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 should 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 should 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 should 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 intermediary and, if necessary, to the State Medicaid Director.

2184 - Operation of HHAs Cross State Lines

(Rev. 1, 05-21-04)

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 State 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.

In most circumstances, the provision of services across State lines is appropriate. 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 in all States in which it provides services and its personnel must be qualified in all States in which they provide services. Certification activities within a particular State are done by the appropriate SA for that State. 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 served by the HHA 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 a reciprocal agreement on assuring the necessary surveys of the branch, 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 285 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 CMS RO responsible for the State in which the parent resides should take the lead in assuring that the required survey and certification activities are met.

A branch office may also be physically located in a neighboring State if it is near enough to the parent agency to share administration, supervision, and services on a daily basis, and 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.

2186 - Health Facility-Based HHAs

(Rev. 1, 05-21-04)

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 concurrent use of personnel 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 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)

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 Survey Frequency

(Rev. 1, 05-21-04)

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.

A - An HHA may be placed on a 36-month survey cycle if it meets the following criteria:

- No condition-level deficiencies in the last three recertification surveys;
- No deficiencies at 42 CFR Part 484.18 or 42 CFR Part 484.55 in the previous standard survey; and
- No complaints resulting in deficiency citations since the previous survey.

In order to avoid giving notice of the survey, conduct the standard survey during a range of 30 - 36 months.

B - An HHA may be placed on a 12 - 36-month survey cycle if the following criteria are met:

- No condition-level deficiencies within 24 months of the most recent survey;
- No complaints resulting in deficiency citations since the previous survey; and
- Deficiencies at 42 CFR Part 484.18 and/or 42 CFR Part 484.55 in the previous standard survey, and the plan of correction was acceptable. In these situations, consider the following criteria in determining survey frequency:
    - Number of standard-level deficiencies cited;
    - Deficiencies cited under 42 CFR Parts 484.10 and/or 484.14(g); 484.18, and/or 484.55;
    - Number and resolution of complaints received concerning the HHA;
    - Changes in HHA management; and
    - Licensure information.

We expect that the majority of these HHAs will be surveyed at least every 24 months; however, SAs may use their discretion in surveying more or less often.

C - An HHA must be placed on a 12-month survey cycle if the following criteria are met:

- An HHA has been Medicare-approved for less than 3 years at its most recent survey;
- An HHA has had a change of ownership since the previous standard survey;
- An HHA had a condition-level deficiency cited within 24 months;
- An HHA had a complaint survey resulting in deficiency citations since the last standard survey; or
- An HHA has been reviewed by a State, regional, or national fraud and abuse initiative.

In order to avoid giving notice of the survey, you should conduct the standard survey during a range of 9 - 15 months.

D - More Frequent Surveys

An HHA that fails to meet one or all of the Medicare CoPs will be considered to be providing substandard care and will require closer scrutiny. Such an HHA will be placed under the appropriate termination procedures until the HHA comes into compliance with the CoPs or is terminated. If the HHA comes back into compliance with the CoPs, the HHA will receive a standard survey within 4 - 6 months from the date that compliance was established. If the HHA continues to comply with the CoPs, then the HHA will be placed on the 12-month survey cycle until the HHA is free of condition-level deficiencies for no less than 2 consecutive years.

E - Random Surveys

Each SA will randomly select, on an annual basis, a 5 percent sample of HHAs on the 36-month survey cycle. Surveyors will conduct a standard survey on this sample of HHAs within 16 - 20 months following the recertification survey. Appropriate survey frequency decisions may be made based on the results of the random survey.

SURVEY FREQUENCY GUIDELINES	
Frequency	Requirements
36 months	No CoP(s) out in the last 3 recertification surveys; AND
	No deficiencies at 42 CFR Part 484.18 (i.e., acceptance of patients, PoC, and medical supervision) or 42 CFR Part 484.55 Comprehensive Assessment of Patients in the previous standard survey; AND
	No complaints with deficiency citations since the previous survey.
12 - 36 months	No CoP(s) out within 24 months of the most recent survey; AND
	No complaints with deficiency citations since the previous survey; AND
	Deficiencies at 42 CFR Part 484.18 and/or 42 CFR Part 484.55 in the previous standard survey with an acceptable plan of correction. In these situations, the State also considers the following criteria in determining survey frequency:
	Number of standard-level deficiencies;
	Deficiencies cited under 42 CFR Part 484.10 (i.e., patient rights), Part 484.14(g) (i.e., coordination of patient services), Parts 484.18, and 484.55;
	Number and resolution of complaints received concerning an individual HHA;
	Changes in HHA management; and
	Licensure information.
12 months	Medicare-approved for less than 3 years at its most recent survey; OR
	Change in ownership since the previous standard survey; OR
	CoP(s) cited within 24 months of the most recent survey; OR
	Complaint survey with deficiency citation since the last standard survey; OR
	Review by a State, regional, or national fraud and abuse initiative.
4 - 6 months	CoP(s) out and resolved.

2195.1 - Tracking and Monitoring the Survey Cycles

(Rev. 1, 05-21-04)

The following codes should be entered into the ASPEN system to enable the SAs and ROs to track and monitor the survey cycles of HHAs. The code is required when the survey is completed and the survey results are ready for upload to the national system. Surveyors or other appropriate staff should clearly mark the length of the survey cycle on the Application (Form CMS-1572A) tab in the designated field. The codes are outlined below:

A = 36 months

B = 12-36 months

C = 12 months

D = 4-6 months

E = 18 months (5% sample)

With the exception of code B, the codes will identify the survey interval for all HHAs, i.e., code A HHAs will be surveyed every 36 months, code C HHAs will be surveyed every 12 months, etc. Survey the majority of code B HHAs at least every 24 months; however, SAs may use their discretion in surveying more or less frequently. HHAs that meet the criteria for a code A as the result of their last survey may be selected for the 5% sample in 18 months and entered into the system as a code "E."

Once the survey frequency code has been entered and uploaded to the national system, the SA cannot change it unless another certification survey is entered. Should a change have to be made between surveys, the SA must notify the RO and the change must be entered by the RO. Be alert for the two most likely reasons to change the code between surveys: complaint investigation with deficiency citations and a change of ownership. When a new survey code is entered, the code for the previous survey will be retained in the national system so that eventually, we will have a survey history for each HHA.

2196 - HHA Survey Process for Determining Quality of Care

(Rev. 1, 05-21-04)

The HHA survey process provides for a standard survey, a partial extended survey, and an extended survey. All HHAs must undergo a standard survey. The standard survey determines the quality and scope of patient care services provided by an HHA as measured by indicators of medical, nursing, and rehabilitative care. Each HHA that is found to have one or more condition-level deficiencies under a standard or partial extended survey must undergo an extended survey to review and identify the policies and

procedures which produced the substandard care and to determine if the HHA meets all of the CoPs.

An HHA may also be subject to a partial extended or extended survey at the discretion of CMS or the State.

Any data tag that is not a condition-level data tag is a standard-level tag. Any deficiency at any data tag that is not a condition-level deficiency is a standard-level deficiency.

2196.1 - Definitions

(Rev. 1, 05-21-04)

2196.1A - Standard Survey

(Rev. 1, 05-21-04)

Conducted to determine the quality of care and services furnished by the HHA as measured by indicators of medical, nursing, and rehabilitative care. The surveyor uses the Functional Assessment Instrument (FAI) (Form CMS-1515) to record information obtained during home visits and clinical record reviews. The surveyor reviews the HHA's compliance with:

- Patient rights (42 CFR Part 484.10);
- Release of Patient Identifiable OASIS Information (42 CFR Part 484.11);
- Federal, State, and local laws and regulations, the disclosure of ownership and management information, and accepted professional standards and principles (42 CFR Part 484.12);
- Coordination of patient services (42 CFR Part 484.14(g));
- Acceptance of patients, PoC, and medical supervision (42 CFR Part 484.18);
- Home health aide services (42 CFR Part 484.36);
- Clinical records (42 CFR Part 484.48); and
- Comprehensive assessment of patients (42 CFR Part 484.55).

Section 1891(c)(2)(C)(i)(II) of the Act requires that the standard survey include "a survey of the quality of care and services furnished by the agency as measured by indicators of medical, nursing, and rehabilitative care." Therefore, it is essential that the surveyor review the HHA's compliance with the comprehensive assessment regulation (42 CFR 484.55) (which incorporates the OASIS data elements) as well as identifies how the HHA

defines, plans for, delivers, and measures anticipated outcomes for patients. The OASIS coordinators will check for compliance with the OASIS data transmission regulation (42 CFR 484.20) (which requires electronic submission of OASIS information to the State), offsite, and report any concerns to the SA surveyors.

2196.1B - Partial Extended Survey.--Is conducted:

(Rev. 1, 05-21-04)

- When standard-level deficiencies are found during the standard survey and it is suspected that a more comprehensive review of the CoPs examined under the standard survey would determine condition-level rather than standard-level deficiencies; or

- To determine if standard or condition-level deficiencies are present in the CoPs not examined in the standard survey.

2196.1C - Extended Survey

(Rev. 1, 05-21-04)

Is conducted:

- To review and identify the HHA's policies and procedures that produced the substandard care (one or more condition-level deficiency(ies) identified under the standard or partial extended survey; and

- To determine whether the HHA is in compliance with all of the CoPs.

2196.2 - Home Health Functional Assessment Instrument (FAI)

(Rev. 1, 05-21-04)

Exhibit 103 contains the FAI instructions and an example of the 5 Modules and 1 Calendar Worksheet that constitute the FAI. In general, surveyors should use the modules A, B, C and the Calendar Worksheet of the FAI to record individual items of information in a systematic way to determine whether an HHA is furnishing individual care and services in compliance with the regulations. Include identifying information on the FAI official Worksheets to assist in later review.

MODULE A: Use Module A to collect discreet patient-centered medical information to determine the appropriateness of the care or services being furnished. It is not necessary to complete each item for each patient. An option to using Module A is to request the HHA to copy the most current plan of care for each patient in the survey sample (and/or the previous Form CMS-485, if appropriate) that identifies baseline medical information for the attachment to the patient's FAI.

MODULE B: Use only for those patients whose admitting diagnosis(es) or complications of the secondary diagnosis(es) directly affect the patient's potential to meet his or her own activities of daily living (ADLs) and when there is reason to expect that skilled patient care interventions by the HHA will have helped the patient move toward achieving his/her highest maximum potential of functioning. The surveyor records only information that helps compare the progress (or lack of progress) of the patient's functional abilities at two points in time; at admission and at the survey clinical record review. If progress is not being made, determine if intervening events are recorded.

MODULE C: Use Module C for home visit guidance only. It is not necessary to complete each item for each patient because the information needed to determine the appropriateness of the care or services being furnished to the individual patients varies with each patient situation.

MODULE D: Complete each item in Module D for each patient in the survey sample to record the surveyor's decision about the appropriateness of the HHA's care and services for each individual patient.

MODULE E: Complete each item in Module E to summarize the surveyor or team's decision about the care and services provided by the HHA for all of its patients and to complete the survey process.

CALENDAR WORKSHEET: Use the Calendar Worksheet to determine compliance with 42 CFR Part 484.18(a) and (b) and 42 CFR Part 484.55 or to record any other information that seems appropriate to the patient's specific condition or services provided.

2196.3 - Clinical Laboratory Improvement Amendments

(Rev. 1, 05-21-04)

Regulations implementing the provisions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) were published February 28, 1992, and became effective September 1, 1992. Additional changes were published in an update to the CLIA regulations dated January 19, 1993. If the HHA is providing laboratory testing as set forth in 42 CFR Part 493, the SA must request to see the CLIA certificate applicable to the testing being performed, i.e., a Certificate of Waiver, a Certificate for Provider Performed Microscopy Procedures, Certificate of Accreditation, Certificate of Registration or Certificate of Compliance. HHAs holding a Certificate of Waiver are limited to performing only those tests determined to be in the waived category. HHAs holding a Certificate for Provider Performed Microscopy Procedures are limited to performing only those tests determined to be in the Provider Performed Microscopy Procedure Category or in combination with waived tests. All other testing performed by the HHA requires either a Registration Certificate (which allows the performance of such testing until a determination of compliance is made), a Certificate of Accreditation, or a

certificate of compliance (issued upon the determination of compliance after an onsite survey). If the facility does not possess the appropriate CLIA certificate, the SA informs the facility that it is in violation of the CLIA law and that it must apply immediately to the SA for the appropriate certificate.

Assisting individuals in administering their own tests, such as finger stick blood glucose testing, is not considered testing subject to the CLIA regulations.

NOTE: Some States have laboratory licensure programs approved by CMS as meeting the CLIA requirements. The laboratories in these States must hold the applicable State license for the level of testing being performed.

2198 - Standard Survey - Structure

(Rev. 1, 05-21-04)

2198A - Components

(Rev. 1, 05-21-04)

Under the standard survey, the surveyor is required to:

- Select and review, to the extent practical, a case-mix, stratified sample of clinical records for individuals receiving items and/or services provided by the HHA; and

- Conduct RN home visits to those patients who have given consent, or family/caretaker consent if the patient is unable to give consent as a result of his or her medical, mental, or emotional problems.

Although the focus of the standard survey is on patients receiving skilled services, non-skilled patients may also be included in the samples for review.

2198B - Activities

(Rev. 1, 05-21-04)

During the standard survey, the surveyor determines the HHA's compliance with:

- Patient rights (42 CFR Part 484.10);

- Release of patient identifiable OASIS information (42 CFR Part 484.11);

- Federal, State, and local laws and regulations, the disclosure of ownership and management information, and accepted professional standards and principles (42 CFR Part 484.12);

- Coordination of patient services (42 CFR Part 484.14(g));
- Acceptance of patients, PoC, and medical supervision (42 CFR 484.18);
- Home health aide services (42 CFR Part 484.36);
- Clinical records (42 CFR Part 484.48); and;
- Comprehensive assessment of patients (42 CFR Part 484.55).

2198C - Applicability

(Rev. 1, 05-21-04)

All HHAs are required to have an unannounced standard survey no later than 36 months after the date of the previous standard survey. Each State must follow CMS' instructions for survey frequency within this 36-month interval commensurate with the need to assure the delivery of quality home health services. (See §2195.) Periodically, branch locations should be included in, or replace, the unannounced standard survey of a parent HHA or of an HHA subunit with branches. Routinely conduct the recertification survey at a branch location when that location serves more patients than the parent, and visit all locations of an HHA during the survey whenever possible.

The SA conducts a standard survey:

- Of HHAs making initial application for Medicare approval. If the HHA patient census is inadequate to provide the samples necessary (see §2200), include the requirements under 42 CFR Part 484.14 as part of the standard survey. Follow-up in several months, if warranted;
- Within two months after a significant number of complaints about an HHA have been received by the State since the HHA's last survey. Investigate each complaint alleging noncompliance (see §3281); and
- Within two months of an HHA's change in ownership, management, or administration (see 42 CFR Part 484.12(b)) to determine whether the change has resulted in any decline in the quality of care furnished by the HHA (if you believe such a survey is necessary).

The standard survey may not be conducted by an individual who is serving (or has served within the previous 2 years) as a member of the staff of, or as a consultant to, the HHA being surveyed for compliance with the CoPs, or who has a personal or familial financial interest in the HHA being surveyed. (See §1891(c)(2)(C)(iii)(I-III) of the Act.)

Neither CMS nor the RHHI requires a survey when a new service is added to an approved HHA. The SA directs the HHA to notify the RHHI about the added service.

Review the new service at the next scheduled survey unless you receive a complaint about the HHA or you have concerns about the ability of the HHA to provide the service.

2200 - Survey Tasks

(Rev. 1, 05-21-04)

The outcome-oriented survey process for HHAs involves the following six steps:

- Task 1 - Pre-Survey Preparation
- Task 2 - Entrance Interview
- Task 3 - Information Gathering
- Task 4 - Information Analysis
- Task 5 - Exit Conference
- Task 6 - Formation of the Statement of Deficiencies

2200A - Task 1 - Pre-Survey Preparation

(Rev. 1, 05-21-04)

Prior to each survey, review the HHA file (or application, in the case of an initial) in accordance with §2704. Follow §2710, Reviewing Forms at the Beginning of a Survey. Also review the information in the State files relating to the disclosure of information statement made by the HHA (Form CMS-1513). Check this information for accuracy with the information obtained during the course of the survey. In addition, review any complaint data, previous survey data, and reports generated from the OASIS data These reports contain valuable information that may assist you in identifying areas of concern during the survey and possibly identify individuals to be included in the sample selection. Ask the OASIS Educational Coordinator or the OASIS Automation Coordinator for pertinent information regarding compliance with the OASIS CoPs that can be monitored offsite. Available OASIS reports can be generated for specific time periods (e.g., case-mix, adverse event, risk adjusted OBQI reports).

Specifically, using the worksheet in Exhibit 285 conduct a review of the following five OASIS reports:

OBQM Adverse Event Outcome Report

OBQI Outcome Report

OBQI Case Mix Report

Submission Statistics by Agency Report

Error Summary Report by HHA.

2200A1 - OBQM Adverse Event (AE) Outcome Report and Patient Listing

(Rev. 1, 05-21-04)

As part of the pre-survey process, review the most recent quarter (3 months) or whatever time period is necessary to reach at least 60 patients.

Tier 1 AE Outcomes

The threshold for each Tier 1 outcome is **one** patient. Therefore, the surveyor must—

- Identify if any agency patients experienced either of the 2 adverse event outcomes:

  a. Emergent care for injury caused by a fall or accident at home; or

  b. Emergent care for wound infections, deteriorating wound status.

- During the onsite survey, select patient records and home visits that focus on either (or both) outcome(s) identified on the report.

Tier 2 AE Outcomes

There are six Tier 2 AE Outcomes for consideration. The following thresholds must be met for an outcome in Tier 2 to become a focus area:

- There must be patients who experienced the outcome; and

- The HHA's current incidence rate must be equal to or greater than twice the reference rate.

During the onsite survey, select patient records and home visits that focus on the outcomes identified on the report that met the investigation thresholds of equal to or greater than twice the reference value. In addition to providing **areas** for focus during the onsite survey, the AE Patient Listing Report provides surveyors the opportunity of selecting closed records of specific patients under those outcomes meeting the investigation criteria.

If, after working through the Tier 2 AE outcomes, none of the outcome rates are greater than or equal to twice the reference rate, surveyors may optionally focus on other AE outcomes (not listed on the Worksheet) with incidence rates equal to or greater than twice the reference rate.

2200A2 - OBQI Outcome Report

(Rev. 1, 05-21-04)

As part of the pre-survey process, using the Worksheet as a guide for reviewing the HHA's most recent Risk-adjusted and Descriptive Outcome Report, review the report for those outcomes listed on the Worksheet and choose (if possible) 2 outcomes for focus during the onsite survey that have:

- At least 30 eligible cases;
- A large and unfavorable magnitude of difference between the HHA's and the national reference rates (specific thresholds are described for each of the target outcomes on the Worksheet); and
- Statistical significance equal to or less than 0.10 (as depicted by one or two asterisks).

To calculate the percentage point difference between the agency and the reference outcomes, compare the reference percentage point value (found at the end of the "reference" bar) and the agency percentage point value (found at the end of the "current" bar). When looking at "Acute Care Hospitalization," determine if the HHA's outcome is at least 10 **percentage points** higher than the reference value. When looking at the remaining nine outcomes on the worksheet, evaluate whether the agency's outcome is lower than the reference outcome by an amount equal to or greater than the listed threshold.

During the onsite survey, select patient records and home visits that focus on the outcomes identified on the OBQI report meeting the individual investigation thresholds.

If none of the 10 listed outcomes on the Worksheet trigger the selection criteria, another outcome should be selected from the OBQI report that is not on the Worksheet but meets the selection criteria. If there are no statistically significant outcomes that meet the selection criteria, the survey will not focus on an OBQI Outcome.

2200A3 - OBQI Case Mix Report

(Rev. 1, 05-21-04)

The OBQI Case Mix Report identifies the HHA patient population trends to investigate during the onsite survey. As part of the pre-survey process:

- Use the OBQI Case Mix report for the same timeframe as the OBQI Outcome Report;
- Focus on acute conditions and home care diagnoses that are statistically significant and are equal to or greater than 15 percentage points higher than the reference rate;
- Choose up to three conditions or diagnoses that meet the criteria; and
- Select one or two records of patients with diagnoses that meet the criteria for review with or without home visits.

If no conditions or diagnoses trigger the investigation criteria, this will not be an area of focus during the survey.

2200A4 - Submission Statistics by Agency Report

(Rev. 1, 05-21-04)

As part of the pre-survey process, determine whether the HHA:

- Is submitting data less often than monthly; and/or
- Has greater than 20 percent of records rejected in accordance with Worksheet instructions.

If either probe is triggered, investigate compliance with the OASIS transmission requirements (42 CFR 484.20, Reporting OASIS Information) during the onsite survey through the partial extended survey process.

2200A5 - Error Summary Report by HHA

(Rev. 1, 05-21-04)

As part of the pre-survey process:

- Focus on four errors listed on the Worksheet--

    1. Error 102, Inconsistent Lock Date – According to the current regulations for OASIS reporting, assessments must be reviewed, corrected as needed, and data- entered and locked within a 7-day period. Investigate further if the HHA's percent of assessments with this error is at or above 20 percent.

    2. Error 262, Inconsistent M0090 date – M0090 is the date the assessment is completed. The recertification assessment must be done on an every 60-day cycle. Investigate if the HHA's percent of assessments with the error is at or above 20 percent.

    3. Error 1003, Inconsistent effective date sequence – This error warns the HHA that the effective date of the assessment it just submitted was earlier than the most current assessment received. Investigate further if the HHA's percent of assessments with this error is at or above 10 percent; and
    4. Error 1002, Inconsistent record sequence – This error warns the HHA that the assessment it just submitted does not logically follow the previous one submitted and may indicate the HHA has missed submitting a record. Investigate further if the HHA's percent of assessments with this error is at or above 10 percent.

- Note whether the error appears on the report **and** meets or exceeds the identified thresholds by checking "Y" or "N" on the Worksheet.

If any of the 4 errors listed on the Worksheet meet the investigation thresholds, further investigate compliance with the applicable OASIS reporting requirements (42 CFR 484.20, Reporting OASIS Information) during the onsite survey through the partial extended survey process.

- Effective December 8, 2003, and until further notice, State Survey Agencies (SAs) must not cite any deficiency for an HHA's failure to include the OASIS data set as part of the patient-specific, comprehensive assessment for non-Medicare non-Medicaid patients as required by 42 CFR 484.55.

Initial Certification

Before the initial certification survey is conducted, the SA must have received documentation submitted by the HHA requesting an initial certification survey.

1. Prior to the survey, the SA must have evidence that the HHA:

   - Is operational;
   - Has completed the Medicare Enrollment Application Form CMS-855 and had this form verified by the assigned RHHI;
   - Met the surety bond and capitalization requirements;
   - Is providing nursing and at least one other therapeutic service (physical therapy, speech language pathology, occupational therapy, medical social services or home health aide);
   - Can demonstrate the operational capability of all facets of its operations;
   - Has successfully completed an OASIS transmission to the State repository; and
   - Has provided care to a minimum of 10 patients requiring skilled care (not required to be Medicare patients). At least 7 of the 10 required patients should be receiving care from the HHA at the time of the initial Medicare survey. If the HHA is located in a medically underserved area, as determined by the CMS RO, the CMS RO may reduce the number of minimum patients from 10 to 5. At least 2 of the 5 required patients should be receiving care from the HHA at the time of the initial Medicare survey.

2. Follow the guidelines in the §2008.A, "Early Surveys of New Providers and Suppliers."

3. Determine that the HHA is in compliance with §1861(o)(4) of the Act and §2180 regarding licensure requirements.

2200B - Task 2 - Entrance Interview

(Rev. 1, 05-21-04)

The entrance interview, which sets the tone for the entire survey, is the critical first stage of the actual survey process. The surveyor must establish rapport with the HHA staff and establish his or her authority as the leader of the survey.

1. Upon arrival at the HHA, complete the following primary activities.

- Present identification and introduce the survey team members.
- Request a meeting with appropriate staff based on the organizational characteristics of the HHA. Request a copy of the organization chart, if available.
- Inform the HHA administrator, director, or supervisor of the purpose of the survey.
- Ask the administrator to explain the organization, services provided (directly and under arrangement) and the relationship to any corporate structure.
- Explain the survey process, and estimate the number of days onsite.
- Be aware that the unannounced survey may be disruptive to the normal daily activities of the HHA.
- Discuss the extent to which the HHA staff may be involved during the survey.
- Set up the schedules for any necessary interviews with staff.
- Request space to work.

Investigate during the survey any discrepancies in information obtained during the entrance interview through a review of source documents and interviews with key staff.

2. Gather the following information during the entrance interview:

- HHA location (including any branches);
- Access to clinical records, personnel files, policies, and procedures;
- Documentation of home health aide training and/or competency evaluations;
- Information concerning services not provided directly;
- Number of unduplicated patients admitted receiving skilled services during recent 12-month period;
- List or access to names of patients scheduled for a home visit during the survey;
- List of current employees (including name, title);
- CLIA certificate (if applicable);

- Forms to complete: Forms CMS-1513 and CMS-1572;

- Names of key staff (i.e., staff persons most knowledgeable about the home health aides, in-service training, clinical supervision);

- Clinical staff person who will be the primary resource to respond to the surveyor's questions;

- Access to **all** active patient names (Medicare/Medicaid/private pay) receiving skilled services that identifies the start of care (SOC) date, primary diagnosis, and services provided. This will aid in selecting the sample for home visits with record review based on the review of the OBQM and OBQI reports;

- Specific closed records for review from the agency's AE Patient Listing report; and

- If applicable, the HHA's rationale for stating that it is provider-based. (See §2004.)

2200C - Task 3 - Information Gathering

(Rev. 1, 05-21-04)

The information-gathering task is an organized, systematic, and consistent process designed to enable surveyors to make decisions concerning the HHA's compliance with each of the regulatory requirements reviewed during the survey. Action steps involve observation, interviewing, and record review.

2200C1 - Responsibilities include but are not limited to:

(Rev. 1, 05-21-04)

- Reviewing how the HHA performs the comprehensive assessment of patients incorporating the OASIS items;

- Determining if the comprehensive assessment accurately and completely reflects the patient's status for all assessment time points for all patients;

- Reviewing how the HHA determines the appropriate care, services, and treatments for patients to achieve desired health outcomes;

- Reviewing how the HHA delivers care to patients and measures needed and desired patient outcomes;

- Evaluating patient satisfaction with the HHA's services;
- Reviewing how the HHA uses OBQM and OBQI reports available from the OASIS data;
- Reviewing how the HHA's performance has impacted positively and negatively on patients, especially in terms of the care and services that the patients actually experience;
- Determining if the HHA provides care to patients that assists patients to attain and maintain their highest practicable functional capacity;
- Determining if the PoC is consistently implemented, evaluated, reviewed and updated based on the response, outcomes and needs of the patients;
- Selecting a sample for record reviews with home visit;
- Selecting a sample for record reviews without home visit;
- Arranging for and conducting home visits;
- Obtaining patient consent;
- Observing patient care;
- Interviewing staff and patients;
- Reviewing a sample of home health aides files; and
- Reviewing how the HHA complies with CoPs.

2200C2 - Request the following:

- Clinical records;
- Sample of personnel files, and sample of home health aide files;
- Documentation of aide training and/or competency evaluations; and
- Other relevant documents (i.e., policies and procedures) as necessary.

2200C3 - When discussing observations:

(Rev. 1, 05-21-04)

- Use observational skills at all times during the survey and discuss your observations, as appropriate, with team members and HHA personnel;
- Ask pertinent questions to obtain a baseline of information that expands early observations;
- Maintain an open and ongoing dialogue with HHA personnel;
- Give the HHA the opportunity to provide additional information before making compliance decisions;
- Ask staff to describe the usual procedural timeframes for filing pertinent clinical information in the record; and
- Question staff, as appropriate, about incomplete information or inconsistencies in recordings to clarify pertinent observations. Ask that missing information be provided within a reasonable timeframe during the survey.

2200C4 - Clinical Record and Home Visit Selection for Standard Survey

(Rev. 1, 05-21-04)

The surveyor selects, to the extent practical, a case-mix, stratified sample of clinical records of patients who have received or who are currently receiving items and skilled therapeutic services by the HHA under a PoC. "Stratified' means patients selected for a functional assessment are grouped (stratified) based on the primary admitting diagnosis for which the patient is receiving care and treatment from the HHA. "Case-mix" means that the sample includes patients receiving different services from different HHA caregivers (nurse, therapist, social worker, home health aide).

For example, a patient who is admitted to the HHA for treatment of a post-surgical wound is considered in a different stratum from the post-stroke patient. Since HHAs treat patients with a wide range of medical conditions, the review is to encompass patients with varying needs and services. The surveyor may also select some patients for review based on OASIS reports reviewed during pre-survey preparation. The OASIS reports only represent Medicare and Medicaid skilled patients. The sample selected for record review with home visits and record review without home visits should include patients from all payment sources. The patients selected through the use of the OBQM and OBQI reports should not replace the entire stratified sample. Additional current patients should be selected for record review with home visits and record review without home visits.

The surveyor uses the approximate number of unduplicated admissions from all payor sources for skilled services to the HHA (including branches) during the 12 months prior to the survey to determine both the number of clinical record reviews with home visits and the number of clinical record reviews without home visits.

The surveyor uses 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 closed records. The surveyor works with HHA staff to develop, as simply as possible and in the shortest period of time, a survey sample that meets, in its entirety, the following criteria:

- The sample includes a range of primary admitting diagnoses (stratification); and
- The sample represents patients who are receiving various kinds of services (case-mix).

2200C5 - Selecting a Sample of Patients for Clinical Record Review With Home Visits

(Rev. 1, 05-21-04)

Surveyors may conduct home visits to any patient receiving skilled services who grants permission. For clinical record reviews with home visits, the surveyor identifies and selects patients who will receive skilled services at their residence during the remaining days of the survey. Whenever possible, include (at a minimum) at least one patient who is receiving a "high-tech" service. For example, an ideal selection might include (at a minimum) at least one home visit with a registered nurse (RN), one home visit with a therapist, and one home visit with a home health aide. Other home visits could replicate the ideal selection or add more visits of one service based on the HHA's current visit schedule. The surveyor includes patients receiving only home health aide or personal care services to complete the survey sample size, if necessary.

Surveyors must:

- Select one or two patients triggered to be "at risk" of Tier 1 AE outcomes.
- Select one or two patients triggered to be "at risk" for Tier 2 AE outcomes of:
    a. Emergent Care for Improper Medication Administration and Side Effects; and
    b. Emergent care for Hypo/hyperglycemia.
- Select one or two patients with a medical condition relevant to the OBQI outcomes triggered. (For example, if the outcome "Improvement in Urinary

Incontinence" is a focus outcome, select one or two patients with urinary incontinence.)

The number of records reviewed, based on the total number of unduplicated admissions requiring skilled services during a recent 12-month period, is as follows:

All Patients Requiring Skilled Services Admitted During Recent 12 Month Period	Record Reviews With Home Visit to Patients Requiring Skilled Services Admitted During Recent 12-Month Period
less than 150	3-5
150-750	5-7
751-1,250	7-10
1,251 or more	25 or more*

***NOTE:** In certain situations, the number of record reviews with home visit may be decreased for HHAs with greater than 1,250 unduplicated admissions for skilled services.

In general, use the lower number in the range for HHAs that historically, in the SA's judgment, have performed well, e.g., have had no conditions out of compliance or few standard level deficiencies in the most recent survey. The range of numbers for home visits contained in the chart suggests minimums. The surveyor conducts more home visits, if necessary.

Therefore, when scheduling the home visits for HHAs with greater than 1,250 admissions, first select a case-mix, stratified subset of 10-12 patients from the original sample of 25 patients. Then review the records and conduct the home visits of these 10-12 patients. If the following three criteria are met, then it is not necessary to complete the remaining record reviews with home visits in the original sample at this point:

- If the findings of the review to this point did not result in your having to conduct a partial extended or extended survey; (See §2196 for guidelines on when to expand the standard survey.)

- If there has been no change in ownership or management of the HHA since the previous State certification survey; and

- If no conditions were found out of compliance during the previous State certification survey. However, if at any time later in the survey process you find it necessary to conduct a partial extended or extended survey, you must complete the remainder of record reviews with home visits from the original sample of 25 patients.

During a survey, patients may be selected for clinical record review with home visit and clinical record review without home visit, regardless of payor source. If the surveyor is unable to draw the required sample size for home visits, increase the clinical record reviews without home visits by one for each home visit not made. If the HHA patient census is inadequate to provide the samples necessary, include the requirements under 42 CFR Part 484.14 as part of the standard survey.

2200C6 - Selecting Sample of Clinical Records of Patients Who Will Not Receive Home Visit

(Rev. 1, 05-21-04)

Select both closed and active clinical records for review based on the Adverse Event and OBQI outcome(s) triggered for focus and targeted case mix characteristics. If possible, review of closed clinical records identified on the AE Patient Listing report under any triggered outcomes can begin while the HHA obtains the patient roster and home visit schedule.

Select one or two clinical records for review for each Tier 1 AE outcome triggered.

Select one or two clinical records for review for each Tier 2 AE outcome triggered.

NOTE: Patients experiencing more than one Tier1/Tier2 AE outcome are good candidates for clinical record reviews.

For clinical records without home visits the surveyor uses the clinical records of any patients not selected for home visits, regardless of payor source. If additional records are needed to complete the sample size, include records of patients visited 1 to 2 weeks prior to the survey or patients discharged within the same 1 to 2 week period. The number of records reviewed, based on the number of unduplicated admissions of all patients receiving skilled services during a recent 12-month period, is as follows:

All Patients Requiring Skilled Services Admitted During Recent 12-Month Period	Record Reviews of All Patients Requiring Skilled Services Admitted During Recent 12-Month Period
less than 150	8
150-750	10
751-1,250	12
1,251 or more	15 or more

2200C7 - Recording Information

(Rev. 1, 05-21-04)

a. Clinical Record Review

The arrangement and format of clinical records vary among HHAs. To minimize surveyor time spent in reviewing a clinical record and maximize the substantive information that can be obtained, we suggest that the following approach be implemented:

- Review the arrangement and format of one or two records with the HHA staff person recommended by the administrator to answer your questions about how services are organized, delivered, and evaluated. Ask him/her where you are likely to find the information in the clinical record.

- Review the most recent PoC for the primary admitting diagnosis, and the goals to be accomplished by the care.

- Determine if the PoC is current and has been appropriately signed and dated by the physician in compliance with the HHA's policies and procedures. Also, determine if verbal orders have been recorded to initiate appropriate professional services for the patient until the written PoC is received from the physician.

- Determine if the comprehensive assessment accurately reflects the patient's status.

- Evaluate the current status of the patient as reflected in the assessment, PoC, and visit notes.

- Verify that drugs and treatments are provided according to a physician's order and that all drugs have been reviewed by the HHA for potential adverse effects and drug reactions.

- Review the PoC to identify whether the HHA used the comprehensive assessment to make sound care planning decisions appropriate to the patient's needs.

- Review the timeliness of services provided to the patient.

- Evaluate the HHA's ability to coordinate care and services.

- Review the patient's progress toward the achievement of desired outcomes.

- Review the RN's initial assessment and a sample of clinical notations by all personnel providing services. Determine if the comprehensive assessment, the PoC and the frequency of visits are clinically congruent or complementary. Did

interventions follow the PoC? Were clinical notes specific to changes in the patient's status?

- Based on the initial assessment and current clinical notes, determine if the patient's medical situation, drug regimen and functional abilities have progressed in relation to the specific care that has been provided. If the patient's clinical and functional abilities have not progressed, have intervening events been recorded appropriately?

- Determine how the HHA ensures coordination of services among and between personnel providing services. What evidence do you find in the clinical record(s) that this is occurring?

- Determine if home health aide recordings document the individual status of the patient. Also, determine if supervisory visits are being made.

- Determine if changes in the patient's medical condition are reported to the physician and recorded, including documentation of verbal orders with written confirmation.

- Determine if the patient's continuation of services or discharge seems appropriate at the time of record review.

- If information cannot be found or cannot be interpreted or integrated, ask the HHA staff to either find the information or help you understand its content.

- Complete Module D immediately after the home visit and/or clinical record review is completed.

b. Compete Surveyor Summary, Module E

If the surveyor determines that the patient care items and services provided by the HHA and reviewed in the standard survey do not pose an immediate and serious threat to the health and safety of its patients, the surveyor chooses one of the three options in the Surveyor Summary block, Module E, to determine what, if any, further survey action to take.

The surveyors record their determination in item 23 of Form CMS-1572(b) (see Exhibit 14D), and select the appropriate action according to the following choices:

- Based on the evaluation of the HHA's compliance with the requirements reviewed as the standard survey, there is no evidence of need for a partial extended or extended survey, the survey is complete Record any standard-level deficiencies identified during the standard survey and request a PoC according to CMS procedures.

- If it is necessary to conduct a partial extended survey and no further deficiencies are found, or if only more standard-level deficiencies are found, the survey is complete. The surveyor records any further deficiencies and requests a PoC according to CMS procedures.

c. Recording Findings From Partial Extended or Extended Surveys

The surveyor uses the HHA interpretive guidelines (see Appendix B) to conduct partial extended and extended surveys to determine compliance with HHA requirements that are not included in the standard survey. The surveyor uses ASPEN or Form CMS-1572 to record deficiencies found as a result of conducting a partial extended survey or extended survey. If either of these surveys include more clinical record reviews with home visits or clinical record reviews without home visits, use the appropriate FAI Modules for gathering and recording information. When conducting a partial extended or extended survey, the surveyor follows the instructions in §2700 as applicable to HHAs.

NOTE: An HHA may, at the discretion of the SA, be subject to an extended or partial extended survey regardless of the findings of the standard survey.

2200C8 - Conducting Home Visits

(Rev. 1, 05-21-04)

a. Prior to Making Home Visits

The surveyor visits patient homes or other places of residence only when patients have given prior consent for the visit. Patient participation is strictly voluntary. Home visits may be made before or after reviewing a patient's clinical record. It is preferable to review the comprehensive assessment and PoC before meeting the patient since this may assist you in making appropriate observations and asking pertinent questions during the home visit.

It is important to contact the patient before you arrive at the home or place of residence, if possible, because the first onsite contact may be intimidating to the patient or may generate some fear that would interfere with access to the patient's home or the quality of the interview. In most situations, the HHA representative who provides care or services should contact the patient/family/caretaker to request permission and make the arrangements for the home visit. However, you may choose to contact the patient/family/caretaker directly.

Be sure that the HHA representative explains clearly to the patient/family/caretaker that the permission for the RN surveyor home visit is voluntary and that refusal to consent to the home visit will not affect his or her Medicaid/Medicare, or other health benefits.

If a patient refuses to have the RN surveyor accompany the HHA representative, select an alternate patient care situation from the sample. A home visit is more effective in

assessing the scope and quality of care being provided if the surveyor is able to observe how HHA personnel implement one or more parts of the patient's PoC. There may be circumstances, however, that should be reviewed during a home visit without the HHA representative being present. If you believe that the HHA representative is not representing the purpose of the visit fairly or appears reluctant to contact the patient/families in the sample, or if you have suspicions or concerns about the care being provided, you may contact the patient/family/caretaker directly to request permission to make the home visit by yourself.

b. Conducting Visit at Home or Place of Residence

When the surveyor arrives at the home or other place of residence, he/she explains that the purpose of the visit is to ensure that care being provided by the HHA meets the health and safety standards of the Medicare program and is done in accordance with the PoC ordered by his or her physician. The surveyor asks the patient to sign a Consent for Home Visit Form (see Exhibit 104), and leaves a copy of the signed consent form with the patient and a copy of signed consent form is filed in the patient's clinical record. Also, the surveyor maintains a copy of the consent statement in the survey file. A Spanish version of the Consent for Home Visit Form is also available.

The surveyor must be continuously aware that as a guest in a patient's home or place of residence, courtesy, common sense, and sensitivity to the importance of an individual's own environment is absolutely essential regardless of the condition of the home.

The surveyor should observe, but not interfere with, the delivery of care or the interaction between the HHA representative and the individual patient/family/caretaker.

Prior to interviewing the patient/family/caretaker, the surveyor reassures them that any discussion is voluntary and refusal to participate will not affect his or her Medicare/Medicaid or other health benefits, they may be entitled to.

c. Discontinuing Interview

Discontinue the interview if:

The patient shows signs of being uncomfortable or seems reluctant to talk, and if, after asking the patient, he or she says they would rather discontinue the discussion;

- The patient appears tired, overly concerned, agitated, etc., and would like to end the interview, or, if in your judgment, it appears to be in the patient's best interest to end the interview; or

- Conditions in the patient' home, such as safety factors, perceptions of intimidation, etc., are of concern to you or the HHA representative.

2200D - Task 4 - Information Analysis

(Rev. 1, 05-21-04)

The information analysis process requires surveyors to review the information gathered during the survey process and to make judgments about the compliance of the HHA. Onsite compliance decisions must not be based solely on OASIS data. The OASIS reports are simply a tool to be used to help guide the onsite survey and identify areas for additional investigation, not to make quality of care determinations. All aspects of patient care must be evaluated. Additional follow-up activities and investigation through record reviews, home visit observations and interviews must substantiate and support any findings of non-compliance with the conditions of participation. When analyzing information and making determinations about the importance of the incidents, the following guidance should be helpful:

Analyze findings relative to each requirement for:

- The effect or potential effect on the patient care outcomes;
- The degree of severity;
- The frequency of occurrence; and
- The impact on the delivery of services.

An isolated incident that has little or no effect on the delivery of patient services does not warrant a deficiency citation. On the other hand, a CoP may be considered out of compliance for one or more deficiencies, if, in a surveyor's judgment, the deficiency constitutes a significant or a serious problem that adversely affects, or has the potential to adversely affect patients. Evaluation of whether a finding constitutes a deficiency, and whether a condition-level deficiency exists must not be made until all necessary information has been collected.

2200E - Task 5 - Exit Conference

(Rev. 1, 05-21-04)

Following a standard, partial extended, and/or extended survey, the surveyor conducts an exit conference in accordance with §2724. The purpose of the exit conference is to inform the HHA staff of the observations and preliminary findings of the survey.

Information recorded on the component parts of the FAIs or other comments recorded on Form CMS-1572 serve as the surveyor's official worksheets. They are not to be given to or copied by HHA staff.

Follow these guidelines during the exit conference:

- Clarify the names and positions of all HHA personnel or other individuals attending the meeting.

- Summarize the facts of the onsite evaluation (team size, composition, days onsite, the sample size for record review and home visits) to set the tone for understanding the overall recommendations that the SA will make to CMS regarding compliance determinations.

- Present findings regarding citations of deficient practice(s) in a straightforward, understandable way, and in a clear logical sequence. Offer examples to support the findings as appropriate.

- Offer the HHA the opportunity to ask questions regarding the findings or provide further pertinent information for the surveyors to consider offsite prior to making formal citation recommendations to CMS on Form CMS-2567.

- Respond to any HHA procedural questions with timely and accurate survey process information (i.e., recertification status: the timeframe for receiving Form CMS-2567 and submitting a PoC to the SA in response to the written citations). Clarify any areas for which further deficiency citations may be made offsite after further analysis with team members or the SA supervisor.

- Provide instructions and timeframe necessary for submitting a PoC as referenced in §2724.

- Describe the procedures that are not in compliance with regulations and the findings that substantiate the deficiencies, identifying specific regulatory references in response to questions raised by staff.

Present Form CMS-2567 onsite or in accordance with the SA's policy, but no later than 10 calendar days after the exit conference.

NOTE: Surveyors should refer to §2724 for additional information on the exit conference, presence of counsel, taping of the conference, and situations that would justify refusal to conduct or continue an exit conference.

2200F - Task 6 - Formation of the Statement of Deficiencies

(Rev. 1, 05-21-04)

knowledgeable person to understand the aspects of each requirement not met. SOM §2728 provides detailed instructions on the effective completion of Form CMS-2567.

2202 - Outcome and Assessment Information Set (Oasis) Requirements

(Rev. 1, 05-21-04)

The home health regulations now require that each patient receive from the HHA a patient-specific, comprehensive assessment, and that as part of the comprehensive assessment, HHAs use a standard core assessment data set, the OASIS, when evaluating adult, non-maternity patients. These changes are detailed in the January 25, 1999, "Federal Register" (64 FR 3764) and at 42 CFR Part 484. This regulation is referred to as the "collection regulation."

The regulations also require that OASIS data be electronically transmitted to the SA or CMS OASIS contractor. These requirements are detailed in the January 25, 1999, "Federal Register" (64 FR 3748) and at 42 CFR Part 484. 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 require HHAs to maintain privacy of their OASIS data. Regulations concerning State survey, certification, and enforcement responsibilities are found at 42 CFR Part 488.68.

In a "Federal Register" notice published June 18, 1999,(64 FR 32984), CMS re-established the effective date for the mandatory use, collection, encoding, and transmission of OASIS data for all Medicare/Medicaid patients receiving skilled services. Mandatory collection and transmission of OASIS data were delayed shortly after the initial publication of the OASIS regulations in order to ensure the proper balance between preserving individual privacy and fulfilling the statutory requirement to improve quality and pay providers fairly.

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: For patients receiving personal care only services, regardless of payor source, the requirements regarding the comprehensive assessment and OASIS reporting have been delayed until further notice.

- 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 42 CFR 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. 1, 05-21-04)

OASIS - 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.

- **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 Medicare and Medicaid patients. 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/Resumption of Care, (2) Follow-up, (3) Transfer, and (4) Discharge. HHAs should 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 - 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 State survey agency. 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. In accordance with the regulations, the initial visit must be made by a registered nurse or, for therapy-only cases, 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 completed after the specific time frames defined in the regulations.

Lock - To review, edit, and finalize encoded OASIS data in order to create a file that is transmitted to the SA. Once a data record is locked, no further edits are permitted prior to submission of the data record.

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. HAVEN currently

automatically masks certain individually identifiable data elements on non-Medicare and non-Medicaid assessments that HHAs may voluntarily submit to the SA.

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 MDCN is that it is provided at no cost to the HHAs. HHAs may also apply for an MDCN User ID and password for each of their branches for direct transmissions from their branches. Use of the MDCN allows for all data submitted to our 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 MDCN, are also automatically encrypted and decoded. This network encryption occurs automatically when the HHA uses the MDCN and requires no special action on the part of the HHA other than using browser software that supports industry standard encryption.

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 first two of three outcome reports based on OASIS data. The OBQM reports include the case mix and adverse event outcome reports.

Overdue OASIS - OASIS assessments not received by the OASIS State System within the specific time frames defined by the regulations. (See also Late Assessment.)

Reason For Assessment (RFA) - Reason for conducting the assessment, e.g., Start of Care (SOC), Resumption of Care (ROC), Follow-Up found in M0100.

ROC - The day that care resumes after an inpatient stay. 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. In order to receive a new case-mix assignment for purposes of payment during the 60-day episode, 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. This provides an opportunity for HHAs under PPS to adjust resource levels during a given 60-day episode to account for an unanticipated

change in the patient's condition that requires a change in case mix level. The SCIC adjustment is the proportional payment adjustment reflecting the time both before and after the patient experienced a significant change in condition during the 60-day episode. The SCIC relates to the OASIS data set for ROC (if the SCIC follows an inpatient stay) and "other" Follow-Up (if the SCIC does not involve an inpatient stay).

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 SOC, ROC, Follow-Up, transfer to an inpatient facility, and discharge (including death).

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. 1, 05-21-04)

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. Some points to remember about the integration of OASIS data items into an HHA's assessment process:

2202.2A - Current Version of OASIS

(Rev. 1, 05-21-04)

The most current version of OASIS is found on the OASIS Web site at http://www.cms.hhs.gov/oasis/. In the OASIS User's Manual, also found on the OASIS Web site, Appendix B lists the current OASIS items to be used at each assessment time point as separate documents.

2202.2B - OASIS as Part of the HHA's Comprehensive Assessment

(Rev. 1, 05-21-04)

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 B-1 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

(Rev. 1, 05-21-04)

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 (M00 numbers) when incorporating the OASIS. In this way, the clinician will know that the M00 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.

2202.2D - Copyright Release

(Rev. 1, 05-21-04)

Appendix B of the OASIS User's Manual contains a copyright release for the OASIS. While OASIS may not be copyrighted by any other party, the copyright release document grants the right for home care providers and related organizations, businesses, and individuals to copy, reprint and use the OASIS at no cost, as long as acknowledgment of authorship is noted. A sample acknowledgment is included in the release document.

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. 1, 05-21-04)

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+Choice Organization (MCO)

Medicare beneficiaries who elect to have Medicare services provided by an MCO are entitled to all the Medicare-covered services that are available to beneficiaries residing in the MCO's geographic area. MCOs that contract with Medicare to furnish HHA services may provide such services either directly or through Medicare-approved HHAs that have a provider agreement/number with Medicare. (See 42 CFR Part 422.112). If an MCO provides home health services directly as an integral part of the MCO, it is referred to as an MCO-operated HHA, and the MCO itself must meet the HHA CoPs. MCO beneficiaries covered under Medicare Part C are not subject to the coverage rules for PPS, including the consolidated billing requirements.

2. Medicaid Home Health Programs/Medicaid Waiver Programs

The comprehensive assessment regulations apply to HHAs that are required to meet the Medicare home health CoP. An HHA that currently must meet the Medicare CoP under Federal and/or State law must meet the Medicare CoP 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 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 + Choice Home Health Care	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 accredited HHAs that participate in Medicare and to HHAs that are required to meet the Medicare CoP, including Medicaid HHAs.

2202.3C - Non-Medicare/Non-Medicaid Patients

(Rev. 1, 05-21-04)

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. HHAs are not required to submit their OASIS data on non-Medicare and non-Medicaid patients but they may do so as a system to mask their identity has been developed and is accomplished automatically using the current HAVEN software. 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.

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. 1, 05-21-04)

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 1/5/00 a patient under the care of the agency turns 18 and is transferred to an inpatient facility on or after 1/5/00, 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

(Rev. 1, 05-21-04)

Effective July 19, 1999, and revised December 8, 2003, 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)	7/19/99	7/19/99	8/24/99
SKILLED Non-Medicare/Non-Medicaid: Workers' Compensation Title Programs Other Government Private insurance Private HMO/Managed Care Self-pay; other; unknown	7/19/99 Temporary Suspension effective 12/08/03	Delayed	Delayed
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	Delayed	Delayed	Delayed
EXCLUDED Patients under age 18; Patients receiving pre & post partum maternity services; Patients receiving only chore and housekeeping services	Excluded	Excluded	Excluded

2202.4A - Comprehensive Assessment and OASIS Collection

(Rev. 1, 05-21-04)

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 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
1/15/2004	1/15/2004 - 3/14/2004	3/10/2004 - 3/14/2004
1/15/2004	3/15/2004 - 5/13/2004	5/09/2004 - 5/13/2004
1/15/2004	5/14/2004 - 7/12/2004	7/08/2004 - 7/12/2004

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. 1, 05-21-04)

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, checked for errors, and locked within 7 days of collection using HAVEN or HAVEN-like software, i.e., made transmission-ready.

1. Availability of HAVEN

The HAVEN software is available for downloading free of charge from the OASIS Web site. HAVEN is also available on compact disk (CD) at no charge. HHAs can request the HAVEN CD by calling the HAVEN help line at: 1-877-201-4721. Specific information describing how to operate the HAVEN software is in the OASIS User's Manual, described below. Each SA is mailed one copy of the current HAVEN software on CD.

2. Errors and Warnings in Encoding and Locking

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 be locked and 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

(Rev. 1, 05-21-04)

1. HHA Submissions

At least once a month, HHAs will retrieve all of their locked data from the previous month that has not yet been transmitted and send it to the SA (or other designated location) using the Medicare Data Communications Network. HHAs may transmit their OASIS data more frequently if they choose but must submit it no later than the last day of the month following the month in which it was locked. Data received outside of these time frames is considered overdue. Specific information describing how HHAs are to transmit OASIS data to the SA is in the OASIS User's Manual.

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 (e.g., PC Anywhere software), and technical assistance from CMS and the CMS OASIS contractors.

2202.5 - Outcome-Based Quality Improvement (OBQI)

(Rev. 1, 05-21-04)

OBQI is a systematic approach that HHAs can implement and follow in order to continuously improve the quality of care they provide. 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 exempted by regulation.

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. 1, 05-21-04)

The OBQM reports consist of the case-mix and adverse event outcome reports, which are derived from the OASIS data that HHAs submit to the State. The OBQM reports are available to both the HHA providers and SAs. The case-mix and adverse event outcome 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. Case-Mix Report

The case-mix 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 Case-Mix and Adverse Event Outcome 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. Adverse Event Outcome Report

The adverse event outcome 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. Optionally (after the first report), it also may compare an agency to itself at an earlier point in time. Adverse events serve as markers for potential problems in care because of their negative nature and relatively low frequency. Surveyors do not look at the adverse event outcome 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, 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 had access to the OBQM reports since January 26, 2001, and should be incorporating a review and investigation of these reports into their evaluation and patient care review programs and including 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.

Until a regulation is published requiring HHA use of OBQM and OBQI reports, CMS does not require HHAs to use the OBQI reports. CMS expects 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, such as decreased hospitalization rates. The OBQI reports represent, for the first

time, a system of benchmarking that is case-mix adjusted for each HHA. This means that every HHA can be compared to national reference values regardless of the types of patients it serves 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 risk-adjusted OBQI report.

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. 1, 05-21-04)

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 maintain appropriate administrative, technical, procedural, and physical safeguards sufficient to protect the confidentiality of the patient identifiable data and to prevent unauthorized access to the data. Each user is required to have an individual valid User ID and a secure password. Each user is obligated to protect the confidentiality of the OASIS data. As noted in the June 18, 1999, and December 27, 2001, "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.

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 OBQM and OBQI Reports

(Rev. 1, 05-21-04)

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 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 MDCN and selecting the applicable menu option.

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 User's Manual

(Rev. 1, 05-21-04)

The OASIS User's Manual is intended for use by HHAs in implementing the regulations for comprehensive patient assessments, including data collection and reporting using the OASIS. In hard copy form, it consists of three separate manuals in a single volume. The manuals are also available for download (as individual components) from the OASIS Web site. In addition, each State receives a copy on CD. Hard copies of the OASIS User's Manual, as well as other OASIS documents, are available from the National Technical Information Service by calling: 1-800-553-6847. The electronic version of the manual (both downloadable and CD) is indexed to facilitate topical and/or text searches. The components include the following.

1. OASIS Implementation Manual: Implementing OASIS at an HHA to Improve Patient Outcomes

   This manual was prepared by the Center for Health Services Research, Denver, Colorado. 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. Many of the questions HHAs ask specific to the types and uses of OASIS data sets and OASIS data items are answered in the OASIS User's Manual. Specifically, in Chapter 8 - OASIS in Detail, each data item is identified and defined. Information that includes the time point the item is to be collected by the HHA and instruction for responses and assessment strategies is also present.

2. OASIS National Automation Project: HHA System User's Guide

   This manual was prepared by the Iowa Foundation for Medical Care (IFMC), West Des Moines, Iowa. It 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.

3. OASIS HAVEN System Reference Manual

   This manual was prepared by Fu Associates, Arlington, Virginia. It 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.

As updates are made to the OASIS User's Manual, each State is provided with one set of hard copy change pages. In addition, all updates to the manual are posted on the OASIS Web site.

2202.6B - Other Manuals

(Rev. 1, 05-21-04)

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.

2202.6C - Other Teaching Tools

(Rev. 1, 05-21-04)

In addition to the OASIS User's Manual for HHAs, there are other sources of information available to help States implement OASIS. They are:

1. The OASIS Trainer's Manual

   This manual was distributed together with the OASIS User's Manual at OASIS trainings held October 1998. This manual was developed to assist State OASIS educational coordinators and related State staff in the planning and implementation of OASIS training programs for HHAs in their States. The Trainer's Manual is not available on the OASIS Web site.

2. A Computer-Based Training (CBT) CD Demonstrating the OASIS Data Submission Process

   One copy of this CD was mailed to each SA. States should determine how best to make this CD available to HHAs in their State for training purposes. There are no restrictions on duplicating this CBT. States may make as many copies as they determine necessary or order extra copies from IFMC. Topics covered on this CD include:

   - Establishing the Communication Connection;
   - Submitting OASIS Data Files; and
   - Initial Feedback and Validation Reports.

3. A Computer-Based Training CD Demonstrating use of the HAVEN Software

   One copy of this CD was mailed to each SA. States should determine how best to make this CD available to HHAs in their State for training purposes. There are no restrictions on duplicating this CBT. States may make as many copies as they determine necessary or order extra copies from IFMC. Topics covered on this CD include:

   - A HAVEN Overview;
   - Maintaining an Agency Database;
   - Maintaining an Employee Database;
   - Maintaining a Patient Database;
   - Assessment Addition;
   - Exporting a File; and
   - Assessment Correction and Deletion.

4. QIES Technical Support Office (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/

5. OASIS Web site (http://www.cms.hhs.gov/oasis/)

   The CMS OASIS Web site was made available in July 1998 to store and disseminate 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.

6. OASIS Web-based Training Internet site

The OASIS Web-based Training (WBT) Internet site was made available in October 2003 as a comprehensive training tool designed to provide home health agency clinicians and state agency surveyors with detailed instructions on each OASIS item. The WBT covers the following topics:

- Why OASIS?
- OASIS and the Comprehensive Assessment;
- How to effectively conduct a comprehensive assessment; and
- OASIS Conventions, as well as providing detailed instruction and quizzes on each OASIS item.

Each of the lessons contains an introduction, the rationale of why the topic is important, the lesson objective, assessment strategies for items or groups of items within the lesson, special notes or alerts on the respective OASIS items, and a wrap-up.

CMS is providing this new training tool to individual clinicians and home health agencies nation-wide at no cost. This interactive and interesting Internet site is available at: http://www.oasistraining.org/.

CMS expects this training will allow independent access for individual clinicians and others to understand the OASIS items and the most effective assessment leading to greater accuracy and consistency in selecting responses. We hope that the positive clinician behavior demonstrated in the videos will motivate clinicians to learn how to effectively perform a comprehensive assessment without fatigue to the patient or the clinician.

This Internet site offers many benefits to the home health agency. This site could be useful for orienting clinicians new to home care, as a resource to clarify a specific OASIS item for seasoned clinicians, it facilitates competency testing, and develops staff who are effective and efficient in conducting assessments. For individual clinicians this is a site

that offers opportunities to expand assessment approaches and strategies in self-study continuing education, free of charge, while it presents essential content to increase accuracy and provided clinical decision-making skill through principle-based presentation. The site offers additional resources for investigation, and is accessible from any modern computer with Internet access from work or home. We hope this site will promote peer interaction regarding the patient situations, while facilitating group communication about clinical skills, care, and assessment and intervention strategies.

7. 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 HAVEN_help@IFMC.org.

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.

2202.7 - OASIS and the Home Health Prospective Payment System (PPS)

(Rev. 1, 05-21-04)

The home health PPS has been in effect since October 1, 2000, to help ensure appropriate reimbursements for quality, efficient home health care. Additional information on the home health PPS can be found in the Medicare Home Health Agency Manual, sections 201 through 201.14. This and other PPS information is available on the CMS Web site at http://www.cms.hhs.gov/providers/hhapps/default.asp. The following are highlights of the home health PPS system:

- 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.

- 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). The 60-day episode rates are adjusted by case mix methodology based on data elements from the OASIS. The data elements of the case mix adjustment methodology are organized into three dimensions that capture clinical severity factors, functional severity factors, and service utilization factors influencing case mix.

- 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 will be a 60/40-split percentage payment. An initial percentage payment of 60 percent of the episode will be 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 will be paid at a 50/50 percentage payment split.

- Payment rates will be adjusted to reflect significant changes in a patient's condition during each Medicare-covered episode of care. Payment adjustment will occur due to an unanticipated, significant change in condition (SCIC). In order to receive a new case mix assignment due to a SCIC, the HHA must complete an OASIS assessment and obtain the necessary physician change orders reflecting the significant change in treatment approach in the patient's plan of care. The total significant change in condition payment adjustment is a proportional payment adjustment reflecting the time both before and after the patient experienced a SCIC during the 60-day episode.

- An episode with four or fewer visits is paid as a "Low Utilization Payment Adjustment," (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.

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 M0825 (Therapy Need) response selection is provided below.

A - PPS Start-up

For new patients after October 1, 2000, all 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 42 CFR 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 M0825 = 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 M0825 = 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. SCIC With Intervening Hospital Stay During (But Not at the End of) Current Episode

ROC: M0100 = RFA 3 and M0825 = 0-No or 1-Yes (or NA if no SCIC).

- If patient was transferred to the hospital and returns during the current episode, HHA completes the ROC assessment (RFA 3) within 48 hours of the patient's return, as required**.** The ROC assessment (RFA 3) also serves to determine the appropriate new case mix assignment for the SCIC adjustment.

- It is recommended that for Medicare PPS patients, HHAs complete transfer without discharge assessment at the time of transfer, in case the patient returns to the HHA within the current 60-day period.

F. SCIC With Intervening Hospital Stay and Return Home During the Last 5 Days of an Episode (Days 56-60)

HHA completes ROC: M0100 = RFA 3 and M0825 = 0-No or 1-Yes and Follow-Up (M0100) = RFA 4 and M0825 = 0-No or 1-Yes.

NOTE: The requirement to complete two assessments in this situation is unique to PPS patients. With all other pay sources, only the ROC is necessary if the two time periods overlap.

- If patient was transferred to the hospital and returns home during the last 5 days of the current episode (days 56-60), HHA completes the ROC assessment (RFA 3) within 48 hours of the patient's return, as required. M0825 = 0-No or 1-Yes, based on therapy need for the current certification period.

- The Follow-Up assessment (RFA 4) is required during the last 5 days of the certification period. For payment purposes, this assessment serves to determine the case mix assignment for the subsequent 60-day period. A new Plan of Care is required for the subsequent 60-day episode.

- The Follow-Up assessment (RFA 4) is required in addition to the ROC assessment (RFA 3) if claiming a SCIC adjustment for the last few days of the current episode because the adjusted portion of the current episode and the new 60-day episode are subject to separate payment categories, i.e., home health resource groups (HHRGs).

- If no change in case-mix or HHA chooses not to claim a SCIC adjustment, only a ROC assessment is needed, as above. Remember that M0825 will be used to predict therapy need for the next 60 days and should be completed with this in mind.

G. SCIC Without Intervening Hospital Stay

Other Follow-Up Assessment: M0100 = RFA 5 and M0825 = 0-No or 1-Yes.

H. 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 (M0825) select 0-No or 1-Yes.

I. 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 M0825 = 0-No or 1-Yes. When patient returns home, new orders and plan of care are necessary.

- At time of transfer to inpatient facility, HHA completes transfer. If transferred without discharging, starts new episode and completes a new SOC assessment when patient returns home.

NOTE: M0825 = NA is applicable for non-Medicare patients and Medicare patients where a SCIC adjustment is not indicated (for example, patient returns to home care from the hospital within the current episode and ROC indicates no change in current case mix.)

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

(Rev. 1, 05-21-04)

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 payor 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 42 CFR 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 ensure that the patient's most critical needs for home care services are identified and met in a timely fashion. 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 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. 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);

- 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 a hospital stay of 24 hours or more for any reason except diagnostic tests (ROC OASIS data set);

- Within 48 hours of (or knowledge of) the patient's return home from an inpatient stay other than a hospital; and (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).

- 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, 2004, the patient would be reassessed between August 18 and August 22, 2004.

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).

NOTE: The ROC and Other Follow-up OASIS data sets are used to determine a SCIC payment adjustment for PPS patients, as applicable. The HHA own

comprehensive assessment can be used without OASIS data for assessing a major decline or improvement in the patient's health status.

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 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 M00 numbers when integrating is also recommended. In this way, the HHA will know that the M00 labeled items are items that MUST be assessed and completed. This will minimize delays in encoding due to uncompleted 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 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. 1, 05-21-04)

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. Although not required, it is recommended that HHA should print hard copies of the electronic validation records received from the SA and store the validation records in an electronic format for twelve months, until the next set of OBQI reports are available.

2202.8C - Condition of Participation: Reporting OASIS Information

(Rev. 1, 05-21-04)

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 data entry (lock) for all applicable patients in the agency within 7 days of completing an OASIS data set.

   Once the OASIS data set has been collected at the specified time points described above, HHAs may take up to 7 calendar days after the date of collection to enter and lock the assessment into their computer systems. For example, if the comprehensive assessment is completed on May 2, then, the data must be encoded and locked by May 9. (HHAs should consider implementing a tracking system that considers the 7-day window for correcting OASIS assessments that need corrections before locking.) 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 locked 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 locked during the previous month for each patient (as applicable) to the SA. These monthly transmissions include the SOC comprehensive assessments for patients admitted on or after July 19, 1999, and all other subsequent comprehensive assessments as appropriate for new admissions. These monthly transmissions also include OASIS data collected at the appropriate time points (other than SOC) on patients admitted to the HHA prior to July 19, 1999.

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 payor 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 payor 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 MDCN to the SA (or other designated location), transmits the export file, and receives validation information. CMS provides HHAs access to the MDCN, a private communications network CMS purchased to ensure the security of OASIS data transmissions to the State. Use of the MDCN 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 MDCN, are also automatically encrypted and decoded. This network encryption occurs automatically when the HHA uses the MDCN 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 MDCN and one set to access the OASIS State System. The MDCN 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 MDCN. This software, i.e., the AT&T Global Network Dialer for Windows software is available by download from the AT&T Global Network Web site (http://www.attbusiness.net/softctr/dialer95.html). 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 State 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 identification name or number may be incorrect or does not match the name or identification number at the State, the number of records indicated in the trailer record does not match the actual number of records submitted, the branch ID may be missing or incomplete, or the incorrect version of the OASIS data specifications is used. 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. Registered HAVEN users will be mailed a copy of 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 State 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 allows the user to select Medicare/Medicaid only assessments, non-Medicare/non-Medicaid assessments only, or all assessments. The HAVEN export function produces an ASCII text file from the HAVEN database. This file meets the OASIS data specifications that must be transmitted to the SA. Therefore, the HHA controls assessments to be sent to the SA. The OASIS State System will reject all assessments with a non-Medicare/non-Medicaid payment source, unless they are masked.

The following chart summarizes the required time points and time frames outlines 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)	Within 7 calendar days following the Info Comp Date (M0090)	No later than the last day of the month following the month the assessment was locked.
02*	SOC - no further visits planned	Within 5 calendar days following the SOC Date (M0030)	Within 7 calendar days following the Info Comp Date (M0090)	No later than the last day of the month following the month the assessment was locked.
03	ROC - after inpatient stay	Within 2 calendar days following the ROC Date (M0032)	Within 7 calendar days following the Info Comp Date (M0090)	No later than the last day of the month following the month the assessment was locked.

RFA Type	RFA Description	Assessment Completed	Locked Date	Submission Timing
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	Within 7 calendar days following the Info Comp Date (M0090)	No later than the last day of the month following the month the assessment was locked.
05	Other Follow-up	Complete assessment (M0090) within 2 calendar days following identification of significant change of patient's condition	Within 7 calendar days following the Info Comp Date (M0090)	No later than the last day of the month following the month the assessment was locked.
06	Transferred to inpatient facility - not discharged from agency	Within 2 calendar days following or knowledge of disch/trans/death date (M0906)	Within 7 calendar days following the Info Comp Date (M0090)	No later than the last day of the month following the month the assessment was locked.
07	Transferred to inpatient facility - discharged from agency	Within 2 calendar days following or knowledge of disch/trans/death date (M0906)	Within 7 calendar days following the Info Comp Date (M0090)	No later than the last day of the month following the month the assessment was locked.
08	Died at home	Within 2 calendar days following or knowledge of disch/trans/death date (M0906)	Within 7 calendar days following the Info Comp Date (M0090)	No later than the last day of the month following the month the assessment was locked.
09	Discharged from agency: Not to inpatient facility	Within 2 calendar days following or knowledge of disch/trans/death date (M0906)	Within 7 calendar days following the Info Comp Date (M0090)	No later than the last day of the month following the month the assessment was locked.
10*	Discharged from agency: Not to inpatient facility: No visits since SOC assessment	Within 2 calendar days of or knowledge of disch/trans/death date (M0906)	Within 7 calendar days following the Info Comp Date (M0090	No later than the last day of the month following the month the assessment was locked.

*Not required after 12/16/2002

2202.8D - Condition of Participation: Release of Patient Identifiable OASIS Information

(Rev. 1, 05-21-04)

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 the purpose in which it is intended, 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. 1, 05-21-04)

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, health insurance claim number, 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. 1, 05-21-04)

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 they can transmit OASIS data prior to the initial certification survey. Specifically, new HHAs must apply for temporary user identification numbers and passwords from the State OASIS automation coordinator in order to electronically transmit to the OASIS State 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 accrediting organizations (AOs) 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 meet the OASIS transmission requirements prior to the initial certification survey, new HHAs need two different sets of temporary user identification numbers and passwords; one set to access the MDCN and one set to access the OASIS State System.

The OASIS automation coordinator in each SA should assist the new HHA in obtaining the temporary user identification numbers and passwords 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 State 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 State System confirming data transmission. Once Medicare approval has been determined, the State assigns a permanent user identification number and password for the new HHA's access to the OASIS State System. The HHA must apply for permanent user identification numbers and passwords for access to the MDCN by contacting the MDCN help desk at 1-800-905-2069.

Transmissions of test data prior to the official date of approval should be deleted from the OASIS State System by the SA.

2210A - Determining Compliance With the OASIS Transmission Requirements

(Rev. 1, 05-21-04)

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 temporary 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 State System via the software vendor. The HHA should have a written contract that describes this arrangement. The HHA or its software vendor must apply for the applicable temporary user identification numbers and passwords from the SA in order to establish connectivity with the OASIS State 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 temporary 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 State System via the other established certified HHA. The new HHA or other HHA must apply for temporary user identification numbers and passwords, unique to the new agency, from the SA, in order to establish connectivity with the OASIS State 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 State System with the new HHA.

2210B - HHAs Seeking Initial Certification Through an Approved Accreditation Organization (AO)

(Rev. 1, 05-21-04)

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 two AOs with deeming authority - the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Community Health Accreditation Program (CHAP). HHAs seeking initial certification through the deemed status option still must apply to the SA for user identification numbers and passwords 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 JCAHO or CHAP, 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.

2210C - Exceptions to Demonstrating Compliance With OASIS Submission Requirements Prior to Approval

(Rev. 1, 05-21-04)

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 MDCN for the applicable user identification numbers and passwords.

2210D - Compliance Dates and PPS

(Rev. 1, 05-21-04)

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 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.

2210E - Instructions for Handling Medicare Patients in HHAs Seeking Initial Certification

(Rev. 1, 05-21-04)

If the HHA is confident that it has met all CoPs and all other Medicare requirements at the time the initial survey is completed, the HHA is advised to do a new SOC assessment, (RFA 1) on each of its Medicare patients at the first billable visit after the onsite survey. The HHA should delay encoding and transmitting the assessment until the Medicare provider number is assigned.

Once the provider number 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 Medicare provider number 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.

2210F - Instructions to New HHAs Concerning all Other Patients

(Rev. 1, 05-21-04)

For all other patients treated by the HHA (i.e., non-Medicare patients), if a new start of care date is not required by the patient's pay 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. 1, 05-21-04)

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.

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. 1, 05-21-04)

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

   If an assessment was erroneously submitted in a masked format, that is, it was later discovered that the patient was a Medicare or Medicaid patient but was not originally indicated as such at M0150, then an inactivation must be submitted. Normally, the HHA will also submit a new, corrected assessment in this situation. For example, if the value at M0150 for a submitted and accepted assessment is not equal to 1, 2, 3, or 4, **and it should have been**, then an inactivation request should be submitted

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. 1, 05-21-04)

In certain infrequent situations, inactivation is not sufficient to correct assessment errors since inactivation alone does not remove the assessment record from the OASIS State System. Two situations require deletion of an erroneous assessment, rather than inactivation. States will continue to need to submit deletion requests on behalf of HHAs, upon request, to IFMC 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 State 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 State 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 State's 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.

The HHA must send the following information in writing to the State OASIS coordinator to request deletion of an assessment:

- HHA Name;
- HHA ID;
- Patient ID;
- Patient Name (First and Last);
- SSN;
- RFA type;
- Effective Date;*

- 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 IFMC the following information to request deletion of an assessment:

- HHA_AGENCY_ID;
- M0020_PAT_ID;
- M0040_PAT_FNAME;
- M0040_PAT_LNAME;
- M0064_SSN;
- M0100_ASSMT_REASON;
- Effective Date;*
- Submission Date/time;
- Submission Batch Id;
- Assessment Internal Id; and
- 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 IFMC the 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:

IFMC 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 IFMC that the information is accurate and should be deleted from the State's database.
- IFMC will consult with CMS on any questionable deletion requests.
- IFMC will delete the data upon approval from CMS.
- IFMC will keep a log of all deleted data from each State's database.

The deletion request information should be communicated to IFMC by one of the following methods:

- Faxing the requested information to 1-888-477-7871; or

- Mailing the information to: IFMC
  6000 Westown Parkway
  Suite 350E
  Des Moines, IA 50266-7771.

NOTE: This information MUST NOT be sent via e-mail due to the confidentiality of the information.

States may use the worksheets available in QTSO Memorandum 2001-043 (available on the QTSO Web site) to effectuate deletion requests or devise their own, as long as all the necessary information is captured. The deletion request sheets must be submitted to IFMC by the State. Requests received directly from HHA will not be accepted.

2202.11C - Types of Corrections an HHA Can Make in HAVEN

(Rev. 1, 05-21-04)

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 (the lock date changes to reflect the date the correction was made), make the necessary changes, re-lock the assessment, 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 State 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 State 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 State 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 State 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. When this type of correction occurs, the rule requiring the lock date to be within 7 days of the assessment's completion date (M0900) is waived for the corrected record.

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 "Locked (Export Ready)." The "X" indicates that this assessment has been prepared for inactivation.

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 make any corrections to this 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. The lock date changes to reflect the date the correction was made.

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. 1, 05-21-04)

Currently there are no requirements regarding the timeliness of correcting and inactivating assessment records, either in terms of when they must be completed (locked) or submitted. However, 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. This 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. 1, 05-21-04)

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 payor 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, although a system to mask their identity has been developed and incorporated into current versions of HAVEN. 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 collection 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 and locked 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. 1, 05-21-04)

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 42 CFR parts 484 and 488, 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. 1, 05-21-04)

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 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. 1, 05-21-04)

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 both the "Initial Feedback Report" and 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 because it is not stored by the system. 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 42 CFR 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. 1, 05-21-04)

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.

2202.12E - Replication to the CMS Repository

(Rev. 1, 05-21-04)

Each State's OASIS database will be transmitted to 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, we recommend 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. 1, 05-21-04)

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 42 CFR 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 IDs 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. 1, 05-21-04)

OASIS data is encoded and transmitted from HHAs to SAs via the MDCN, 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 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.

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. 1, 05-21-04)

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 name of the system is HHA OASIS, (System No. 09-70-9002).

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 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. 1, 05-21-04)

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. 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 Center for Medicaid and State Operations, 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. 1, 05-21-04)

ROs also have educational and automation coordinators for the implementation and automation of OASIS. Designated RO staff provide information about OASIS in the region, answer OASIS-related questions, administer survey and certification funds, and administer 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 Budget Call Memorandum. 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 provides training and technical assistance to the States in OASIS implementation requirements and provides continuing education about the OASIS program.

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. 1, 05-21-04)

The OASIS Educational and Automation Coordinators participate in various training programs concerning OASIS, monthly teleconferences to discuss OASIS implementation 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.

2202.15B - RO

(Rev. 1, 05-21-04)

The RO OASIS Coordinators participate in regularly scheduled teleconferences with central office to discuss issues concerning implementing and maintaining OASIS and other related survey issues. RO staff participate in periodic meetings for OASIS updates and other matters related to home health services as scheduled.

2202.15C - HHAs

(Rev. 1, 05-21-04)

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 a.m. and 7 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 implementation, HAVEN, and the OASIS State System, are distributed via the OASIS Web site.

2202.16 - Fax Transmission of OASIS or Other Patient Identifiable Information

(Rev. 1, 05-21-04)

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. Inasmuch as the CMS takes its responsibility seriously to protect patient specific information once it has been transmitted to the State, we expect HHAs to provide the same protections to OASIS data while it is maintained at the HHA.

The home health CoP at 42 CFR 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.

State survey agencies should follow the same guidelines outlined above when using fax machines for doing such things as 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. 1, 05-21-04)

It is imperative that the Medicare provider number 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 42 CFR Part 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 provider number are terminated. Agency B retains its existing provider agreement and provider number. 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 42 CFR Part 489.18 and §3210, when there is a change in ownership and the new owner accepts assignment of the existing provider agreement, 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 provider number 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 42 CFR Part 489.18 and §3210, when there is change of ownership and the new owner rejects this 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 42 CFR 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 42 CFR Part 484, for all patients of the former owner it accepts for care.

Voluntary Terminations

In accordance with 42 CFR Part 489.52 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. CMS recommends the HHA that is terminating its provider agreement should provide a discharge comprehensive assessment for each patient prior to the effective date of the termination.

Involuntary Terminations

The RO may terminate an agreement with an HHA, in accordance with 42 CFR 489.53. 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.

2202.18 - Wound Ostomy Continence Nurses Society (WOCN) OASIS Guidance

(Rev. 1, 05-21-04)

The CMS collaborated with clinical wound care experts from the WOCN to clarify the definitions for "fully granulating, early/partial granulation, and not healing" for 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 www.wocn.org.

HHA clinicians are encouraged to use the WOCN guidance to assist with clinical assessments of patient wounds. The WOCN OASIS Guidance follows:

Overview and Background

Home Health Reimbursement shifted to a prospective payment system effective October 2000. Under this system, payment is based on the patient's clinical severity, functional status, and therapy requirements. The system for wound classification uses terms such as "nonhealing," "partially granulating," and "fully granulating"; these terms lack universal definition and clinicians have verbalized concerns that they may be interpreting these terms incorrectly. The WOCN Society has therefore developed the following guidelines for classification of wounds. These items were developed by consensus among the WOCN's panel of content experts.

M0 445: Does the patient have a Pressure Ulcer?

M0 450 Current number of Pressure Ulcers at Each Stage

M0 460 Stage of Most Problematic (Observable) Pressure Ulcer

Stage I

Stage II

Stage III

Stage IV

NANo observable pressure ulcer

Definitions:

Pressure Ulcer: Any lesion caused by unrelieved pressure resulting in damage of underlying tissue. Pressure ulcers are usually located over bony prominences and are staged to classify the degree of tissue damage observed.

Stage I: Non-blanchable erythema of intact skin, the heralding lesion of skin ulceration. In individuals with darker skin, discoloration of the skin, warmth, edema, induration, or hardness may also be indicators.

Stage II: Partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents as an abrasion, blister, or shallow crater.

Stage III: Full thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.

Stage IV: Full thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures (e.g. tendon, joint capsule). Undermining and sinus tracts may also be associated with Stage IV pressure ulcers.

Non-observable: Wound is unable to be visualized due to an orthopedic device, dressing, etc. A pressure ulcer cannot be accurately staged until the deepest viable tissue layer is visible; this means that wounds covered with eschar and/or slough cannot be staged, and should be documented as non-observable.

M0 464: Status of Most Problematic (Observable) Pressure Ulcer

1 Fully granulating

2 Early/partial granulation

3 Not healing

NANo observable pressure ulcer

Fully Granulating: Wound bed filled with granulation tissue to the level of the surrounding skin or new epithelium; no dead space, no avascular tissue; no signs or symptoms of infection; wound edges are open.

Early/Partial Granulation: ≥ 25% of the wound bed is covered with granulation tissue; there is minimal avascular tissue (i.e., <25% of the wound bed is covered with avascular tissue); may have dead space; no signs or symptoms of infection; wound edges open.

Non-healing: Wound with ≥25% avascular tissue OR signs/symptoms of infection;

OR clean but non-granulating wound bed OR closed/hyperkeratotic wound edges;

OR persistent failure to improve despite appropriate comprehensive wound management. Note: A new Stage 1 pressure ulcer is reported on OASIS as not healing.

M0 468: Does the patient have a stasis ulcer?

M0 470: Current number of Observable Stasis Ulcer(s)

M0 474: Does this patient have at least one Stasis Ulcer that cannot be observed?

M0 476: Status of the Most Problematic (Observable) Stasis Ulcer

1 Fully granulating

2 Early/partial granulation

3 Not healing

NANo observable stasis ulcer

Definitions:

Fully Granulating: Wound bed filled with granulation tissue to the level of the surrounding skin or new epithelium; no dead space, no avascular tissue; no signs or symptoms of infection; wound edges are open.

Early/Partial Granulation: ≥ 25% of the wound bed is covered with granulation tissue; there is minimal avascular tissue (i.e., <25% of the wound bed is covered with avascular tissue); may have dead space; no signs or symptoms of infection; wound edges open.

Non-healing: Wound with ≥25% avascular tissue OR signs/symptoms of infection OR clean but non-granulating wound bed OR closed/hyperkeratotic wound edges OR persistent failure to improve despite appropriate comprehensive wound management.

M0 482: Does the patient have a Surgical Wound?

M0 484: Current number of (Observable) Surgical Wounds

M0 486: Does the patient have at least one Surgical Wound that cannot be observed due to the presence of a non-removable dressing?

M0 488: Status of the most problematic (Observable) Surgical Wound

1. Fully granulating

2. Early/partial granulation

3. Not healing

NANo observable surgical wound

Description/classification of wounds healing by primary intention (i.e., approximated incisions)

Fully granulating/healing: incision well-approximated with complete epithelialization of incision; no signs or symptoms of infection; healing ridge well defined

Early/partial granulation: incision well-approximated but not completely epithelialized; no signs or symptoms of infection; healing ridge palpable but poorly defined

Non-healing: incisional separation OR incisional necrosis OR signs or symptoms of infection OR no palpable healing ridge

Description/classification of wounds healing by secondary intention (i.e., healing of dehisced wound by granulation, contraction and epithelialization)

Fully Granulating: Wound bed filled with granulation tissue to the level of the surrounding skin or new epithelium; no dead space, no avascular tissue; no signs or symptoms of infection; wound edges are open.

Early/Partial Granulation: $\geq$ 25% of the wound bed is covered with granulation tissue; there is minimal avascular tissue (i.e., <25% of the wound bed is covered with avascular tissue); may have dead space; no signs or symptoms of infection; wound edges are open.

Non-healing: Wound with $\geq$ 25% avascular tissue OR signs/symptoms of infection OR clean but non-granulating wound bed OR closed/hyperkeratotic wound edges OR persistent failure to improve despite comprehensive appropriate wound management.

GLOSSARY

Avascular: Lacking in blood supply; synonyms are dead, devitalized, necrotic, and nonviable. Specific types include slough and eschar.

Clean Wound: Wound free of devitalized tissue, purulent drainage, foreign material or debris

Closed Wound Edges Edges of top layers of epidermis have rolled down to cover lower edge of epidermis, including basement membrane, so that epithelial cells cannot migrate from wound edges; also described as epibole. Presents clinically as sealed edge of mature epithelium; may be hard/thickened; may be discolored (e.g., yellowish, gray, or white).

Dead Space: A defect or cavity

Dehisced/Dehiscence: Separation of surgical incision; loss of approximation of wound edges

Epidermis: Outermost layer of skin

Epithelialization: Regeneration of epidermis across a wound surface

Eschar: Black or brown necrotic, devitalized tissue; tissue can be loose or firmly adherent, hard, soft or soggy.

Full Thickness: Tissue damage involving total loss of epidermis and dermis and extending into the subcutaneous tissue and possibly into the muscle or bone

Granulation Tissue: The pink/red, moist tissue comprised of new blood vessels, connective tissue, fibroblasts, and inflammatory cells, which fills an open wound when it starts to heal; typically appears deep pink or red with an irregular, "berry-like" surface

Healing: A dynamic process involving synthesis of new tissue for repair of skin and soft tissue defects.

Healing Ridge: Palpatory finding indicative of new collagen synthesis. Palpation reveals induration beneath the skin that extends to approximately 1 cm on each side of the wound. Becomes evident between 5 and 9 days after wounding; typically persists till about 15 days post-wounding. This is an expected positive sign.

Hyperkeratosis: Hard, white/gray tissue surrounding the wound

Infection: The presence of bacteria or other microorganisms in sufficient quantity to damage tissue or impair healing. Wounds can be classified as infected when the wound tissue contains 10^5 (100,000) or greater microorganisms per gram of tissue. Typical signs and symptoms of infection include purulent exudate, odor, erythema, warmth, tenderness, edema, pain, fever, and elevated white cell count. However, clinical signs of infection may not be present, especially in the immunocompromised patient or the patient with poor perfusion

Necrotic Tissue: See avascular.

Non-granulating: Absence of granulation tissue; wound surface appears smooth as opposed to granular. For example, in a wound that is clean but

non-granulating, the wound surface appears smooth and red as opposed to berry-like.

Partial Thickness: Confined to the skin layers; damage does not penetrate below the dermis and may be limited to the epidermal layers only

Sinus Tract: Course or path of tissue destruction occurring in any direction from the surface or edge of the wound; results in dead space with potential for abscess formation. Also sometimes called "tunneling." (Can be distinguished from undermining by fact that sinus tract involves a small portion of the wound edge whereas undermining involves a significant portion of the wound edge.)

Slough: Soft moist avascular (devitalized) tissue; may be white, yellow, tan, or green; may be loose or firmly adherent

Tunneling: See sinus tract

Undermining: Area of tissue destruction extending under intact skin along the periphery of a wound; commonly seen in shear injuries. Can be distinguished from sinus tract by fact that undermining involves a significant portion of the wound edge, whereas sinus tract involves only a small portion of the wound edge.

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.

Ambulatory Surgical Centers (ASCs)

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. 1, 05-21-04)

The SA reviews and evaluates the information on the Request to Establish Eligibility, Form CMS-29 and documents submitted with the request, and as necessary consults with the RO to obtain a determination whether the basic requirements discussed below are met. (The RO will seek the assistance of the Health Resources and Services Administration (HRSA) in this matter.) These requirements are:

2242A1 - Location of Clinic

(Rev. 1, 05-21-04)

Subpart A of 42 CFR 491 sets forth the conditions that RHCs must meet in order to qualify for certification under Medicare and Medicaid. The clinic must be located in a rural area that is designated as a shortage area. A shortage area is a defined geographic area designated by the Secretary as having either a shortage of personal health services or a shortage of primary medical care manpower. State governors are authorized to designate areas of States as having a shortage of personal health services if the Secretary also certifies the areas as such. (See Appendix G, Condition IIB.) Question I on Form CMS-29 asks for the location of the clinic and defines location as "the location at which health services are furnished." The procedures for determining location eligibility, including those for mobile units, are described in Appendix G. If documents submitted with Form CMS-29 demonstrate compliance with the location requirements, the RO

determines the clinic's location eligibility. The RO may have to consult with HRSA as to whether the area has ever been reviewed for designation and request any other information that might be relevant.

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. 1, 05-21-04)

The SA indicates in question III.B. and/or III.C. on Form CMS-29 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, use only the time personnel are present in the clinic or are providing RHC services away from the clinic site. (A clinic located on an island does not have to meet this requirement.) Furthermore, a clinic 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.

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. 1, 05-21-04)

If the clinic is not located in an area that is non-urbanized as defined by the Bureau of the Census, is not located in an eligible shortage area (see Appendix G), and does not meet the "rural" location requirement, medical direction requirement, or physician assistant, nurse practitioner, and/or certified nurse-midwife requirement, the SA notifies the clinic. (See Exhibit 26.)

2242C - Basic Requirements Are Met

(Rev. 1, 05-21-04)

When it is determined that the basic requirements are met, the SA sends a letter to the facility notifying it that a survey will be conducted and which materials must be available at the time the survey is conducted. (See Exhibit 25.)

2242D - Identifying Clinic as Provider-Based

(Rev. 1, 05-21-04)

If the RHC claims to be provider based, the SA ascertains whether it is operated as part of the provider and is under its control. If the RHC is an integral part of the provider, the SA considers it provider-based and notes this on the survey report. The SA consults with the RO for assistance if there is a problem in making the identification.

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 Approval

(Rev. 1, 05-21-04)

The RO notifies a facility of its approval or disapproval to participate in the Medicare program not later than **60 days** after the date the SA has determined that the facility is or is not in compliance with all the RHC requirements, or the date of the facility's

application, whichever is later. The RO sends the notification, as indicated below, to avoid confusion about future billing under Medicare and Medicaid as well as to alert other Federal components that have financial interest in the clinics. See §2784 to determine the effective date of participation.

- The RO sends a copy of Form CMS-2007 to the Medicare intermediary that has been designated as the regional fiscal agency and another to the SMA that has billing jurisdiction for RHCs.

- For provider-based clinics, the RO sends a copy of Form CMS-2007 to the intermediary who normally services that provider.

- The RO sends a copy of the letter accepting 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).

Community Mental Health Centers

2250 - Community Mental Health Centers (CMHC) - Citations and Descriptions

(Rev. 1, 05-21-04)

2250A - General

(Rev. 1, 05-21-04)

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. The regulations are found at 42 CFR Chapter IV, Parts 400, 410, 424, and 489.

2250B - Special Requirements

(Rev. 1, 05-21-04)

Section 1866(e)(2) of the Act and 42 CFR Part 489.2(c)(2) recognize CMHCs as providers of services for purposes of provider agreement requirements, but only with respect to providing partial hospitalization services.

2250C - Community Mental Health Centers

(Rev. 1, 05-21-04)

1 - A CMHC, in accordance with §1861(ff)(3)(B)(ii) of the Act, is an entity that meets applicable licensing or certification requirements for CMHCs in the State in which it is located; and

2 - In accordance with §1861(ff)(3)(B)(i) of the Act, §1913 (c)(1) of the Public Health Service Act (PHSA), and the Medicare, Medicaid, and State Children's Health Insurance Program Benefits Improvement and Protection Act of 2000 (BIPA), a CMHC must provide all of the following core services to meet the statutory definition of a CMHC. However, effective March 1, 2001, in the case of an entity operating in a State that by law precludes the entity from providing the screening services, the entity may provide for such service by contract with an approved organization or entity (as determined by the Secretary) that, among other things, meets applicable licensure or certification requirements for CMHCs in the State in which it is located. Pursuant to 42 CFR Part 410.110, a CMHC may receive Medicare reimbursement for partial hospitalization services only if it demonstrates that it provides such services. The core services include:

- Outpatient services, including specialized outpatient services for children, the elderly, individuals who are chronically mentally ill, and residents of the CMHC's mental health service area who have been discharged from inpatient treatment at a mental health facility;

- 24 hour-a-day emergency care services;

- Day treatment, or other partial hospitalization services, or psychosocial rehabilitation services; and

- Screening for patients being considered for admission to State mental health facilities to determine the appropriateness of such admission.

2250D - Partial Hospitalization Program (PHP)

(Rev. 1, 05-21-04)

A PHP, for Medicare purposes, is a program that is furnished by a hospital to its outpatients or by a CMHC that provides partial hospitalization services.

2250E - Partial Hospitalization Services Provided by CMHCs or by Others Under Arrangements With the CMHC

(Rev. 1, 05-21-04)

In accordance with 42 CFR Parts 410.2 and 410.43, partial hospitalization services for Medicare purposes, means a distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care and that furnishes 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. Include any of the following:

    - Individual and group therapy with physicians or psychologists or other mental health professionals authorized or licensed by the State in which they practice (e.g., licensed clinical social workers, clinical nurse specialists, certified alcohol and drug counselors);

    - Occupational therapy requiring the skills of a qualified occupational therapist. Occupational therapy must be a component of the physician's treatment plan for the individual;

- Services of other staff (social workers, trained psychiatric nurses, and others) trained to work with psychiatric patients;

- Drugs and biologicals that cannot be self-administered and are furnished for therapeutic purposes (subject to limitations specified in 42 CFR Part 410.29);

- Individualized activity therapies that are not primarily recreational or diversionary. These activities must be individualized and essential for the treatment of the patient's diagnosed condition and for progress toward treatment goals;

- Family counseling, the primary purpose of which is treatment of the patient's condition;

- Patient training and education, to the extent that training and educational activities are closely and clearly related to the individual's care and treatment of his/her diagnosed psychiatric condition; and

- Medically necessary diagnostic services.

NOTE: Since the word "any" could be misinterpreted, we want to be clear that we would not consider delivery of an instance of any one of these services to itself constitute a covered partial hospitalization service. PHPs are intensive, active treatment programs that offer a combination of services and a multi-disciplinary team approach to address each patient's symptoms and functional level.

A program comprised primarily of diversionary activity, social activity, or recreation therapy does not constitute a partial hospitalization program.

The following services are excluded from the scope of partial hospitalization services defined in §1861(ff) of the Act:

- Services to hospital inpatients;

- Meals, self-administered medications, transportation; and

- Vocational training.

2250F - Definitions of Core Services

(Rev. 1, 05-21-04)

The CMS defines the CMHC core services as follows:

- **Outpatient Services** are separate from partial hospitalization services and contain the elements of diagnosis, treatment, and follow-up (as appropriate). Screening and referral do not constitute the provision of outpatient services.
    - **Specialized outpatient services to children -** In this context; "children" are defined as persons through the age of 21 years.
    - **Specialized outpatient services to the elderly -** In this context, "elderly" are defined as persons aged 62 years and older.
    - **Specialized outpatient services to the chronically mentally ill -** Chronic mental illness should be evidenced by a psychiatric diagnosis as defined by the current edition of the American Psychiatric Association's Diagnostic and Statistical Manual.
    - **Specialized outpatient services to patients discharged from a mental health facility -** Such services must be supported by evidence of a prior psychiatric inpatient hospitalization.
- **24 hour Emergency Care Services** must be available through a system that provides for access to a clinician and appropriate disposition with follow-up documentation of the emergency in the patient's CMHC medical record. A psychiatric emergency may occur at any time, and a patient must have access to evaluation and stabilization services after normal business hours. A range of emergency interventions may be necessary and should be available to the patient, including a face-to-face interview, medication evaluation, and hospitalization. While hot lines, beepers and answering services may be facets of emergency services, they may not constitute their totality.
- **Day Treatment or Other Partial Hospitalization Services, or Psychosocial Rehabilitation Services** are structured day programs (less than 24 hours per day) that use a multidisciplinary team approach to develop treatment plans that vary in intensity of services and the frequency and duration of services provided based on the needs of the patient.

Partial hospitalization programs are to provide intensive psychiatric care of an acute nature, utilizing the clinically recognized therapeutic items and services identified in §1861(ff) of the Act. The treatment program of a PHP is:

1. Similar to that of a highly structured, short-term hospital inpatient program;

2. At a level more intense than outpatient day treatment or psychosocial rehabilitation;

3. Active treatment that incorporates an individualized treatment plan which describes a coordination of services wrapped around the particular needs of the patient;

4. Provided through a multi-disciplinary team approach to patient care under the direction of a physician, who certifies the patient's need for PHP services;

5. The program reflects a high degree of structure and scheduling;

6. In accordance with current practice guidelines, the treatment goals developed for each partial hospitalization patient should be measurable, functional, time-framed, medically necessary, and directly related to the reason for admission.

To be covered by Medicare, PHPs must be distinct from other outpatient, day treatment, or psychosocial rehabilitation programs.

The Medicare statutory requirements applicable to PHP are set forth in §1861(ff) of the Act. Based on that section, the term "partial hospitalization services" means the items and services that are prescribed by a physician provided under a program under the supervision of a physician pursuant to an individualized written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate PHP staff), which sets forth the physician's diagnosis, the type, amount, frequency, and duration of services provided under the PHP treatment plan and the goals for treatment.

- **Screening for Patients Being Considered for Admission to State Mental Health Facilities to Determine the Appropriateness of Such Admission -** Constitutes the performance of at least one of the steps in a process by which an individual is clinically evaluated, pursuant to State law, for the appropriateness of admission to a State mental health facility by an entity that has both the appropriate clinical personnel, and authorization under State law, to perform all of the steps in the clinical evaluation process except those required to be provided by a 24-hour facility.

NOTE: Some State laws allow only certain entities to perform this type of screening. When a situation is discovered where the State limits screening to specific entities, the RO should discuss the matter with the Regional Attorney before denying entry to the CMHC applicant or terminating existing CMHCs because they are unable to conduct screening because of the State requirements. (See §2252.H below for changes to this requirement that resulted from the passage of BIPA.)

As a result of BIPA amendments to the Act (See §2250 C), a CMHC that is precluded by State law from providing the core service related to screening described in

§1913(c)(1)(E) of the Public Health Service Act (PHSA) may provide the screening under a contract with an approved organization or entity that is determined to be acceptable by CMS on behalf of the Secretary. Thus, effective March 1, 2001, screening may be performed by a CMHC via a contract in spite of the State law preclusion. The BIPA language applies to both those CMHCs participating currently in the Medicare program as well as new applicants requesting participation in the program.

It is important to distinguish the term "contract" used in the BIPA amendments and the term "under arrangement" defined in §2250 of the SOM and in the Medicare General Information, Eligibility, and Entitlement Manual, Pub. 100-1, Chapter 5, §10.3. A CMHC may provide one or more core services "under arrangement" with another entity if the service is authorized by State law, the CMHC retains full legal responsibility, and a written agreement is in place as explained in §2250 of the SOM. All requirements for performing a core service either directly or "under arrangement" remain intact and unaffected by the BIPA amendments.

The BIPA amendments allow a CMHC to provide screening by "contract" in the limited circumstance when the CMHC has not been given the authority to provide the service itself under State law. For purposes of §1861(ff)(3)(B), we believe a "contract" ought to provide the following:

1. The name, address, and provider number, if applicable, of the contractor(s);

2. That the contractor meet applicable licensing or certification requirements in the State in which the CMHC is located to conduct screening for patients being considered for admission to State mental health facilities to determine the appropriateness of such admission;

3. That the contractor must provide the CMHC with the results of the screening for the patient(s) for which the CMHC requested screening;

4. The date the contract became effective, the term of the contract, and the manner of the contract's termination or renewal; and

5. A statement that the contract will be made available to CMS, the State survey agency, the CMHC's Medicare fiscal intermediary (FI) and the onsite contractor upon request.

The CMS regional office, on behalf of the Secretary, may approve an entity or organization as a contractor for the purpose of the BIPA screening provision if the organization's or entity's contract with the CMHC meets all of the terms of the contract as described above. The CMS will not grant a "blanket approval" for an entity or organization to conduct screening under a contract with a CMHC, but instead, must review each contract to ensure that it meets the prescribed contract terms. A contractor may contract with more than one CMHC to provide screening, and a CMHC may contract with more than one entity or organization to provide screening.

Although the State, the FI or the onsite contractor may recommend to CMS that the CMHC's contract to conduct screening in accordance with §1861(ff)(3)(B)(i)(II) be approved, CMS itself must determine if the screening is with an approved organization or entity. The CMHC must maintain documentary evidence that screening occurred in a particular case and provide a copy of the contract for screening to CMS upon request.

The BIPA amendments make no substantive changes to the PHSA/CMS requirement that the CMHC must provide the core services described in section 1913(c)(1) of the PHSA (including screening) and not just be capable of providing the services. Therefore, the "Threshold and Service Requirements" contained in the SOM must continue to be followed.

When screening is going to be provided under contract, under the newly revised terms of §1861(ff)(3)(B), the CMHC must maintain and provide documentary evidence to CMS that the screening occurred even though the CMHC may not be legally responsible for the screening results. Providing a service under contract does not mean merely referring an individual to another organization or entity.

- **Core Services Provided Under Arrangement -**A CMHC may provide one or more core services under arrangement with another individual, group, or entity only when the following criteria are met:

    - **Service Authorized by State Law -** In no case may a CMHC provide a service under arrangement when the CMHC has not been given authority to provide the service itself directly under State statute, licensure, certification, or regulation. However, as a result of the BIPA provisions, and under the circumstance described previously, a CMHC or proposed CMHC may provide screening via a contract.

    - **Full Legal Responsibility -** A CMHC that provides a core service under arrangement with another entity remains the legally responsible authority through which comprehensive mental health services are provided. It is not sufficient for the arrangement to be a referral process where the CMHC does not assume overall management responsibility for the provision of core services by a separate individual, group, or entity. The CMHC must retain complete accountability for the services provided under arrangement. The CMHC must retain legal, professional, and administrative responsibility to coordinate care, supervise and evaluate the services, and ensure the delivery of high quality mental health treatment.

    - **Written Agreement -** If a CMHC provides services under arrangement with another party or person, there must be a written agreement or contract between the two parties that specifies the services to be rendered, and the manner in which the CMHC exercises its legal, professional and administrative responsibility for these services. Furthermore, for the

agreement to serve as the vehicle through which the CMHC meets the requirement to provide one or more of the core services, the terms of the agreement must be adhered to in practice. The provider's professional supervision over arranged-for services requires application of many of the same quality controls as are applied to services furnished by salaried employees. The provider must accept the patient for treatment in accordance with its admission policies, and maintain a complete and timely clinical record on the patient, which includes diagnoses, medical history, physician's orders, and progress notes relating to all services received, and must maintain liaison with the attending physician regarding the progress of the patient and the need for revised orders. In order to verify the nature of the relationship between the CMHC and the other party, the agreement must be accessible to CMS or its agents, and the documentation for all services rendered under arrangement must be maintained by the CMHC at the site identified in the provider agreement.

2250G - Threshold and Service Requirements for CMHCs

(Rev. 1, 05-21-04)

The statute requires that an applicant CMHC be providing the core services at the same time of certification, not at some future point in time. Accordingly, CMS will look for evidence that the applicant is already providing the core services as a pre-condition for certification. For example, CMS will look to see that the applicant:

- Is fully operational for one entire business quarter;
- Has served, as evidenced by complete, onsite medical record documentation from within three months of the date of the initial Medicare application for new applicants or the date of sale for changes of ownership, a sufficient number of persons to enable us to be reasonably assured that the facility is, in fact, complying with basic program requirements. We believe, that to achieve this objective, a facility should have served at least ten non-Medicare patients, including:
    - A minimum of three patients for which medical records demonstrate that the CMHC has:
        - The legal capacity under State law to provide screening services for admission to State mental health facilities (or provides screening under a contract with an approved organization or entity, see §2252.H),
        - The capability and clinical expertise to provide such screening services (or provides screening under a contract with an approved organization or entity, see §2252.H); and,

- Provided screening services for the specific purpose (e.g., reason for referral) of assessing the patient's need for admission to a State mental health facility. Where there are State requirements for the completion of required forms, court documents or any other required documentation in response to the screening request, these documents would be evidence of providing the service. Otherwise, evidence in the screening assessment must include a clinical decision regarding the appropriate level of care and follow-up placement (or provides screening under a contract with an approved organization or entity, see §2252.H);

- A minimum of three-day treatment or other partial hospitalization or psychosocial rehabilitation for patients (this is group treatment and three patients is the smallest number the CMHC could justify as a group); and

- At least one patient from each of the four outpatient categories:

    - Children;

    - Elderly;

    - Chronically mentally ill; and

    - Residents of its mental health service area who have been discharged from inpatient treatment at a mental health facility.

NOTE: At this time, there are no prior service requirements regarding the following core service: 24-hour a day emergency care services. However, please be aware that the CMHC must be able to demonstrate that it can provide 24-hour emergency care services. If a CMHC is approved for Medicare participation, it is expected to continue to provide the core services at §1913(c)(1). Providing the services described at §1913(c)(1) of the PHSA is ongoing and not a one time qualifying event for Medicare participation.

2250H - Revisions to the Core Service Screening Requirements as the Result of the Passage of BIPA

(Rev. 1, 05-21-04)

As a result of the passage of BIPA, there have been changes to the Act with respect to CMHCs. Section 431 of BIPA amended §1861(ff)(3)(B) of the Act concerning the qualifications that must be met by some CMHCs to participate in Medicare. This section is quoted below:

(i) "(B) for purposes of sub paragraph (A), the term "community mental health center" means any entity that

(ii) (1) provides the mental health services described in §1913(c)(1) of the Public health Service Act; or (II) in the case of an entity operating in a State that by law precludes the entity from providing itself the service described in subparagraph (E) of such section, provides for such service by contract with an approved organization or entity (as determined by the Secretary);

(iii) Meets applicable licensing or certification requirements for community mental health centers in the State in which it is located; and

(iv) Meets such additional conditions as the Secretary shall specify to ensure (I) the health and safety of individuals being furnished such services, and (II) the effective and efficient furnished such services, and (III) the compliance of such entity with the criteria described in §1931(c)(1) of the Public Health Service Act."

NOTE: The reference in the BIPA provision relating to §1931(c)(1) of the PHSA is a transposition error and should be read as 1913(c)(1) of the PHSA.

Thus as a result of BIPA amendments to the Act, a CMHC that is precluded by State law from providing the core services related to screening described in §1913(c)(1)(e) of the Public Health Service Act (PHSA) may provide the screening under a contract with an approved organization or entity that is determined to be acceptable by CMS on behalf of the Secretary. Consequently, effective March 1, 2000, screening may be performed by a CMHC via a contract in spite of State law preclusion, and any prior conflicting guidance is superseded.

For example, several of the Model letters contained in the SOM Exhibits referencing a denial of a CMHC's request for Medicare participation or termination of a CMHC because of a service being precluded under State law must be amended before usage to reflect the change made by the BIPA provision. The BIPA language applies to both those

CMHCs participating currently in the Medicare program as well as new applicants requesting participation in the program.

It is important to distinguish the term "contract" used in the BIPA amendments and the term "under arrangements" defined in SOM, §2250, and in the Medicare General Information, Eligibility, and Entitlement Manual, Pub. 100-1, Chapter 5, §10.3. A CMHC may provide one or more core services "under arrangement" with another entity if State law authorizes the service, the CMHC retains full legal responsibility, and written agreement or contract is in place as explained in SOM §2250. All requirements for performing a core service either directly of "under arrangement" remain intact and unaffected by the BIPA amendments.

The BIPA amendments allow a CMHC to provide screening by "contract" in the limited circumstances when the CMHC has not been given the authority to provide the service itself under State law. For purposes of §1861(ff)(3)(B) of the Act, we believe a "contract" ought to provide the following:

1. The name, address, and provider number, if applicable, of the contractor(s);

2. That the contractor meet applicable licensing or certification requirements in the State in which the CMHC is located to conduct screening for patients being considered for admission to State mental health facilities to determine the appropriateness of such admission;

3. That the contractor must provide the CMHC with the results of the screening for the patient(s) for which the CMHC requested screening;

4. The date the contract became effective, the term of the contract, and the manner of the contract's termination or renewal; and

5. A statement that the contract will be made available to CMS, the State survey agency, the CMHC's FI and the RO upon request.

The CMS RO, on behalf of the Secretary, may approve an entity or organization as a contractor for the purpose of the BIPA screening provision if the organization or entity's contract with the CMHC meets all of the terms of the contract as described in the memorandum. The CMS will not grant a "blanket approval" for an entity or organization to conduct screening under a contract with a CMHC, but instead, must review each contract to ensure that it meets the prescribed contract terms. A contractor may contract with one or more than one entity or organization to provide screening.

Although the State or the FI may recommend to CMS that the CMHC's contract to conduct screening in accordance with §1861(ff)(3)(B)(I)(II) of the Act be approved, CMS itself must determine if the screening is with an approved organization or entity. The CMHC must maintain documentary evidence that screening occurred in a particular case and provide a copy of the contract for screening to CMS upon request.

The BIPA amendments make no substantive change to the PHSA/CMS requirement that the CMHC must provide the core services described in §1913(c)(1) of the PHSA (including screening) and not just be capable of providing the services. Therefore, the "Threshold and Service Requirements" contained in the SOM must continue to be followed.

When screening is going to be provided under contract, under the newly revised terms of §1861(ff)(3)(B) of the act, the CMHC must maintain and provide documentary evidence to CMS that the screening occurred even though the CMHC may not be legally responsible for the screening results. Providing a service under contract does not mean merely referring an individual to another organization or entity.

The BIPA provision in §431 which added a new paragraph relating to "additional conditions as the Secretary shall specify…" will require consideration by CMS to determine whether there is a need to establish additional conditions.

The FIs and contractors who conduct CMHC site visits will also be notified of these changes.

2252 - Certification Process

(Rev. 1, 05-21-04)

2252A - General

(Rev. 1, 05-21-04)

The fiscal intermediary (FI) will verify enrollment information on the Form CMS-855A submitted by CMHCs seeking initial enrollment or undergoing changes of ownership (CHOWs). Once the FI has completed their review and recommended that the enrollment application or that the CHOW be approved, the FIs will forward any request for a site visit to the appropriate CMS Regional Office (RO), Division of Medicaid and State Operations (DMSO) who will then conduct the site visit.

The CMS ROs are responsible for approving or denying CMHCs for Medicare participation and for notifying CMHCs and the appropriate SA of the approvals or denials based on the Fiscal Intermediary (FI) certification recommendations, information gained from an onsite visit to the CMHC by the RO. As part of the process to approve or deny CMHC applications, ROs are responsible for conducting the site visit including medical records, the completed Site Visit Assessment Tool, and the completed Site Visit Summary. The purpose of the RO's site visit is to ensure that CMHC applicants provide the required core services, as well as meet the threshold and service requirements before allowing those applicants to enter into the Medicare program.

2252B - Request to Participate

(Rev. 1, 05-21-04)

CMHCs that wish to participate in the Medicare program for the purpose of providing partial hospitalization services must request application materials from the fiscal intermediary (FI), and must complete and submit the Form CMS-855A - Application for Health Care Providers that will Bill Medicare Fiscal Intermediaries (see §2003), and a separate statement over a penalty clause attesting that they meet the requirements for CMHCs contained in the Social Security Act and CMS Regulations (See Exhibit 275).

The CMHCs require an on-site visit prior to enrollment. Follow FIs should follow current procedures for provider enrollment, including communicating and sharing information with the State agencies (SAs) (or for FIs in RO IX, your RO) regarding enrollment up to and including verification of the Form CMS-855A. If the Form CMS-855A cannot be verified, follow current procedures for recommending denial of enrollment.

In addition to the FI's current provider enrollment procedures, check for a completed and signed CMHC attestation statement from the SA (or for FIs in RO IX, your RO). If the CMHC has not filed a completed attestation statement with the SA (or for FIs in RO IX, your RO), follow current procedures for recommending denial, and file a recommendation for denial.

If the Form CMS-855A has been verified, and the CMHC has filed a completed attestation statement, the FI should send a copy of the Form CMS-855A to the SA (or for FIs in RO IX, your RO) for retention, and issue their recommendation for approval. Using the form Attachment B below "Community Mental Health Center Site Visit Request Form," the FI should contact the appropriate CMS RO, DMSO via e-mail to initiate a site visit of the CMHC applicant. The FI should send carbon copies of the request to the SA, and the appropriate RO provider enrollment contact.

Once the site visit is completed, the RO DMSO will contact the FI via the provider agreement tie-in notice to inform them of the outcome of the site visit review process and the effective date of Medicare participation, if applicable.

2252C - Information to be Sent to CMHC Applicant

(Rev. 1, 05-21-04)

The SA mails copies of the following to applicant CMHCs, including those undergoing a change of ownership:

- The statutory requirements for CMHCs including the revised PHSA, §1913(c)(1). Also send a copy of the applicable CMS CMHC regulations.

- Exhibit 282. Model letter explaining participation in Medicare as a CMHC (including threshold and service requirements). The CMHC's response to this letter serves as its Medicare application.

- Exhibit 131. CMHC Crucial Data Extract (CDE).

- Exhibit 276. Provider Agreement

- Exhibit 275. Attestation Statement

- The CMHC will download a copy of the Form CMS-855A from the CMS Web site at http://www.cms.hhs.gov/providers/enrollment/forms.

2252D - Processing CMHC Requests, FI Role

(Rev. 1, 05-21-04)

The FI follows these steps when processing applications from CMHCs for Medicare participation and non-assigned provider agreement CMHC changes of ownership. If the provider agreement is not assigned, the new owner can only gain entry into the Medicare program as an initial applicant.

- The FI forwards concurrently to the SA and the RO, the CMHC's completed Form CMS-855A along with the CMHC's response to the model letter (application) and a copy of the signed attestation statement. The application must contain at least the following information:

    - The name and address of the facility;

    - The name of the facility's responsible agent, including the agent's address and telephone number;

    - The facility's Medicare provider number, if it is already participating in the Medicare program as a part of another type of provider;

    - The identification of all locations where the facility proposes to operate, if it plans to operate at other alternative sites in the community it serves through its provider agreement;

    - The Medicare provider number of the other entity, if the facility is operated as part of and under control of another entity that is participating in the Medicare program (provider based);

    - The services provided, with the number of full-time equivalent employees;

    - The type of ownership or control (i.e., nonprofit, Government);

- A signed attestation statement over a penalty clause (separate from the application) indicating that the facility complies with all of the Federal requirements in §1861(ff) of the Act, the Medicare regulations, and specifically with the requirements contained in §1913(c)(1) of the PHSA;

- A completed and signed Form CMS-855A; and

- A signed Form CMS-1561, Provider Agreement. (The SA should never indicate or suggest to the CMHC that it is approved and/or that it may begin providing partial hospitalization services to Medicare beneficiaries, because until the RO determines that all requirements are met, it will not sign off on the provider agreement.) The date the RO signs off on the provider agreement will be the CMHC's effective date.

The FI's primary role with respect to CMHC applicants is to verify the information provided on the Form CMS-855A and recommend to the RO and SA approval or denial of the enrollment application. Also, the FI will contact the RO to verify that the applicant CMHC or CMHC undergoing change of ownership has the legal capacity to provide screening services for admission to State mental health facilities. (See §2250.H.) However, the FI will not request the RO to conduct an onsite visit until it has completed its review and verified the information provided on the Form CMS-855A, because there is no point in conducting an onsite visit if the CMHC is denied enrollment based on the Form CMS-855A review, or the CMHC has not provided all of the information necessary to make an enrollment decision. When making an on-site visit, the RO will copy medical records to confirm the provision of the core services, record its findings on the CMHC Site Visit Assessment Tool and the CMHC Site Visit Summary and then forward these documents to the SA.

The FI will make a recommendation to the RO, and the SA, of approval or denial of the CMHC's request for Medicare enrollment/participation based on its review of the Form CMS-855A. The FI should not indicate in any way to the CMHC that it might begin to provide partial hospitalization services to Medicare beneficiaries at any point in the enrollment process. The provider's effective date (in the case of approvals), or application denial will be determined by the RO.

2252E - Processing CMHC Requests, SA Role

(Rev. 1, 05-21-04)

In particular, CMS looks to the SA to evaluate whether the applicant CMHC meets applicable licensing or certification requirements for CMHCs in the State in which it is located, develop any provider based-issues, and comment on the CMHC's plan to operate an alternative site (the proposed alternative site must be a part of the community where the applicant intends to locate the CMHC that is seeking Medicare approval). (See §2252.I.) The SA should also comment on any reason it has to believe or disbelieve that

the CMHC applicant is providing the core services or, in change of ownership cases, has moved from its original service area. For example, if the SA knows that State law precludes the CMHC from performing the core service requirement related to screening, it should make the RO aware of this. In fact, if the SA knows that the CMHC does not meet State licensure or certification requirements, it should forward all application materials, including Form CMS-855A to the RO for a denial of the request to participate in Medicare. The SA will process CMHC certifications pursuant to applicable instructions in §§2760-2776 and the following SOM sections. This includes completing the appropriate blocks of Part I and Part II of the Form CMS-1539 and completing the CMHC Crucial Data Extract based on the information provided by the CMHC

2252F - Processing CMHC Requests, RO Role

(Rev. 1, 05-21-04)

The RO will adjudicate the CMHC's request to be a provider of partial hospitalization services, or in cases where the CMHC is already in the Medicare program, will determine if the CMHC meets all applicable requirements to remain in the Medicare program and conduct a site visit that focuses on whether the CMHC meets or continues to meet core service requirements. The RO will evaluate the CMHC's application and the recommendations of the SA and FI, the materials collected by the site visit (the Site Visit Assessment Tool, the CMHC Site Visit Summary and the medical records), as well as the applicable sections of the Act, CMS Regulations, PHSA, and the guidance contained in the SOM, as a part of its decision. If there are issues of provider-based, alternative sites, or operating across State lines, these should be resolved concurrently with a decision to approve or deny the CMHC for Medicare participation. At the request of the FI, at the time of Medicare enrollment, the RO will also consult with its Regional Attorney regarding State screening laws to determine their applicability to applicant CMHCs and those undergoing change of ownership. (See §2250.H.) The RO will then provide to the FI verification, based on State law or other designation, as to whether the applicant CMHC or CMHC undergoing change of ownership has the legal capacity to provide screening services for admission to State mental health facilities. In addition, if the RO is determining if an existing CMHC should remain in the Medicare program, then the RO should note whether the CMHC (including any alternative sites) has moved from the community it originally was approved to serve, and terminate the provider agreements of those CMHCs that have moved to a different community where they have not been approved to operate as a CMHC. The RO should also consider the following in making its decision:

- Whether the CMHC applicant has reasonably demonstrated to CMS that it is providing the core PHSA services. To substantiate the provision of 24-hour emergency services, the RO may invoke unconventional measures such as calling the CMHC after hours to assess the response to, and management of, emergency calls;

The RO will not approve an entity as a CMHC unless and until the CMHC has reasonably demonstrated that it has provided the core services to a sufficient number of patients in accordance with §2250.G. Additional records aside from those that were collected as part of the onsite visit that show provision of the core services by the CMHC must be sent to CMS upon request and must be available at the site for which the CMHC is requesting Medicare approval. This includes records for patient services provided by a CMHC under an arrangement, because the CMHC is responsible for those patients the same as if the services were provided directly by the CMHC. In cases where there is doubt about the validity of medical records submitted by a CMHC during the onsite visit to substantiate the delivery of core services, the RO may also contact the beneficiaries (or their representatives) whose medical records are in question to validate the services cited in the medical records (if necessary, contact CMS' Office of Financial Management, Program Integrity Group, Division of Provider and Supplier Enrollment for further guidance on handling beneficiary interviews or if you require additional assistance or support in making the interviews);

- Whether, based on information collected during the onsite visit, the CMHC applicant has reasonably demonstrated to CMS that it has met all of the service and threshold requirements required of all new CMHCs, per §2250.G;

- Whether the facility is providing all of the core services with the exception of one that you determine it cannot provide due to preclusion under State law. Consult with your Regional Attorney before issuing a denial of the applicant's request for Medicare approval based on an issue of State law; and

- That an entity applying as a CMHC does not have to receive block grant funds in order to meet Medicare requirements as a CMHC.

The RO should also be aware that to preserve the consistency of information being released to the public, it will serve as the contact point for inquires regarding Medicare CMHC applicants. However, as always, press inquiries should be referred to the CMS Press Office.

2252G – Onsite Visit to the CMHC

(Rev. 1, 05-21-04)

The RO will make an onsite visit to an applicant CMHC, complaint visits to participating CMHCs and other necessary visits to CMHCs.

2252H - Facility Alleges it is Provider-Based

(Rev. 1, 05-21-04)

Medicare coverage of partial hospitalization services provided by a hospital to its outpatients 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. 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.

2252I - Facility Requests an Alternative Site to be Approved Initially or Subsequent to Approval

(Rev. 1, 05-21-04)

In accordance with §1913(c)(1) of the PSHA, CMHCs are required to provide mental health services principally to individuals who reside in a defined geographic area (service area). The service area means the geographic territory that includes a community that is served or proposed to be served by an existing or proposed CMHC. A service area may be delineated by factors such as population distribution, natural geographic boundaries, and transportation accessibility. Specific examples of a service area may include townships, school districts and municipalities. A CMHC must be able to serve persons in or near where the CMHC is, or is to be, situated. Therefore, CMHCs must service a distinct and definable community. If the CMHC intends to operate outside the community, it must have a separate Medicare provider agreement/number. Some CMHCs will propose to serve at an alternative site to its primary location. The RO determines the confines of the community in the event that the CMHC requests to operate such an alternative site. In making this judgment, the RO will consider the actual demonstrated transportation patterns of the CMHC clients within the community to assure that all core services and partial hospitalization services are available from each alternative site within the community. Also, the RO, with any necessary assistance from the SA, will determine if the proposed alternative site is permissible or whether the entity must seek a separate provider agreement/number for the proposed alternative site because it serves a different community. If a CMHC operates a CMS-approved alternative site, the site is not required to provide all of the core PHSA services. However, a patient must be able to access and receive the services he/she needs at the approved primary site, or at an alternative site that is within the distinct and definable community served by the CMHC. Approvals of such alternative sites should be very limited, because CMHCs must serve a distinct and definable community, and also because CMS has not limited the number of CMHCs an entity may submit for Medicare approval as long as these proposed CMHCs serve different communities. Each case considered for an alternative site will be based on its own merits. The following guidelines also apply when making determinations relating to alternative sites of CMHCs:

- An applicant CMHC must identify for CMS the site where it intends to operate the CMHC as well as any proposed alternative sites where it intends to provide

partial hospitalization services. This information is specifically requested on the Form CMS-855A. The RO will inform the CMHC if it determines that the proposed alternative site must be separately approved because it is not a part of the community where the CMHC is located;

- CMHCs are required to notify CMS if, after approval and issuance of a provider agreement, they propose to add or delete an alternative site (SOM §3224). Reporting such a change is also a part of the CMS enrollment process (§2005.D.1);

- The PHSA core service records, as well as the partialization hospitalization records of the primary site and any other approved alternative sites within the CMHC's community, must be available for review at the primary site; and

- When the onsite visit is made to a CMHC subsequent to its approval, the RO conducting the visit will request the CMHC to identify any and all alternative sites it may have operating and requesting payment through the approved provider agreement/number, and completed Site Visit Assessment Tool. Assuming that the RO was aware of the alternative sites, it may re-evaluate its previous decision under these guidelines and determine if these locations may continue to be approved under the existing provider agreement or must be approved as a separate CMHC. The RO may also give this consideration to those CMHCs that failed to notify CMS of the alternative site. In either situation, if the RO determines that these locations are not located within the CMHC's distinct and definable community, it will inform the CMHC that if it has not requested approval for the site(s) as CMHCs within 60 days of RO notification to the CMHC, the RO will request the FI to deactivate the CMHC's billing number until such time as the CMHC either ceases to provide services at the unauthorized alternative site or until the alternative site requests and receives a billing number of its own as a CMHC. If the CMHC does not request approval of the outside-the-community operation that it has been told must have its own provider agreement/number, and does not notify CMS of its intentions with respect to this location, the RO may terminate the CMHC's provider agreement if it determines that the CMHC is not providing services principally in the original service area for which it was approved.

2252J - RO Approval of CMHC Request for Medicare Approval

(Rev. 1, 05-21-04)

If the RO approves a CMHC for Medicare participation, it assigns the CMHC a provider number from the series 1400-1499, 4600-4799, and 4900-4999 (§2779), and determines the effective date of the provider agreement. The effective date of Medicare participation is the date the RO signs the provider agreement, after determining that all Medicare requirements, including enrollment, are met (§2004). A CMHC that only receives Federal funds through Medicare Part B is not required to comply with various civil rights

statutes enforced by the Department of Health and Human Services (DHHS), Office for Civil Rights. However, if the CMHC 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.

The RO will notify the applicant CMHC of its decision. The notice will also address any related issues such as approval/disapproval of the CMHC as provider-based and approval/disapproval of additional offices, as appropriate. The RO will send copies of its notification to the FI and the SA.

2252K - RO Denial of CMHC Request for Medicare Approval

(Rev. 1, 05-21-04)

If the RO determines that a CMHC applicant's request for Medicare must be denied, the reason will usually relate to the applicant's failure to provide the core PHSA services or the applicant's failure to meet threshold and service requirements. Use the Model Denial Letter for CMHC Applicants, Failure to Provide Core Services, if you determine that the applicant fails to provide one or more of the core PHSA services. Model Denial Letter for CMHC Applicants, State Restriction on Screening, is designed for use when an application for participation as a CMHC in the Medicare program is being denied SOLELY because the CMHC is precluded by State law or regulation from providing the core service of screening for patients being considered for admission to State mental health facilities to determine the appropriateness of such admission. Be mindful of the BIPA provision that allows a CMHC to contract for screening (see §2250.C).

Model Denial Letter for CMHC Applicants, Failure to Meet Threshold and Service Requirements, should be sent when the RO determines that the CMHC applicant does not meet the minimum threshold and service requirements. All model letters provide the applicant with an opportunity for a reconsideration of the decision to deny the application. If the applicant is being denied for another reason under 42 CFR Part 489.12(a), you must develop a notice to advise the applicant CMHC of the reason for the denial. When the onsite visit is made to the CMHC, and the CMHC cannot be located, deny the application.

If the applicant CMHC requests a timely reconsideration, examine any evidence submitted by the applicant CMHC as to why it believes the initial determination was incorrect. If you determine that the denial must be affirmed, provide the CMHC with an adequate explanation of your findings of non-compliance for each of the unmet core service requirements. Specifically address any new evidence submitted via Statement of Findings and/or via Statement of Threshold and Service Requirement Findings. Offer the denied applicant an opportunity for an Administrative Law Judge (ALJ) hearing.

2252L - Approved Provider Changes Ownership

(Rev. 1, 05-21-04)

CMHCs undergoing a Change of Ownership (CHOW) are treated as other providers (See SOM §§3210-3210.5, and §2005.F.) with the following exceptions:

2252L1 - Provider Agreement is Assigned, FI Role

(Rev. 1, 05-21-04)

The provider is required to report the CHOW to the FI and submit a Form CMS-855A as soon as possible. If this reporting is not done, or not done timely, the provider agreement is automatically assigned. (If the CHOW is reported to the SA or RO, the FI or RO will forward the CHOW to the FI to initiate the CHOW.) The FI will send the new owner a copy of all of the materials under §2252.C and follow the instructions in SOM §3210.5 for an assigned provider agreement. The new owner must obtain a copy of the Form CMS-855A from the CMS Web site http://www.cms.hhs.gov/medicare/enrollment/forms and submit the completed form to the FI. The FI upon receipt of the requested materials (attestation, pertinent application information about the new owner, Form CMS-855A, Assigned Provider Agreement), the FI:

- Will verify and process the Form CMS-855A in accordance with current procedures. If the Form CMS-855A cannot be verified, follow current procedures for issuing are commendation for denial.

- Check for a completed and signed CMHC attestation statement from the SA (or for FIs in RO IX, their RO). If the CMHC buyer applicant has not filed a completed attestation statement with the SA (or for FIs in RO IX, your RO), follow current procedures found in the Medicare Program Integrity Manual (PIM), Chapter 10, §14.3, for recommending denial, file a recommendation for denial, citing the reason.

- Check to ensure that the CMHC has not changed its address. If the CMHC has changed its address, notify the RO in writing. Use the form in Attachment A, to do so. Continue to process the application according to the time frame established in the PIM, Chapter 10, §15. If the RO DMSO does not approve the change of address, follow current procedures found in the PIM, Chapter 10, §14.3, for recommending denial and file a recommendation for denial, citing the reason.

- If the Form CMS-855A is verified, the CMHC buyer applicant has filed a completed attestation statement, and has not changed its address, send a copy of the Form CMS-855A back to the SA (or for FIs in RO IX, their RO) for retention, and issue the recommendation for approval.

- Three months after the Form CMS-855A verification, or sooner if the CMHC buyer applicant is suspect but enrollment cannot be denied based solely on the information provided on the Form CMS-855A, using the form is, contact the RO DMSO via e-mail to initiate a site visit of the CMHC. Send copies of the request to the SA (or for FIs in RO IX, their RO), and the appropriate RO provider enrollment contact. The RO DMSO may contact FI prior to the site visit for information about the CMHC prior to and after the CHOW, including:
    - Any significant cost report audit information;
    - Any significant medical review information;
    - Any significant fraud information;
    - HCIS data from the two most recent completed data years on the CMHC to be visited; and
    - Any information regarding overpayments from the overpayments database.

Provide this information upon request or as soon as possible. The FI may also provide this information with their request for the site visit. Direct all calls and correspondence regarding the CMHC site visit process to the appropriate RO DMSO address.

Once the site visit has been completed, the RO DMSO will contact the FI with the outcome of the site visit review process. In addition, the RO DMSO may determine that the results of the site visit warrant action such as payment suspension.

2252L2 - Provider Agreement is Assigned, SA Role

(Rev. 1, 05-21-04)

If the SA is aware that the CMHC does not meet the core service screening requirement at §1913(c)(1) of PHSA because it is not among the entities that may conduct screening in the State or does not have a contract with and approved entity or organization to provide screening; (See §2250.H.); or it does not meet applicable State licensing or certification requirement for CMHCs, or the new owner has moved the CMHC to a new community without notifying CMS, the SA will provide this information directly to the FI and the RO for an involuntary termination of the provider agreement.

In the absence of any of the above situations that may result in a termination of the provider agreement, once the FI receives the application materials and has completed its review of those materials and finds no issue with the CHOW, the FI contacts the RO to initiate a site visit within 6 months.

2252L3 - Provider Agreement is Assigned, RO Role

(Rev. 1, 05-21-04)

The RO will follow SOM §§3210-3210.5 and §2000.F in initially processing the CHOW unless the RO is aware that the screening State licensure or State certification requirements are not met by the CMHC, absent the on-site visit (see §2250.H). If there are requirements that are not met, the RO should follow procedures to terminate the provider agreement. The RO should also ascertain if the CMHC has moved to a different community from that for which it was originally approved as a CMHC. If so, the RO may terminate the assigned provider agreement because the CMHC has moved, without notification to and subsequent approval from the RO, to a different community than the one it was approved to serve. If the CMHC does not meet any of the termination criteria, after 6 months, a site visit will be conducted of the new owner. (Follow procedures in §2252.F for reviewing site visit materials.) If it is determined from the site visit that the new CMHC owner is not in compliance with all Federal and State requirements and/or has moved since the CHOW to a new community, consider terminating the provider agreement. In some instances the site visit documentation may not yield enough substantial evidence to justify termination of the new CMHC owner's provider agreement. However, there may be sufficient cause to investigate the matter further.

If after the site visit the RO has determined that the CMHC has not moved from its community and meets all applicable State and Federal requirements, it should indicate this determination to the FI and SA. The RO should note that if the CMHC does not report the CHOW timely, the provider agreement is automatically assigned to the new owner. Note that the effective date for all CHOWs is the date of the sale.

NOTE: If a potential purchaser of a CHOW should ask the SA, FI or RO prior to consummating a CHOW, about what will happen if he/she buys a CMHC that is not permitted to do screening in the State, or has a State licensure or certification problem with respect to licensure or certification for CMHCs, or if he/she intends to relocate the CMHC to another community, he/she should be forewarned about the possibility of termination of the provider agreement. The RO should check with the State to determine if, under the State law, provision of screening extends to the new owner.

2252L4 - Approved Provider Changes Ownership, Provider Agreement Is Not Assigned

(Rev. 1, 05-21-04)

If the CMHC buyer does not or will not be accepting assignment, the CMHC seller must submit the Form CMS-855A to apprise the FI of the CHOW as soon as possible. The CMHC buyer should submit a new Form CMS-855A and be treated as an initial applicant, in accordance with the PIM, Chapter 10, §10, and all other applicable instructions and procedures for initial applicants, with one exception: the FI should

contact the RO DMSO three months after the date of the CMHC sale/CHOW to initiate the site visit.

Before initiating a site visit, the FI must check to ensure that the CMHC has not changed its address. If the CMHC has changed its address, notify the RO in writing. Use the form in Attachment A, "Community Mental Health Center Notification and Approval of Address Change," to do so. Continue to process the application according to the time frame established in the PIM, Chapter 10, §15. If the RO DMSO does not approve the change of address, follow current procedures found in the PIM, Chapter 10, §14.3, for recommending denial and file a recommendation for denial citing the reason.

Once a site visit has been completed, the RO will terminate the CMHC seller's provider agreement effective with the date of the CMHC sale. In addition, the RO should note that in checking the new CMHC owner's compliance with the threshold and service requirements, the date of the sale is the first day of the new owner's first business quarter. If all Federal and State requirements are met, the RO will issue a new provider agreement to the new CMHC owner. If the CMHC does not meet all necessary requirements, the RO will issue a notice of that determination to the FI and SA. Note that the effective date of all CHOWs is the date of sale.

2252M - Voluntary Termination

(Rev. 1, 05-21-04)

A Medicare participating CMHC may voluntarily terminate its provider agreement at any time. The RO will follow the guidance in SOM §§3046, 3047, and 3048 in processing the termination. Also, if you are unable to locate the CMHC at the site approved for entry into the Medicare program, and you have exhausted all reasonable attempts to locate the CMHC, including a contact with the FI to ascertain if the CMHC has been billing Medicare, you should process an involuntary termination. (See "Model Letter for CMHC that has Ceased Operating," Exhibit 281.)

2252N - Involuntary Termination

(Rev. 1, 05-21-04)

An involuntary termination of a CMHC's provider agreement will usually be based on an onsite visit in which it is discovered that the participating CMHC is not providing one or more of the core services. The onsite visit may have resulted from a complaint, a periodic revalidation of the provider or because the CMHC met the most egregious criteria discussed in §2252.O. Following a review of the site visit findings and any other relevant information, if the RO determines that a termination is in order, it will use the Model Letters, "Notice of Termination of Provider Agreement," Exhibit 280, and "Notice of Findings of Non-Compliance," Exhibit 279 in notifying the CMHC of the termination. If the CMHC provides additional documentation of having provided the core services subsequent to the notification of Findings of Non-Compliance, work closely with your

Regional Attorney in making a determination of whether to continue with the termination. If the CMHC moves from the approved site issued by the Provider Agreement/Number to a different community, this should be treated as an involuntary termination (see §2252.M).

2252O - Identifying the "Most Egregious" CMHCs for Termination Action

(Rev. 1, 05-21-04)

Since there are no Conditions for Participation for CMHCs, many participating CMHCs have never had an onsite visit and are in the Medicare program solely because their attestation of compliance with the Federal requirements has never been challenged. The CMS has developed criteria as a way of identifying CMHCs that may be among the worst program offenders in terms of not meeting Federal requirements for CMHCs. The criteria are as follows:

- **History of Inappropriate Billing Data -** Inappropriate billing is any one of the following circumstances:
    - Unusual pattern of billed charges per patient per CMHC which significantly deviates from the State or national CMHC payments per patient (as determined by RO review of HCIS data for a recent 6-month period);
    - Denial of 50 percent or more of services reviewed (after focused medical review by the FI (e.g., 15 percent of total charges submitted));
    - Overpayment in excess of 15 percent of the CMHC's total Medicare payments (identified by FI);
    - CMHC's cost report shows no other services rendered other than services reimbursed by Medicare or no charges/services paid for by personnel needed to render all of the required core services. (RO or FI to refer to Worksheet S, Part II, lines 14 through 23, and worksheet C, lines 29-38.)

NOTE: When a cost report shows Medicare as the sole source of income, the RO should request documentation from the CMHC to determine if core services are being provided. If documentation is not provided or is inadequate, termination of the Provider Agreement should be considered and recommended for review by the Regional Attorney.

- Failure of CMHC to provide two or more of the core services described in §1913(c)(1) of the PHSA as determined by:
    - RO review of onsite inspection findings; or

- RO review of documentation voluntarily provided from any source, including a CMHC, SA, or FI, or any documentation requested for review by the RO.

- **The RO Review of Any Relevant Documentation or Information -** The RO should review the CMHC's inappropriate billing data obtained from the FI that indicates that the CMHC may not meet the Federal requirements in the Act, including those provisions that are cross-referred to the PHSA. If an onsite visit is necessary, the RO, considering the recommendation of the national site visit contractor, will determine whether the CMHC meets the requirements in §1861(ff) of the Act with specific attention given to the PHSA core service provisions and other regulatory requirements such as whether physicians' orders and plans of care exist for the Medicare partial hospitalization billings.

A final determination that a CMHC meets the "most egregious" criteria will be based on a full review of all relevant facts, and not solely on issues related to inappropriate billing or failure to provide one of the core services.

- **Deactivation of the CMHC's Medicare Provider Billing Number -** The FI will periodically review CMHC billing records. If the FI observes that for the past 12 months the CMHC has not submitted any claims for partial hospitalization services, it may deactivate the CMHC's billing number rendering the CMHC an inactive Medicare provider. Deactivation is neither a termination of the provider agreement nor a suspension of Medicare payment. It simply means the Medicare provider agreement remains in effect, but the FI will make no further payments to the CMHC until it receives from the CMHC an updated Form CMS-855A that it must verify. The FI will use the "Medicare Provider Billing Number Deactivation Letter," Exhibit 277 when notifying the CMHC of the deactivation. Since this is not a termination, if the CMHC is using its Medicare approval in order to receive Medicaid benefits, it could continue to receive Medicaid. If the FI subsequently learns that the CMHC wants its provider agreement terminated, it will inform the RO.

2252P - For Visits to Existing Medicare CMHCs

(Rev. 1, 05-21-04)

There may be instances, such as a CMHC audit, which may prompt the RO DMSO to conduct a site visit of an existing CMHC. The RO DMSO may contact the FI prior to the site visit for information about the CMHC, including:

- Significant cost report audit information;

- Significant medical review information;

- Significant fraud information;

- CMS Customer Information System (HCIS) data from the two most recent completed data years on the CMHC to be visited; and

- Any information regarding overpayments from the overpayments database.

If possible, the FI should provide this information upon request, or as soon as possible. In instances where a site visit is completed for an existing CMHC that does not have the Form CMS-855A on file, request that the CMHC download and complete the Form CMS-855A. The FI should direct all calls and correspondence regarding the CMHC site visit process to the appropriate RO DMSO address

Attachment A - Community Mental Health Center Notification and Approval of Address Change

(Rev. 1, 05-21-04)

COMMUNITY MENTAL HEALTH CENTER NOTIFICATION AND APPROVAL OF ADDRESS CHANGE

Date_____

Dear CMS Regional Office, Division of Medicaid and State Operations:

In processing the following Medicare Community Mental Health Center's (CMHC) change of ownership (CHOW) application, it was discovered that the CMHC applicant buyer has undergone a change in address. In order to complete the enrollment process, it is necessary for the fiscal intermediary (FI) to verify with you in writing that the CMHC applicant will still be serving the same community it served before the address change.

Please complete the regional office (RO) Division of Medicaid and State Operations (DMSO) portion of this form and return it to the FI contact person at the address, fax number, or e-mail address listed below within 14 days.

Thank you.

The CMHC applicant has reported the following information on the Form CMS-855A:

FI completes the following for the CMHC applicant

Doing Business as Name:
_____

Legal Name:_____

Current Address:_____

Previous Address:_____

Current Phone Number:_____

Previous Phone Number:_____

Owner(s) Name:_____

Managing Employee:_____

Contact Person:_____

CHOW date:_____

FI completes the following for the FI:

FI Name:_____

Address:_____

Phone Number:_____

Fax Number:_____

Regional Office, Division of Medicaid and State Operations completes the following:

Date: _____

The address change reported for the CMHC applicant noted above (check one):

_____ **HAS BEEN approved.**

OR

_____ **HAS NOT been approved.**

RO DMSO Contact Person:
_____

Phone Number: _____

Fax Number: _____

E-mail Address: _____

Attachment B -Community Mental Health Center Site Visit Request Form

(Rev. 1, 05-21-04)

COMMUNITY MENTAL HEALTH CENTER SITE VISIT REQUEST FORM

Date of request: _____

Check type of site visit:

_____ Initial applicant

_____ Change of ownership with assignment

_____ Change of ownership without assignment

_____ Other - (explain reason for visit)
_____

Please complete the following for the CMHC applicant requiring a site visit:

Name: _____

Address: _____

Phone Number: _____

Owner(s) Name: _____

Managing/Directing Employee: _____

Contact Person: _____

Please complete the following for the fiscal intermediary:

Name:
_____

Address: _____

Phone Number: _____

Fax Number: _____

E-mail Address: _____

Contact Person:
_____

Corresponding CMS Regional Office:
_____

CMS Regional Office Contact:
_____

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. 1, 05-21-04)

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.

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."

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 - ESRD Citations

(Rev. 1, 05-21-04)

The statutory basis for coverage of ESRD services is found in §1881 of the Social Security Act (the Act). ESRD facilities are suppliers of services. The Conditions for Coverage are found in 42 CFR Part 405, Subpart U, Conditions for Coverage of Suppliers of End Stage Renal Disease Services. Appendix H contains surveyor and interpretive guidelines.

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.

2272 - Types of ESRD Facilities

(Rev. 1, 05-21-04)

2272A - Renal Transplantation Center

(Rev. 1, 05-21-04)

A hospital unit which is approved to furnish, directly, transplantation and other medical and surgical specialty services required for the care of ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement. A renal transplantation center may also be a renal dialysis center.

2272B - Renal Dialysis Center

(Rev. 1, 05-21-04)

A renal dialysis center is a hospital unit that is approved to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients (including inpatient dialysis furnished directly or under arrangement and outpatient dialysis). A hospital need not provide renal transplantation to qualify as a renal dialysis center.

2272C - Renal Dialysis Facility

(Rev. 1, 05-21-04)

A renal dialysis facility is a unit that is approved to furnish dialysis service(s) directly to ESRD patients.

2272D - Self-Dialysis Unit

(Rev. 1, 05-21-04)

A self-dialysis unit is a unit that is part of an approved renal transplantation center, renal dialysis center, or renal dialysis facility, and which furnishes self-dialysis services.

2274 - ESRD Application Requirement

(Rev. 1, 05-21-04)

Filing of Application

To establish eligibility to provide ESRD services under Medicare, an applicant must complete Part I of the End Stage Renal Disease Application and Survey and Certification Report, Form CMS-3427.

Application must be made:

- To request initial approval;
- To request expansion or addition of stations (see Exhibit 27);
- For change in location;
- For change of ownership (CHOW). Ownership means the responsibility and liability for operational decisions of a health care enterprise. A CHOW only occurs when there is a change in the identity of the governing body having ultimate operational responsibility for carrying out ESRD care in the facility; and/or
- For change in service(s) provided, including reuse.

2276 - SA Control of Form CMS-3427

(Rev. 1, 05-21-04)

The SA sets up a control mechanism to assure that a facility requesting an application completes and returns Part I of Form CMS-3427 in a timely manner. If Form CMS-3427 is not received within 30 days, the SA contacts the facility to find out if the completed application (Part I) will be returned. The SA date-stamps all Form CMS-3427s, Part I and application-related correspondence, 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 (Exhibit 9) to

transmit these materials. The SA enters the name and address of the facility, and in "Remarks" list the ESRD forms and related materials transmitted. If appropriate, the SA shows "SPRDF" in "Remarks." The SA contacts the facility to schedule a date for the onsite survey. Certification approvals of SPRDFs are time-limited and are not renewable. The SPRDF must reapply, be surveyed, and be approved annually in order to continue participation.

2278 - ESRD Survey Procedures

(Rev. 1, 05-21-04)

2278A - Facility Withdraws Application Prior to Survey

(Rev. 1, 05-21-04)

If, prior to the survey, a facility states it no longer wishes to be considered for ESRD program participation, the SA requests that the facility submit a statement of voluntary withdrawal. The SA notifies the facility that a properly authorized representative of the facility must sign the statement. The SA forwards the statement to the RO.

2278B - Conducting SA Survey

(Rev. 1, 05-21-04)

The SA certifies ESRD compliance with health and safety standards, using the Survey Procedures and Interpretive Guidelines for End Stage Renal Disease Facilities (Appendix H) and Form CMS-3427A (see Exhibit 84), Part I (Exhibit 31). Unlike other Medicare certifications, compliance with health and safety requirements is not the sole basis for approval of ESRD services. Additional statutory and regulatory requirements include furnishing data and information for ESRD program administration, and participation in network activities. The SA assists the RO in gathering specified information relating to these regulations. (See pages 2 and 3 of Form CMS-3427A and Appendix H.) In the case of SPRDFs, the SA contacts the facility representative to schedule a date for the onsite survey.

2278C - Certificate of Need (CON)

(Rev. 1, 05-21-04)

Each application, except for a SPRDF, must be accompanied by evidence of a CON in all States where it is required by State law. If a CON is not required by State law, then evidence of a CON is not required.

The SA informs prospective applicants that incomplete applications will be returned without action if a required CON is not submitted. The SA returns applications that do not include the CON on the basis of an incomplete application, using the model letter in

Exhibit 30. If the applicant insists on filing the application without the required supportive documentation, the SA accepts the application and immediately forwards it to the RO. The RO will send a denial to the facility.

2278D - Initial RO Approval

(Rev. 1, 05-21-04)

A facility must complete Part I of Form CMS-3427A, "End Stage Renal Disease Application and Survey and Certification Report," have an on-site survey by the State Agency (SA), and be in compliance with the ESRD Conditions for Coverage to receive payment for ESRD services. In addition, 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). (See Exhibit 153.) After the survey by the SA, the RO reviews all available information and determines whether the facility is in compliance with the ESRD Conditions for Coverage.

The RO mails the determination notice to the facility. (See Exhibits 154 and 155.) An informational copy is forwarded to the SA. If an approval, the RO assigns the ESRD provider number and sends a modified Form CMS-2007 (Exhibit 156) with a copy of the facility notification to the intermediary. The RO processes the required Online Survey Certification and Reporting (OSCAR) input.

2278E - Expansion or Addition of Services - RO Procedures

(Rev. 1, 05-21-04)

A facility must complete Part I of the Form CMS-3427A when it requests expansion of the number of stations or desires to change its services, including reuse. A SA survey is required if the facility has not been surveyed in more than 6 months, or if substantial changes have been made.

When no survey is required, the RO includes, in the "Remarks" item of Form CMS-1539, an appropriate statement and rationale justifying why a survey was not performed.

Following receipt of the survey report, Part II of Form CMS-3427A from the SA, the RO reviews all available material and prepares the determination notice. (See Exhibit 157.)

The RO forwards a copy of the determination notice to the SA. The RO forward to the intermediary the modified Provider Tie-In Notice, Form CMS-2007, accompanied by a copy of the determination notice, and provide for entry of appropriate data.

2278F - RO Recertification

(Rev. 1, 05-21-04)

Following receipt of the Form CMS-3427 and Form CMS-1539 from the SA, the RO reviews the intermediary reports and prepares a formal determination. (See Exhibit 158.)

The RO forwards an informational copy of the determination notice to the SA. The RO also forwards a modified Form CMS-2007 to the intermediary if there has been a change in services furnished. The RO provides for the entry of appropriate data.

2278G - Invalid Application

(Rev. 1, 05-21-04)

Technical Denials - Except for SPRDFs, all Part I, Form CMS-3427A applications must be accompanied by CON approval when required by State law.

2279 - Additional Conditions Assessed by the RO

(Rev. 1, 05-21-04)

The health and safety conditions begin with 42 CFR 405.2135, compliance with Federal, State and local laws and regulations, through 42 CFR 405.2171, minimal service requirements for a renal transplantation center. SA certification is not the sole requirement for coverage of ESRD services. Additional areas that tie into the statutory and regulatory requirements involve the ESRD facility's participation in the activities of the network, and furnishing data and information for ESRD program administration. The SA does not certify the requirements of 42 CFR 405.2130 through 405.2134, 405.2163(b) and 405.2171(d), but assists the RO in gathering specified items of information relating to these regulations.

The additional conditions assessed by the RO are:

- 42 CFR 405.2122, Facility classification;
- 42 CFR 405.2131, Provider status: Renal transplantation center and renal dialysis center;
- 42 CFR 405.2133, Furnishing data and information for ESRD program administration;
- 42 CFR 405.2134, Participation in network activities;
- 42 CFR 405.2163(b), Minimal service requirements for a renal dialysis center and renal dialysis facility: laboratory services; and

- 42 CFR 405.2171(d), Minimal service requirements for a renal transplantation center: laboratory services.

2280 - RO Facility Classification (42 CFR 405.2122)

(Rev. 1, 05-21-04)

An ESRD facility is defined as a facility that is approved to furnish at least one specific ESRD service. The RO classifies facilities according to the following definitions:

2280A - Renal Transplantation Center (RTC)

(Rev. 1, 05-21-04)

This designates a unit of a Medicare-certified hospital that is ESRD-approved to furnish transplantation and other medical and surgical specialty services directly that are required for the care of ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement.

- Dialysis performed in an RTC is considered secondary to the transplant surgery and is payable as part of the transplantation procedure.

- An RTC must be found in compliance with all applicable Conditions for Coverage, 42 CFR 405.2135 through 42 CFR 405.2171.

2280B - Renal Dialysis Center (RDC)

(Rev. 1, 05-21-04)

This designates a Medicare-certified hospital-owned and-operated unit that is ESRD-approved to furnish the full spectrum of diagnostic, therapeutic (including inpatient dialysis furnished directly or under arrangement), and rehabilitative services, except renal transplantation, required for the care of ESRD patients and outpatient dialysis.

An RDC must be in compliance with the Conditions for Coverage in 42 CFR 405.2135 through 42 CFR 405.2163.

2280C - Renal Dialysis Facility (RDF)

(Rev. 1, 05-21-04)

This designates a freestanding unit that is approved to furnish dialysis services to ESRD patients. It may or may not be located in a hospital.

An RDF must be in compliance with Conditions in 42 CFR 405.2135 through 42 CFR 405.2163.

2280D - Special Purpose Renal Dialysis Facility (SPRDF)

(Rev. 1, 05-21-04)

An SPRDF is approved on a short-term basis for special rehabilitation or emergency purposes, where patients cannot otherwise be accommodated. An SPRDF may be approved to serve:

- **Vacation Areas -** ESRD patients in a vacation area that is remote from existing approved facilities, or that is near an approved facility that does not have sufficient available capacity to serve a number of vacationing patients; or

- **Emergency Patients** - ESRD patients on an emergency basis when approved permanent facilities close due to natural disasters, strikes, or bankruptcies and the back-up facilities in the area cannot accommodate the patients of the closed facilities.

An SPRDF must meet all Conditions for Coverage applicable to RDFs (42 CFR 405.2130 through 42 CFR 405.2164) with the following exceptions:

- 42 CFR 405.2134, participation in network activities; and

- 42 CFR 405.2137, patient long-term program and patient care plan.

The SPRDF must consult the patient's physician to assure that the care provided is consistent with the patient long-term program and patient care plan (see 42 CFR 405.2137). The period of approval of an SPRDF may not exceed eight calendar months (which need not be consecutive) in any calendar year.

The same reimbursement rules, composite payment rates and exception criteria applied to permanent facilities are applicable to SPRDFs. For prospective payment purposes, determine whether the unit is hospital-based or an independent freestanding unit.

In SPRDF approval notifications, the RO must clearly specify the limited nature of the approval, the period covered and the automatic termination of payment on the last day of the approved period. The prospective payment status determination must be included.

SPRDFs of the vacation-type place the responsibility on the patient and treating physician to arrange the patient's return to his regular treating facility well in advance of the scheduled closing date of the SPRDF.

Where the SPRDF is established on an emergency basis (e.g., in case of a strike, earthquake, or flood), the scheduled closing date is contingent upon the termination of the

emergency condition. The RO may extend emergency SPRDF certifications, where necessary, beyond the routine eight-month period established for vacation-type SPRDFs.

In emergency situations, the RO should coordinate with the State Health Department and the network to relocate all patients to permanent facilities prior to the scheduled closing date of the SPRDF. In non-emergency situations, the treating physician is responsible for the patient's relocation and/or return to a permanent dialysis facility.

2280.1 - Provider Status: Renal Transplantation Center and Renal Dialysis Center (42 CFR 405.2131)

(Rev. 1, 05-21-04)

An RTC or RDC operated by a hospital may qualify for approval under the ESRD program **only** if the hospital is an approved Medicare provider, since the center's primary mission is to furnish inpatient care to ESRD patients. A separate, independent dialysis unit located in a Medicare-approved hospital cannot be approved as an RTC or RDC.

All Medicare-participating hospitals that perform transplants must be members of and abide by the rules of the Organ Procurement and Transplantation Network (OPTN). No RTC can be approved until the RO determines it is a member of the OPTN. The United Network for Organ Sharing (UNOS) is the contractor serving as the OPTN. Therefore, the RTC must provide documentation that it is a member of UNOS. If there is any question about the hospital's membership status, the RO should call the manager, Membership Affairs, UNOS, at (804) 755-1600.

A Medicare or non-Medicare hospital may participate in the ESRD program as an RDF if it has been classified as an outpatient provider of dialysis services, which does not wish to furnish inpatient services.

2280.2 - Furnishing Data and Information for ESRD Program Administration (42 CFR 405.2133)

(Rev. 1, 05-21-04)

As a condition of approval, a facility must furnish data and information 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.

The RO reviews ESRD-PMMIS records to verify that the facility is participating in the ESRD-PMMIS. Participating facilities failing to submit the requested cost information within the specific time period are subject to a suspension of payment. If the facility submits the required data, payment is reinstated.

Suspension of ESRD payment is handled between the CO, the intermediary, and the RO. The intermediaries and CO keep the RO informed of all suspension and resumption of payment activity.

If the facility refuses to submit the required data, the RO initiates termination action on the basis of noncompliance with 42 CFR 405.2133.

2280.3 - Participation In Network Activities (42 CFR 405.2134)

(Rev. 1, 05-21-04)

The RO verifies that the facility participates in network activities and pursues network goals. The ESRD network is responsible for notifying the RO of a facility's failure to participate.

NOTE: Compliance with this condition is waived for SPRDF applicants.

2280.4 - Minimal Laboratory Service Requirements for a Renal Dialysis Facility or a Renal Dialysis Center (42 CFR 405.2163(b)) and a Renal Transplantation Center (42 CFR 405.2171(d))

(Rev. 1, 05-21-04)

The SA verifies that the dialysis facility makes laboratory services available (other than the specialty of tissue pathology and histocompatibility testing), to meet the needs of the ESRD patient. An appropriately certified laboratory in accordance with 42 CFR Part 493 must perform all laboratory services. If the renal dialysis facility furnishes its own laboratory services, the SA verifies that it meets applicable requirements established for certification of laboratories found in 42 CFR Part 493. If the facility does not provide laboratory services, the SA verifies that it has made arrangements to obtain these services from a laboratory certified in the appropriate specialties and subspecialties of service in accordance with the requirements of 42 CFR Part 493.

The SA verifies that the Renal Transplantation Center makes available, directly or under arrangements, laboratory services to meet the needs of ESRD patients. Laboratory services are performed in a laboratory facility certified under 42 CFR Part 493.

2281 - Participation of Veterans Administration (VA) Hospitals in the ESRD Program

(Rev. 1, 05-21-04)

VA hospitals may participate in the Medicare program as community hospitals to provide ESRD services (see Exhibit 159 for the list of VA hospitals participating). To be considered a Medicare-participating hospital it must have:

- A sharing agreement with a community hospital;
- VA CO approval to seek Medicare approval;
- A Utilization Review Plan, which may be limited to services furnished to Medicare beneficiaries in the ESRD outpatient program; and
- Institutional planning, whereby the plan may be limited to services furnished to beneficiaries in the ESRD program.

If the VA hospital does not meet these requirements, the RO informs the hospital that no further action will be taken until these criteria are met. If the hospital meets them, the RO processes Part II of the Form CMS-3427A.

2281A - Survey Responsibility

(Rev. 1, 05-21-04)

The SA or the RO may receive inquiries and requests from VA hospitals to participate as suppliers of renal transplantation and dialysis services. However, ROs handle the survey and certification of all Federal facilities including VA hospitals desiring to participate in Medicare's ESRD program. Where the RO is unable to perform the survey, the RO may deputize an individual from the SA.

2281B - Special Survey Interpretations

(Rev. 1, 05-21-04)

The RO uses the following interpretations to accommodate the Federal status of the VA hospital, its limitations, and its participation under sharing agreements with community hospitals.

1. **Condition: Provider Status (42 CFR 405.2131) -** Any Federal hospital desiring to participate in the ESRD program must have approval as a provider in the Medicare program.

2. **Condition: Participation In Network Activities (42 CFR 405.2134) -** VA hospitals supplying ESRD services to the Medicare program must participate in ESRD network activities and pursue network goals.

3. **Condition: Compliance with Federal, State, and Local Laws and Regulations (42 CFR 405.2135) -** Since the VA hospital is located on a Federal property, and because it is a Federal institution, it is not subject to State and local government control.

4. **Condition: Governing Body and Management (42 CFR 405.2136) -** In a Federal hospital operated by the Veterans Administration, the governing body is the VA executive department or service which has responsibility for operation of the hospital. VA manuals and directives set forth the general policies and procedures to be followed at the hospital. The hospital administrator is the onsite delegate to assure that the directives are executed. He/she selects an individual who acts as the ESRD activity's "chief executive officer."

5. **Condition: Staff of an ESRD Dialysis Facility (42 CFR 405.2162) -** The nurse in charge of the nursing activity in the dialysis unit may be licensed and registered in a State other than that in which the VA hospital is situated. However, other qualifications in standard 42 CFR 405.2102(d) in regard to education (status as registered nurse), training and experience must be met. The VA employs former medical corpsmen in many capacities, and has utilized such personnel as physicians' assistants. However, for purposes of the ESRD program, evaluate each of these individuals as to whether they meet requirements for the particular job. They are frequently utilized as dialysis technicians, as well as unit managers. So long as there is a registered nurse in charge of the nursing activities, such personnel may function within the scope of their qualifications according to the VA job description covering their duties and responsibilities.

6. **Condition: Minimal Service Requirements for a Renal Dialysis Facility or Renal Dialysis Center (42 CFR 405.2163) -** A VA hospital may contract with its sharing hospital to supply all support services for non-veteran patients by means of the services and personnel at the sharing hospital, or to have the sharing hospital procure such supportive services.

7. **Condition: Minimal Service Requirements for a Renal Transplantation Center (42 CFR 405.2171) -** The sharing agreement with the community hospital may specify that the community hospital is responsible for furnishing directly or procuring the services for non-veteran patients.

8. **Letter of Notification -** For all VA hospitals, the RO adds a paragraph to approval letters as follows:

   "Since your hospital's approval as a supplier of ESRD services to the Medicare program is dependent upon you having in effect a current

sharing agreement for renal services with a community hospital, please keep us informed as to whether such agreements continue to be in effect, and whether they are to be renegotiated or cancelled at the end of the period of the agreement. Please notify us immediately if it is necessary to cancel Medicare approval for sharing of renal services."

2281C - Designated Intermediary/Carrier

(Rev. 1, 05-21-04)

The designated intermediary for all VA participating hospitals is:

Group Hospitalization, Inc.
550 Twelfth St., S.W.
Washington, D.C. 20024

2282 - RO Use of Provider Tie-In Notice, Form CMS-2007, for Suppliers of ESRD Program Services (Exhibit 156)

(Rev. 1, 05-21-04)

Form CMS-2007 serves as the official notice to the intermediary of program actions affecting ESRD facilities that supply Medicare program services. The RO completes the form each time an ESRD facility in the region is added to or deleted from an intermediary's listing of suppliers of a particular ESRD service under the classification transplantation, dialysis or self-care training facility. The RO completes the form for each ESRD facility approved as follows:

Item I - Identifying Information: Show the name of the ESRD unit, and its address. If it is owned and operated by a hospital, show the hospital's name and address, if different, and provider number under Item V Remarks.

Item II - New Supplier Certification: Assign a new provider number to each approved ESRD facility. For its initial approval, show the required intermediary identification.

Item III - Change of Intermediary: Complete this section, where appropriate.

Item IV - Terminations: Complete this section for all voluntary and involuntary terminations. When the facility is owned and operated by a participating Medicare provider, indicate under Remarks that the action applies to the particular ESRD service only, and not to the provider.

Item V - Remarks: Show the following data for every initial approval:

- ESRD facility classification (renal transplantation center, renal dialysis center, or renal dialysis facility). For SPRDFs, record the specific period for which approved;

- Type of service(s): transplantation, dialysis, home training and home support; and

- If dialysis and/or home training, the number of stations.

2283 - Change of Ownership of Hospital-Located Outpatient Renal Dialysis Facilities (From Hospital to Nonhospital) - RO Procedures

(Rev. 1, 05-21-04)

Change occurs most frequently when a physician or corporation takes over the operation of a formerly hospital-based dialysis unit, frequently under a lease arrangement. The RO clarifies the arrangement as rapidly as possible, since the provider (hospital) cannot bill and collect on behalf of the supplier.

When a hospital ceases to provide any direct services in connection with dialysis treatment, or to exercise professional responsibility over the patient's care, it is **not** eligible to bill for these outpatient dialysis treatments, and the unit's prospective payment status must be reviewed.

The RO informs the intermediary as soon as possible of the effective date of change of ownership and whether suspense action should be instituted pending approval of the new owner. The intermediary continues to pay billings for dialysis services furnished by the hospital up to the date of change of ownership. The new owner must request approval and meet the regulatory requirements prior to approval. If approved, the RO assigns a new provider number and prepares the Provider Tie-In Notice, Form CMS-2007, annotated to indicate termination of the dialysis unit operation by the hospital, and start-up of the approved dialysis services by the new owner.

When a new owner will not participate, the RO informs patients utilizing the dialysis as soon as possible that Medicare will no longer pay for their care at the unit. The SA or the RO informs the patients of other dialysis facilities in the area that are approved under the Medicare program.

2284 - Termination Procedures

(Rev. 1, 05-21-04)

See Chapter 3.

2285 - Alternative Sanctions for Failure to Participate in Network Activities

(Rev. 1, 05-21-04)

If an ESRD facility fails to participate in the activities and pursue the goals of the ESRD network in its geographic area (42 CFR 405.2134), and the failure does not jeopardize patient health and safety or justify termination, the RO may impose an alternative sanction as specified:

- Denial of payment for services furnished to patients first accepted for care after the effective date of sanction, as specified in the sanction notice;
- Reduction of payments for all ESRD services furnished by the supplier by 20 percent for each 30-day period after the date of sanction; and
- Withholding of all payments, without interest, for all ESRD services furnished by the supplier to Medicare beneficiaries.

2285.1 - Identification of Facilities That Fail to Participate in Network Activities

(Rev. 1, 05-21-04)

The ESRD network organization recommends the imposition of a sanction against a participating facility to the RO. This process is similar to the receipt and review of the SA's certification decisions. If the network organization identifies a facility that is not participating with network goals and objectives and recommends imposition of a sanction, it forwards documentation to the RO stating the basis for its recommendation. The network organization will only recommend a sanction if it documents that the facility:

- Consistently fails to cooperate with network plans or goals as specified in the network's contract with CMS;
- Consistently fails to follow recommendations of the medical review board, which have been approved by CMS;
- Fails to permit the network medical review board, without just cause, to conduct an on-site review; or
- Fails to submit data as required.

This documentation must include, at a minimum, the rationale and specific actions of the facility that resulted in the recommendation. The RO reviews this documentation and accepts or rejects the network's recommendation. If the RO has questions or concerns

regarding the recommendation, it discusses the situation with the network organization directly and/or contacts the project officer of the network organization in CO.

2285.2 - Imposition of the Sanction

(Rev. 1, 05-21-04)

If the RO accepts the recommendation of the ESRD network to impose a sanction, it decides which sanction to impose and notifies the facility. The sanction the RO imposes is at its discretion. However, the RO should select the mechanism that provides the most effective means to encourage the facility to come into compliance with the requirement. The network may be able to assist the RO in determining which sanction to impose. The RO notifies the facility of the sanction imposed, the facility's appeal rights (see §2285.4) and the procedure for removal of the sanction. (See Exhibit 160) The effective date of the sanction is at least 30 days after the date of the notice. The RO notifies the intermediary of the specific sanction with the "Provider Tie-In Notice," Form CMS-2007 and its effective date. Also, the RO informs the appropriate network organization and CMS.

2285.3 - Duration and Removal of the Sanction

(Rev. 1, 05-21-04)

An alternative sanction remains in effect until the facility is in substantial compliance with the requirement to participate in the network's activities and pursue the network's goals, or the facility is terminated from the Medicare program for lack of compliance. The RO removes the sanction when the supplier demonstrates and documents that the reason for the sanction is eliminated.

The form and substance of the documentation required to remove the sanction depends upon the reasons for applying a sanction. For example, if a facility is sanctioned for failing to submit data forms, the RO removes the sanction when the facility submits the delinquent forms. A site visit to verify compliance is not necessary. On the other hand, if the RO sanctions a facility for failure to comply with established criteria and standards relating to quality and appropriateness of care, then a plan of correction in conjunction with a site visit might be necessary to document when the reason for the sanction has been eliminated.

Each sanction notice must explain what is required for correction of the particular problem or problems. Once the facility informs the RO of its corrective actions, the RO verifies its compliance with the requirements and informs the intermediary that the sanction is to be removed with the "Provider Tie-In Notice," Form CMS-2007. Also, the RO informs the network organization and CMS.

2285.4 - Notice and Appeal Rights

(Rev. 1, 05-21-04)

If the RO proposes to apply an alternative sanction, it gives the facility notice of the proposed sanction and 15 days in which to request a hearing. The effective date of the sanction should be 45 days from the date of the notice, which allows the RO to implement the sanction immediately if the facility does not request a hearing. After 15 days, the RO notifies the public about the reasons for the sanction and when it will take effect unless the facility requests a hearing. If it requests a hearing, the RO provides an informal hearing by an official who was not involved in making the appealed decision. During the informal hearing, the facility:

- May be represented by counsel;
- Has access to the information on which the allegation was based; and
- May present, orally or in writing, evidence and documentation to refute the finding of failure to participate in network activities and pursue network goals.

If the written decision of the informal hearing supports application of the alternative sanction, the RO provides the facility and the public at least 30 days notice before the effective date of the sanction that specifies the effective date and the reasons for the sanction.

2286 - Continuous Ambulatory Peritoneal Dialysis Coverage (CAPD) and Continuous Cycling Peritoneal Dialysis (CCPD)

(Rev. 1, 05-21-04)

The Medicare program has approved coverage for CAPD and CCPD. Since the CAPD and CCPD procedure are ones that the patient can carry out in many locations, training and support services are the only facility services involved.

2286A - How CAPD is Performed

(Rev. 1, 05-21-04)

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 pours into the peritoneal cavity. Four to six hours later, the patient drains the fluid into the same plastic bag, detaches it, attaches a new bag and refills the 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 him a diet without many of the restrictions associated with other types of dialysis.

How CCPD is Performed

CCPD uses an automated peritoneal dialysis machine to pour a measured amount of dialysate into the abdomen and drain it, usually 45 minutes later, 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.

2286B - Application and Determination Procedure

(Rev. 1, 05-21-04)

Facilities must file Form CMS-3427, Part I, plus a detailed statement explaining how they expect to meet the criteria for delivering CAPD/CCPD. Unless CON approval specifically for the CAPD/CCPD services is required by State law, a CAPD/CCPD facility is not required to document "need."

Approval is based on the following:

- The facility must furnish CAPD/CCPD training directly, but may provide the required support services via an arrangement or an agreement with another ESRD-approved facility.

- The director of the renal dialysis center or renal dialysis facility must agree to furnish a certificate of completion, including any pertinent limitations, whenever a patient has successfully completed a course of training. He/she must also assure that instructional materials are available for use of all trainees during training and at times other than during the dialysis procedure. The director must also assure that personnel involved in training have adequate knowledge of the CAPD process.

- The nurse responsible for CAPD/CCPD training must meet the standards in 42 CFR 405.2102(d) and have documented experience in peritoneal dialysis and in the care and maintenance of peritoneal access devices.

- Upon completion of the patient's CAPD/CCPD training, the facility must furnish the following support services either directly or under arrangement with another ESRD facility approved to furnish staff-assisted peritoneal dialysis or peritoneal self-dialysis training:

    - Surveillance of the CAPD/CCPD patient's home adaptation, including provisions for visits to the home or patient visits to the facility;

- Consultation for the CAPD/CCPD patient with a qualified social worker and a qualified dietitian;

- A record-keeping system which assures continuity of care for the CAPD/CCPD patient;

- CAPD/CCPD equipment and supplies ordered on an ongoing basis;

- Periodic visits, at least once every 90 days, to monitor the CAPD/CCPD patient's medical condition, review his continuing capability to perform CAPD/CCPD, and record whether the patient has, or has had, peritonitis requiring physician or hospital care; and

- Hemodialysis or intermittent peritoneal dialysis as required.

The RO notifies the facility of its determination and forwards a copy of all such letters to the SA. (See Exhibit 161.)

The RO prepares a Form CMS-1539 indicating denial or approval. In addition, the RO completes the "Provider Tie-In Notice," Form CMS-2007, and under item V, "Remarks," enters: "Approval of training and support services in CAPD/CCPD."

2287 - Classification of Maintenance Dialysis Facilities as Hospital-Based or Independent: Prospective Payment

(Rev. 1, 05-21-04)

Based on the regularly scheduled ESRD survey results and any additional information forwarded by the facility's intermediary, the RO prepares a classification determination as to whether an ESRD facility is hospital-based or an independent entity. The RO determines classification in the course of the regular scheduled ESRD survey cycle.

If inconsistencies are noted between the SA survey and the intermediary's findings regarding a facility's classification, the RO recontacts the SA, intermediary, and facility, as necessary, to resolve any differences or discrepancies.

The RO determines the classification using the following criteria:

2287A - Hospital-Based ESRD Facility

(Rev. 1, 05-21-04)

An ESRD facility is hospital-based if it is an integral and subordinate part of a hospital and is operated with other departments of the hospital under common licensure, governance, and professional supervision, with all services of the hospital and facility fully integrated. A renal dialysis unit is considered hospital-based only if all of the

following criteria are met. These criteria are based upon regulations at 42 CFR 413.174(c).

- The 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 board which has final administrative responsibility over both entities. The common governing body approves all personnel actions and appoints medical staff in addition to other management functions.

- There is a clearly established line of authority between the facility's director or administrator and the hospital's chief executive officer. The director or administrator of the dialysis facility reports to the common governing body through the chief executive officer of the hospital.

- The facility has personnel policies and practices that conform to those of the hospital.

- There is a merging of administrative functions between the facility and the hospital. For example, there is an integration of records, housekeeping and laundry services, and common purchasing and billing practices.

- The dialysis facility and hospital are financially integrated and the hospital is required to allocate hospital overhead costs to the facility through the required step-down methodology. For example, where a single dialysis department in a hospital is responsible for inpatient and outpatient dialysis and the costs are subsequently split between inpatient and outpatient, the RO classifies the department as hospital-based. In determining compliance with this criterion, the key issue is whether §2306 of the Provider Reimbursement Manual would require the hospital to make this cost allocation, rather than whether the hospital has actually made the allocation. If no allocation is made because the hospital failed to follow §2306 of the Provider Reimbursement Manual, the hospital must resubmit a corrected cost report, and the facility will normally be classified as hospital-based.

The RO should not give any weight to the existence of an agreement between the facility and hospital for referral of patients, a shared service arrangement, or the physical location of the dialysis unit on the premises of the hospital, in determining whether a facility is hospital-based.

2287B - Independent ESRD Facility

(Rev. 1, 05-21-04)

Any ESRD facility that does not qualify as a hospital-based facility is an independent renal dialysis facility.

Providers of Outpatient Physical Therapy or Outpatient Speech Pathology (OPT/OSP) Services

2290 - OPT/OSP - Citations

(Rev. 1, 05-21-04)

The statutory basis for providers of OPT/OSP services is found in §1861(p) of the Act. The CoPs are found in 42 CFR 485, Subpart H. Appendix E contains surveyor and interpretive guidelines.

2292 - Types of OPT/OSP Providers

(Rev. 1, 05-21-04)

There are three types of organizations that may qualify as OPT/OSP providers:

2292A - Rehabilitation Agency

(Rev. 1, 05-21-04)

An agency that provides an integrated, multidisciplinary program designed to upgrade the physical functions of handicapped, disabled individuals by bringing together, as a team, specialized rehabilitation personnel. At a minimum, a rehabilitation agency must provide physical therapy or speech language pathology services and a rehabilitation program which, in addition to physical therapy or speech language pathology services, includes social or vocational adjustment services.

2292B - Clinic

(Rev. 1, 05-21-04)

A facility established primarily for the provision of outpatient physicians' services. To meet the definition of a clinic, the facility must meet the following test of physician participation:

- The medical services of the clinic are provided by a group of three or more physicians practicing medicine together; and

- A physician is present in the clinic at all times during hours of operation to perform medical services (rather than only administrative services).

2292C - Public Health Agency

(Rev. 1, 05-21-04)

An official agency established by a State or local government, the primary function of which is to maintain the health of the population served by providing environmental health services, preventive medical services, and in certain instances, therapeutic services.

2294 - Exceptions to CoPs

(Rev. 1, 05-21-04)

In order for clinics, rehabilitation agencies, and public health agencies to be eligible to participate as providers of OPT/OSP services, they must be in compliance with all applicable CoPs, except the following: 42 CFR 485.709, Administrative Management, is not applicable to public health agencies, and 42 CFR 485.717, Rehabilitation Program, is not applicable to clinics or public health agencies.

2296 - SA Verification of Services Provided

(Rev. 1, 05-21-04)

During the course of the SA survey, it verifies that the services that the provider proposes to offer are actually being provided. The SA evaluates the cumulative records of services actually provided. Work schedules of personnel providing services will show utilization data for various services.

2298 - Site of Service Provision

(Rev. 1, 05-21-04)

2298A - Limitations

(Rev. 1, 05-21-04)

An OPT/OSP provider may provide services on its own premises, on the premises of another **provider** of services, e.g., hospital or SNF, or in the individual's place of residence. The services **may not** be furnished on the premises of a supplier of services, unless they are provided under arrangements with the supplier by public health agencies.

A public health agency may arrange to provide physical therapy or speech pathology services on the premises of a supplier of services if:

- That supplier does not have the capacity to provide an adequate program;

- Such services are not provided on an outpatient basis in another accessible, certified provider; and

- Applicable health and safety requirements are met.

2298B - Services Provided at More Than One Location Controlled by OPT/OSP Provider

(Rev. 1, 05-21-04)

An OPT/OSP provider (normally a rehabilitation agency) may provide services from multiple locations that it controls (e.g., buildings or space it owns or rents). These locations may be freestanding offices, suites in office or medical buildings or, in some cases, spaces in existing Medicare participating LTC facilities. However, the OPT/OSP provider must designate one location as its primary site for certification purposes. It is possible to provide a service directly at one location while providing it under arrangements at another. A patient's home is not considered to be an extension location.

2298C - OPT/OSP Services at Locations Other than Those Provider Controls

(Rev. 1, 05-21-04)

OPT/OSP providers may also provide services from locations other than their primary sites and other than locations that they control directly. These non-controlled locations are defined as extension locations. Normally, an OPT/OSP provider, usually one classified as a rehabilitation agency, will provide services in a nursing home (participating or nonparticipating in Medicare) and treat both inpatients of the facility and outpatients from the surrounding community. The extension unit is an area of the facility that is set aside for the provision of OPT/OSP services. It may be a vacant patient room or a general-purpose room. In all cases, the OPT/OSP primary site must provide the services that are provided at the extension locations. However, it is possible to provide a service directly at one location while providing it under arrangements at another.

NOTE – An OPT/OSP may have an unlimited number of extension locations at a SNF. However, the OPT/OSP must notify the SA/RO of all extension locations.

2300 - SA Annual Report to RO on Locations of Extensions Locations

(Rev. 1, 05-21-04)

OPT/OSP providers are required to report the proposed addition of all new extension locations. In addition, on an annual basis or on or before January 1 of the calendar year, the SA forwards a copy of the Identification of Extension Locations of OPT/OSP Providers (Form CMS-381) (see Exhibit 56 and 57) to all OPT/OSP providers. If possible, the SA should complete this activity within the same time period for all

OPT/OSP providers. Each provider providing services from extension locations is to indicate, in the appropriate spaces, the name, address of primary site, and the provider number, as well as the name(s) and address(es) of extension location(s) and, under Part B, the specific services (OPT, OSP, or both) each extension location provides. Upon receipt of this form from the OPT/OSP provider, the SA reviews this information and forwards a summary annual report of the information to the RO noting the number of extension locations for each certified OPT/OSP provider.

2302 - SA Survey of OPT/OSP Controlled and Extension locations of Providers Offering OPT Only

(Rev. 1, 05-21-04)

NOTE: A SA may survey a rehabilitation agency extension location in lieu of a survey of the primary site. The extension location must meet all applicable CoPs. The SA may survey as many facility locations as it deems necessary to adequately determine the rehabilitation agency's overall compliance with the CoP.

NOTE: The extension location concept for OPT is applicable only in those cases in which a separate area is set aside within the other provider for the treatment of patients. Do not survey as an extension location if the OPT only treats inpatients in their rooms.

The SA surveys each condition and standard in the OPT/OSP CoPs at each multiple and extension unit with the following exceptions:

- 42 CFR 485.709(a) (Standard: Governing body) is based upon the evaluation of the total agency that has responsibility for the primary location as well as all extension locations. When this requirement is met for the primary location, it is met for all locations;

- Condition 485.717 (Rehabilitation program) is applicable only to a rehabilitation agency;

- Condition 485.725 (Infection control) is applicable only where physical therapy services are being rendered; or

- Condition 485.715 (Speech pathology) is applicable only when speech pathology is rendered.

The SA completes a separate survey report, Form CMS-1893, for each surveyed OPT location. Failure to correct deficiencies noted as a result of a survey at any location (extension location, or primary site) will jeopardize the certification of the OPT provider in its entirety. The SA completes only one Form CMS-2567, and indicates the names of all locations (primary, extension location) found to be deficient with respect to each survey item. Also, the SA completes only one Form CMS-1539, and notes the names of all facilities that serve as extension locations in "State Agency Remarks." Surveys of all

locations must be coordinated; therefore, schedule and complete surveys of all locations within the same time period.

When the SA is certifying compliance, findings at all locations are to be considered as a whole. If the OPT provider has deficiencies in only some locations, but they are judged significant enough to warrant termination, the SA initiates termination proceedings. Cessation of services at the location(s) at which the deficiency(ies) existed, in lieu of initiating corrective action, would enable the OPT provider to retain its certification.

EXECPTION - OPT/OSP providers, regardless of Medicare certification, who wish to establish an extension location outside the State must have a written reciprocal agreement with the state in which the extension location is located. The extension location must conform to **all** regulatory requirements. The appropriate RO will have the OPT/OSP provider sign separate provider agreements. The SA notifies the provider of this requirement if it learns of such situations.

2306 - OPT/OSP Provider Relinquishes Primary Site to CORF

(Rev. 1, 05-21-04)

The OPT/OSP provider, following the conversion of its primary site to a CORF, may select one of its extension locations as a new primary site. The SA notifies the RO via Form CMS-1539 of the new primary location and existing, associated, certified extension locations for OPT/OSP services.

The SA surveys and certifies the new primary location under the OPT/OSP CoPs. If the extension unit now identified as the new primary location was never surveyed and approved, it must now be surveyed. However, existing extension locations do not have to be resurveyed with the survey of the new primary location.

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. 1, 05-21-04)

A CORF must provide, at a minimum, physicians' services, physical therapy, and social 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).

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.

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. 1, 05-21-04)

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.

2364B - Sharing of Equipment

(Rev. 1, 05-21-04)

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.

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.

Certification of Chiropractors to Furnish Specified Services

2450 - Chiropractors - Citations and Description of Services Covered

(Rev. 1, 05-21-04)

The Act defines the term "physician" to include chiropractors that meet specific qualifying requirements, but only for purposes of providing limited services. Regulations covering this service are found in 42 CFR Part 410.22.

Part B payment may be made only for the chiropractor's manual manipulation of the spine to correct a subluxation (demonstrated by x-ray to exist) that has resulted in a neuromusculoskeletal condition for which such manipulation is an appropriate treatment. Chiropractors may not be reimbursed for x-rays or any other diagnostic or therapeutic services.

2452 - Education and Training Requirements for Chiropractors

(Rev. 1, 05-21-04)

2452A - Chiropractors Qualified Prior to July 1, 1974

(Rev. 1, 05-21-04)

Chiropractors licensed or authorized to practice prior to July 1, 1974, and those individuals who commenced their studies in a chiropractic college before that date must meet each of the following standards in order to qualify for reimbursement under the program (see Exhibit 38).

- Preliminary education equal to the requirements for graduation from an accredited high school or other secondary school;

- Graduation from a chiropractic college approved by the State's Board of Chiropractic Examiners or its equivalent whose curriculum included the completion of a course of study covering a period of not less than three school years of 6 months each year in actual continuous attendance. The course of study must include adequate courses in anatomy, physiology, symptomatology and diagnosis, hygiene and sanitation, chemistry, histology, pathology, and principles and practice of chiropractic, including clinical instruction in vertebral palpitation, nerve tracing, and adjusting; and

- Passage of an examination prescribed by the State's Board of Chiropractic Examiners or its equivalent covering the subjects listed in the above paragraph. However, in those States requiring successful completion of a Basic Science

Examination as a condition of licensure as a chiropractor, it is not necessary for the applicant to have been specifically and separately tested in the enumerated subjects for his/her chiropractic license, providing the basic science exam included testing on the specified subjects or their equivalency as set forth above.

2452B - Individuals Commencing Their Studies in Chiropractic College After June 30, 1974

(Rev. 1, 05-21-04)

These individuals must meet the following requirements in addition to those in subsection A (see Exhibit 39).

- Satisfactory completion of two years of pre-chiropractic study at the college level;
- Satisfactory completion of a 4-year course of 8 months each year (instead of a 3-year course of 6 months each year) at a college or school of chiropractic. This educational requirement includes not less than 4,000 hours in the scientific and chiropractic courses (see second bullet under subsection A) and courses in the use and effect of x-ray and chiropractic analysis; and
- The practitioner must be over 21 years of age.

2454 - SA Participation in Approving Chiropractors

(Rev. 1, 05-21-04)

Since the majority of chiropractors are now participating or have had their qualifications evaluated, there is no SA certification process. Ordinarily, the State authority for licensure of chiropractors provides the RO with current listings of qualified practitioners. The SA should maintain contact with the State Board of Chiropractic Examiners or its equivalent in case questions arise regarding the qualifications of a chiropractor.

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. 1, 05-21-04)

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/MR 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. 1, 05-21-04)

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

2470E - Substitution of State Fire Code for the Life Safety Code (LSC)

(Rev. 1, 05-21-04)

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/MR 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/MR 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. 1, 05-21-04)

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/MR. The State LSC surveyor recommends waivers, but CMS ROs grant the waivers. Therefore, LSC requests the SA receive from all providers except ICF/MRs must be forwarded to the RO for adjudication. For ICFs/MR, 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. 1, 05-21-04)

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/MR 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. 1, 05-21-04)

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/MR, 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/MR, 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. 1, 05-21-04)

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/MR -Small Facilities; 2000Code.

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

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

4. Form CMS-2786Y, Fire Safety Survey Report ICF/MR- 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. 1, 05-21-04)

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/MR;
- 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. 1, 05-21-04)

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/MR, however, CMS must grant the waiver, not the State. There are no waivers for ICFs/MR 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. 1, 05-21-04)

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/MR well in advance of the scheduled expiration date of the time limited agreement (approximately three months) 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. 1, 05-21-04)

The Survey Team Composition and Workload Report (Form CMS-670) (see Exhibit 74) 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 and/or Medicaid providers and suppliers and CLIA laboratories. Exhibit 74 also contains instructions for completing Form CMS-670.

In addition to the instructions in Exhibit 74, the SA follows these guidelines:

- If a survey does not include an onsite visit, do not enter arrival, departure, onsite, and travel dates or times on Form CMS-670. Enter all other appropriate fields. (See Form CMS-670 edits);

- Include on Form CMS-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 Form CMS-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 Form CMS-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 Form CMS-670 for visits conducted solely for licensure purposes;

- Treat multiple complaints investigated at the same time as one complaint survey and enter on one Form CMS-670;

- If complaints are conducted concurrently with a recertification survey or follow up, report the complaint on a separate Form CMS-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 OSCAR. Therefore, do not complete Form CMS-670 for PPS surveys;

- Prepare separate Form CMS-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 Form CMS-670s (one for health and one for LSC);

- Supervisory review time reported on Form CMS-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 Form CMS-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 Form CMS-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 Form CMS-670 if they participate;

- If more than 10 surveyors participate in a survey, use continuation forms to input survey data into the system. The OSCAR system has been reconfigured to accept up to 990 surveyors. These are accessed in the system by the "PF" key;

- If errors are made in data entry, change the information by accessing ODIE's "update" mode;

- For supervisors who review a CHOW in house, **DO NOT** enter the time in ODIE, unless a survey is conducted in conjunction with the CHOW;

- Do not enter QIO staff on Form CMS-670 since they are not part of the survey staff;

- Use Form CMS-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 Form CMS-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. 1, 05-21-04)

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/MR 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. 1, 05-21-04)

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/MR 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. 1, 05-21-04)

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/MR). (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/MR

(Rev. 1, 05-21-04)

Appendix N describes the procedure(s) that must be applied when surveying a SNF/NF or ICF/MR 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/MR. (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. 1, 05-21-04)

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/MR, 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/MR Survey Report

(Rev. 1, 05-21-04)

Form CMS-3070G-I (see Exhibit 80) is keyed to the CoPs for ICFs/MR in the Medicaid program. Surveyors use the form in conjunction with the interpretive guidelines and survey procedures for ICFs/MR (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. 1, 05-21-04)

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, 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, and a copy is provided at the conclusion of the conference. It is at the sole discretion of the surveyor(s) to determine if videotaping is permitted.

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. 1, 05-21-04)

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 to discuss preliminary survey findings and thereby assist the provider or supplier in developing an acceptable PoC, if appropriate and required. 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. 1, 05-21-04)

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 team, the State, and/or the RO after the conference. (See §2728.B. concerning provider attempts to refute survey findings on the Form CMS-2567.)

2724C - Presentation of Findings

(Rev. 1, 05-21-04)

In presenting findings, avoid reading your findings or referring to them by their data tag number. Explain why the findings are a violation of Medicare requirements. If the

provider asks for the regulatory basis, provide it. 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. Avoid statements such as, "The condition was not met," or "The standard was not met."

2724D - Closure

(Rev. 1, 05-21-04)

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

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

Notices of Medicare recertification from the RO are not necessarily sent unless there are changes in approved services or in sizes of distinct parts certified. Notices of reapproval of NFs and ICFs/MR 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. 1, 05-21-04)

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 (not data tags or regulation citations) 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/MR

(Rev. 1, 05-21-04)

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/MR, 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. 1, 05-21-04)

The outcome-oriented survey process for SNFs, NFs, HHAs and ICFs/MR 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/MR.

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 Certification to RO

(Rev. 1, 05-21-04)

The RO uses the SA certification as the primary item of evidence to support its decisions to approve or disapprove Medicare provider participation or coverage of supplier services. The SA sends the entire certification packet to the RO in an initial certification, a termination, or any action other than a routine periodic recertification. (See Exhibit 3.) In routine recertifications, the SA inputs the data into the OSCAR system and, as appropriate, forwards an abbreviated packet of documents to the RO.

The SA completes the appropriate crucial data extract (CDE) to distill essential information from the survey report for input into the OSCAR system. (See Exhibits 14A-140.) Each CDE 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 CDE.

The SA completes all pertinent documentation relating to certification actions for each provider/supplier or action category and forwards it to the RO (or 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. 1, 05-21-04)

The SA uses Form CMS-1539 to certify findings to the RO or SMA 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. Part I of the form is completed by the SA and Part II by the RO or SMA. Form CMS-1539 may be computer generated (ASPEN), but it must be an exact replica of the actual form. (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.

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. 1, 05-21-04)

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 indicating in Item 16 that "this certification is amending the certification dated_____."

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

(Rev. 1, 05-21-04)

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

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

Item 1 - Medicare/Medicaid Provider No

Leave this item blank on all initial certifications. The RO assigns the identification numbers for all new providers and suppliers and furnishes the SA with the number via a copy of the acceptance letter. On all subsequent certification actions such as resurveys, CHOWs, and name and address changes, the SA inserts the facility's assigned provider/supplier number.

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

A - Long-Term Care Facilities with Distinct Parts

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

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

B - LTC Distinct Part Units of Hospitals

Provider numbers are assigned in the following fashion:

1 - Hospital with Distinct-Part SNF

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

2 - Hospital with Distinct-Part NF

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

3 - Hospital with Distinct-Part SNF/NF

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

C - "Swing-Bed" Hospitals

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

D - PPS-Excluded Hospitals

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

Item 2 - State Vendor or Medicaid Number

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

Item 3 - Name and Address of Facility

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

Item 4 - Type of Action

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

A - Code 1 (Initial Survey)

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

B - Code 3 (Termination)

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

C - Code 5 (Sample Validation)

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

D - Code 7 (Onsite Visit)

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

1. Onsite revisit to verify that the deficiencies cited on the original survey are corrected and a Form CMS-2567B is completed;

2. Onsite visit to verify that a hospital meets the criteria for hospitals operating with multiple components; and

3. Onsite visit to verify that an HHA's satellite meets the branch/subunit criteria.

E - Code 9

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

Item 5 - CHOW Date

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

Item 6 - Survey Date

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

Item 7 - Provider/Supplier Category

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

A - Code 02 - (SNF/NF)

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

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

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

C - Code 04 - (SNF)

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

1. Freestanding SNF; or

2. SNF distinct part of hospital.

D - Code 10 - (NF)

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

E - Code 11 - (ICF/MR)

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

Item 8 - Accreditation Status

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

Item 9 - Fiscal Year Ending Date

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

Item 10 - State Agency Certification

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/MR)

(Rev. 1, 05-21-04)

1 - Denial of Payments Recommended

The SA marks "B" in the first block when a recertified SNF, NF, or ICF/MR 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. 1, 05-21-04)

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/MR. The SA inserts the recommended beginning (FROM) and ending (TO) dates of the TLA. If ICFs/MR 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/MRs)

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/MRs)

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

Item 14 - SNF, NF, and ICF/MR 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/MR). 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/MR providers.

Item 15 - Nonparticipating Emergency Hospitals and NFs

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

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

Item 16 - State Survey Agency Remarks

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

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

EXAMPLE 1

1. Provider Number

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

7. 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/MR |

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/MR |

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/MR
	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/MR |

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/MR
		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/MR |

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/MR
		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/MR
		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/MR
	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/MR
	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/MR
	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/MR
		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/MR
		140	

EXAMPLE #12 - 30 bed ICF/MR (free-standing)

1. Provider Number

| X | X | G | 0 | 0 | 0 | (ICF/MR)

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/MR
			30

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

Beds are distributed as follows:
30 beds - Title 19 NF
20 beds - Title 19 ICF/MR

NOTE: Prepare two Forms CMS-1539 identifying the NF and ICF/MR 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/MR
		30	

1. Provider Number

| X | X | G | 0 | 0 | 0 | (ICF/MR)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
| 1| 1| (IMR)	2 0	2 0

14.
LTC Certified Bed Breakdown

SNF	SNF/NF	NF	ICF/MR
			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.

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

(Rev. 1, 05-21-04)

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

Item 19 - Determination of Eligibility

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

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

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

Item 22 - Original Date of Participation

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

Items 23-25 - ICF/MR Certification Period

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

Item 26 - Termination Action

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

1 - Voluntary

Code 1 - Enter when a facility closes or merges.

Code 2 - Enter when a provider or supplier is voluntarily withdrawing because of dissatisfaction with reimbursement.

Code 3 - Enter when a facility is leaving the program because it is at risk of being involuntarily terminated.

Code 4 - Enter when a provider or supplier no longer wishes to participate in the program for some other or unknown reason.

2 - Involuntary

Code 5 - Enter when a facility fails to meet health or safety requirements.

Code 6 - Select this code when a provider fails to abide by the agreement.

3 - Other

Code 7 - Select this code when you terminate a currently assigned provider number. Examples include:

- Medicare SNF or dually-participating SNF/NF elects to participate in the Medicaid program only;
- Medicaid NF elects to participate in the Medicare or Medicare and Medicaid programs; and

- ASC, ESRD, or RHC facility elects to participate as free-standing instead of hospital-based and vice versa.

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

Item 27 - Intermediate Sanctions (ICF/MR Only)

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

1 - Suspension of Admissions

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

2 - Rescind Suspension Date

a - Significant Compliance with Program Requirements

Enter the date the denial of payment is rescinded.

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

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

b -Significant Effort or Progress

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

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

- The denial of payments could be rescinded;
- Effort and progress would be documented;
- The SA would certify "not in compliance"; and
- The extension would remain in effect.

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

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

Item 28 - Termination Date

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

Item 29 - Intermediary/Carrier Number

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

Item 30 – Remarks

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

Item 31 - RO Receipt of Form CMS-1539

Enter the date that a certification package is received.

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

Item 32 - Determination Approval

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

2765 - Intermediary Tie-In Activities

(Rev. 1, 05-21-04)

The SA maintains a list of the intermediaries available to serve providers in the area (See http://www.cms.hhs.gov/contacts/incardir.asp). The SA includes this list in the initial mailing kit sent to new provider candidates. This list contains the intermediaries' names, addresses, telephone numbers, and service areas. It also indicates that intermediary elections are subject to approval by the RO and that questions regarding intermediary selection should be addressed to the RO. The RO furnishes updated lists to the SA when the availability of intermediaries changes.

The SA forwards the Expression of Intermediary Preference form to the RO as soon as it is received from the provider. If the provider seeks guidance or otherwise wishes to discuss its choice of intermediary, the SA refers the provider to the RO. The RO retains the "Expression" form in the provider file. If the designated intermediary is unavailable, the RO informs the provider and obtains an alternate selection.

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. 1, 05-21-04)

With the exception of State-operated NFs, which are certified by CMS, the SA completes all Medicaid-only certifications and forwards them to the State Medicaid agency (SMA) within 45 days after the survey. The SMA initiates appropriate action based on the SA's certification of the Medicaid-only provider. After this action is completed, the SMA forwards the case (with the exception of Form HHS-441, Assurance of Compliance with the Department of Health and Human Services Regulations under Title V of the Civil Rights Act of 1964, or a comparable form) to the SA for entry into the OSCAR system. Before the initial certification is entered into the OSCAR system, the SA assigns a provider number to the NF or ICF/MR. The OSCAR 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. 1, 05-21-04)

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.

2778 - Objectives of RO Certification Review

(Rev. 1, 05-21-04)

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

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

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

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

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

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

If a deficiency is subsequently corrected, the corrective action will be shown on Form CMS-2567 or the Post-Certification Revisit Report, Form CMS-2567B, as appropriate. If the deficiencies have not been corrected at the time of the revisit, they are shown on a new Form CMS-2567. The OSCAR system accumulates data on the ability of providers and suppliers to meet program participation requirements at the time of the survey. OSCAR data from Form CMS-2567 and Form CMS-2567B are used to measure the extent of progress providers and suppliers make in complying with program requirements.

In case of an unreconciled interpretive disagreement with the SA, the RO can arrive at a determination disagreeing with the SA, **provided there is evidence to support a contrary decision**. If the RO disagrees with the SA certification, it justifies its rejection

in writing and attempts to resolve the disagreement. If necessary, a disagreement over interpretive policy can be referred to CMS CO for resolution.

2779 - RO Assignment of Provider and Supplier Identification Numbers

(Rev. 1, 05-21-04)

2779A - Numbering System for Medicare Providers and Suppliers of Service

(Rev. 1, 05-21-04)

Processing of requests for payment is keyed to the identification number. The RO enters provider and supplier identification numbers on all forms and communications and maintains adequate controls.

2779A1 - Provider Identification Numbers

(Rev. 2, Issued 08-20-04, Effective: N/A/ Implementation: N/A)

The identification numbers for providers and suppliers paid under Part A have six digits. The first two digits identify the State in which the provider is located. The last four digits identify the type of facility.

Following is a list of all State Codes:

Alabama	01	New Hampshire	30
Alaska	02	New Jersey	31
Arizona	03	New Mexico	32
Arkansas	04	New York	33
California	05, 55	North Carolina	34
Colorado	06	North Dakota	35
Connecticut	07	Ohio	36
Delaware	08	Oklahoma	37
District of Columbia	09	Oregon	38
Florida	10, 68	Pennsylvania	39
Georgia	11	Puerto Rico	40
Hawaii	12	Rhode Island	41
Idaho	13	South Carolina	42
Illinois	14	South Dakota	43
Indiana	15	Tennessee	44
Iowa	16	Texas	45, 67
Kansas	17	Utah	46
Kentucky	18	Vermont	47
Louisiana	19	Virgin Islands	48
Maine	20	Virginia	49

Maryland	21, 80	Washington	50
Massachusetts	22	West Virginia	51
Michigan	23	Wisconsin	52
Minnesota	24	Wyoming	53
Mississippi	25	Canada	56
Missouri	26	Mexico	59
Montana	27	American Samoa	64
Nebraska	28	Guam	65
Nevada	29	Commonwealth of the Northern Marianas Islands	66

Assign the last four digits sequentially from within the appropriate block of numbers.

Use the following blocks of numbers for the types of facilities 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	Reserved for future use
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 (4900-4999 series)
1500-1799	Hospices
1800-1989	Federally Qualified Health Centers
1990-1999	Religious Nonmedical Health Care Institutions (formerly Christian Science Sanatoria (Hospital Services)
2000-2299	Long-Term Hospitals (Excluded from PPS)
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 PPS)
3100-3199	*Home Health Agencies*
3200-3299	Continuation of Comprehensive Outpatient Rehabilitation Facilities (4800-4899) Series
3300-3399	Children's Hospitals (Excluded from PPS)

3400-3499	Continuation of Rural Health Clinics (Provider-based) (3975-3999) Series
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)
3975-3999	Rural Health Clinics (Provider-Based)
4000-4499	Psychiatric Hospitals (Excluded from PPS)
4500-4599	Comprehensive Outpatient Rehabilitation Facilities
4600-4799	Community Mental Health Centers
4800-4899	Continuation of Comprehensive Outpatient Rehabilitation Facilities (4500-4599 Series)
4900-4999	Continuation of Community Mental Health Centers (4600-4799) Series
5000-6499	Skilled Nursing Facilities (See §1060.D.)
6500-6989	Outpatient Physical Therapy Services
6990-6999	Numbers Reserved (formerly Christian Science Sanatoria (Skilled Nursing Services)
7000-8499	**Continuation of Home Health Agencies (3100-3199) Series**
8500-8899	Continuation of Rural Health Clinics (Provider-Based) (3400-3499) Series
8900-8999	Continuation of Rural Health Clinics (Free-Standing) (3800-3974) Series
9000-9799	*Continuation of Home Health Agencies (8000-8499) Series*
9800-9999	*Reserved for Future Use*

Before the reserved numbers identified above are used, obtain clearance from CO.

1/ These facilities (SPRDFs) will be assigned the same provider number whenever they are recertified.

NOTE: Religious Nonmedical Health Care Institutions (RNHCI) are not certified by SAs. The provider numbers for RNHCIs are assigned by the Boston RO.

EXCEPTION - Organ procurement organizations (OPOs) are assigned a six-digit alphanumeric identification number. The first two digits identify the State code. The third digit is the alpha character "P." The remaining three digits are the unique facility identifier.

2779A2 - Supplier Identification Numbers

(Rev. 1, 05-21-04)

Suppliers that are paid by Part B carriers have a ten-digit alphanumeric identification number. The first two digits identify the State in which the supplier is located. (See list of State codes under subsection 1.) The third digit is an alpha character that identifies the type of facility. The remaining seven digits are the unique facility identifier.

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

The last seven digits of the identification numbers for the above suppliers will be within the number series 0000001-9999999.

Examples:

ASC	10C0001062
CLIA	45D0634589
Portable X-Ray	21X0009807

2779B - Numbering System for Medicaid Providers

(Rev. 2, Issued 08-20-04, Effective: N/A/ Implementation: N/A)

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

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

A001-A999	NF (Formerly assigned to Medicaid SNF)
B001-B999	NF (Formerly assigned to Medicaid SNF)
	Expansion of A001-A999
E001-E999	NF (Formerly assigned to ICF)
F001-F999	NF (Formerly assigned to ICF)
	Expansion of E001-E999
G001-G999	ICF/MR
H001-H999	ICF/MR
	Expansion of G001-G999
K001-K999	Medicaid HHAs
L001-L999	*Psychiatric Residential Treatment Facilities (PRTF)*

2779C - Special Numbering System for Units of Hospitals That Are Excluded From Prospective Payment System (PPS) and Hospitals with SNF Swing-Bed Designation

(Rev. 1, 05-21-04)

An alpha character in the third position of the provider number identifies either hospitals with swing-bed approval, or rehabilitation units, or psychiatric units excluded from PPS payment. The first two 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 three digits must be exactly the same as the last three digits of the parent provider.**

EXAMPLE: 21-0101 - ABC Hospital
21-T101 - ABC Hospital Rehabilitation Unit

The RO assigns the following alpha-characters in the third position as indicated:

S - Psychiatric Unit
T - Rehabilitation Unit

U - Swing-Bed Hospital Designation for Short-Term Hospitals
W - Swing-Bed Hospital Designation for Long Term Care Hospitals
Y - Swing-Bed Hospital Designation for Rehabilitation Hospitals
Z - Swing-Bed Designation for Critical Access Hospitals

2779D - Assigning LTC Provider Numbers

(Rev. 1, 05-21-04)

The RO assigns only one provider number per facility. (For purposes of this section, "facility" means an institution providing SNF and/or NF or ICF/MR 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/MR
PROVIDER NUMBER	XX-5000 XX-E000	XX-A000 or	XX-G000

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

FACILITY TYPE	18/19 SNF/NF Dually participating Dually participating	18 SNF or 18/19 Dually participating with SNF or NF DP	18 or 18/19 with SNF or NF DP
PROVIDER NUMBER	XX-5000	XX-5000	XX-5000

FACILITY TYPE	19 NF	19 NF	With ICF/MR DP
PROVIDER NUMBER		XX-A000	XX-A000 or XX-E000 or XX-G000*

***EXCEPTION**: As the chart indicates, the RO always assigns a separate ICF/MR (XX-G000) number to an ICF/MR or ICF/MR 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 Identification Numbers (Non-Participating Hospitals)

(Rev. 1, 05-21-04)

The identification number for emergency hospitals is a six-position alphanumeric code. The first two digits are the State code used for provider numbers. 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 number in Maryland would have the number "21-034E." The RO assigns the numbers 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 identification number. For a non-participating hospital that is now fully participating, see subsection I.

2779F - Merger of Facilities or CHOW

(Rev. 1, 05-21-04)

The RO does not change the identification number merely because the institution has been sold, or has changed ownership or its form of business organization. If two 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/identification number.

When the RO assigns a single identification number, 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 identification number 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 identification number previously assigned to the larger of the merging facilities or, in the case of the merger of two provider corporations, uses the identification number 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 Identification Number

(Rev. 1, 05-21-04)

To notify the intermediary of a correction of a provider number, 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 Identification Numbers

(Rev. 1, 05-21-04)

Provider numbers 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 identification number 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 Identification Numbers

(Rev. 1, 05-21-04)

The RO may give responsibility for assigning identification numbers 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 Identification Numbers

(Rev. 1, 05-21-04)

It is important for both reimbursement and survey purposes to assign the ESRD facility the correct identification number in accordance with the guidelines contained in §2779.A.1.

ESRD facilities and their identification numbers 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 supplier numbers 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 supplier numbers 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 provider number 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 identification number 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 an identification number change. Satellite ESRD facilities must be hospital owned and are considered hospital-based. A hospital may have more than one ESRD satellite facility.

The Medicare identification number 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 identifying ESRD number 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 facility number 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 identification number 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 OSCAR/ODIE data system.

When ROs send correspondence concerning certification to ESRD facilities, the following information should always appear:

- The assigned CMS identification number with caption;
- CMS cross reference provider number 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

Identification Number	**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 Identification Numbers

(Rev. 2, Issued 08-20-04, Effective: N/A/ Implementation: N/A)

HHA Branches are identified by the assignment of a 10-digit alpha-numeric number. Each branch is numbered with the same provider identification number as the parent or subunit with two 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. Branch identification numbers will be used only once. In the event that an HHA branch closes, its unique branch identification number 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 provider identification number is 017001. ABC's three branches would be assigned the branch identification numbers 01Q7001001, 01Q7001002, and 01Q7001003.

2780 - Effective Date of Provider Agreement, Form CMS-1561

(Rev. 1, 05-21-04)

The earliest that Form CMS-1561 (see Exhibit 4A) can be effective is the date the onsite health and safety survey is completed (42 CFR 489.13). The survey findings and the provider's subsequent actions determine whether the agreement is made effective on that date or at a later date. This also applies to the Rural Health Clinic Benefits Agreement (Form CMS-1561A). (See Exhibit 4B.) Note: The entity must be operational prior to survey.

2780A - Compliance With All Requirements

(Rev. 1, 05-21-04)

The agreement is effective on the date the onsite survey s completed if, on the date of the survey the entity meets all Federal health and safety CoPs or Requirements (for SNFs/NFs) and any other requirements imposed by CMS.

2780B - All Requirements Are Not Met on the Day of the Survey

(Rev. 1, 05-21-04)

If the provider fails to meet any of the requirements, the agreement is effective on the earlier of the following dates:

- The date on which the provider meets all requirements;
- Except for SNFs, the date the provider meets all the CoPs and submits an acceptable PoC or approvable waiver request, or both, for standard level deficiencies and/or other deficiencies.; or
- The date on which the SNF or NF is in substantial compliance (See §7001) and submits, if applicable, an approvable waiver request.
- See §2004.A for effective date for CMHCs and FQHCs.

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 ICF-MRs are approvable. LSC waivers for Medicaid NFs require the RO's approval.

Retroactive certifications prior to the survey 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. 1, 05-21-04)

Form CMS-2007 (Exhibit 156) is the official notice to the intermediary of changes in its list of providers (additions, deletions, corrections, recertifications, and terminations).

2783B - RO Responsibility for Form CMS-2007 Completion

(Rev. 1, 05-21-04)

The RO completes a Form CMS-2007 each time a provider is added to or deleted from an intermediary's list of providers or when current provider tie-in records require correction and sends it at the time the provider agreement is countersigned by its office. In termination actions, the RO sends it at the same time it issues official notification to the provider.

2783C - RO Completion of Form CMS-2007

(Rev. 1, 05-21-04)

Item I - Identifying Information - This section is self-explanatory. Complete it in all instances.

Item II - New Provider Certification - The RO completes this section when a new provider enters the program or when a participating provider institution 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, the RO shows the month and day of the provider's fiscal year ending date for Medicare cost report purposes if the information is available or is readily obtainable. The RO contacts the provider directly or solicits the aid of the intermediary to determine the provider's 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 the RO contacts a responsible official or officer of the provider for this information and allows several days for the provider 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 Intermediary - The RO completes this section.

Item IV – Termination -This section is completed when a provider voluntarily or involuntarily ends its participation in the program. If, following a change in ownership, the new owner does not wish to participate, the RO treats it as a voluntary termination and note in the "Remarks" section: "Change of ownership--new owner does not wish to participate."

Item V – Remarks - The RO 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, 1994. As with all providers, this termination takes effect on October 15, 1994, and not at the close of October 15, 1994. 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, 1994, to beneficiaries admitted to the facility **before** October 15, 1994. Do not make payment for new admissions which occur **on or after** October 15, 1994."

2783D – Distribution

(Rev. 1, 05-21-04)

Form CMS-2007 is a 5-part multicolored snap-out form. The RO distributes copies as follows:

1 - White Copy – Intermediary

Whenever there is a change to Form CMS-2007 (new provider, CHOW, change in intermediary, or termination) the RO forwards the white copy to the provider's servicing intermediary.

Refer to the CMS Intermediary and Carrier Directory, CMS Publication HID-1, for the current listing of addresses of commercial, independent, and State intermediaries.

2 - Yellow Copy

Discard.

3 - Pink Copy

Forward to the Medicare Financial Management Branch (or analogous Branch) within your RO.

4 - Gold Copy

Retain copy in your provider file.

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. 1, 05-21-04)

When employees of a participating hospital, SNF/NF or ICF/MR 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

(Rev. 1, 05-21-04)

The Omnibus Budget Reconciliation Act (OBRA) of 1986 amended the Social Security Act (the Act) by adding §1138 authorizing the Secretary to provide payment under Medicare and Medicaid 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 (see §2812.1), or has been certified or recertified by the Secretary within the previous two 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 Public Health Service Act (PHSA). (The United Network for Organ Sharing (UNOS) operates the OPTN under a contract with PHS.)
- Allocates organs, within its service area, and nationally, in accordance with medical criteria and the policies of the OPTN; and
- Is designated or redesignated 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.

2810.1 - Definitions

(Rev. 1, 05-21-04)

Certification or recertification means a CMS determination that an entity meets the standards for a qualified OPO at 42 CFR 486.304 and is eligible for designation if it meets the additional conditions for coverage in 42 CFR 486.306 and 486.310.

Designation or redesignation means CMS approval of an OPO for coverage of its services to transplant centers.

Interim designation period means a designation for a period of time, not to exceed 180 days, after the normal designation period has expired.

Open area means a service area for which CMS has notified the public that it is accepting applications for designation.

Service area means a geographical area of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs and that either includes an entire standard metropolitan statistical area or does not include any part of such an area and that meets the certification standards.

Transplant Center means a hospital approved by the OPTN that furnishes directly, for one or more specified organs, transplant services and other medical and specialty services for the care of transplant patients.

Metropolitan Statistical Area encompasses the current metropolitan area categories (as defined by the Office of Management and Budget based on the 1990 Census) of primary metropolitan statistical areas and New England County metropolitan statistical areas.

2811 - OPO Application Process - RO Responsibilities

(Rev. 1, 05-21-04)

The RO publishes a public notice in area newspapers when a service area is open for competition. The RO provides each interested applicant with Form CMS-576, OPO Request for Designation as an OPO (Exhibit 167), and Form CMS-576A, Agreement with OPO Pursuant to §1138(b) of the Act. (See §2812.)

Procedures for the review and approval of new applicants include:

- Initial submission of the application;
- Initial review of the application;
- Submission of additional information if there is a need for additional information; and
- A final review and determination made.

If a determination cannot be made prior to the end of the designation period, the RO designates an OPO for an interim recertification period not to exceed 180 calendar days. The organization that is designated for an interim period must meet all requirements of §371(b) of the PHSA which include:

- Is a nonprofit entity;

- Has accounting and other fiscal procedures necessary to assure the fiscal stability of the organization;

- Has an agreement with the Secretary to be paid under title XVIII of the Social Security Act for the procurement of kidneys;

- Has procedures to obtain payment for non-renal organs provided to transplant centers;

- Has a defined service area that is of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs, and that either includes an entire metropolitan statistical area or does not include any part of the area;

- Has a director and such other staff, including organ donation coordinators and organ procurement specialists necessary to effectively obtain organs from donors in its service area; and

- Has a board of directors or an advisory board that contains members specified by the Secretary.

The OPO must not be out of compliance with any other requirements of §§1138(b)(1)(B) through (E) of the Act which are:

- Is a qualified organ procurement organization or has been certified or recertified by the Secretary within the previous two years as meeting the standards to be a qualified OPO;

- Meets the requirements that are applicable under such title for organ procurement agencies;

- Meets performance-related standards prescribed by the Secretary;

- Is a member of, and abides by the rules and requirements of, the Network; and

- Allocates organs, within its service area, and nationally, in accordance with medical criteria and the policies of the Network.

The applicable Conditions for Coverage are found at 42 CFR 486.304 through 486.310 that are listed in Exhibit 168.

2812 - OPO Initial Designation Requirements

(Rev. 1, 05-21-04)

The initial designation is for two years. The OPO must at the time of application and throughout the period of designation meet the standards at 42 CFR 486.304 - General Qualifications, 42 CFR 486.306 - Qualifications for Designation, and 42 CFR 486.308 - Participation in the OPTN. The OPO is not required to demonstrate compliance with the standards at 42 CFR 486.310(a)(1) and (2) for the years prior to calendar year 1996. The OPO that is initially designated for a particular service area is exempt from meeting the performance standards at 42 CFR 486.310(b)(1) through (5) for its first 2 years of designation as the OPO for that area.

2812.1 - Public Health Service (PHS) Grantees

(Rev. 1, 05-21-04)

The RO verifies that the organization is a qualified OPO operating under a grant made under §371(a) of the PHSA. (See Exhibit 169.) Updated information about PHS grantees may be obtained by calling the CO.

2812.2 - OPO Network Membership

(Rev. 1, 05-21-04)

The RO verifies that the organization is a member of the OPTN, currently United Network for Organ Sharing. Exhibit 169 lists the United Network for Organ Sharing members. Updated information about the current OPTN members is available from the CO. The organization must meet the requirements of the current OPTN for the allocation of organs within both the service area and nationally. The OPTN will inform CMS of any OPO that fails to meet those requirements. No OPTN policy will be considered a rule or requirement of the OPTN unless the Secretary has formally approved it. No Medicare or Medicaid hospital or OPO is considered out of compliance with §1138(b)(1)(D) of the Act unless CMS has given the OPTN formal notice that it approves the decision to exclude the entity from the OPTN and also has notified the entity in writing. The RO sends the Model OPO Denial Letter (see Exhibit 170) to those organizations whose application is denied because they do not meet the statutory or regulatory requirements for designation. The RO sends the Model OPO Denial Letter (see Exhibit 171) to those organizations whose application meets the statutory or regulatory requirements, but is denied because of competitive factors only.

2812.3 - Designation of One OPO for a Service Area

(Rev. 1, 05-21-04)

To assure that the RO is not designating more than one OPO per service area, it should plot the proposed service areas of all applicants prior to taking any certification action. Under the statute, it is critical that the service areas of OPOs not overlap. If an applicant designates a service area that crosses RO boundaries, the physical location of the OPO's main office determines which RO controls the review of the application. In these situations, coordinate certification action between the appropriate RO(s).

If there is no competition within a given service area and the applicant meets the statutory and regulatory requirements, the RO sends the organization the Model OPO Approval Letter (see Exhibit 172). If the OPO is not hospital-based, assign a provider number with an alpha "P" in the third position of the provider number. For example, the RO inputs the information 21P001 into the Online Survey Certification and Reporting System/Online Data Input and Edit (OSCAR/ODIE) systems.

Each applicant must describe its unique service area. Whenever two or more applications specify the same or overlapping areas and both meet the statutory and regulatory requirements, the RO makes a designation based upon the tie breaking criteria specified at 42 CFR 486.316. (See §2813.)

NOTE: If the OPO is hospital-based, the hospital's intermediary will service the OPO and no special provider number is needed.

2812.4 - Finding of Compliance

(Rev. 1, 05-21-04)

If the OPO is in compliance with all requirements, the RO redesignates it for 2 years. Send the Model Letter: OPO Approval (Exhibit 172).

2812.5 - Finding of Noncompliance

(Rev. 1, 05-21-04)

The RO terminates OPOs which are not in compliance with the following conditions for coverage:

42 CFR 486.304 (OPO Designations - General);

42 CFR 486.306 (Qualifications required of an organization for it to be a designated OPO);

42 CFR 486.308 (Organ Procurement and Transplantation Network Participation); and

42 CFR 486.310(b) (Performance standards for OPO).

The RO processes an OPO found not in compliance with these requirements as if it is an unqualified applicant. (See termination procedures at 42 CFR 4103.3.) Send the OPO Model Denial Letter (see Exhibit 170). The RO then opens the service area for competitive application. (See §2817.)

The RO schedules OPOs for terminations that are not in compliance with the requirements, at any time, in accordance with the procedures at §3012, Termination of Organ Procurement Organizations.

If an OPO is not in compliance with the qualifications for 24 donors, and the OPO has historically been in compliance with the requirement, the RO initiates an exception process as specified in 42 CFR 486.307(d)(3) or (d)(4). To qualify for an exception, the OPO must demonstrate that:

- It failed to meet the 24-donor criterion due to unusual circumstances beyond its control;
- It has historically maintained a service area sufficient to assure effective procurement and equitable distribution (achieved the 24 donors per year); and
- It has a specific plan to achieve 24 donors per year.

2813 - OPO Designation Procedures in Service Areas With Competing Applications

(Rev. 1, 05-21-04)

The RO designates only one OPO per service area. If more than one OPO applies and meets the requirements in a given service area, the parties may be able to negotiate a settlement of the conflicting area between or among themselves. The RO may approve a service area smaller than requested by an OPO if doing so will not injure an applicant or an existing OPO's ability to satisfy the OPO designation requirements of §§2812 - 2812.5. The RO must not reduce an area by splitting a Metropolitan Statistical Area. Otherwise, in determining which OPO to designate, the RO considers the following:

- Prior experience, including the previous year's experience in terms of the number of organs procured and wasted and average cost per organ;
- Actual number of donors compared to the number of potential donors;
- The nature of relationships and degree of involvement with hospitals in the service area;

- Bed capacity associated with the hospitals with which the organizations have a working relationship;
- Willingness and ability to place organs within the service area; and
- Proximity of the OPO to the donor hospitals.

The RO designates the organization that meets these requirements more substantially and fully documents the basis of its decision. Once a decision is made, the RO follows the designation procedures. (See §2812.)

2814 - Redesignation of OPOs

(Rev. 1, 05-21-04)

To be redesignated as the OPO for a service area, the OPO must be recertified within a two-year period. All OPO recertification reviews are to be conducted by the RO's staff. It is at the RO's discretion whether these reviews will be conducted onsite. The SAs have no responsibilities for OPO certifications or designations. The RO informs the OPO in writing at the beginning of the calendar year of their anniversary date and of its intent to recertify them. The RO follows the Procedures and Guidelines for OPOs (see Exhibit 168).

2815 - OPOs Operating in a Noncontiguous U.S. State

(Rev. 1, 05-21-04)

OPOs operating in a noncontiguous U.S. State, U.S. territory, or U.S. commonwealth, such as Hawaii and Puerto Rico, may be granted an exception from the performance standards listed in 42 CFR 486.310(c) because of special geographically-related characteristics, such as difficulty in transporting organs to the mainland, that impede satisfaction of the national rate of organ procurement. They must meet the performance standards at 42 CFR 486.310(c) and maintain working relationships with hospitals and/or transplant centers and 50 percent of the national average of all OPOs for kidneys recovered and transplanted per million population, respectively.

2816 - Interim Designations

(Rev. 1, 05-21-04)

An interim designation or redesignation is a period of time needed to finalize the designation determination. The interim designee may either be the OPO previously designated for the service area or another organization. The interim designation period does not exceed 180 calendar days after the normal designation period has expired. The designee must meet all requirements of §371(b) of the PHSA and must not be out of compliance with the requirements of §§1138(b)(1)(B) through (E) of the Act.

2817 - Opening Service Area for Competition

(Rev. 1, 05-21-04)

The RO opens the service area for competition when:

- The normal two-year designation period or brief interim redesignation period has ended;
- The designation status of the existing OPO is terminated;
- When no OPO has been designated for the area; or
- An OPO ceases to operate, or CMS has reasonable grounds for anticipating it will cease to operate.

In cases of urgent need (medically or ethically unsound practices), the RO terminates the OPO immediately. If an OPO voluntarily or involuntarily withdraws from the program, or if existing OPOs merge or consolidate operations without the Secretary's approval, the RO informs CO. If the OPO fails to get the Secretary's approval of a change in its service area, the RO terminates it and opens the service area for competitive applications. (See §2813.) The service area remains open until an OPO is designated. (See Exhibits 173, 174, and 175.)

2818 - Unserved Service Area

(Rev. 1, 05-21-04)

A service area that contains at least one hospital will not go unserved by an OPO. An OPO that does not meet the performance standards or is performing below standards will not be terminated as long as another OPO does not compete for the service area. The OPO will retain its designation and submit a corrective action plan if no other OPO, that is performing acceptably, is willing to assume the service area. (See Exhibit 176.) The designation will continue until the next re-designation period.

2819 - Changes in Ownership or Service Area

(Rev. 1, 05-21-04)

The RO requires the OPO to notify it in writing if it is considering a change in ownership or a change in its service area. This notification is made prior to the change. The RO assures that the new organization has not changed to an extent that it no longer satisfies the requirements for Medicaid/Medicare participation or is no longer, in essence, the organization that was designated. The RO considers a change in ownership if one or more entities merge or consolidate with another.

For mergers or consolidation, the OPOs must submit a new application form. The reorganized OPO's period of designation remains the same. If more than one designated OPO is involved, the designation period that is the longest becomes the designation period. If a designated OPO requests a change in its service area, the RO must approve the change before it can be effective. In the case of a service area change that results from a change in ownership, the entities must submit the information required in the application (see Exhibit 167), or other written documentation. The RO determines that the new entity continues to satisfy the Medicare/Medicaid requirements. If the new entity meets all the necessary requirements, the RO sends a letter notifying it of its period of designation. If the entity has changed and does not satisfy the requirements for Medicare/Medicaid participation, the RO terminates the OPO and declares the service area open.

Federally Qualified Health Centers

2825 - Federally Qualified Health Centers (FQHCs) - Citations and Description

(Rev. 1, 05-21-04)

2825A - Citations

(Rev. 1, 05-21-04)

Section 4161(a)(2) of OBRA '90 (P.L. 101-508) amended §1861(aa) of the Act and established FQHC services as a new benefit under the Medicare program effective October 1, 1991. The statutory requirements that entities must meet to be an FQHC are at §1861(aa)(4) of the Act. Regulations establishing the FQHC benefit were published on June 12, 1992, in the "Federal Register" (57 FR 24961) and became effective on the date of publication. 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. 1, 05-21-04)

FQHCs are considered "suppliers" under Part B of Medicare and are paid Part B benefits for FQHC services. An entity is eligible to qualify as an FQHC if it:

- Is receiving a grant under §330 of the Public Health Service (PHS) Act;
- Is receiving funding from a grant under a contract with the recipient of the grant and meets the requirements to receive a grant under §330 of the PHS Act;
- Is determined by the Secretary to meet the requirements for receiving such a grant (look-alikes) based on the recommendation of the Health Resources and Services Administration (HRSA); 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. 1, 05-21-04)

2826A - General

(Rev. 1, 05-21-04)

The SA survey and certification process does not apply to FQHCs. HRSA will supply CMS with a list of those entities that meet the first or second grant requirements above. For those entities requesting participation as look-alikes, HRSA will review the entities' applications and provide CMS with recommendations regarding whether they meet the grant requirements. CMS will make the final determination whether entities meet the requirements. (Part D concerns tribes and tribal organizations and urban Indian organizations attempting to qualify as FQHCs.)

ROs are responsible for approving and obtaining Medicare agreements from entities approved as FQHCs for Medicare participation. The RO notifies the FQHCs, HRSA, Central Office, the Indian Health Service, as appropriate, and the appropriate intermediaries of approvals. Provider-based FQHCs use the same intermediary as the host facility. The RO sends the tie-in-notice for independent FQHCs to the national FQHC Intermediary (one intermediary services all independent FQHCs). Any new provider-based FQHCs applications will be forwarded to the national Intermediary for processing. The National Intermediary will forward completed applications to the RO for approval. The RO will send the tie-in notice to the provider's host intermediary and also send notification of approval to the National Intermediary.

The RO investigates complaints that allege an FQHC does not meet applicable Medicare requirements.

2826B - Request to Participate

(Rev. 1, 05-21-04)

To participate in the Medicare program, FQHC applicants must submit to the RO:

- A signed and dated 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 benefit agreement;

- A completed FQHC crucial data extract sheet (Exhibit 178);

- HRSA "Notice of Grant Award" or Look-Alike Status;

- A copy of the form that lists the service sites "Exhibit B" or "Form 5-Part B from the plan of scope covered by this grant;

- CLIA Certificate;

- State License (If Applicable); and

- The application is initially submitted to the FI and the FI forwards the completed application to the RO.

2826C - Information to Be Sent to Applicant by the RO

(Rev. 1, 05-21-04)

Mail applicants copies of:

- Cover letter to FQHC applicants (Exhibit 179);

- FQHC Crucial Data Extract (Exhibit 178);

- Attestation Statement for FQHCs (Exhibit 177); and

- The statutory requirements (§1861(aa)(4)), and applicable FQHC regulations.

These documents are forwarded to the applicant by the National FQHC Intermediary for the RO.

2826D - Processing Requests

(Rev. 1, 05-21-04)

The FI will review all paperwork for complete data entry and forward to the RO. The RO verifies that the applicant's attestation statement is complete, and that the applicant's enrollment information has been verified by the National FQHC Intermediary. Each RO will have a primary point-of-contact (POC) for coordination with the National FQHC Intermediary and central office.

- For applicants the RO confirms their attestation by reviewing the list of entities that HRSA determined meet the requirements of §1861(aa)(4) of the Act. The RO informs applicants who do not meet §1861(aa)(4) requirements that they are not eligible for FQHC status and should contact HRSA to establish their eligibility.

- 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 their attestation by

using the Indian Health Care Service (IHS) lists of facilities or organizations provided by CO or by contacting Central Office or the IHS for applicants not on the list.

2826E - RO Assigning Applicants an FQHC Provider Number

(Rev. 1, 05-21-04)

The RO assigns each FQHC (including satellites, expansions and mobile units) approved an identification number using the 1800-1989 series. This includes RHCs converting to FQHCs.

An RHC cannot concurrently be approved for Medicare as both an RHC and FQHC. Retire the provider number of a RHC converting to an FQHC and notify the RHC of its new number.

If after 30days the National FQHCI Intermediary has not received RO approval, an e-mail will be forwarded to the RO POC.

2826F - RO Completion of Forms

(Rev. 1, 05-21-04)

The RO completes the State/County and State/Region codes on the FQHC Crucial Data Extract (Exhibit 178) after the FQHC completes the other sections and submits it with an attestation statement.

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 notify intermediaries of changes (additions, deletions, and corrections) in their lists of providers. (See §2783.) If the FQHC indicates on the Crucial Data Extract that it is part of an existing Medicare/Medicaid provider, the RO sends the tie-in-notice to the provider's intermediary and for independent FQHCs to the intermediary.

2826G - Complaint Investigations

(Rev. 1, 05-21-04)

The RO uses the instructions in the §5101, the Act, FQHC regulations, and the appropriate sections of the Interpretive Guidelines for RHCs (Appendix G) in making determinations whether Medicare requirements are met.

When the RO refers a complaint to another agency, Indian Health Service (IHS) or Health Resources Services Administration (HRSA), for investigation action; the RO must

request a written report on the results of the investigation. Regardless of who conducts the investigation, the RO has the responsibility to assess compliance with Federal conditions or requirements. The time frames for investigations are not altered by the referral to another agency.

IHS investigation referrals are coordinated with RO Indian Health Service Coordinators. HRSA investigations referrals are coordinated with HRSA's Bureau of Primary Care's Office of Policy Evaluation and Data.

2826H - Effective Date

(Rev. 1, 05-21-04)

The effective date for an FQHC's Medicare participation is the date the RO signs the FQHC agreement after determining that all Medicare requirements, including enrollment requirements, are met. (See §2004). The FI will send you a letter of recommendation notifying you when it has verified all information contained in the providers application.

If the application is complete and all requirements have been met when the RO reviews the application, the RO will use the date on the intermediary's recommendation letter as the effective date. You must sign the attestation on the date of your review. Your letter to the FQHC will reflect an effective date that corresponds with the FI's date of recommendation.