CHAPTER 2

THE CERTIFICATION PROCESS

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Identification of Providers and Suppliers and
Related Presurvey Activities

2000. CERTIFICATION SURVEYS - CITATIONS AND RESPONSIBILITY

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 l902(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 Part 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 a SA function. When the SA certifies for Medicare purposes, it is submitting evidence and recommendations for a RO determination. When the SA certifies for Medicaid purposes, it is reporting its own adjudicative determination.

2002. MEANING OF PROVIDERS AND SUPPLIERS

The Medicare law differentiates between providers and suppliers. The general distinction between providers and suppliers is that Aproviders@ 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.)

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 Part 498.2.)

Portable x-ray services, rural health clinics (RHCs), end stage renal disease (ESRD) facilities, physical therapists in independent practice (PTIPs), occupational therapists in independent practice (OTIPs), 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. 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.

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 refers to all providers of services (including individual practitioners and groups of practitioners).

2003. SA IDENTIFICATION OF POTENTIAL PROVIDERS AND SUPPLIERS

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 HCFA or the SMA about providers and suppliers that are potential program participants.

A. Assisting Applicant Providers and Suppliers.--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 an initial certification survey shows that all the CoPs, conditions for coverage, or Requirements for SNFs are met, or the date on which the provider or supplier submits an acceptable PoC or an approved waived 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 Part 442.13 and 489.13.) Since there are not any Medicare conditions for CMHCs and FQHCs, the effective date is the date the RO signs the provider agreement, after determining that all Medicare requirements, including enrollment are met.

B. Initial Certification "Kits".--When an entity wishes to participate initially in either or both programs, the SA mails the initial certification materials under cover of the appropriate form letter. (See Exhibits 1A-1F and Exhibit 63.) As part of the enrollment process (see §2005), the State survey agency is responsible for providing Form HCFA-855 to most Medicare provider/supplier applicants (those that the State survey agency currently surveys on behalf of HCFA) as part of the initial certification package. The RO must provide Form HCFA-855 to applicants that are not surveyed by the State.

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 a facility 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, you must notify the RO immediately. The SA works in conjunction with the RO and the intermediary to gather the appropriate documentation from the entity that supports its position 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, along with the Title VI Assurance of Compliance with Civil Rights (Form HHS-690) or the comparable form, the Financial Solvency Statement (Form HCFA-2572), the intermediary preference form, and the documentation submitted by the entity along with the SA's recommendation regarding provider-based status under the Medicare program to the RO. In Title XIX-only cases, the SA sends the HHS-690 or comparable form to the SMA.

The SA refers questions about intermediaries, payment rules, financial solvency, or title VI clearance to the RO or the State Medicaid agency, as appropriate.

2004. PROVIDER-BASED DESIGNATION

The following instructions must be used by the RO with the assistance of the SA and the fiscal intermediary, in making determinations regarding provider-based and free-standing designation decisions. 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 free-standing entities are paid appropriately.

After reviewing the documentation from the entity which supports its request and the recommendations of both the SA and the fiscal intermediary, the RO makes a determination and notifies the provider and its fiscal intermediary in writing of its decision.

The use of these criteria in making provider-based designations/determinations may result in identification of previous provider-based decisions that would not be in accordance with the criteria above. In those instances, the ROs are not precluded from taking a corrective action on such erroneous designations/determinations. However, any corrective action is to be applied prospectively.

Designation Requirements.--The following requirements apply to provider-based determinations made in conjunction with all initial certification decisions and recertifications, as well as decisions of providers to add new services or expand their existing services, 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.

1. The entity is physically located in close proximity of the provider where it is based, and both facilities serve the same patient population (e.g., from the same service, or catchment area);

2. The entity is an integral and subordinate part of the provider where it is based, and as such, is operated with other departments of that provider under common licensure (except in situations where the State separately licenses the provider-based entity);

3. The entity is included under the accreditation of the provider where it is based (if the provider is accredited by a national accrediting body), and the accrediting body recognizes the entity as part of the provider;

4. The entity is operated under common ownership and control (i.e., common governance) by the provider where it is based as evidenced by the following:

" The entity is subject to the bylaws and operating decisions of the governing body of the provider where it is based;

" The provider has final responsibility for administrative, final approval for personnel actions, and final approval for medical staff appointments in the provider-based entity; and

" The entity functions as a department of the provider where it is based with significant common resource usage of buildings, equipment, and service personnel on a daily basis.

5. The entity director is under the direct day-to-day supervision of the provider where it is located, as evidenced by the following:

" The entity director or individual responsible for day-to-day operations at the entity maintains a daily reporting relationship and is accountable to the chief executive officer of the provider and reports through that individual to the governing body of the provider where the entity is based; and

" Administrative functions of the entity, e.g., records, billing, laundry, housekeeping, and purchasing are integrated with those of the provider where the entity is based.

6. Clinical services of the entity and the provider where it is located are integrated as evidenced by the following:

" Professional staff of the provider-based entity have clinical privileges in the provider where it is based.

" The medical director of the entity (if the entity has a medical director) maintains a day-to-day reporting relationship to the chief medical officer or other similar official of the provider where it is based

" All medical staff committees or other professional committees at the provider where the entity is based are responsible for all medical activities in the provider-based entity;

" Medical records for patients treated in the provider-based entity are integrated into the unified records system of the provider where the entity is based;

" Patients treated at the provider-based entity are considered patients of the provider and have full access to all provider services; and

" Patient services provided in the entity are integrated into corresponding inpatient and/or outpatient services, as appropriate, by the provider where it is based.

7. The entity is held out to the public as part of the provider where it is based (e.g., patients know they are entering the provider and will be billed accordingly);

8. The entity and the provider where it is based are financially integrated as evidenced by the following:

" The entity and the provider where it is based have an agreement for the sharing of income and expenses; and

" The entity reports its cost in the cost report of the provider where it is based using the same accounting system for the same cost reporting period as the provider where it is based.

2005. MEDICARE HEALTH CARE PROVIDER/SUPPLIER ENROLLMENT

The Health Care Financing Administration (HCFA) is authorized to collect the information requested on the Form HCFA-855 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, HCFA 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 and provide all necessary documentation to show they are qualified to perform the services for which they are 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 HCFA uses to ensure that providers/suppliers meet these requirements is referred to as the enrollment process. The Medicare General Enrollment Health Care Provider/Supplier Application (Form HCFA-855) is the document used to collect information and documentation to be verified to assure that the applicant is qualified and eligible to participate in the Medicare program. This form standardizes 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 HCFA-855 need only be completed for initial certifications and changes of ownership. An applicant will complete the Form HCFA-855 application in order for HCFA to obtain certain required information before a survey is conducted. The Form HCFA-855 replaces the Form HCFA-1513 for all initial Medicare providers/suppliers and changes of ownership. The Form HCFA-855 or Form HCFA-855C (Change of Information Health Care Provider/Supplier Application) will be used for subsequent updates to these providers/suppliers. HCFA will continue to collect the Form HCFA-1513 for providers/suppliers that have not completed the Form HCFA-855, for Medicaid only providers and for CLIA laboratories that do not participate in Medicare. The Form HCFA-855 will be processed by either the fiscal intermediary or the carrier, depending on which contractor is responsible for processing bills or claims for the provider/supplier. The State survey agency will be responsible for providing the Form HCFA-855 to most Medicare provider/supplier applicants (those that the State survey agency currently survey on behalf of HCFA) as part of the initial certification package. The RO will provide the Form HCFA-855 to applicants that are not surveyed by the State. **On page I (roman numeral one) of the HCFA-855 stamp or write in the address of the State agency or RO, whomever the form will be returned to, in the space entitled "Upon completion, return this application and all necessary documentation to:".** It is essential that information be inserted in this section so that the applicant will know the address to mail the Form HCFA-855 when it is completed. Providers/suppliers should be informed of the enrollment process so that they do not expect instant enrollment. The State survey agency or RO will supply the applicant with an intermediary/carrier contact person's name and telephone number should the applicant have any questions concerning the form. When the State survey agency or RO, as appropriate, receives the Form HCFA-855, it should photocopy, log receipt of the form, and forward the Form HCFA-855 that contains an original signature to the appropriate contractor as follows:

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

o Carrier.--Send the carrier the Form HCFA-855 for portable x-ray suppliers, ambulatory surgical centers (ASC), and physical therapists in independent practice/occupational therapists in independent practice (PTIP/OTIP).

o Both Fiscal Intermediary and Carrier.--Rural health clinics (RHC), federally qualified health centers (FQHC), and laboratories may bill either the intermediary, the carrier or both. For these facilities, send the Form HCFA-855 to whomever the applicant indicates (intermediary or carrier) at the top of page one of the Form HCFA-855 for the item entitled "Where will applicant be submitting billings?" If the applicant checks "Both," send the Form HCFA-855 to the intermediary.

o Specialty Intermediaries.-- Send the specialty intermediary the Form HCFA-855 for home health agencies (HHA), hospices, independent RHCs, freestanding FQHCs, and Christian Science Sanatoria. (See §2005.J for further information on specialty intermediaries.)

NOTE: The Form HCFA-855 will be distributed and routed by the RO for OPOs, FQHCs, and Indian Health Service (IHS) hospitals.

A. Initial Certifications.--Distribute the Form HCFA-855 to applicants who request enrollment in the Medicare program. The Form HCFA-855, along with the Intermediary Preference Form (for fiscal intermediary-serviced providers), and a list of available intermediaries or carriers will be a part of the initial certification packet for new applicants. The Form HCFA-855 does not replace existing certification applications. Provider specific forms will continue to be used in addition to the Form HCFA-855. (Forms that are to be sent to a specific provider are listed in Exhibit 63.) **Insert the name and address of the individual in your office to whom the Form HCFA-855 should be returned in the space marked "Upon Completion, return this application and all necessary documentation to:," located on page I of the instructions of the Form HCFA-855.** The RO will mail out applications for applicants applying to become certified as OPO, FQHC, IHS hospitals, and for CMHC when the State survey agency has no involvement. The State survey agency will mail out applications to applicants requesting to become any other type of provider or supplier. The State survey agency or RO will supply the applicant with the name and telephone number of a fiscal intermediary/carrier contact person to assist the applicant in completing the form. The applicant will complete all forms in the packet and return them to the State survey agency or the RO, whichever office originally mailed out the Form HCFA-855 to the applicant. It is important that all application packages be completed by prospective providers as early as possible since the initial clearance of the Form HCFA-855 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, photocopy and log the receipt of the Form HCFA-855 and forward the signed original Form HCFA-855 and any supporting documentation related to the Form HCFA-855 to the appropriate intermediary or carrier. A list of fiscal intermediaries and carriers will be provided by the RO and maintained by the State survey agency. Ensure that the Form HCFA-855 contains an original signature. The State survey agency will be responsible for verifying any licensure documents that they have issued and have control over. Do not review the Form HCFA-855 for completeness or accuracy, and do not provide guidance in completing the Form HCFA-855 because this will be done by the appropriate intermediary/carrier. However, do look at the item entitled, "Where will applicant be submitting billings?" at the top of page one of the Form HCFA-855 to determine if the provider is billing a fiscal intermediary or carrier, and forward the application to the appropriate entity. If the applicant checks "Both" on this item, send the original application to the fiscal intermediary. The RO will then send a copy of the Form HCFA-855 to the carrier after the application has been approved. The fiscal intermediary/carrier will be responsible for verifying the Form HCFA-855 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.

1. Request for Additional Information.--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 the initial distributor of the application, 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.

2. Approval.--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 HCFA-855. The notification will be in written form. It will be accompanied by a copy of the completed Form HCFA-855, if changes were made to the Form HCFA-855 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.

a. Applicant In Compliance.--The surveying agency (State survey agency/RO) surveys the provider/supplier and finds 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 (HCFA-2007), when applicable, and/or a copy of the provider's approval letter which 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 HCFA-855 that the intermediary sent with the recommendation of approval. On page one of the Form HCFA-855 if "Both" is checked for the item entitled "Where will applicant be submitting billings?", then also send a copy of the Form HCFA-855, and the provider's approval letter which includes the provider's identification number to the carrier.

b. Applicant Not in Compliance.--The surveying agency surveys the provider/supplier and finds 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 3 months of the date of the denial letter, then the previous Form HCFA-855 that was approved by the intermediary/carrier may still be used for this provider/supplier. The enrollment process does not have to be repeated. If the State surveys the applicant later than 3 months from the date of the denial letter, then the applicant will have to submit a new Form HCFA-855. The State survey agency will forward the new Form HCFA-855 to the intermediary/carrier. The applicant has to repeat the enrollment process if it is surveyed after 3 months from the date of the denial letter.

3. Denial.--After a complete review and verification of the application, the intermediary or carrier may make a recommendation of denial to the RO for the following reasons:

o 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).

o 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".

o 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.

o 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.

o 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.

o 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.

a. 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 intermediary/carrier notifies the RO and the State survey agency of the recommendation for denial. 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:

ABased 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):

o [Name(s) of excluded persons or organizations] is/are currently excluded from participating in the Medicare program by the Office of the Inspector General.

o [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.

o [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.

o [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.

o [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.

o [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 days from the date of this notice to appeal this denial."

Exhibit No. 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.

b. 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 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 HCFA has relied upon is incorrect, or that HCFA has misapplied or misinterpreted accurate information. An example of a fact-based appeal would be if there is 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.

(1) Applicant Submits Information or Documentation to Appeal Denial.--The applicant may submit information or documentation to support an appeal within 60 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 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.

(a) 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 HCFA-855 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.

(b) 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 which will 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.

(2) 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 day appeal time frame, then the denial remains in effect. No further action is necessary.

B. Recertification.--[RESERVED]

C. Clinical Laboratory Improvement Amendments of 1988 (CLIA) Laboratories.--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 HCFA-855 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.

The SA will mail out the Forms HCFA-116, HCFA- 855 or HCFA-1513, and any other forms needed for CLIA registration to the laboratory. A CLIA laboratory is only required to complete a Form HCFA-855 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 the Forms HCFA-116 and HCFA-855. Inform the laboratory, via a cover letter on the Form HCFA-855, that any questions about the form should be addressed to the intermediary/carrier. The laboratory will complete and return the Form HCFA-116 and the Form HCFA-855 to the SA. The SA will enter the Form HCFA-116 into the CLIA data system, and the system will assign a CLIA number to the laboratory. The SA will forward the Form HCFA-855 to the intermediary/carrier. 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 HCFA-855. For CLIA laboratories, the intermediary/carrier will be responsible for all aspects of the Form HCFA-855 and Medicare enrollment processing. After the intermediary/carrier has reviewed and verified the Form HCFA-855, it will send a completed copy of the Form HCFA-855 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 HCFA-855 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 HCFA-116 and HCFA-1513 and return them to the State survey agency. The Form HCFA-1513 will be retained in the provider file. The Form HCFA-1513 will be used for identifying owners, operators, and directors in case of existing or future CLIA sanctions. The Form HCFA-1513 will be reviewed by the State survey agency or the RO to ensure that the above mentioned individuals are not currently sanctioned

under CLIA. Information on the Form HCFA-1513 will not be reviewed by fiscal intermediaries/carriers, and the other criteria applicable to Form HCFA-855 review under Medicare provider enrollment requirements will not apply.

D. Supplementary Applications.--Additional application forms are used for supplementary purposes to support the Form HCFA-855. These applications are the Medicare Change of Information Health Care Provider/Supplier Application (Form HCFA-855C) and the Medicare Individual Reassignment of Benefits Health Care Provider/Supplier Application (Form HCFA-855R).

1. Form HCFA-855C.--This application is used for reporting changes in provider/supplier information. Changes on this form are those made most frequently by providers/suppliers. The following information only may be updated by using the Form HCFA-855C:

- Name;
- Telephone number;
- Fax number;
- E-mail address;
- Mailing address;
- Practice location address;
- Pay to address;
- Billing agency address;
- Specialty;
- Addition/deletion of authorized representative;
- Potential termination of current ownership;
- Deactivation of Medicare billing number(s); and
- Surety bond change or renewal information.

When a provider experiences a change of ownership the current owner will check the box marked "potential termination of current ownership" on the Form HCFA-855C.

Providers/suppliers that previously enrolled using the Form HCFA-855 will complete the Form HCFA-855C to report any of the changes stated above. The provider/supplier completes and submits the Form HCFA-855C directly to the State survey agency. The State survey agency may make and retain a copy of the Form HCFA-855C for its records. The State survey agency immediately forwards the completed Form HCFA-855C to the intermediary/carrier. There should not be any delay in sending the form to the intermediary/carrier. If the provider/supplier submits the Form HCFA-855C directly to the intermediary/carrier, then the intermediary/carrier will forward a copy of the form to the appropriate State survey agency. Voluntary use of the Form HCFA-855C is encouraged for providers/suppliers that were previously certified without completing the Form HCFA-855. However, these providers/suppliers may submit these changes in writing on letterhead with an authorized signature.

2. Form HCFA-855R.--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 HCFA-855R. Organizations that are likely to receive reassigned benefits are: hospitals, hospices, SNF, ESRD, RHC, CORF, FQHC, and CMHC.

The State survey agency will mail the Form HCFA-855R out to applicants that request the form. The State survey agency should inform the applicant that any questions concerning the Form HCFA-855R

should be directed to the intermediary or carrier. When the State agency receives the Form HCFA-855, it will forward the Form HCFA-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.

E. Application Changes.--Application changes are changes to any items on the Form HCFA-855 that cannot be reported on the Form HCFA-855C. These changes require the submission of the appropriate updated sections of the Form HCFA-855 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 HCFA-855 with the updated/changed information to the State agency or RO that distributed the initial application.

F. Changes of Ownership.--See §3210 for a full discussion of change of ownership (CHOW). These procedures apply to all provider/supplier types, except PTIP/OTIP.

1. CHOW Occurs.--For a CHOW, the current owners will submit a Form HCFA-855C citing the termination of current ownership. The current owner will check the box marked "potential termination of current ownership" on the Form HCFA-855 C 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 HCFA-855.

The current and new owners will submit the Form HCFA-855 and Form HCFA-855C along with any supporting documents to the State survey agency. The State agency will make a copy of each form along with any supporting documentation, and immediately forward them to the intermediary/carrier. The State agency may forward each form as it is received. The State does not need to wait to receive both forms before forwarding to the intermediary/carrier. The State agency will simultaneously forward copies of the forms with documentation to the RO for review. The RO has the responsibility 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 State 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 HCFA-855 and HCFA-855C and may take one of three actions on a CHOW: recommendation for approval, recommend for denial, or request for additional information.

a. Recommendation for Approval 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 recommendation for approval of 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 HCFA-855 and HCFA-855C, if any changes were made to the forms.

(1) RO Determines CHOW Has Occurred.--If the RO determines that a CHOW has occurred, the RO waits until it receives the intermediary/carrier's recommendation for approval 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.

(2) 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.

b. 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 HCFA-855 based on one or more of the reasons for denial stated in 2005.A.3 (Denial). The intermediary/carrier will send the recommendation of denial to the RO/SA.

For a CHOW, the provider agreement is usually 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, the new owner must enroll the same as any other new applicant (see 3210). The RO/SA cannot deny an agreement that already exists. However, the RO may terminate the provider agreement based on 42 CFR 489.53(a) if it is determined that the provider/supplier: is not complying with Title 18 or applicable regulations; fails to furnish information that HCFA finds necessary; refuses to permit examination of its fiscal records for verification of information; or fails to furnish ownership information. If the intermediary/carrier recommends denial of the HCFA-855, the RO may terminate the provider/supplier.

The RO will prepare a letter notifying the provider/supplier that it is subject to termination. The letter will state the reason(s) for the pending termination and inform the applicant of the right to appeal the termination (Exhibit 150A). The RO will forward a copy of the notification of pending termination to the SA and the intermediary/carrier. Even if the RO determines that a CHOW has occurred, the CHOW paperwork should not be processed if information on the Form HCFA-855 cannot be verified or is incorrect. If the applicant chooses to appeal the termination, follow the instructions at 2005.A.3.b (Procedure for Appeals).

(1) Provider/Supplier Submits an Appeal.--To request a reconsideration of a pending termination, the provider/supplier must submit a written request to the RO within 60 days from the date of the notification of the pending termination. The RO will forward the reconsideration request along with any supporting documentation to the intermediary/carrier for review. The intermediary/carrier will review the documentation and advise the RO of its decision. If the intermediary determines that the provider/supplier meets the requirements for enrollment, it will process the HCFA-855 and notify the RO. The RO will make a determination of whether or not a CHOW has occurred and take the appropriate action. If the intermediary/carrier still recommends denial of the HCFA-855, the RO will issue a final termination notice (Exhibit 150B), following the procedures for termination actions.

(2) Provider/Supplier Does Not Submit an Appeal.--If the provider/suppler does not respond to the notification of pending termination within a reasonable amount of time, then the RO will issue a final termination notice (Exhibit 257B), following the procedures for termination actions. For CLIA labs take all appropriate CLIA-related actions.

c. Return for Additional Information.--If required information is missing or information on the Form HCFA-855 cannot be verified, the intermediary/carrier may request additional information directly from the applicant. The intermediary/carrier may request additional information by telephone or by sending a letter to the applicant. If the request is made by letter, the intermediary will forward a copy of the request for additional information to the RO/SA.

2. Change in Intermediary as Result of CHOW. --If there is a change in intermediary as the result of a CHOW, the RO will notify both the current and new intermediaries. All CHOW applications should be processed by the intermediary who has been processing claims for the existing provider (current intermediary). The current intermediary will process the Form HCFA-855 and
forward the Form HCFA-855 to the new intermediary. The new intermediary should always be given the signed original of the Form HCFA-855. The current intermediary will also forward a completed copy of the Form HCFA-855 to the RO after processing. The RO will notify the State survey agency of the CHOW by forwarding a copy of the completed Form HCFA-855 to the State survey agency.

3. CHOWs Involving Multi-Regional Chain Organizations.--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 HCFA-855 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.

4. Change of Owners, but Not CHOW.--A provider/supplier may experience a change of owners, but a CHOW does not occur. For example, a provider/supplier may add or delete owners without experiencing a CHOW. In these situations, the provider/supplier should complete section 10 (Ownership Information) on the Form HCFA-855. 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 HCFA-855 directly to the intermediary/carrier. The intermediary/carrier will send a copy of the Form HCFA-855 to the SA/RO when it has completed its verification.

In certain situations, based on the review of the Form HCFA-855, the intermediary/carrier may suspect that a CHOW has occurred. 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 HCFA-855 and any supporting documentation. The RO will investigate whether a CHOW has actually occurred and report its findings to the intermediary/carrier and the State survey agency.

I. Voluntary Terminations.-- If a provider/supplier entered the Medicare program under the Form HCFA-855 process, it may voluntarily terminate from the Medicare program by checking the box entitled "Deactivation of Medicare Billing Number(s)" on the Form HCFA-855C. The provider/supplier should send the Form HCFA-855C to the State survey agency. The State survey agency or RO will maintain a copy of the Form HCFA-855C, and promptly send the completed original Form HCFA-855C to the fiscal intermediary/carrier. If the provider/supplier sends the Form HCFA-855C 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 HCFA-855C. Voluntary use of the Form HCFA-855C is encouraged for providers/suppliers who were certified without completing the Form HCFA-855. However, these providers/suppliers may voluntarily terminate by sending a letter on letterhead with an authorized signature.

J. Specialty Intermediaries.--Specialty intermediaries process applications and claims for independent RHCs, freestanding FQHCs, Christian Science Sanatoria, HHAs, and hospices. If a RHC or FQHC indicates it is freestanding or independent, then forward the Form HCFA-855 to the specialty intermediary. If a RHC or FQHC indicates on the Form HCFA-855 that it is provider-based, then forward the application to the parent provider's intermediary. All Christian Science Sanatoria applications will be forwarded to the same specialty intermediary. Hospice and HHA applications will always be processed by the specialty intermediary 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.

1. Independent RHC Intermediaries
   - o Veritus, Inc.
   - o Associated Hospital Services of Maine
   - o New Hampshire/Vermont Health Service
   - o Blue Cross/Blue Shield of Texas
   - o Riverbend Government Benefits Administrators (formerly Blue Cross/Blue Shield of Tennessee)

2. Freestanding FQHC Intermediary
   - o Blue Cross of Wisconsin

3. Christian Science Sanatoria Intermediary
   - o Riverbend Government Benefits Administrators

4. Regional Home Health Intermediaries and Hospice Intermediaries
   - o Blue Cross of Maine
   - o Palmetto Government Benefits Administrator (formerly Blue Cross of South Carolina)
   - o Health Care Service Corporation
   - o Blue Cross of Wisconsin
   - o Wellmark, Inc. (formerly IASD Health Services Corporation)
   - o Blue Cross of California

2008. PRIORITIZING SA SURVEY WORKLOAD - INITIAL SURVEYS AND RECERTIFICATIONS

A. Early Surveys of New Providers and Suppliers.-- 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. This may be as few as one patient, but only if, in the surveyor's judgement, compliance can be determined by reviewing a single patient record.

NOTE: That in order to be "furnishing all services necessary to meet the applicable provider definition," the HHA applying for initial Medicare certification must be able to demonstrate that it has furnished at least skilled nursing and one other therapeutic service. An HHA having furnished only personal care attendant or homemaker services would not meet this requirement. (See §1861 of the Act.)

When the provider notifies the SA of full operation, it documents the file with the date of notification. Contact the provider and confirm that it is fully operational. Conduct the survey within 21 calendar days of the date of full operation, if possible. (See §2700.)

B. Initial Surveys of HHAs.--In addition to an onsite survey to determine compliance with the health and safety conditions of participation (CoP), an HHA must now meet the initial capitalization requirements, and complete the enrollment information contained on the Form HCFA-855 (Medicare General Enrollment Health Care Provider/Supplier Application), which includes the HHA's ownership information. Also, the Health Care Financing Administration (HCFA) 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.

C. New CMHC Applicants.--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 HCFA 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 HCFA upon request and must be available at the site for which the CMHC is requesting Medicare approval.

D. Effective Date of Provider Agreement or Approval for Suppliers.--If all Federal requirements are not met on the date of the survey, the effective date of participation is the date on which the provider, supplier, or CLIA lab meets all Federal health and safety requirements 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 substantial compliance and submits, if applicable, an approvable waiver request. (A hospital ASC's special agreement is effective at the start of the hospital's next cost reporting year.)

E. Administrative Considerations.--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.)

F. SA Scheduling of Resurveys.--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 days before the expiration date of the current TLA agreement or certification since a survey conducted earlier than 120 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 state-wide 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 3 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.

2010. ASCERTAINING COMPLIANCE WITH CIVIL RIGHTS REQUIREMENTS

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 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.

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 reconditions to approving the provider's participation in the Medicaid program.

2012. SA IDENTIFYING ELIGIBLE PROVIDERS AND SUPPLIERS

Initial certifications of providers or suppliers involve steps to identify eligible, interested prospective 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 phone 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 Requirements for SNFs, and is in full compliance with all other requirements, i.e., no deficiencies, send the Certification and Transmittal (Form HCFA-1539) and all other documents to the RO within 10 calendar days of the survey; or

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o 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 days of the facility's receipt of the official Form HCFA-2567. The entity may be granted additional time if the plan is complex. (See Chapter VII 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 HCFA-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.

2014. STATEMENT OF FINANCIAL SOLVENCY (FORM HCFA-2572)

Effective February 27, 1989, providers that have filed a petition for bankruptcy, or those who have court proceedings pending regarding bankruptcy or insolvency, are not precluded from participation in the Medicare program. If the provider has been involved in bankruptcy, the provider is required to inform the SA or the RO via Form HCFA-2572 (Exhibit 5) prior to acceptance of the provider agreement. The RO should retain Form HCFA 2572 in the provider file.

2016. READMISSION TO MEDICARE OR MEDICAID PROGRAM AFTER INVOLUNTARY TERMINATION - REASONABLE ASSURANCE

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

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

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

o Except for SNFs, the provider or supplier is found to meet all CoPs and submits a plan of correction acceptable to HCFA for lower-level deficiencies or an approvable waiver request or both; or

o For SNFs, is in substantial compliance and submits, if applicable, an approvable waiver request; and

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

B. Reasonable Assurance Concept.--A Medicare provider terminated under 42 CFR Part 489.53 and reinstated under 42 CFR Part 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 Part 416.35(e)), FQHCs (42 CFR Part 405.2440), RHCs (42 CFR Part 405.2404(e)), and ESRD facilities (42 CFR Part 405.2180(c)).

The length of this "reasonable assurance" period is determined by the RO after an evaluation of the provider's 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 HCFA 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 under served 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 which 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.

EXAMPLE A: The Sunset Nursing Home was terminated on August 21, 1996. The provider corrected the deficiencies that caused the termination and requested readmission to the program. The RO established 80 days from October 20, 1996, the last date of the survey which confirmed that deficiencies had been corrected, as the reasonable assurance period. On November 11, 1996, the facility was purchased by John Anderson. Mr. Anderson owns two other SNFs which have excellent compliance histories.

Reasonable Assurance: Despite Mr. Anderson's facilities' excellent compliance histories, Sunset Nursing Home is assigned the 80 day reasonable assurance period because the facility was purchased after the reasonable assurance period had been established for the previous owner.

EXAMPLE B: The Happy Hill Convalescent Home was terminated on September 15, 1996. The provider was cited for several life safety code (LSC) violations; primarily, the absence of sprinklers in hazardous areas and of smoke barriers in patient areas. The owner argued that corrective action was too expensive. On October 1, 1996, the facility was purchased by John Swift. Mr. Swift owns several SNFs in the State and is known to be a reputable provider. All of Mr. Swift's other facilities meet the LSC.

Reasonable Assurance - Mr. Swift may participate when the LSC deficiencies have been corrected and all other requirements for SNFs are in substantial compliance because a reasonable assurance period was not in effect when the facility was purchased.

EXAMPLE C: Pleasant Plains Skilled Nursing Home was terminated on September 20, 1996. The provider corrected the deficiencies which led to termination and requested readmission on October 15, 1996. The RO reviewed the provider's history of compliance and found that historically the provider met substantially all participation requirements. Documentation reveals that the provider was the subject of a one-time uncontrollable staffing shortage which led to the deterioration of care and services and noncompliance with the requirements. The first reasonable assurance survey affirms that the staffing problems have been resolved.

Reasonable Assurance - The RO establishes 30 days from October 15, 1996, as reasonable based on the provider's good compliance history and the resolution of the problems that led to termination.

EXAMPLE D: 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 E: 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 F: 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 G: 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 H: Pleasant Plains ICF/MR was terminated by HCFA 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.

C. Request For Readmission.--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 HCFA-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.

D. Reasonable Assurance Surveys.--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. (HCFA, 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 7301.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 HCFA-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

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 HCFA-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 §7301.c.).

If the RO determines after the second survey that the reasons for termination exist again 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 §7301.c. for the exception for SNFs and NFs.)

E. Effective Date of Provider Agreement.--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 §7301.c). 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 the provider or supplier submits a PoC acceptable to HCFA, an approvable waiver request, or both. (See 42 CFR Part 489.13.)

F. Readmission of ICF/MR After Termination.--Before the SMA readmits an ICF/MR to the Medicaid program after termination by HCFA 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 HCFA to continue to disallow FFP for services furnished by that facility. (See 42 CFR Part 442.30 and 431.610(f)(1).)

G. "Grandfathering" Under LSC at Time of Readmission.--

1. Termination Based on LSC.--Upon readmission, an institution that was terminated for noncompliance with the LSC is not entitled to be "grandfathered" under an earlier edition of the Code, but must be surveyed under the latest edition of the Code in effect under current regulations. (Note that compliance with a later edition is usually not more costly than compliance with an earlier edition.)

2. Termination Based on Health Conditions.--An institution that was "grandfathered" under an earlier edition of the LSC and was in compliance with the Code, but was terminated on the basis of noncompliance with health conditions, is still eligible to be "grandfathered" absent evidence of noncompliance with the LSC during the period it did not participate in the program.

2017. READMISSION FOLLOWING VOLUNTARY TERMINATION OF PROGRAM PARTICIPATION

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 applies. 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

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 Areasonable assurance@ concept in these situations. (See §1883(c) of the Act.)

Hospitals

2020. HOSPITALS - DEFINITION AND CITATIONS

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 an eligible hospital. Section 1861(f) defines eligible psychiatric hospitals. 42 CFR 482 sets forth the CoPs for hospitals, including psychiatric hospitals. The interpretive guidelines for surveyors 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)

A. Notice That Participating Hospital Has Been Accredited.--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 §3260. The SA executes Form HCFA-1539 to report the accreditation.

B. Recertification.--The SA recertifies the compliance of accredited hospitals on a schedule consistent with the accreditation interval, which may be only every 3 years. Exhibit 63 has a complete listing of documents to be completed and included in the certification packet.

C. Notification of Withdrawal or Loss of Accreditation.--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 HCFA-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

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

A. Hospitals (Other Than Psychiatric Hospitals).--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.

B. Excluded Non-Service Units May be Appropriate.--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 which are separately identifiable units which do not meet the §1861(e)(1) or (j)(1) definitions.

2030. TEMPORARY WAIVERS APPLICABLE TO RURAL HOSPITALS

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:

o The hospital is located in a rural region. Rural is defined as all areas not delineated as "urbanized" areas by the Census Bureau in the most recent census. (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);

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

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

o 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;

o 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;

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

o 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

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:

o The duration of the waiver;

o A list of deficiencies; and

o 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. HOSPITAL PROVIDERS OF EXTENDED CARE SERVICES ("SWING-BEDS") - CITATIONS AND DESCRIPTION

Section 1883 of the Act (see exhibit 83) authorizes payment under Medicare for post-hospital SNF services provided by any hospital that:

o Has a Medicare provider agreement;

o Has fewer than 100 beds (excluding newborn, ICU, and CCU beds, beds in separately certified "distinct part" SNFs and NFs, and beds in PPS-excluded distinct part psychiatric or rehabilitation units);

o Is located in a rural (non-urbanized) region;

o Has been granted a Certificate of Need (CON) for the provision of extended care services if required by the State in which it is located;

o Does not have in effect a 24-hour nursing waiver;

o Has not had a swing-bed approval that was terminated within the last 2 years; and

o Meets the SNF CoPs on resident rights, specialized rehabilitation services, dental services, social services, resident activities, discharge planning, admission, transfer and discharge rights and resident behavior and facility practices.

A. Transfers to SNFs.--Hospitals that have 50 - 99 beds and meet the above criteria must also meet the 5 weekday transfer rule. Under that rule the hospital must:

o Have a policy that when there is an available bed in a Medicare-participating SNF with which the hospital has an availability agreement in the geographic region (see §2038.F) of the hospital, a swing-bed patient must be transferred within 5 workdays (excluding weekends and holidays) of the availability date unless the patient's physician certifies that transfer is not medically appropriate; and

o Have "availability" agreements with all the SNFs in the geographic region. (See §2038.F.)

2038. REQUIREMENTS ASSESSED PRIOR TO SURVEY FOR SWING-BED APPROVAL

A. Screening.--Prior to scheduling a survey, the SA reviews the Hospital Request for Certification in the Medicare/Medicaid Program, Form HCFA-1514, on file and other information maintained on the hospital to ascertain whether the first six basic requirements are met. If these requirements are met and the hospital has begun to provide swing-bed services, the SA announces and schedules a survey. No hospital may receive initial swing-bed approval without an onsite survey of the actual provision of such services. It is not possible to assess a hospital's compliance adequately until it provides the services. The SA sends model letter exhibit 82 and reviews the information received regarding the hospital's eligibility.

B. Provider Agreement.--The SA verifies that the hospital has a valid provider agreement under Medicare.

C. Calculation of Bed Count.--Exclude from the bed count beds that, because of their special nature, e.g., newborn and intensive care beds, beds in separately certified "distinct part" SNFs and NFs and beds in a distinct part psychiatric or rehabilitation unit that is excluded from PPS (also see §2762 B.2), are not available for swing-bed use. Also, exclude beds in separately certified distinct part SNFs and NFs.

A hospital licensed for more than 49 beds may be eligible for swing-bed approval in the 49 or fewer bed category if it utilizes and staffs for fewer than 50 beds. Likewise, a hospital licensed for more than 99 beds may be eligible for approval in the 50 - 99 bed category. In either situation, the SA forwards to the RO documentation that the hospital is operating within the bed category for which it is requesting approval (include floor plans, bed assignments by room number, staffing schedules, and census information for the previous 12 months). The SA obtains from appropriate hospital officials written assurance that the hospital will not operate with a greater number of inpatient hospital beds than permitted by the category for which approval is requested (excluding newborn

and intensive and coronary care beds, separately certified "distinct part" SNFs and NFs, and "distinct part" psychiatric or rehabilitation units that are excluded from the prospective payment system) except in connection with a catastrophic event. The form of an acceptable assurance is as follows:

> "[Name of hospital] is eligible to provide Medicare skilled nursing services under the terms of §1883 of the Social Security Act which requires that it be a hospital of [fewer than 50 inpatient beds] or [greater than 49 beds and fewer than 100 inpatient beds].
>
> "The hospital hereby assures that it shall operate and be staffed for [not more than 49 inpatient hospital beds] or [greater than 49 beds and fewer than 100 inpatient beds], exclusive of beds for newborn and intensive care beds in separately certified "distinct part" SNFs and NFs, and in a distinct part psychiatric or rehabilitation unit that is excluded from the prospective payment system, except during the event of a catastrophe (disaster, epidemic) to which the hospital shall respond.
>
> "We understand that, should the Health Care Financing Administration accept this assurance, failure to meet all terms of §1883 of the Act will terminate the special Medicare approval to provide skilled nursing services and that after termination, the hospital may not have another such approval for a period of two years."

Section 1913 of the Act permits payment for post-hospital NF services to hospitals.

D. Rural Area.--The SA includes as eligible those facilities that are not located in "urbanized areas" based on the most recent census of the Census Bureau. The SA uses the material in Appendix G, Standard IIA and at the end of Appendix G to determine whether a facility is located in a urbanized area. Before concluding that a hospital is ineligible on the basis of location, the SA telephones the Census Bureau RO for verification. The Census Bureau occasionally modifies the definition of "urbanized" as well as the boundaries of urbanized areas.

(NOTE: Section 4008(j)(3) of OBRA-90 protects swing-beds approved before May 1, 1987, from losing their approval if the hospital in which they are located is no longer considered to be in a rural area based on the most recent census information.)

E. CON Approval.--States that have a CON requirement for the initiation or expansion of long-term care (LTC) services may require the designation of a specific number of beds on the CON request or may grant a CON for a limited number of beds for LTC use. HCFA cannot intervene in the State's determination. If a hospital fails to adhere to a CON limitation, it fails to satisfy the swing-bed eligibility requirement for a CON.

F. Availability Agreements.--Unless a Medicare-participating SNF is not available or the SNFs are not willing to enter into an agreement when one is offered, a hospital of more than 49 and fewer than 100 beds must have in effect an availability agreement with all of the SNFs in the geographic region which specifies that:

- The SNF will notify the hospital when a post-hospital SNF care bed becomes available and the date it becomes available;
- The hospital agrees to transfer the patient to the SNF within 5 work days (excluding weekends and holidays) of the availability date unless the patient's physician certifies that the transfer is not medically appropriate; and
- If beds are available in more than one SNF, the patient will choose the SNF to which he or she will transfer. The transfer must occur, however, within 5 work days from the day the first bed becomes available.

"Geographic region" for swing-bed hospital purposes means an area that includes the Medicare SNFs with which a hospital has traditionally arranged transfers and all other Medicare SNFs within the same proximity to the hospital. In the case of a hospital without existing transfer practices upon which to base a determination, the geographic region is an area that includes all the SNFs within 50 miles of the hospital unless the hospital can demonstrate that the SNFs are inaccessible to its patients. In the event of a dispute as to whether a SNF is within a hospital's geographic region or the SNF is inaccessible to hospital patients, the RO makes the determination.

The burden to show that the SNF is not within the hospital's geographic region is with the hospital. The hospital must affirmatively demonstrate that travel from the hospital to the affected SNF is substantially longer or substantially more difficult travel from the hospital to other SNFs in the geographic region. To establish a standard to measure travel distance in the geographic region, the RO determines the longest travel time currently established between the hospital and a SNF with a current transfer agreement.

If travel times to other SNFs in the proximate area are relatively equal to or less than that measure, even those SNFs must be included in the geographic region and they must enter into transfer agreements with the swing-bed hospital. In no instance may a hospital establish a geographic region that excludes a SNF in which travel time is less than the time it takes to reach a SNF that has traditionally maintained a transfer agreement.

2040. SURVEY PROCEDURES FOR SWING-BED APPROVAL

The SA surveys any hospital that meets the first six items listed in §2036 and that has begun to provide post-hospital SNF and NF care services. The SA uses the Swing-Bed Survey Report (Form HCFA-1537C) to record survey findings, and the Hospital Survey Report Crucial Data Extract (Form HCFA-1537E) to record the bed-count category. The SA assures that hospitals with greater than 49 and fewer than 100 beds have policies that address the 5 weekday transfer requirements.

A hospital requesting approval in the 50 - 99 swing-bed category may request retroactive approval back to the date it began providing the service, but not prior to April 1, 1988, the statutory effective date of §1883(b)(1). To qualify for a retroactive approval date, the hospital must be in compliance with all requirements at the time of survey. Therefore, the SA reviews the hospital's records to determine that there is reasonable assurance that the hospital was continuously in compliance with all requirements from the date it requested approval.

The SA documents at the end of Form HCFA-1537C when there is reasonable assurance that the hospital was continuously in compliance with the provisions of 42 CFR Part 482.66, and the special requirements for hospitals in the 50 - 99 bed category. (See §2036.)

For resurveys of unaccredited hospitals, the SA may combine the swing-bed survey with the general hospital survey. For surveys of accredited hospitals, the SA performs an onsite survey of only the items contained on the Swing-Bed Survey Report. Failure to satisfy requirements for swing-bed approval ordinarily does not affect Medicare approval as a provider of hospital services. However, if the SA obtains information during the swing-bed certification process that suggests a deficiency in a CoP in an accredited hospital, follow the procedures in §§3260ff.

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

2041. POST-SURVEY PROCEDURES FOR SWING-BED HOSPITALS

For swing-bed hospitals in the 49 or fewer bed category, the SA transmits its recommendations to the RO on Form HCFA-1539, Medicare and Medicaid Certification and Transmittal.

For swing-bed hospitals in the 50 - 99 bed category, the SA forwards to the RO:

- Request for Approval as Hospital Provider of Extended Care Services (Swing-bed) in the Medicare and Medicaid Programs, Form HCFA-605 (exhibit 81);
- Medicare/Medicaid Hospital Swing-Bed Survey Report, Form HCFA-1537C;
- A list of SNFs with which the hospital has availability agreements; and
- Medicare and Medicaid Certification and Transmittal, Form HCFA-1539.

To receive swing-bed approval, a hospital in the 50 - 99 bed category must be found in compliance with the provisions of 42 CFR Part 482.66, the special requirements for hospitals in the 50 - 99 bed category (see §2036.1) and the specific skilled nursing requirements in 42 CFR 483 that apply to swing-bed hospitals. (See Appendix T.)

Effective dates for all swing-bed approvals are based on the provisions at 42 CFR Part 489.13 which state that 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. (See §2040 for retroactive approval for 50-59 beds.) 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 HCFA.

If there is a dispute regarding the geographic region between a SNF and the swing-bed hospital, in addition to the above materials, the SA forwards to the HCFA RO:

- A copy of the documentation provided by the hospital and the SNF(s) supporting their positions; and
- The SA's recommendation regarding the dispute.

2041.1 RO Approval Procedures for Swing-Bed Approval.--The RO prepares a formal determination and notifies the hospital of its approval or denial. For hospitals in the 50-99 bed category, the approval letter must stress notification and transfer obligations. (See Exhibit 162.) At the time the RO releases the approval letter, it informs all the SNFs in the geographic region of their obligation to inform the swing-bed hospital of the availability of SNF beds for swing-bed patients. (See Exhibit 163.)

2042. PSYCHIATRIC HOSPITALS

The statutory requirements for psychiatric hospitals are found in §1861(f) of the Act. The term psychiatric hospital means an institution which:

o Is primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons;

o Satisfies the requirements of §§1861(e)(3) through (e)(9) (general hospital requirements);

o 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

o 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."

2044. ACCREDITED HOSPITALS NOT DEEMED TO MEET SPECIAL CoPs

Psychiatric hospitals accredited by JCAHO under its hospital accreditation program or under its 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. (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. If the hospital is deemed to meet the general hospital CoPs, a complete survey is not required.

The SA completes the Medicare/Medicaid Psychiatric Hospital Survey Data, Form HCFA-724, and all other relevant survey documents (Form HCFA-2567, etc.) for the survey of accredited psychiatric hospitals.

2048. DISTINCT PART PSYCHIATRIC HOSPITAL

A. General.--A psychiatric hospital may elect to participate in its entirety, or it may designate a distinct part and apply for participation of that portion only.

The distinct part provisions of the law are designed to permit the participation of those identifiable units or 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 standards and have appropriate treatment services available. Patients in the distinct part must be provided treatment which 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.

B. Physical Identification.--To qualify for participation as a distinct part psychiatric hospital, the distinct part must be physically identifiable; 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.

Although the distinct part must be identified, it need not be confined to a single location within the hospital. For example, it may consist of several floors or wards, a specific group of beds in a single building, or floors or wards or a specific group of beds located in several different buildings.

Intermediate Care Facilities for the Mentally Retarded

2130. ICFs/MR - CITATIONS AND DESCRIPTION

A. Citations.--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 s 435, Subpart K (Federal Financial Participation) and Part 440, Subpart A (Definitions), augment the CoPs listed in 42 CFR Part 483.

B. Definition.--An ICF/MR is an institution which 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

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 may not 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, but otherwise, the unit houses all ICF/MR residents in the institution.

2138. APPROVAL PROCEDURES FOR ICFs/MR

A. Initial Certification of ICF/MR.--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.

If a facility has 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, then it may request that the SA review relevant aspects of its existing immediate track record as part of the initial survey process. 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.

B. Multiple Certification of Dispersed Locations.--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.

C. Minimum Size of ICF/MR.--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.)

D. Interpretive Guidelines For ICFs/MR.--Guidelines for surveying ICFs/MR are located in Appendix J. They provide an interpretation of the ICF/MR regulations which 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.

E. Survey Report (Form HCFA-3070G-I).--To survey ICFs/MR, the SA must use the Interpretive Guidelines and Survey Procedures (see Appendix J) in conjunction with Form HCFA-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.

F. Application of LSC to ICFs/MR of 16 Beds or Less.--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), 1985 edition.

G. Ownership and Control Interest Disclosure Statement (Form HCFA-1513). Disclosure of ownership and control interest information is required for participation in Medicaid. Instructions are provided on the form. (See Exhibit 6.)

H. Schedule For Recertification.--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 2 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

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:

A. Comprehensive Functional Assessment.--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, and 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.

B. Individual Program Plan (IPP).--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.

C. Program Implementation.--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 who work with the individual, except that only licensed personnel may implement certain areas of the program.

D. Program Documentation.--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.

E. Program Monitoring and Review.--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 HCFA-3070G-I and Form HCFA-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

A. ICF/MR Room Size and Occupancy.--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 4 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 4 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 4 individuals.

B. Waiver of LSC.--(§ 2472.)

2141. TIME-LIMITED CERTIFICATIONS - ICFs/MR

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.

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

B. Conditional 12 Month Agreement Subject To Automatic Cancellation Clause.--Where an ICF/MR is in compliance with the CoPs but has deficiencies which 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 which is automatically cancelled, the agreement ends at the close of the predetermined date specified in the automatic cancellation clause.

C. Period of Certification Which Expires 60 Days After PoC.--Where an ICF/MR has deficiencies, the SA may recommend a short period of certification that expires 2 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.

D. Extending the Term of ICF/MR TLA.--The term of an agreement may be extended by the SMA for a single period of 2 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

A. Benefit Period Provision.--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.

B. Defining Medicare Eligible Individual's "Home" For Purposes of Durable Medical Equipment (DME) and Home Health Benefits.--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.

C. Defining "Institution" For Ambulance Benefit.--Another use of §1861(e)(1) or §1819(a)(1) of the Act's definitions is to help determine that 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

The term "hospital" as used in §1861(e) of the Act and State licensure laws has a generally accepted meaning which is seldom questioned. A problem arises, however, with respect to distinct parts of hospitals which 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

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. Where this is the case, any nursing home licensed in such States could not 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

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 HCFA-1539A, Certification and Transmittal for Spell of Illness Determination.)

A. Nursing Services.--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 consider this condition met even if the nurse is also the administrator of the facility or is employed on a part-time basis.

B. 24-Hour Nursing Services.--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.

C. Nurse Bed-Ratio.--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 3 8-hour shifts must have a minimum of the equivalent of 3 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.

D. Other Services.--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

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 HCFA-1537 for hospitals or Form HCFA-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

A. Citations.--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.

B. Types of Agencies.--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 hospitals.

C. General Requirements.--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 Conditions 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.

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

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;

o The responsibility for participating in developing plans of care;

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

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

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

2182. ORGANIZATION OF HHA

A. 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.

B. 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.

C. 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 HCFA-1572 (a), (b), (c), (d), and (e)), Form HCFA-2567, and Form HCFA-1539 for the parent organization and one for each subunit. The SA does not conduct the initial survey of a subunit prior to the initial survey of the parent agency.

D. 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.--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 HCFA 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 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 subunits 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.--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 presence of an effective full time branch supervisor or manager, who is formally appointed by and under the supervision of the parent, should not be an exclusive cause for denying a branch application.

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.

Additional factors include "serves patients in a geographic area different from that of the parent" and "too far from the parent to share administration, supervision, and services on a daily basis." While factors relating to each determination may vary, the Departmental Appeals Board (DAB) concluded in one case that where the driving time between a parent office and branch had the potential to take as long as 11/2 hours, it was too long to ensure safe and timely treatment of the branch's patient on a shared basis with the parent. (See Homelife Nursing Inc. v. HCFA, DAB Decision No.CR 417 (March 26, 1996).)

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.

1. 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.

2. 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.

3. 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.

4. 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.

5. State licensure laws which 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.

6. The fact that the Joint Commission on the Accreditation of Healthcare Organizations or the Community Health Accreditation Program have awarded branch status to a location will not affect HCFA's parent/non-parent decision. HCFA's 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.--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 HCFA RO. However, if you discover a "branch" that has never been identified to the SA or HCFA 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 HCFA determines on the basis of the information provided, is a subunit.

2182.4 HCFA Approval Necessary for Non-Parent Locations.--As part of the provider certification process, an existing Medicare-approved HHA must provide notification to HCFA through the SA of its proposal to add a non-parent location, i.e., branch or subunit. 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).

HCFA must then determine if the CoPs continue to be met with the inclusion of the additional location. In the absence of notification, HCFA 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 HCFA RO in a particular case, it is the HCFA RO which has the authority for determining the non-parent's status as a branch or subunit.

The HCFA RO will review each HHA's request for a branch office on a case by case basis, and consider all the national guidelines. The HCFA RO will communicate its final decision in writing to the parent and copy the SA and the regional home health intermediary (RHHI). 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.

2183. SEPARATE ENTITIES

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.--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;

- o Current listing of staff employed by or contracted to the HHA;
- o Personnel records;
- o Time sheets or other records to demonstrate distinct assignment of personnel to the HHA; and
- o Separate budgets.

2183.2 Consumer Awareness.--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 telephone 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.--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:

- o 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;
- o 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;
- o 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
- o 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 ACROSS STATE LINES

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.

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 which 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

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

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

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 HCFA-1572. The SA completes Form HCFA-2567, obtains a PoC when necessary, and sends this information along with a completed Form HCFA-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

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:

- o No condition-level deficiencies in the last three recertification surveys;
- o No deficiencies at 42 CFR Part 484.18 or 42 CFR Part 484.55 in the previous standard survey; and
- o 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:

- o No condition-level deficiencies within 24 months of the most recent survey;
- o No complaints resulting in deficiency citations since the previous survey; and
- o 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:

- o An HHA has been Medicare-approved for less than 3 years at its most recent survey;
- o An HHA has had a change of ownership since the previous standard survey;

- o An HHA had a condition-level deficiency cited within 24 months;
- o An HHA had a complaint survey resulting in deficiency citations since the last standard survey; or

o 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

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.

2196. HHA SURVEY PROCESS FOR DETERMINING QUALITY OF CARE

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 HCFA 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.--

A. Standard Survey.--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 HCFA-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 identifies how the HHA defines, plans for, delivers, and measures anticipated outcomes for patients.

B. Partial Extended Survey.--Is conducted:

- 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.

C. Extended Survey.--Is conducted:

o 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

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

2196.2 Home Health Functional Assessment Instrument (FAI).--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 Form HCFA-485 for each patient in the survey sample (and/or the previous Form HCFA-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 Outcome And Assessment Information Set (OASIS) Requirements.--OASIS requirements for Medicare-approved HHAs were published on January 25, 1999, in the ***Federal Register*** document: Medicare and Medicaid Programs: Reporting OASIS Data as Part of the Conditions of Participation for Home Health Agencies and Comprehensive Assessment and Use of the OASIS as Part of the Conditions of Participation for Home Health Agencies; Final Rules. The following CoPs were included in this document:

o 42 CFR Part 484.11, Condition of Participation: Release of Patient Identifiable OASIS Information;

o 42 CFR Part 484.20, Condition of Participation: Condition of Participation: Reporting OASIS Information; and

o 42 CFR Part 484.55, Condition of Participation: Condition of Participation: Comprehensive Assessment.

Offsite and onsite monitoring are both required to determine compliance with the OASIS CoPs. The OASIS Educational Coordinator and/or the OASIS Automation Coordinator can assist in providing available oasis reports (e.g., data management and quality monitoring reports) to surveyors.

2196.4 Clinical Laboratory Improvement Amendments.--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 HCFA 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

A. Components.--Under the standard survey, the surveyor is required to:

o 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

o 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.

B. Activities.--During the standard survey, the surveyor determines the HHA's compliance with:

o 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).

C. Applicability.--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 HCFA's 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 2 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 2 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 HCFA 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

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

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

A. Task 1 - Pre-Survey Preparation.--Prior to each survey, review the HHA file (or application, in the case of an initial) in accordance with SOM §2704. Also review the information in the State files relating to the disclosure of information statement made by the HHA (Form HCFA-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 any available reports generated from the OASIS data (e.g., case-mix, adverse event, risk adjusted OBQI reports). 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). Follow SOM §2710, Reviewing Forms at the Beginning of a Survey.

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:

- o Is operational;
- o Has completed the Medicare Enrollment Application Form HCFA-855 and had this form verified by the assigned RHHI;
- o Met the surety bond and capitalization requirements;
- o Is providing nursing and at least one other therapeutic service;
- o Can demonstrate the operational capability of all facets of its operations;
- o Has successfully completed an OASIS transmission to the State repository; and

- o 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 HCFA RO, the HCFA 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 SOM §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 of the SOM regarding licensure requirements.

B. Task 2 - Entrance Interview.--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 patient list, 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 of patients scheduled for a home visit during the survey;

- List of current employees;
- CLIA certificate (if applicable);
- Forms to complete: Forms HCFA 1513 and 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; and
- If applicable, the HHA's rationale for stating that it is provider-based. (See SOM §2004.)

C. Task 3 - Information Gathering.--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.

1. Responsibilities include but are not limited to:

- Reviewing how the HHA performs the comprehensive assessment of patients incorporating the OASIS items;
- Determining if the comprehensive assessment accurately reflects the patient's status;
- 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, and reviewed 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;

- o Observing patient care;
- o Interviewing staff and patients;
- o Reviewing a sample of home health aides files; and
- o Reviewing how the HHA complies with CoPs.

2. Request the following:

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

3. When discussing observations:

- o Use observational skills at all times during the survey and discuss your observations, as appropriate, with team members and HHA personnel.
- o Ask pertinent questions to obtain a baseline of information that expands early observations.
- o Maintain an open and ongoing dialogue with HHA personnel.
- o Give the HHA the opportunity to provide additional information before making compliance decisions.
- o Ask staff to describe the usual procedural timeframes for filing pertinent clinical information in the record.

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.

4. Clinical Record and Home Visit Selection for Standard Survey.--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 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).

5. Selecting a Sample of Patients for Clinical Record Review With Home Visits.-- 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.

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 judgement, 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.)

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

o 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.

6. Selecting Sample of Clinical Records of Patients Who Will Not Receive Home Visit.--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

7. Recording Information.--

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:

o 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.

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

o 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.

o Determine if the comprehensive assessment accurately reflects the patient's

status.

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

o 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.

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

o Review the timeliness of services provided to the patient.

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

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

o 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?

o 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?

o 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?

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

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

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

o 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.

o 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 HCFA-1572(b) (see Exhibit 14D), and select the appropriate action according to the following choices:

o 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. Record any standard-level deficiencies identified during the standard survey and request a PoC. The survey is complete.

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

8. Conducting Home Visits.--

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, at a minimum, 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 on-site 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 the HHA to be 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 reviewing 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.

c. Discontinuing Interview.--Discontinue the interview if:

o 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;

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

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

D. Task 4 - Information Analysis.--The information analysis process requires surveyors to review the information gathered during the survey process and to make judgements about the compliance of the HHA. 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:

- o The effect or potential effect on the patient;
- o The degree of severity;
- o The frequency of occurrence; and
- o 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 judgement, 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.

E. Task 5 - Exit Conference.--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 HCFA-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:

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

o 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 HCFA regarding compliance determinations.

o 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.

o 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 HCFA on Form HCFA-2567.

o Respond to any HHA procedural questions with timely and accurate survey process information (i.e., recertification status: the timeframe for receiving Form HCFA-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.

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

o 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 HCFA-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 SOM §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.

F. Task 6 - Formation Of The Statement Of Deficiencies.--Write the deficiency statement in terms specific enough to allow a reasonably knowledgeable person to understand the aspects of each requirements that are not met. SOM §2728 provides detailed instructions on the effective completion of Form HCFA-2567.

2041. POST-SURVEY PROCEDURES FOR SWING-BED HOSPITALS

For swing-bed hospitals in the 49 or fewer bed category, the SA transmits its recommendations to the RO on Form HCFA-1539, Medicare and Medicaid Certification and Transmittal.

For swing-bed hospitals in the 50 - 99 bed category, the SA forwards to the RO:

o Request for Approval as Hospital Provider of Extended Care Services (Swing-bed) in the Medicare and Medicaid Programs, Form HCFA-605 (exhibit 81);

o Medicare/Medicaid Hospital Swing-Bed Survey Report, Form HCFA-1537C;

o A list of SNFs with which the hospital has availability agreements; and

o Medicare and Medicaid Certification and Transmittal, Form HCFA-1539.

To receive swing-bed approval, a hospital in the 50 - 99 bed category must be found in compliance with the provisions of 42 CFR Part 482.66, the special requirements for hospitals in the 50 - 99 bed category (see §2036.1) and the specific skilled nursing requirements in 42 CFR 483 that apply to swing-bed hospitals. (See Appendix T.)

Effective dates for all swing-bed approvals are based on the provisions at 42 CFR Part 489.13 which state that 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. (See §2040 for retroactive approval for 50-59 beds.) If the provider fails to meet any of the requirements, the approval will be effective on the earlier of the following dates:

o The date on which the hospital meets all requirements, or

o The date the hospital submits a correction plan acceptable to HCFA.

If there is a dispute regarding the geographic region between a SNF and the swing-bed hospital, in addition to the above materials, the SA forwards to the HCFA RO:

o A copy of the documentation provided by the hospital and the SNF(s) supporting their positions; and

o The SA's recommendation regarding the dispute.

2041.1 RO Approval Procedures for Swing-Bed Approval.--The RO prepares a formal determination and notifies the hospital of its approval or denial. For hospitals in the 50-99 bed category, the approval letter must stress notification and transfer obligations. (See Exhibit 162.) At the time the RO releases the approval letter, it informs all the SNFs in the geographic region of their obligation to inform the swing-bed hospital of the availability of SNF beds for swing-bed patients. (See Exhibit 163.)

2042. PSYCHIATRIC HOSPITALS

The statutory requirements for psychiatric hospitals are found in §1861(f) of the Act. The term psychiatric hospital means an institution which:

o Is primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons;

o Satisfies the requirements of §§1861(e)(3) through (e)(9) (general hospital requirements);

o 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

o 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."

2044. ACCREDITED HOSPITALS NOT DEEMED TO MEET SPECIAL CoPs

Psychiatric hospitals accredited by JCAHO under its hospital accreditation program or under its 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. (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. If the hospital is deemed to meet the general hospital CoPs, a complete survey is not required.

The SA completes the Medicare/Medicaid Psychiatric Hospital Survey Data, Form HCFA-724, and all other relevant survey documents (Form HCFA-2567, etc.) for the survey of accredited psychiatric hospitals.

2048. DISTINCT PART PSYCHIATRIC HOSPITAL

A. General.--A psychiatric hospital may elect to participate in its entirety, or it may designate a distinct part and apply for participation of that portion only.

The distinct part provisions of the law are designed to permit the participation of those identifiable units or 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 standards and have appropriate treatment services available. Patients in the distinct part must be provided treatment which 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.

B. Physical Identification.--To qualify for participation as a distinct part psychiatric hospital, the distinct part must be physically identifiable; 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.

Although the distinct part must be identified, it need not be confined to a single location within the hospital. For example, it may consist of several floors or wards, a specific group of beds in a single building, or floors or wards or a specific group of beds located in several different buildings.

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 HCFA-1539. The beds in the distinct part must be physically separate, not commingled with beds not in the distinct part.

C. Documentation of Findings.--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 which 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 which 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

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 which 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

A. Emergency Hospital Services.--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.

B. Preparation of Initial Certification.--

- For the initial certification, the SA obtains a completed Hospital Request to Establish Eligibility, Form HCFA-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 HCFA-1539, completing items 3, 4, 6, 7, 9, 12, 13, and 16 - 18.

C. Recertification and Follow-Up.--The SA maintains an emergency hospital listing on a continuous basis and annually re-check 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 HCFA-1539.

2054. RELIGIOUS NONMEDICAL HEALTH CARE INSTITUTIONS (RNHCIs)

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 Social Security Act (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).--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 §403.720. To qualify as a Medicare or Medicaid RNHCI an institution must meet all ten of the following requirements:

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

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

o 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);

o 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;

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

o 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;

o 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));

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

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

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

A. Other Medicare Conditions of Coverage.--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.

B. Valid Election Requirements.--The regulations at §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:

o 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 HCFA; 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:

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

o Be notarized;

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

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

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

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

o The beneficiary voluntarily revokes the election and notifies HCFA in writing.

NOTE: "Excepted" and "nonexcepted" medical care are defined in §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

A. Citations.--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, as added by §4206(a)(1)(C) of OBRA 1990, P.L. Number 101-508, 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.

B. Description.--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 in hospitals, SNFs, and HHAs, hospices must meet specific CoPs and be separately certified and approved for Medicare participation. (See Exhibit 129 for Hospice Survey and Deficiencies Report, Form HCFA-643 and Exhibit 72 for Hospice Request for Certification in the Medicare Program, Form HCFA-417.)

C. Services and Items Provided.--Substantially all core services must be provided directly by hospice employees on a routine basis. 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.

The following are hospice core services and must be provided directly by hospice employees:

- Nursing care 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;
- Physician's services; and
- Counseling (including dietary and bereavement counseling) with respect to care of the terminally ill individual and adjustment to death.

When included in the patient's written plan of care, the following services must be available as needed and provided by the hospice, either directly or under arrangements made by the hospice:

- 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 Part 484.4 for "home health aide" and must meet all the training, attitude, and skill requirements for a home health aide working in an HHA, as specified in 42 CFR Part 484.36;

o Homemaker services;

o Medical supplies (including drugs and biologicals) and the use of medical appliances related to the terminal diagnosis;

o 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

o 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.

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.

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.

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.

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.

2081. HOSPICE - MULTIPLE LOCATIONS

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 HCFA's responsibility to protect the Medicare trust fund against excessive and unnecessary costs, will also ensure that the locations promote cost effective health care. This includes reimbursing hospices at a rate that has been established for the local area. 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.

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

o 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. Hospice care requires the closest of interventions and a distant "parent" cannot provide the immediate access needed to ensure health and safety.

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

o 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

o 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

There 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 facility 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.

A. Compliance With SNF/NF CoPs.--The SNF/NF CoPs 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. This means that the resident must be assessed using the information contained in the Resident Assessment Instrument (RAI) (which includes both the Minimum Data Set (MDS) and the Resident Assessment Protocols (RAPs)), have a plan of care, which, in this case, will be jointly developed with and agreed upon by the hospice, and be provided with all services contained in the plan of care. The plan of care must be consistent with the hospice philosophy of care.

When a resident of a Medicare/Medicaid participating SNF/NF elects the Medicare hospice benefit, the hospice and the SNF/NF must communicate, establish, and agree upon a coordinated plan of care for both providers which reflects the hospice philosophy, and is based on an assessment of the individual's needs and unique living situation in the SNF/NF. The plan of care must be written in accordance with 42 CFR Part 418.58 and include the individual's current medical, physical, psychosocial, 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).)

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 SNF/NF and the hospice are responsible for performing each of their respective functions which have been agreed upon and included in the plan of care. The hospice retains overall professional management responsibility for directing the implementation of the plan of care. In addition:

o All covered hospice services must be available as necessary to meet the needs of the patient;

o Substantially all core services must be routinely provided directly by hospice employees and cannot be delegated to the SNF/NF. (See 42 CFR Part 418.80);

o Drugs and medical supplies must be provided as needed for the palliation and management of the terminal illness and related conditions. Drugs must be furnished in accordance with accepted professional standards of practice. (See 42 CFR Part §418.96); and

o The plan of care should reflect the participation of the hospice, SNF/NF, and the patient to the extent possible. 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.

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 SNF/NF services must be consistent with the plan of care developed in coordination with the hospice. The hospice patient residing in a SNF/NF should not experience any lack of SNF/NF services or personal care because of his/her status as a hospice patient. 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 SNF/NF must offer the same services to its residents who have elected the hospice benefit as it furnishes to its residents who have not elected the hospice benefit. The patient/resident has the right to refuse any services.

B. Professional Management.--The use of the term "professional management" for a hospice patient who resides in a SNF/NF 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 (physician services, nursing services, medical social services, and counseling) must be routinely provided directly by hospice employees and cannot be delegated. 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. (For example, SNF/NF staff who are 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.)

C. Provision of Non-Core Services To SNF/NF Residents.--The hospice may arrange to have non-core hospice services provided by the SNF/NF 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 Part §418.56.)

D. SNF/NF Residents and Dually-Eligible Beneficiaries.--A Medicare beneficiary who resides in a SNF/NF may elect the hospice benefit when the residential care is paid for by the beneficiary. 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 SMA 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. Room and board services 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, and each program notified as to the patient's decision.

2083. HOSPICE REGULATIONS AND NON-MEDICARE PATIENTS

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

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.

A. Hospice Provides Inpatient Care Directly.--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.

B. Hospice Provides Inpatient Services Under Arrangements.--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 Part 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.

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

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 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 such personnel provide services. Each respective SA must be aware of and approve the action. The involved States should have a reciprocal agreement, either verbal or written, permitting the hospice to provide services in this manner. The SA must verify that each State's applicable personnel licensure and other requirements are met.

2086. HOSPICE HOME VISITS

The SA makes home visits to a sample of Medicare/Medicaid hospice patients 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).)

2087. COMPLIANCE WITH ADVANCE DIRECTIVES

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 with respect to all adult individuals receiving medical care by or through the hospice and must, at the time of initial receipt of hospice care by the individual from the program:

- Provide the individual with written information concerning his or her rights under State law (whether statutory or as recognized by the courts of the State) to make decisions concerning medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives;

- Provide the individual with the hospice's written policies and procedures concerning the implementation of such rights;

- Document in the individual's medical record whether he/she has executed an advance directive;

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

- Ensure compliance with requirements of State law (whether statutory or as recognized by the courts of the State) concerning advance directives; and

- Provide (individually or with others) for education of staff and the community on issues concerning advance directives.

The facility is not required to provide care that conflicts with an advance directive. In addition, the facility is also not required to implement an advance directive if, as a matter of conscience, the facility cannot implement an advance directive and State law allows the provider to conscientiously object.

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

Intermediate Care Facilities for the Mentally Retarded

2130. ICFs/MR - CITATIONS AND DESCRIPTION

A. Citations.--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 s 435, Subpart K (Federal Financial Participation) and Part 440, Subpart A (Definitions), augment the CoPs listed in 42 CFR Part 483.

B. Definition.--An ICF/MR is an institution which 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

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 may not 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, but otherwise, the unit houses all ICF/MR residents in the institution.

2138. APPROVAL PROCEDURES FOR ICFs/MR

A. Initial Certification of ICF/MR.--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.

If a facility has 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, then it may request that the SA review relevant aspects of its existing immediate track record as part of the initial survey process. 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.

B. Multiple Certification of Dispersed Locations.--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.

C. Minimum Size of ICF/MR.--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.)

D. Interpretive Guidelines For ICFs/MR.--Guidelines for surveying ICFs/MR are located in Appendix J. They provide an interpretation of the ICF/MR regulations which 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.

E. Survey Report (Form HCFA-3070G-I).--To survey ICFs/MR, the SA must use the Interpretive Guidelines and Survey Procedures (see Appendix J) in conjunction with Form HCFA-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.

F. Application of LSC to ICFs/MR of 16 Beds or Less.--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), 1985 edition.

G. Ownership and Control Interest Disclosure Statement (Form HCFA-1513). Disclosure of ownership and control interest information is required for participation in Medicaid. Instructions are provided on the form. (See Exhibit 6.)

H. Schedule For Recertification.--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 2 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

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:

A. Comprehensive Functional Assessment.--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, and 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.

B. Individual Program Plan (IPP).--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.

C. Program Implementation.--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 who work with the individual, except that only licensed personnel may implement certain areas of the program.

D. Program Documentation.--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.

E. Program Monitoring and Review.--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 HCFA-3070G-I and Form HCFA-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

A. ICF/MR Room Size and Occupancy.--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 4 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 4 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 4 individuals.

B. Waiver of LSC.--(§ 2472.)

2141. TIME-LIMITED CERTIFICATIONS - ICFs/MR

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.

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

B. Conditional 12 Month Agreement Subject To Automatic Cancellation Clause.--Where an ICF/MR is in compliance with the CoPs but has deficiencies which 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 which is automatically cancelled, the agreement ends at the close of the predetermined date specified in the automatic cancellation clause.

C. Period of Certification Which Expires 60 Days After PoC.--Where an ICF/MR has deficiencies, the SA may recommend a short period of certification that expires 2 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.

D. Extending the Term of ICF/MR TLA.--The term of an agreement may be extended by the SMA for a single period of 2 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

A. Benefit Period Provision.--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.

B. Defining Medicare Eligible Individual's "Home" For Purposes of Durable Medical Equipment (DME) and Home Health Benefits.--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.

C. Defining "Institution" For Ambulance Benefit.--Another use of §1861(e)(1) or §1819(a)(1) of the Act's definitions is to help determine that 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

The term "hospital" as used in §1861(e) of the Act and State licensure laws has a generally accepted meaning which is seldom questioned. A problem arises, however, with respect to distinct parts of hospitals which 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

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. Where this is the case, any nursing home licensed in such States could not 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

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 HCFA-1539A, Certification and Transmittal for Spell of Illness Determination.)

A. Nursing Services.--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 consider this condition met even if the nurse is also the administrator of the facility or is employed on a part-time basis.

B. 24-Hour Nursing Services.--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.

C. Nurse Bed-Ratio.--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 3 8-hour shifts must have a minimum of the equivalent of 3 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.

D. Other Services.--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

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 HCFA-1537 for hospitals or Form HCFA-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

A. Citations.--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.

B. Types of Agencies.--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 hospitals.

C. General Requirements.--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 Conditions 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.

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

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;

o The responsibility for participating in developing plans of care;

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

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

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

2182. ORGANIZATION OF HHA

A. 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.

B. 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.

C. 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 HCFA-1572 (a), (b), (c), (d), and (e)), Form HCFA-2567, and Form HCFA-1539 for the parent organization and one for each subunit. The SA does not conduct the initial survey of a subunit prior to the initial survey of the parent agency.

D. 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.--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 HCFA 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 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 subunits 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.--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 presence of an effective full time branch supervisor or manager, who is formally appointed by and under the supervision of the parent, should not be an exclusive cause for denying a branch application.

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.

Additional factors include "serves patients in a geographic area different from that of the parent" and "too far from the parent to share administration, supervision, and services on a daily basis." While factors relating to each determination may vary, the Departmental Appeals Board (DAB) concluded in one case that where the driving time between a parent office and branch had the potential to take as long as 11/2 hours, it was too long to ensure safe and timely treatment of the branch's patient on a shared basis with the parent. (See Homelife Nursing Inc. v. HCFA, DAB Decision No.CR 417 (March 26, 1996).)

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.

1. 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.

2. 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.

3. 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.

4. 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.

5. State licensure laws which 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.

6. The fact that the Joint Commission on the Accreditation of Healthcare Organizations or the Community Health Accreditation Program have awarded branch status to a location will not affect HCFA's parent/non-parent decision. HCFA's 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.--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 HCFA RO. However, if you discover a "branch" that has never been identified to the SA or HCFA 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 HCFA determines on the basis of the information provided, is a subunit.

2182.4 HCFA Approval Necessary for Non-Parent Locations.--As part of the provider certification process, an existing Medicare-approved HHA must provide notification to HCFA through the SA of its proposal to add a non-parent location, i.e., branch or subunit. 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).

HCFA must then determine if the CoPs continue to be met with the inclusion of the additional location. In the absence of notification, HCFA 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 HCFA RO in a particular case, it is the HCFA RO which has the authority for determining the non-parent's status as a branch or subunit.

The HCFA RO will review each HHA's request for a branch office on a case by case basis, and consider all the national guidelines. The HCFA RO will communicate its final decision in writing to the parent and copy the SA and the regional home health intermediary (RHHI). 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.

2183. SEPARATE ENTITIES

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.--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;

- o Current listing of staff employed by or contracted to the HHA;
- o Personnel records;
- o Time sheets or other records to demonstrate distinct assignment of personnel to the HHA; and
- o Separate budgets.

2183.2 Consumer Awareness.--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 telephone 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.--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:

- o 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;
- o 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;
- o 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
- o 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 ACROSS STATE LINES

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.

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 which 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

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

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

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 HCFA-1572. The SA completes Form HCFA-2567, obtains a PoC when necessary, and sends this information along with a completed Form HCFA-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

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:

- o No condition-level deficiencies in the last three recertification surveys;
- o No deficiencies at 42 CFR Part 484.18 or 42 CFR Part 484.55 in the previous standard survey; and
- o 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:

- o No condition-level deficiencies within 24 months of the most recent survey;
- o No complaints resulting in deficiency citations since the previous survey; and
- o 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:

- o An HHA has been Medicare-approved for less than 3 years at its most recent survey;
- o An HHA has had a change of ownership since the previous standard survey;

- o An HHA had a condition-level deficiency cited within 24 months;
- o An HHA had a complaint survey resulting in deficiency citations since the last standard survey; or

o 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

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.

2196. HHA SURVEY PROCESS FOR DETERMINING QUALITY OF CARE

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 HCFA 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.--

A. Standard Survey.--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 HCFA-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 identifies how the HHA defines, plans for, delivers, and measures anticipated outcomes for patients.

B. Partial Extended Survey.--Is conducted:

- 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.

C. Extended Survey.--Is conducted:

o 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

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

2196.2 Home Health Functional Assessment Instrument (FAI).--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 Form HCFA-485 for each patient in the survey sample (and/or the previous Form HCFA-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 Outcome And Assessment Information Set (OASIS) Requirements.--OASIS requirements for Medicare-approved HHAs were published on January 25, 1999, in the ***Federal Register*** document: Medicare and Medicaid Programs: Reporting OASIS Data as Part of the Conditions of Participation for Home Health Agencies and Comprehensive Assessment and Use of the OASIS as Part of the Conditions of Participation for Home Health Agencies; Final Rules. The following CoPs were included in this document:

o 42 CFR Part 484.11, Condition of Participation: Release of Patient Identifiable OASIS Information;

o 42 CFR Part 484.20, Condition of Participation: Condition of Participation: Reporting OASIS Information; and

o 42 CFR Part 484.55, Condition of Participation: Condition of Participation: Comprehensive Assessment.

Offsite and onsite monitoring are both required to determine compliance with the OASIS CoPs. The OASIS Educational Coordinator and/or the OASIS Automation Coordinator can assist in providing available oasis reports (e.g., data management and quality monitoring reports) to surveyors.

2196.4 Clinical Laboratory Improvement Amendments.--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 HCFA 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

A. Components.--Under the standard survey, the surveyor is required to:

o 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

o 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.

B. Activities.--During the standard survey, the surveyor determines the HHA's compliance with:

o 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).

C. Applicability.--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 HCFA's 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 2 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 2 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 HCFA 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

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

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

A. Task 1 - Pre-Survey Preparation.--Prior to each survey, review the HHA file (or application, in the case of an initial) in accordance with SOM §2704. Also review the information in the State files relating to the disclosure of information statement made by the HHA (Form HCFA-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 any available reports generated from the OASIS data (e.g., case-mix, adverse event, risk adjusted OBQI reports). 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). Follow SOM §2710, Reviewing Forms at the Beginning of a Survey.

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:

- o Is operational;
- o Has completed the Medicare Enrollment Application Form HCFA-855 and had this form verified by the assigned RHHI;
- o Met the surety bond and capitalization requirements;
- o Is providing nursing and at least one other therapeutic service;
- o Can demonstrate the operational capability of all facets of its operations;
- o Has successfully completed an OASIS transmission to the State repository; and

- o 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 HCFA RO, the HCFA 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 SOM §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 of the SOM regarding licensure requirements.

B. Task 2 - Entrance Interview.--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 patient list, 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 of patients scheduled for a home visit during the survey;

- List of current employees;
- CLIA certificate (if applicable);
- Forms to complete: Forms HCFA 1513 and 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; and
- If applicable, the HHA's rationale for stating that it is provider-based. (See SOM §2004.)

C. Task 3 - Information Gathering.--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.

1. Responsibilities include but are not limited to:

- Reviewing how the HHA performs the comprehensive assessment of patients incorporating the OASIS items;
- Determining if the comprehensive assessment accurately reflects the patient's status;
- 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, and reviewed 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;

- o Observing patient care;
- o Interviewing staff and patients;
- o Reviewing a sample of home health aides files; and
- o Reviewing how the HHA complies with CoPs.

2. Request the following:

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

3. When discussing observations:

- o Use observational skills at all times during the survey and discuss your observations, as appropriate, with team members and HHA personnel.
- o Ask pertinent questions to obtain a baseline of information that expands early observations.
- o Maintain an open and ongoing dialogue with HHA personnel.
- o Give the HHA the opportunity to provide additional information before making compliance decisions.
- o Ask staff to describe the usual procedural timeframes for filing pertinent clinical information in the record.

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.

4. Clinical Record and Home Visit Selection for Standard Survey.--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 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).

5. Selecting a Sample of Patients for Clinical Record Review With Home Visits.-- 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.

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 judgement, 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.)

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

o 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.

6. Selecting Sample of Clinical Records of Patients Who Will Not Receive Home Visit.--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

7. Recording Information.--

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:

o 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.

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

o 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.

o Determine if the comprehensive assessment accurately reflects the patient's

status.

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

o 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.

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

o Review the timeliness of services provided to the patient.

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

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

o 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?

o 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?

o 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?

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

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

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

o 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.

o 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 HCFA-1572(b) (see Exhibit 14D), and select the appropriate action according to the following choices:

o 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. Record any standard-level deficiencies identified during the standard survey and request a PoC. The survey is complete.

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

8. Conducting Home Visits.--

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, at a minimum, 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 on-site 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 the HHA to be 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 reviewing 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.

c. Discontinuing Interview.--Discontinue the interview if:

o 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;

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

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

D. Task 4 - Information Analysis.--The information analysis process requires surveyors to review the information gathered during the survey process and to make judgements about the compliance of the HHA. 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;
- 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 judgement, 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.

E. Task 5 - Exit Conference.--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 HCFA-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:

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

o 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 HCFA regarding compliance determinations.

o 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.

o 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 HCFA on Form HCFA-2567.

o Respond to any HHA procedural questions with timely and accurate survey process information (i.e., recertification status: the timeframe for receiving Form HCFA-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.

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

o 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 HCFA-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 SOM §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.

F. Task 6 - Formation Of The Statement Of Deficiencies.--Write the deficiency statement in terms specific enough to allow a reasonably knowledgeable person to understand the aspects of each requirements that are not met. SOM §2728 provides detailed instructions on the effective completion of Form HCFA-2567.

Ambulatory Surgical Centers (ASCs)

2210. ASCs - CITATIONS AND DESCRIPTION

Section 1832(a)(2)(F) of 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 HCFA. 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 ASC may share common space with another hospital function only if the space is never used by the other party during the scheduled hours of ASC operation. The operating room(s) and recovery room(s) are to be used only for patients having surgery.

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 Part 416.30(f)(1).)

The ASC may not perform a surgical procedure on a Medicare patient when, before surgery, an overnight hospital stay is anticipated. There may, however, arise unanticipated medical circumstances that warrant a Medicare patient's hospitalization after an ASC surgical procedure. The ASC must have procedures for the immediate transfer of these patients to a hospital (42 CFR Part 416.41). Such situations should be infrequent.

ASC covered procedures (see 42 CFR Part 416.65) are those that generally do not exceed 90 minutes in length and do not require more than 4 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 Medicare 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 HCFA-377, (Exhibit 64) with a Certification and Transmittal, Form HCFA-1539, to the RO together with any evidence covering the activities operated. Copies of the ASC Health Insurance Benefits Agreement, Form HCFA-370 (Exhibit 65), are signed and processed in the same manner as provider agreements.

Rural Health Clinics (RHCs)

2240. RHCs - CITATIONS AND DESCRIPTION

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 regulations. 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

A. General.--The SA reviews and evaluates the information on the Request to Establish Eligibility, Form HCFA-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:

1. Location of Clinic.--Subpart A of 42 CFR 491 sets forth the conditions that RHCs must meet in order to qualify for payment 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 HCFA-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 HCFA-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.

2. Medical Direction.--Question II on Form HCFA-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. If performed in the clinic, the time spent in this medical direction must be included in the answer to question III.A.

3. Physician Assistant, Nurse Practitioner, and/or Certified Nurse Midwife Staff.--The SA indicates in question III.B. and/or III.C. on Form HCFA-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 1-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.

The request for the waiver must be made more than 6 months after the expiration date of any previous waiver of staffing requirements for the facility.

B. Clinic Is Determined Ineligible.--If the clinic is not located in an area that is nonurbanized 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.)

C. Basic Requirements Are Met.--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.)

D. Identifying Clinic as Provider-Based.--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.

E. Compliance with Civil Rights Statutes.--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.

F. Laboratory Services Provided in RHCs.--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

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 which meet the requirements of the regulation.

2246. CLINIC'S REQUEST TO PROVIDE VISITING NURSE SERVICES

An approved RHC may also seek approval to provide covered visiting nurse services. These services must be furnished by an RN, LPN, or licensed vocational nurse.

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 consult 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

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:

o The facility requests a waiver;

o 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

o 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.

A. Applying Waiver to Applicants.--The initial packet of information sent to RHC applicants by the SA should include a statement that if the applicant plans to request a waiver, the applicant must attach the request to Form HCFA-29 along with appropriate documentation.

B. Applying Waiver to Participating RHCs.--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.

C. Documentation Demonstrating Efforts to Meet Staffing Requirements.--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:

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

o Information about trips to professional meetings, educational institutions, and health care facilities for recruiting purposes;

- o Copies of advertisements for recruiting hires; and
- o Results of personal interviews with potential hires.

D. Monitoring Waivers.--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.

E. Notification.--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

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.

- o The RO sends a copy of Form HCFA-2007 to the Medicare intermediary which has been designated as the regional fiscal agency and another to the SMA which has billing jurisdiction for RHCs.
- o For provider-based clinics, the RO sends a copy of Form HCFA-2007 to the intermediary who normally services that provider.
- o 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 supporting 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

A. General.--Section 4162 of P.L. 101-508 (OBRA 1990), amended §1861(ff)(3)(A) and §1832(a)(2)(J) of the Social Security Act (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.

B. Special Requirements.--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.

C. Community Mental Health Centers.--

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 42 CFR Part 410.2, a CMHC must provide all of the following core services to meet the statutory definition of a CMHC. 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.

D. Partial Hospitalization Program (PHP).--A PHP, for Medicare purposes, is a program that is furnished by a hospital to its outpatients or by a CMHC which provides partial hospitalization services.

E. Partial Hospitalization Services Provided by CMHCs or by Others Under Arrangements with the CMHC.--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:

o 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);

o 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;

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

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

o 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;

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

o 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

o 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.

4. Are 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 Social Security Act:

o Services to hospital inpatients;

o Meals, self-administered medications, transportation; and

o Vocational training.

F. Definitions of Core Services.--HCFA defines the CMHC core services as follows:

o **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.

o **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.

o **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.

o **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.

o **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.

- **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 HCFA 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.

G. Threshold and Service Requirements for CMHCs.--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, HCFA will look for evidence that the applicant is already providing the core services as a pre-condition for certification. For example, HCFA will look to see that the applicant:

o Is fully operational for one entire business quarter;

o Has served, as evidenced by complete, onsite medical record documentation from within 3 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,

+ The capability and clinical expertise to provide such screening services; and

+ Provided screening services for the specific purpose (e.g., reason for referral) of which is to assess 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;

+ A minimum of 3-day treatment or other partial hospitalization or psychosocial rehabilitation 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.

2252. CERTIFICATION PROCESS

A. General.--HCFA ROs are responsible for approving or denying CMHCs for Medicare participation and for notifying CMHCs and the appropriate Fiscal Intermediaries (FI) of the approvals or denials based on the SA certification recommendations, information gained from an onsite visit to the CMHC by a national site visit contractor, and the FI's recommendations as a part of the normal course of CMHC provider enrollment. Therefore, the SA, FI, or national site visit contractor directs all recommendations for approval or denial of the CMHC's request for Medicare participation to the RO, via the SA, following evaluation of the materials submitted with the CMHC's request. As part of the process to approve or deny CMHC applications, ROs are responsible for reviewing the materials collected as the result of the CMHC site visits conducted by the national site visit contractor, including medical records, the completed Site Visit Assessment Tool, and the completed Site Visit Summary. The purpose of the RO's review of these materials 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.

B. Request to Participate.--CMHCs that wish to participate in the Medicare program for the purpose of providing partial hospitalization services must request application materials from the SA, and must complete and submit the Form HCFA-855, and a separate statement over a penalty clause attesting that they meet the requirements for CMHCs contained in the Social Security Act and HCFA Regulations (See Exhibit 275).

C. Information to be Sent to CMHC Applicant.--The SA mails copies of the following to applicant CMHCs, including those undergoing a change of ownership:

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

o 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.

o Exhibit 5. Statement of Financial Solvency, Form HCFA-2572.

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

- Exhibit 256. Form HCFA-855-Enrollment Application

- Exhibit 276. Provider Agreement

- Exhibit 275. Attestation Statement

D. Processing CMHC Requests, SA Role.--The SA 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.

o The SA forwards concurrently to the appropriate fiscal intermediary, the CMHC's completed Form HCFA-855 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 HCFA-855; and

- A signed Form HCFA-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.

o The SA also forwards the completed package from the national CMHC site visit contractor to the appropriate RO, including the medical records collected at the time of the site visit, the Site Visit Assessment Tool, the Site Visit Summary, and all other completed forms and paperwork.

o In particular, HCFA 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 SOM §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 HCFA-855, to the RO for a denial of the request to participate in Medicare. The SA will process CMHC certifications pursuant to applicable instructions in SOM §§2760-2776 and the following SOM sections. This includes completing the appropriate blocks of Part I and Part II of the Form HCFA-1539 and completing the CMHC Crutial Data Extract based on the information provided by the CMHC.

Should the SA receive any inquiries regarding the site visit by the national site visit contractor or other non-SA role activities, those inquiries should be referred to the appropriate HCFA RO.

E. Processing CMHC Requests, FI Role.--The FI's primary role with respect to CMHC applicants is to verify the information provided on the Form HCFA-855. As a part of the enrollment process, the FI will arrange with the national site visit contractor to evaluate the CMHC's attestation that it provides the core services at §1913(c)(1) of the PHSA by conducting an

unannounced, onsite visit at the site of the applicant CMHC. 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. However, the FI will not request the contractor to conduct an onsite visit until it has completed its review and verified the information provided on the Form HCFA-855, because there is no point in conducting an onsite visit if the CMHC is denied enrollment based on the Form HCFA-855 review, or the CMHC has not provided all of the information necessary to make an enrollment decision. When making an on-site visit, the national site visit contractor 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, via the SA, of approval or denial of the CMHC's request for Medicare enrollment/participation based on its review of the Form HCFA-855 and the findings of the national site visit contractor resulting from the onsite visit. Neither the FI nor the national site visit contractor should indicate in any way to the CMHC that it may 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. The SA will ensure that copies of all materials collected as a part of the onsite visit will be submitted to the RO to assist it in its decision. These materials include the completed Site Visit Assessment Tool, medical records, and the CMHC Site Visit Summary. If the FI receives a Form HCFA-855 from the CMHC directly, it should forward the form to the SA for processing as a part of the CMHC application process.

F. Processing CMHC Requests, RO Role.--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. It will evaluate the CMHC's application and the recommendations of the SA and FI, the materials collected by the site visit contractor as a result of 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, HCFA 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. 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 HCFA 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 SOM §2252 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 HCFA 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 HCFA's 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 HCFA that it has met all of the service and threshold requirements required of all new CMHCs, per SOM §2250 G;

- Whether the facility is providing all of the core services with the exception of one which 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 HCFA Press Office.

G. The Role of the National CMHC Site Visit Contractor.--The national CMHC site visit contractor will work in partnership with the RO, SA and FI within the established process for CMHC enrollment to conduct onsite visits of all applicant CMHCs, CMHCs undergoing changes of ownership, and a limited number of existing CMHCs that HCFA has cause to believe are not in compliance with all State and Federal requirements. Therefore, this contractor will conduct a site visit at the request of the FI after the FI has completed its review of Form HCFA-855 and recommended that the CMHC be enrolled in the Medicare program. Once the site visit has been completed, the national site visit contractor will send all of the site visit materials to the SA so that those materials may be forwarded to the RO with all of the other accompanying enrollment paperwork. After the RO receives all of the enrollment paperwork and site visit materials, it will evaluate them, make an enrollment decision, and determine if a CMHC applicant should be approved or denied, or whether an existing agreement should be terminated. As the national CMHC site visit contractor commences its work, it will be contacting the ROs, FIs and SAs to establish contact points and determine best practices for a seamless CMHC enrollment process with the addition of the site visit requirement. Questions regarding the site visit process may be directed to the HCFA's Office of Financial Management, Program Integrity Group, Division of Provider and Supplier Enrollment.

H. Facility Alleges it is Provider-Based.--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 HCFA's 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 HCFA approval as a CMHC, will be developed using the guidelines contained in SOM §2004.

I. Facility Requests an Alternative Site to be Approved Initially or Subsequent to Approval.--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 which 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 judgement, 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 HCFA-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 HCFA 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 HCFA 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 HCFA Form 855. 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 HCFA 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 HCFA enrollment process (SOM §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 national site visit contractor 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 inform the RO via the 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 HCFA 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 HCFA 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.

J. RO Approval of CMHC Request for Medicare Approval.--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 (SOM §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 (SOM §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.

K. RO Denial of CMHC Request for Medicare Approval.--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.

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.

L. Approved Provider Changes Ownership.--CMHCs undergoing a Change of Ownership (CHOW) are treated as other providers (See SOM §§3210-3210.5, and §2005 F.) with the following exceptions:

o Provider Agreement is Assigned, SA Role.--The provider is required to report the CHOW to the SA. If this reporting is not done, or not done timely, the provider agreement is automatically assigned. (If the CHOW is reported to the FI or RO, the FI or RO will forward the CHOW to the SA to initiate the CHOW.) The SA will send the new owner a copy of all of the

materials under SOM §2252 C and follow the instructions in SOM §3210.5 for an assigned provider agreement. The SA, upon receipt of the requested materials (attestation, pertinent application information about the new owner, Form HCFA-855, Assigned Provider Agreement) will forward the Form HCFA-855 to the FI for verification UNLESS 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 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 HCFA. In these cases, the file will be forwarded directly to 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 national site visit contractor to initiate a site visit within 6 months. After the site visit has been completed, the results will be sent to the SA. The SA will subsequently send the completed site visit package as indicated in SOM §2252 D to the RO.

o Provider Agreement is Assigned, FI Role.--The FI will verify the information on the Form HCFA-855 and inform the RO. It will, following verification of the enrollment information, request the national site visit contractor to conduct an onsite visit of the CMHC under the new ownership within 6 months. The site visit results will then be forwarded to the RO for any necessary action depending on the findings.

o Provider Agreement is Assigned, RO Role.--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. 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 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, the national site visit contractor will be conducting a site visit of the new owner, and the resulting documentation from the visit will be forwarded to the RO by the SA. (Follow procedures in SOM §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.

o Approved Provider Changes Ownership, Provider Agreement is not Assigned.--If the new owner chooses not to have the former owner's provider agreement assigned to him/her, the former owner's provider agreement will be terminated and the new owner, if he/she wants to participate in Medicare, must come into the Medicare program as a new applicant (see SOM §2252 B.). 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.

M. Voluntary Termination.--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.)

N. Involuntary Termination.--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 SOM §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 SOM §2252 M).

O. Identifying the "Most Egregious" CMHCs for Termination Action.--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. HCFA 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:

o 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.

o 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.

o 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.

o 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 HCFA-855 which 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.

Rural Primary Care Hospitals (RPCH)

2254. ESSENTIAL ACCESS COMMUNITY HOSPITAL (EACH)/RPCH PROGRAM - CITATIONS AND DESCRIPTION

A. Citations.--Sections 6003(g) and 6116 of OBRA 1989 added §1820 to the Act, and §4008 of OBRA 1990 revised §1820 of the Act to authorize:

1. A grant program in a limited number of States for the development of rural health care plans and rural health care networks, and for hospitals to finance the costs associated with conversion to an EACH or an RPCH;

2. The establishment of two new Medicare provider designations for hospitals (EACHs) and facilities (RPCHs) in the grant States; and

3. The criteria under which a hospital or facility is designated as an EACH or an RPCH by a grant State. The grant States are California, Colorado, Kansas, North Carolina, New York, South Dakota, and West Virginia.

Section 6003 of OBRA 1989 also authorized the Secretary to designate 15 RPCHs that are not located in States receiving EACH/RPCH grants. A special provision of §4008 of OBRA 1990 directs the Secretary, in designating RPCHs, to give preference to facilities that have entered into agreements with rural health networks in an EACH/RPCH-grant State.

The CoPs for RPCHs are found in 42 CFR 485. Appendix W contains the survey tasks and interpretive guidelines for RPCHs.

B. Description.--

1. Rural Health Network consists of the following:

a. At least one hospital that is designated as an EACH, is a regional referral center (RRC) under §1886(d)(5)(C) of the Act, or is located in an urban area and meets the criteria for classification as a referral center under §1886(d)(5)(C) of the Act;

o At least one facility designated as an RPCH; and

o Network members which have entered into agreements regarding patient referral and transfer, development and use of communications systems including, where feasible, telemetry systems and systems for electronic sharing of patient data, and providing emergency and non-emergency transportation among the members.

2. EACH is a hospital that is so designated by the State in which it is located or by the Secretary under the authority at §1820(i)(1) of the Act. To be approved for participation in Medicare as an EACH, a hospital must:

a. Be a Medicare-participating hospital that is in compliance with the hospital CoPs in 42 CFR 482;

b. Be located outside any area that is a Metropolitan Statistical Area (MSA) as defined by the Office of Management and Budget, or outside any area that is recognized as urban under 42 CFR Part 412.62 or 412.63, and has not been classified as an urban hospital for purposes of the standardized payment amount by HCFA;

c. Be located more than 35 miles from any hospital that:

- o Is designated as an EACH;
- o Is a Rural Referral Center (RRC) under 42 CFR Part 412.96; or
- o Is located in an urban area and meets the RRC criteria under 42 CFR Part 412.96;

d. Has at least 75 beds or is located more than 35 miles from any other hospital; and

e. Has agreements with at least one RPCH to:

- o Provide emergency and medical backup services;
- o Accept patients transferred from the RPCH;
- o Receive data from and transmit data to the RPCH; and
- o Grant staff privileges to physicians who furnish care at the RPCH.

3. RPCH is a facility designated as an RPCH by the State in which it is located or by the Secretary under the authority in §1820(i)(2) of the Act. To be approved for participation in Medicare as an RPCH, a facility must:

a. Be a hospital with a Medicare participation agreement at the time it applies for designation as a RPCH and not have been found, on the basis of a survey under §1864 of the Act, to be out of compliance with the Medicare hospital CoPs in 42 CFR 482;

NOTE : A closed facility may be designated as an RPCH by the State or by HCFA and subsequently certified for participation in Medicare as an RPCH if the facility applied to the State or HCFA for RPCH designation within 12 months of the date it closed, and if, at the time it closed, it had a participation agreement under §1866(a) of the Act and had not been found, on the basis of a survey under §1864 of the Act, to be in violation of any requirement for participation as a hospital.

b. Be located in a rural area as defined in §1866(d)(2)(D) of the Act, except that a RPCH located in a MSA or similar area as defined in 42 CFR Part 412.62(f) is deemed to meet this location requirement if the RPCH is located in a county whose geographic area is substantially larger than the average geographic area for urban counties, and if the RPCH's service area is characteristic of service areas of hospitals located in rural areas;

c. Cease, or agree upon certification as an RPCH to cease, providing inpatient care except as permitted in §1820(f)(1)(F) of the Act (i.e., not more than 6 inpatient beds; 12 for swing-bed RPCHs) for providing inpatient care not to exceed 72 hours unless a longer period is required because transfer to a hospital is precluded due to inclement weather or other emergency conditions;

d. Make available 24-hour emergency care;

e. If a member of a rural health network, have in effect an agreement to participate with other network members in the network communications system for the electronic sharing of data; and

f. Meet the hospital staffing requirements at §1861(e) of the Act except that the facility:

o Is not required to meet hospital standards related to the number of hours during the day, or days during the week, that the facility must be open;

o Is not required to meet the hospital requirements for full-time, onsite services of a dietician, pharmacist, laboratory technician, medical technologist, and radiology technologist (these may be met on a part-time, off-site basis); and

o May provide inpatient care as defined at §1820(f)(1)(F) of the Act under the direction of a physician's assistant, clinical nurse specialist, or nurse practitioner.

An RPCH may have a swing-bed agreement. RPCHs with swing-beds may have a total of 12 beds for inpatient care. All 12 beds may be used for any combination of acute care or SNF-level care. RPCH swing-bed patients at an SNF level of care are not subject to the 72-hour length-of-stay requirement.

2256. MEDICARE DESIGNATION AS AN EACH--SA PROCEDURES

When the State has designated a hospital as an EACH, it provides the RO with the name, address, and provider number of the hospital and send all documents considered in making that EACH designation. The EACH documentation must be sufficient to enable the RO to verify the criteria in 42 CFR Part 412.109.

A hospital cannot be an EACH unless it has in effect a network agreement (as described in §2254.B.1) with at least one facility that is currently participating as an RPCH. Designation by the State does not by itself qualify a facility as a currently participating RPCH; the earliest date of RPCH participation will be determined under §2258.F.

A. Application.--A prospective EACH may apply for designation under the Medicare program by submitting the "Hospital Request for Certification in the Medicare/Medicaid Program," Form HCFA-1514, to the RO.

B. Timing of Application.--The SA advises the prospective EACH that to ensure prompt verification and payment at the sole community rate, its application for Medicare designation as an EACH should be submitted to the RO no later than 60 days before the scheduled date of the compliance survey at its affiliated RPCH. Later application may delay the effective date of EACH status.

C. EACH Verification.--The RO will verify that a prospective EACH meets all location and other requirements in 42 CFR Part 412.109, including the requirements relating to accepting RPCH transfer patients and granting privileges to RPCH physicians. Ordinarily, this verification is accomplished by a review of documents at the RO. RO staff will not visit the EACH unless there are issues (such as whether transfer agreements are actually in place and being followed) that can be resolved only by an onsite visit.

D. EACH Surveys.--The EACH/RPCH program does not contain any additional CoPs for hospitals that are approved to participate in Medicare as EACHs. EACHs will continue to be surveyed for hospital participation by either the accrediting body, if accredited, or by the SA for Medicare recertification purposes.

E. Statutory Obligations For EACHs.--A hospital already certified as an EACH must maintain the agreements with an RPCH described at §§1820(e)(4) and (e)(5) of the Act to continue its status as an EACH. The SA notifies the RO promptly if it has reason to believe that a certified EACH does not have in effect the RPCH agreements required in the statute.

2256.1. PROCEDURES FOR EACH APPROVAL BY RO

The RO must verify that a prospective EACH meets all location and other requirements in 42 CFR Part 412.109, including the requirements relating to accepting RPCH transfer patients and granting privileges to RPCH physicians. The RO determines whether the Division of Medicare or the Division of Medicaid and State Operations will process and approve EACH applications. The application and approval processes are as follows:

A. Application.--A prospective EACH applies for Medicare participation as an EACH using the Hospital Request for Certification in the Medicare/Medicaid Program, Form HCFA-1514. After the RO receives the application, it contacts the SA to determine if the hospital has been properly designated as an EACH by the State. Designation of a hospital as an EACH by the State in advance of RPCH participation is not sufficient to qualify a facility as a participating EACH.

B. Verification Criteria.--EACH verification ordinarily requires only a review of documents which are provided to the RO by the SA following the first-time survey of the prospective RPCH in the same network with the prospective EACH. To approve a hospital for Medicare designation as an EACH, the RO verifies that:

1. The hospital participates in a rural health network with a RPCH;

2. The hospital is located in a rural area as described in 42 CFR Part 412.109(c)(1);

3. The hospital has at least 75 inpatient beds or is located more than 35 miles from any other hospital; and

4. The EACH has in effect agreements with a RPCH in the same network as described in 42 CFR Part 412.109(c)(3) to:

- Provide emergency and medical backup services;
- Accept patients transferred from the RPCH;
- Receive from and transmit patient data to the RPCH; and
- Provide staff privileges to physicians providing care at the RPCH.

The RO need not send staff to the EACH unless there are issues (such as whether transfer agreements are actually in place and being followed) that can be resolved only by an onsite visit.

C. Approval Notification.--When the EACH verification is complete, the RO notifies the prospective EACH in writing (use Exhibit 149) that it has been designated as an EACH by HCFA, and that it will be paid as a sole community hospital beginning 30 days after the date of your letter. (See 42 CFR Part 412.92(b)(2)). The RO sends a copy of the notice to the fiscal intermediary. Do not issue the EACH notification until the hospital meets all requirements for designation as an EACH, including an agreement with a participating RPCH. (See 42 CFR Part 412.108(c)(3).)

D. Effective Date.--An EACH cannot be approved for Medicare participation by the RO until at least one RPCH in the same rural health network is approved for Medicare participation. The earliest effective date for participation by an EACH is 30 days after the effective date for participation by a RPCH in the same network. (See 42 CFR Part 412.92(b)(2).)

E. Coordination with RPCH Applications.--When the RO is processing Medicare approval requests for an EACH and a RPCH in the same network, it should coordinate its approval activities (e.g., between DMSO and the Division of Medicare) so that notification letters for both providers are issued on the same date. This ensures that the network EACH is eligible for the sole community rate on the earliest possible date.

2258. MEDICARE PARTICIPATION BY RPCH--SA PROCEDURES

An RPCH must be surveyed for compliance with the CoPs in 42 CFR 485, and if it has swing-bed approval, for compliance with the specific RPCH SNF requirements found in 42 CFR Part 485.645(b).

A. RPCH Applications.--When a hospital that has been designated by the State as an RPCH contacts the SA office to apply for Medicare participation as a RPCH, the SA sends Exhibit 134, "Model Letter: Transmitting Materials to Rural Primary Care Hospitals," to the facility including copies of Form HCFA-1514, "Hospital Request for Certification in the Medicare/Medicaid Program," and Form HCFA-1513, "Ownership and Interest Control Disclosure Statement." When the SA receives the completed RPCH application for Medicare participation, it verifies that the facility has been properly designated as an RPCH by the State government entity responsible for RPCH designation prior to forwarding the application to the RO. The RO will review the application and notify the SA office to survey the prospective RPCH.

B. Arranging RPCH Survey.--After the RO has authorized a survey, the SA sends Exhibit 135, "Model Letter: Notification to Rural Primary Care Hospital Regarding Scheduling a Survey," to the facility, including a copy of the CoPs for RPCHs. When arranging for and conducting the RPCH survey, the SA follows the procedures outlined in Appendix W. The SA contacts the administrator of the facility at least 2 weeks in advance to arrange for survey dates that are mutually acceptable to the SA and the facility. Also, the SA inquires if the RPCH will meet its Quality Assurance (QA) program requirements in 42 CFR Part 485.641(b) through an agreement or arrangement with a hospital. If this is the case, the SA advises the administrator that the individual at the hospital who is responsible for QA at the RPCH must be available at some time during the survey to meet with the survey team.

C. Pre-Survey Activity.--The SA follows the procedures outlined in Part I of Appendix W, "Sequence of Tasks for Rural Primary Care Hospitals (RPCHs)" and the procedure in Task 1, "Pre-Survey Preparation." The SA verifies requirements in the RPCH CoPs in 42 CFR Part 485.608; 485.610; 485.612; and 485.614, from facility files and other documentation available at its office. Also, for a prospective RPCH with swing-bed approval, the SA determines that the swing-bed approval is current. For all first-time applications to participate in the swing-bed program, the SA must determine that the facility has not had a swing-bed agreement terminated within 2 years of the date of the current application.

D. Onsite Survey Activity.--The SA follows the procedures in Part I of Appendix W, to include Task 2 through Task 8 when conducting its onsite survey at the RPCH. The onsite portion of the survey will include all of the CoPs beginning with 42 CFR Part 485.616 through §485.645.

NOTE: Personnel qualifications for mid-level practitioners in a RPCH, including clinical nurse specialists, nurse practitioners, and physician assistants, are described in 42 CFR Part 485.604. When reviewing RPCH personnel files, refer to these requirements and applicable State licensure requirements in determining that RPCH mid-level practitioners have the necessary training and experience.

E. Preparing Statement of Deficiencies.--The SA uses the Statement of Deficiencies and Plan of Correction, Form HCFA-2567, when citing deficiencies, and refers to the manual, "Principles of Documentation," for procedural guidance.

F. RPCH Effective Dates.--After the RO reviews the SA survey findings and recommendation, it will determine whether the RPCH should be certified for participation in Medicare. The effective date will be either the last date of the SA initial survey, if the RPCH was in full compliance at that time, or the date that an approvable PoC for the facility was received at the SA office.

2258.1 RO PROCEDURES FOR RPCH APPROVAL

A prospective RPCH must be surveyed by the SA and be in compliance with the CoPs for RPCHs in 42 CFR Part 485 before it can be approved for participation in Medicare as a RPCH provider.

A. Application.--After the RO receives the application from the prospective RPCH, it contacts the SA to determine that the facility is properly designated as a RPCH by the State. (The 15 RPCHs designated by HCFA do not require State designation.) If the facility has been properly designated, the RO authorizes the SA to conduct a compliance survey following the procedures outlined in Part I of Appendix W of the SOM, and in accordance with the interpretive guidelines for surveyors in Part II of Appendix W.

B. Verification Criteria.--RPCH verification requires that the RO review the SA survey findings contained on the Statement of Deficiencies and Plan of Correction (Form HCFA-2567) to determine if the prospective RPCH is in compliance with the hospital CoPs in 42 CFR 482 at the time it applied. (See §1820(f)(1)(B).)

If the facility requesting Medicare participation as a RPCH is not a member of a rural health network, the RO verifies that the prospective RPCH has agreements or arrangements for the following:

- Physician availability to meet its requirement in 42 CFR Part 485.618(e) and 485.631(b); and

- Inpatient hospital care to meet its requirements in 42 CFR Part 485.635(c)(1)(i).

C. Notification.--If the facility is found to be in full compliance with the CoPs in 42 CFR 485, the RO notifies the facility in writing (use Exhibit 150) that it has been approved for participation and sends a copy of the notice to the FI. Do not issue the letter until the facility is in compliance with all of the CoPs in 42 CFR 485.

D. Effective Dates.--The effective date for participation by an RPCH will be one of the following:

- The last date of the initial survey by the SA, provided the prospective RPCH is in full compliance with the RPCH CoPs on that date and the RO has reviewed and approved the SA recommendation for participation in Medicare; or

- The date that the prospective RPCH submits a correction plan that is acceptable to the RO.

E. Coordination with EACH Applications.--When the RO is processing applications for an EACH and a RPCH in the same network, it coordinates the notification process so that both the EACH and the RPCH are issued notification letters on the same date. This ensures that the network EACH is eligible for the sole community rate on the earliest possible date.

2258.2 PROCEDURES FOR PROCESSING RPCH SWING-BED APPLICATIONS

An RPCH is eligible to participate in the Medicare hospital swing-bed program. A hospital that is already in the swing-bed program may apply to change its Medicare provider status to a swing-bed program. A hospital that is already in the swing-bed program may apply to change its Medicare provider status to a swing-bed RPCH without making a separate application to participate in the swing-bed program (i.e., as a new swing-bed provider), but as a RPCH with swing-beds, its overall bed count may not exceed 12. A facility that has been designated as a RPCH by the State and certified as a RPCH by HCFA may apply at any time to participate in the swing-bed program provided it has not had a swing-bed approval terminated within 2 years prior to application. Application is made using the Request for Approval as a Hospital Provider of Extended Care Services (Swing-Bed) in the Medicare and Medicaid Programs, Form HCFA-605 (See Exhibit 81). Only HCFA can approve an application to participate in the Medicare swing-beds program. When processing a RPCH swing-bed application, the RO follows the procedures outlined in §§2036-2041.1.

2259. RO PROCESSING COMPLAINTS AGAINST EACHs and RPCHs

A. Processing EACH Complaints.--The RO follows the procedures outlined in §§3280-3298 for complaints involving the Medicare hospital CoPs in 42 CFR Part 482. Complaints relating to the EACH requirements in §§1820(e)(4) and (e)(5) of the Act relate to an EACH's eligibility to receive the sole community rate. The RO may determine whether the complaint should be processed by the Division of Medicare or DMSO. The RO will process complaints as follows:

- When an allegation is received from the SA or any other source, the RO reviews the information provided and determine if additional documentation is required to authorize a complaint investigation;

- If, after reviewing the original complaint and any additional documentation that the RO requested, it has reason to believe that an EACH has allowed its RPCH agreements required in §§1820(e)(4) and (e)(5) to lapse, or is not honoring those agreements, the RO authorizes the SA to investigate the allegation(s) at the EACH within 45 days of your notification.

- The RO advises the SA to determine the validity of the complaint, and to forward its findings and recommendations to it within 10 days of its resurvey at the EACH; and

- If the EACH cannot demonstrate compliance with the statutory requirements in §§1820(e)(4) and (e)(5), the RO provides a copy of its findings to the Division of Medicare or DSMO, as appropriate.

The RO notifies the hospital (use Exhibit 151) that its EACH status is revoked. The RO provides a copy of the notification letter to the FI, the SA, and the affiliated RPCH(s) in the same rural health network as the EACH.

B. Processing RPCH Complaints.--When the RO receives a complaint against a RPCH regarding the CoPs in 42 CFR 485, including the SNF requirements for a swing-bed RPCH, it follows the normal complaint process for nonaccredited hospitals in §§3280 and 3298.

2259.1. RO PROCESSING DENIALS OR TERMINATION FOR EACHs AND RPCHs

When the RO is processing denials or terminations for Medicare-participating hospitals that have been certified as EACHs and RPCHs, it follows the normal procedures that apply to Medicare-participating hospitals. For RPCH terminations, the RO uses Exhibit 152.

The EACH denial process discussed in §2259A relates only to a failure by an EACH to meet its responsibilities in 42 CFR Part 412.109.

NOTE: When the RO processes a termination action for a RPCH that is the only RPCH in a rural health network with a hospital that has been certified as an EACH, it immediately notifies the EACH that it no longer meets the requirements to be certified as an EACH. The RO uses Exhibit 151.

2260. RPCH ANTI-DUMPING REQUIREMENTS

Medicare participating hospitals must meet the requirements in §1867 of the Act, "Examination and Treatment of Emergency Medical Conditions and Women in Labor," and the applicable provisions of §1866 of the Act. The regulatory requirements are found in 42 CFR Part 489.24 and 489.20(l), (m), (q), and (r). For purposes of the anti-dumping requirements, the term "hospital" includes RPCHs relative to these requirements. (See 42 CFR Part 489.24(b).)

A. General Rule.--The provisions of §1867 apply to all individuals (not just Medicare beneficiaries) who attempt to gain access to a hospital or an RPCH for emergency care. The statute and regulation defines "hospital with an emergency department" to mean a hospital that offers services for emergency medical conditions within its capacity to do so.

The SA will investigate any alleged violation by a RPCH according to the procedures found in §§3400 through 3412, Conducting Investigations for Alleged Violations of 42 CFR Part 489.20(l), (m) (q), and (r) or 489.24, Responsibilities of Medicare Hospitals in Emergency Cases.

B. Closed RPCHs and 30-Minute Rule.--An RPCH without inpatients is not required to have emergency staff onsite 24-hours-a-day. However, 42 CFR Part 485.618(d) of the RPCH CoPs requires a RPCH to provide a practitioner, either a qualified mid-level practitioner (i.e., a physician assistant, nurse practitioner, or clinical nurse specialist) or a physician (i.e., an M.D. or D.O.), onsite within 30 minutes on a 24-hour-a-day basis to treat its emergency patients. Therefore, when the RPCH practitioner arrives onsite to treat an emergency patient, the anti-dumping law is in effect, but not before the practitioner's arrival.

C. Patient Transfers and Anti-Dumping Requirements.--If a qualified medical person, in consultation with a physician, determines an appropriate transfer is necessary, the RPCH must:

- Provide the medical treatment, within its capacity, which minimizes the risk of transfer to the patient;
- Send all pertinent medical records available at the time of transfer to the receiving hospital;
- Effect the transfer of patients, through qualified personnel and transportation equipment, including necessary life support measures; and
- Obtain the consent of the receiving hospital.

The RPCH may not transfer a patient under the anti-dumping law unless the patient requests the transfer or a physician certifies the medical necessity of the transfer.

2262. ADVANCE DIRECTIVES REQUIREMENTS FOR RPCHS

The regulations apply advance directive requirements to RPCH inpatients, including inpatients receiving a SNF level of care in swing-beds. Therefore, when the SA is conducting an RPCH survey, apply the advance directives requirement to all RPCH inpatients. Refer to Appendix T, "Interpretive Guidelines for Swing-Bed Hospitals" (Data Tag No. A522), for guidance on surveying the advance directive requirement for RPCH swing-bed patients.

End-Stage Renal Disease (ESRD) Facilities

2270. ESRD CITATIONS

The statutory basis for coverage of ESRD services is found in §1881 of the Act. ESRD facilities are suppliers of services. The Conditions for Coverage are found in 42 CFR Part, 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

A. Renal Transplantation Center.--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.

B. Renal Dialysis Center.--A hospital unit which 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.

C. Renal Dialysis Facility.--A unit which is approved to furnish dialysis service(s) directly to ESRD patients.

D. Self-Dialysis Unit.--A unit that is part of an approved renal transplantation center, renal dialysis center, or renal dialysis facility, and which furnishes self-dialysis services.

E. Special Purpose Renal Dialysis Facility (SPRDF).--A facility or unit that is approved to furnish dialysis service(s) on a short-term basis for special rehabilitative or emergency purposes, when patients cannot otherwise be accommodated, for two purposes:

- To serve 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; and

- To serve ESRD patients on an emergency basis when approved permanent facilities close due to natural disasters, strikes, or bankruptcies and the backup facilities in the area cannot accommodate the patients of the closed facilities.

2274. ESRD APPLICATION REQUIREMENT

A. 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 HCFA-3427.

Application must be made:

- To request initial approval;

- To request expansion or addition of stations (see exhibit 27);

o For change in location;

o 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

o For change in service(s) provided, including reuse.

2276. SA CONTROL OF FORM HCFA-3427

The SA sets up a control mechanism to assure that a facility requesting an application completes and returns Part I of Form HCFA-3427 in a timely manner. If Form HCFA-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 HCFA-3427s, Part I, and application-related correspondence and reviews the forms and documentation for completeness. The SA forwards the original and one copy of Form HCFA-3427, Part I, and the related materials to the RO within 3 days, using the Medicare/Medicaid Certification and Transmittal, Form HCFA-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 facility is contacted by the SA 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

A. Facility Withdraws Application Prior to Survey.--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 the statement must be signed by a properly authorized representative of the facility. The SA forwards the statement to the RO.

B. Conducting SA Survey.--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 HCFA-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 HCFA-3427A and Appendix H.)

C. Certificate of Need (CON).--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, 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.

D. Initial RO Approval.--A facility must complete Part I of Form HCFA-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 HCFA-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.

E. Expansion or Addition of Services-RO Procedures.--A facility must complete Part I of the HCFA-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 six months, or if substantial changes have been made.

When no survey is required, the RO includes, in the "Remarks" item of Form HCFA-1539, an appropriate statement and rationale justifying why a survey was not performed.

Following receipt of the survey report, Part II of Form HCFA-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 HCFA-2007, accompanied by a copy of the determination notice, and provide for entry of appropriate data.

F. RO Recertification.--Following receipt of the Form HCFA-3427 and Form HCFA-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 HCFA-2007 to the intermediary if there has been a change in services furnished. The RO provides for the entry of appropriate data.

G. Invalid Application.--Technical Denials.--Except for SPRDFs, all Part I, Form HCFA-3427A applications must be accompanied by CON approval when required by State law.

2279. ADDITIONAL CONDITIONS ASSESSED BY THE RO

The health and safety conditions begin with 42 CFR Part 405.2135, compliance with Federal, State and local laws and regulations, through 42 CFR Part 405.2171, minimal service requirements for a renal transplantation center. SA certification is not the sole requirement for coverage of ESRD services. Additional areas which 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 Part 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:

- o 42 CFR 405.2122, Facility classification;
- o 42 CFR 405.2131, Provider status: Renal transplantation center and renal dialysis center;
- o 42 CFR 405.2133, Furnishing data and information for ESRD program administration;
- o 42 CFR 405.2134, Participation in network activities;
- o 42 CFR 405.2163(b), Minimal service requirements for a renal dialysis center and renal dialysis facility: laboratory services; and
- o 42 CFR 405.2171(d), Minimal service requirements for a renal transplantation center: laboratory services.

2280. RO FACILITY CLASSIFICATION (42 CFR Part 405.2122)

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:

A. Renal Transplantation Center (RTC).--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.

- o Dialysis performed in an RTC is considered secondary to the transplant surgery and is payable as part of the transplantation procedure.
- o An RTC must be found in compliance with all applicable Conditions for Coverage, 42 CFR Part 405.2135 through 42 CFR Part 405.2171.

B. Renal Dialysis Center (RDC).--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 Part 405.2135 through 42 CFR Part 405.2163.

C. Renal Dialysis Facility (RDF).--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 Part 405.2135 through 42 CFR Part 405.2163.

D. Special Purpose Renal Dialysis Facility (SPRDF).--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:

o 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

o 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 Part 405.2130 through 42 CFR Part 405.2164) with the following exceptions:

- o 42 CFR Part 405.2134, participation in network activities; and
- o 42 CFR Part 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 Part 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.

RESERVED FOR FUTURE USE

2280.4 PROVIDER STATUS: RENAL TRANSPLANTATION CENTER AND RENAL DIALYSIS CENTER (42 CFR Part 405.2131)

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.

2280.5 FURNISHING DATA AND INFORMATION FOR ESRD PROGRAM ADMINISTRATION (42 CFR Part 405.2133)

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 Part 405.2133.

2280.6. PARTICIPATION IN NETWORK ACTIVITIES (42 CFR Part 405.2134)

The RO verifies that the facility participates in network activities and pursues network goals.

NOTE: Compliance with this condition is waived for SPRDF applicants.

2280.7. MINIMAL LABORATORY SERVICE REQUIREMENTS FOR A RENAL DIALYSIS FACILITY OR A RENAL DIALYSIS CENTER (42 CFR Part 405.2163(b)) AND A RENAL TRANSPLANTATION CENTER (42 CFR Part 405.2171(d))

The RO 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. All laboratory services must be performed by an appropriately certified laboratory in accordance with 42 CFR 493. If the renal dialysis facility furnishes its own laboratory services, the RO 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 RO 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 493.

The RO 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 493.

2281. PARTICIPATION OF VETERANS ADMINISTRATION (VA) HOSPITALS IN THE ESRD PROGRAM

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:

- o A sharing agreement with a community hospital;
- o VA CO approval to seek Medicare approval;
- o A Utilization Review Plan, which may be limited to services furnished to Medicare beneficiaries in the ESRD outpatient program; and
- o 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 HCFA-3427A.

A. Survey Responsibility.--Inquiries and requests from VA hospitals to participate as suppliers of renal transplantation and dialysis services may be received by the SA or the RO. 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.

B. Special Survey Interpretations.--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 Part 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 Part 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 Part 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 Part 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 Part 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 Part 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 Part 405.2163).--A VA hospital may contract with its sharing hospital to supply all support services for nonveteran 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 Part 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 nonveteran 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."

C. Designated Intermediary/Carrier.--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 HCFA-2007, FOR SUPPLIERS OF ESRD PROGRAM SERVICES (Exhibit 156)

Form HCFA-2007 serves as the official notice to the intermediary of program actions affecting ESRD facilities which 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 NON-HOSPITAL)-RO PROCEDURES

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 HCFA-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 - See Chapter 3.

2285. ALTERNATIVE SANCTIONS FOR FAILURE TO PARTICIPATE IN NETWORK ACTIVITIES

If an ESRD facility fails to participate in the activities and pursue the goals of the ESRD network in its geographic area (42 CFR Part 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.

o 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

o 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

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:

o Consistently fails to cooperate with network plans or goals as specified in the network's contract with HCFA;

o Consistently fails to follow recommendations of the medical review board, which have been approved by HCFA;

o Fails to permit the network medical review board, without just cause, to conduct an on-site review; or

o 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

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 HCFA-2007 and its effective date. Also, the RO informs the appropriate network organization and HCFA.

2285.3. DURATION AND REMOVAL OF THE SANCTION

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, HCFA-2007. Also, the RO informs the network organization and CMS.

2285.4. NOTICE AND APPEAL RIGHTS

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)

The Medicare program has approved coverage for CAPD. Since the CAPD procedure is one which the patient can carry out in any location, training and support services are the only facility services involved.

A. How CAPD is Performed.--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 allows him a diet without many of the restrictions associated with other types of dialysis.

B. Application and Determination Procedure.--Facilities must file Form HCFA-3427, Part I, plus a detailed statement explaining how they expect to meet the criteria for delivering CAPD. Unless CON approval specifically for the CAPD services is required by State law, a CAPD facility is not required to document "need."

Approval is based on the following:

o The facility must furnish CAPD training directly, but may provide the required support services via an arrangement or an agreement with another ESRD-approved facility.

o 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.

o The nurse responsible for CAPD training must meet the standards in 42 CFR Part 405.2102(d) and have documented experience in peritoneal dialysis and in the care and maintenance of peritoneal access devices.

o Upon completion of the patient's CAPD 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 patient's home adaption, including provisions for visits to the home or patient visits to the facility;

- Consultation for the CAPD patient with a qualified social worker and a qualified dietitian;

- A recordkeeping system which assures continuity of care for the CAPD patient;

- CAPD supplies ordered on an ongoing basis;

- Periodic visits, at least once every 90 days, to monitor the CAPD patient's medical condition, review his continuing capability to perform CAPD, 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 HCFA-1539 indicating denial or approval. In addition, the RO completes the Provider Tie-In Notice, HCFA-2007, and under item V, Remarks, enters: "Approval of training and support services in CAPD."

2287. CLASSIFICATION OF MAINTENANCE DIALYSIS FACILITIES AS HOSPITAL-BASED OR INDEPENDENT: PROSPECTIVE PAYMENT

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 and intermediary as necessary to resolve any differences or discrepancies.

The RO determines the classification using the following criteria:

A. Hospital-Based ESRD Facility.--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 Part 413.174(c).

o 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.

o 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.

o The facility has personnel policies and practices that conform to those of the hospital.

o 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.

o 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.

B. Independent ESRD Facility.--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

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

There are three types of organizations which may qualify as OPT/OSP providers:

A. Rehabilitation Agency.--An agency which 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 physician therapy or speech language pathology services, includes social or vocational adjustment services.

B. Clinic.--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 3 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).

C. Public Health Agency.--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

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 Part 485.709, Administrative Management, is not applicable to public health agencies, and 42 CFR Part 485.717, Rehabilitation Program, is not applicable to clinics or public health agencies.

2296. SA VERIFICATION OF SERVICES PROVIDED

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

A. Limitations.--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.

B. Services Provided at More Than One Location Controlled by OPT/OSP Provider.--An OPT/OSP provider (normally a rehabilitation agency) may provide services from multiple locations which 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 and this 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.

C. OPT/OSP Services at Locations Other Than Those Provider Controls.--OPT/OSP providers may also provide services from locations other than their primary sites and other than locations which they control directly. These noncontrolled locations are defined as extension units. 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 which 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: There is no restriction as to the number of OPT/OSP primary or extension units that can be located at a SNF.

2300. SA ANNUAL REPORT TO RO ON LOCATION OF EXTENSION UNITS

OPT/OSP providers are required to report the proposed addition of a new extension location or other site. In addition, on an annual basis or on or before January 1st of the calendar year, the SA forwards a copy of the Identification of Extension Units of OPT/OSP Providers (Form HCFA-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 units 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 unit(s) and, under Part B, the specific services (OPT, OSP, or both) each extension unit provides. Upon receipt of this form from the OPT/OSP provider, the SA reviews this information, identify those locations requiring a survey, and schedule the necessary

activity. The SA forwards a summary annual report of the information to the RO noting the number of extension locations for each certified OPT/OSP provider subject to survey.

2302. SA SURVEY OF OPT/OSP CONTROLLED AND EXTENSION UNITS OF PROVIDERS OFFERING OPT ONLY

The SA survey of sites other than the primary site is not required for OSP only providers.

A survey is required for each OPT primary site, for each of the (multiple) locations controlled by the OPT provider, and for each OPT extension location where services are provided (see exhibit 23).

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:

o 42 CFR Part 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;

o Condition 485.717 (Rehabilitation program) is applicable only to a rehabilitation agency;

o Condition 485.725 (Infection control) is applicable only where physical therapy services are being rendered; or

o Condition 485.715 (Speech pathology) is applicable only when speech pathology is rendered.

A separate survey report, Form HCFA-1893, is completed by the SA for each surveyed OPT location in addition to the primary location. Failure to correct deficiencies noted as a result of a survey at any location (extension, multiple site, or primary unit) will jeopardize the certification of the OPT provider in its entirety. The SA completes only one Form HCFA-2567, and indicates the names of all locations (primary, multiple site, or extension unit) found to be deficient with respect to each survey item. Also, the SA completes only one Form HCFA-1539, and notes the names of all facilities which 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.

EXCEPTION: OPT/OSP providers, regardless of Medicare certification, who wish to establish an extension location outside the State must conform to <u>all</u> regulatory requirements and may be treated as a separate provider in each State. 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

The OPT/OSP provider, following the conversion of its primary site to a CORF, may select one of its extension units as a new primary site. The SA notifies the RO via Form HCFA-1539 of the new primary location and existing, associated, certified extension units 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 units do not have to be resurveyed with the survey of the new primary location.

OPT Services Furnished by Physical Therapists in Independent Practice (PTIPs)

2330. PTIPs - CITATIONS AND DESCRIPTION

The statutory basis for OPT services furnished by PTIPs is found in §1861(p) of the Act. The Conditions for Coverage are in 42 CFR Part 486, Subpart D, Parts 486.150 - 486.163. Appendix F contains surveyor and interpretive guidelines.

Physical therapy services under the supplementary medical insurance (Part B) program for individuals under the care of a physician may be performed by physical therapists (PTs) who are certified as independent practitioners. The services may be performed either in the PT's office or in the patient's home. (See §2334 when the office is located in an institution.)

A PTIP is eligible to participate in the Medicare program provided:

- The Medicare PT qualification requirements are met;
- The PTIP is responsible for all services rendered and is free of the administrative and professional control of an employer;
- The individuals treated are the PTIP's own patients, and the PTIP has the right to collect the fee or other compensation for the services rendered;
- An office or office space and equipment necessary to provide an adequate program of physical therapy are maintained at the PTIP's own expense; and
- The PTIP is engaged in such practice on a regular basis.

A PTIP's office, although not limited to such, may be located on the premises of the following: a commercial building, a medical institution housing inpatients, or the PTIP's home.

When a therapist belongs to a partnership or corporation it is extremely questionable whether the therapist is furnishing services on his or her own responsibility without the administrative and professional control of an employer. Evaluating compliance with this requirement involves the SA reviewing the bylaws of the corporation or the partnership agreement, and may involve examining State laws governing the subject. There must be evidence that the therapist is functionally independent to accept and treat patients absent interference from an employer in administrative and professional actions, that the therapist is responsible for the formulation of all financial and clinical policies and procedures governing the practice, and that the therapist is legally responsible and professionally liable for the services rendered.

In addition, when a therapist belongs to a partnership or corporation it is questionable whether the therapist maintains the office space and equipment at his or her own expense. In some instances the therapist may hold the office and equipment as personal assets, or a therapist in a partnership may pay a proportional amount of the expenses for office space and equipment. However, in other instances a corporation may own, maintain, and control the space and equipment. This is in many ways the most difficult of the criteria for the SA to evaluate, and it should be done on a case-by-case basis.

The requirement that a PTIP/OTIP collects fees or other compensation for the services furnished means that payment for the service must be made to the PTIP/OTIP rather than to anyone else. Most Medicare suppliers are permitted, under limited circumstances described in 42 CFR Part 424.80, to allow payment for their services to be made to their employer or another organization with which

they have a contract. A PTIP/OTIP cannot do so because it would violate one of the key elements in the definition of independent practice at 42 CFR Part 410.60(c). The only exceptions that would apply are described at 42 CFR Part 424.80(b)(4), (5) and (6). The exception most likely to be applicable is payment to an agent who furnishes billing and collection services--and this only if the payment is made in the name of the PTIP/OTIP.

A person could not qualify as a PTIP/OTIP if payment for services that he/she furnishes is made to a corporation that employs him/her, or if payment is made to a group, partnership, or other organization under contract. A PTIP/OTIP could not bill under his or her employer's number, but would use his or her own tax identification number and a corresponding billing number from the Medicare carrier. (See Exhibit 24.)

In addition, §2215.F of the Medicare Carrier Manual permits coverage of services performed by support personnel under the direct personal supervision of the PTIP/OTIP only if the support personal are employees of the PTIP and their services are included in the PTIP/OTIP's bill. Services of support personnel are not covered if they are employed by a corporation, group, partnership, or anyone other than the PTIP/OTIP. Medicare payment for covered services of support personnel cannot be made to a corporation, group, partnership, or other organization under contract.

2332. PTIPs IN FULL-TIME TEACHING POSITIONS

A PTIP engaged in full-time teaching of physical therapy courses in a university need not maintain a separate office in order to treat individuals in their homes. In this instance, a PT may be identified as being in independent practice if such individual:

- Is engaged in this activity on a regular basis;
- Has submitted credentials documenting that he/she meets the PT educational requirements;
- Has access to appropriate equipment that he/she uses at his/her own expense; and
- Has submitted verification of full-time teaching of physical therapy at a university.

PTIPs engaged in full-time teaching of physical therapy courses in a university need not maintain a separate office to treat individuals in their homes. Such a therapist may be identified as being in independent practice if he/she is engaged in this activity on a regular basis, meets the PT educational requirements, and can show access to appropriate equipment. This PT may not render services using university premises, equipment, and other resources during the hours he/she is engaged in full-time teaching. Adjustments in the survey procedures are necessary since these PTIPs may not have an office to survey.

2334. PT WITH AN OFFICE IN A MEDICAL INSTITUTION

A PT maintaining an office on the premises of a medical institution (e.g., SNF) may enter into an arrangement/agreement/contract with the institution to provide services to the institution's inpatients and still be eligible to participate as an independent practitioner if the requirements noted in §2330 are met. Arrangements/agreements/contracts of this type are not uncommon. However, it is necessary for the SA to verify the PT's independence as a private practitioner and confirm that the treatment of his/her own patients is not subject to external control. Closer scrutiny than usual is

required when reviewing the eligibility of a PT whose office is located on the premises of a medical institution. The therapist must be able to continue to function as an independent practitioner even if removed from the institutional environment. To assure that the physical therapy practice is functioning as an independent operating unit, the SA reviews indicative business documents such as the rental agreement; linen supply contract (if the institution provides linen, the cost to the physical therapy practice should either be borne separately or be indicated as part of the rental agreement); utility bills; evidence of payroll disbursement for supportive personnel (e.g., physical therapy assistant, aide, clerical) where applicable; and disbursements for office supplies and equipment. The SA also reviews patient treatment records to ascertain that patient referrals also come from physicians who are not financially or administratively affiliated with the institution. If treatment is not rendered to patients who are referred from other than these institutionally connected physicians, it may be indicative that the PT does not hold himself/herself out to the public and, therefore, may not be in independent practice.

The following criteria are indicative of administrative and professional independence:

- The PT assumes administrative and professional responsibility for physician contact;
- The confidentiality of patient and accounting records is maintained;
- The PT retains the right to schedule patients, the right to refuse to treat patients, and is legally responsible and professionally liable for the services rendered;
- The PT is responsible for the formulation of the policies and procedures governing the practice (in the case of a corporation/partnership with more than one principal, each PT desiring certification as an independent practitioner is expected to share responsibility for policy and procedure formulation); and
- The PT has unrestricted access at all times to the office premises.

2336. SA REVIEW OF PTIP REQUEST TO ESTABLISH ELIGIBILITY

The SA reviews the information submitted on the Physical Therapist Request for Certification (Form HCFA-262, see Exhibit 21). If Items I-IV have not been completed according to the instructions, the SA should return the form to the PTIP and take no further action until the form is resubmitted with the appropriate corrections.

In verifying the information in Section II to determine whether the individual meets Medicare educational qualifications to provide physical therapy services, it may be necessary for the SA to request assistance from the State Board of Physical Therapy Examiners and/or to review grade transcripts or other documentation. This documentation may already be available in files of the State Board if the therapist is licensed.

When review indicates the PTIP may be eligible for participation, the SA schedules a survey (considering the days and hours of operation as indicated on Form HCFA-262).

If the information furnished in Sections II and IV of Form HCFA-262 indicates that program requirements are <u>not</u> met, the therapist is not eligible for certification. The SA notifies the therapist that he/she does not qualify for certification as a PTIP and forwards a recommendation for denial to the RO.

2338. SPECIAL INSTRUCTIONS FOR SA COMPLETION OF PHYSICAL THERAPIST IN INDEPENDENT PRACTICE SURVEY REPORT, FORM HCFA-3042

The SA assures that the correct identifying information is entered on page 1 of Form HCFA-3042 and designates whether the candidate is a corporation, individual, partnership, or group practice. If an individual, the SA inserts the individual's name in the space provided. If the PT is part of a group practice, the SA inserts the individual's name and the names and social security numbers of the other group members in the spaces provided.

Where a corporation or partnership is designated, the SA inserts the organizational business name of the organization (e.g., corporation or partnership) in the "name" space provided at the top of Form HCFA-3042 directly below the name under which the practice operates (e.g., John Smith, P.T.; Smith, Marks, and Flowers, Valley Physical Therapy). The SA inserts the social security numbers of the PTIPs and notes the names and social security numbers of the other corporate members or partners in the spaces provided. Remember that independent practitioner status is granted to individuals and not to group practices, partnerships, or corporations. Although a PT member of a group practice, partnership, or corporation may not meet the definition of a PTIP, other PTs associated with that group practice, partnership, or corporation may still be qualified. Where additional space is required for completion of identifying information, the SA adds an attachment to Form HCFA-3042.

The SA surveyors enters their signature, professional title (e.g., PT, RN), and the date of the survey in the upper right-hand corner, indicating whether this is an initial survey or a resurvey.

2340. CERTIFICATION OF PTIPs

The SA forwards Form HCFA-3042 and a copy of Form HCFA-262 (Exhibit 22) to the RO. A separate Form HCFA-3042 is required for each PT in a group practice. A separate Form HCFA-3042 is also required for each office location for a partnership or corporation. The SA does not prepare separate certifications for individual PTs in an organization being certified.

2342. RECERTIFICATION OF PTIPs

Periodic recertification of PTIPs is not routinely required. The appropriateness of resurveys is determined by the RO for purposes of evaluating correction of deficiencies and ascertaining continued compliance with regulations.

2344. DUAL CERTIFICATION AS PTIP AND PROVIDER OF OPT/OSP SERVICES

Medicare certification of a PT as both an OPT/OSP provider and as a PTIP is permissible only when separate locations are established for each practice. The applicable regulations must be met for each practice, and separate certification actions are necessary in cases of dual certification.

2346. PT WITH OFFICES IN MULTIPLE STATES

A PTIP certified in one State need not maintain an office in an adjoining State(s) in which services are provided. In such cases, however, the SAs of all States involved should be aware of the PT's practice and should make certain that all State requirements incorporated into Medicare and Medicaid requirements are met. The SA in the State in which the PTIP's office is located is responsible for the survey.

Outpatient Occupational Therapy (OOT) and Occupational Therapists in Independent Practice (OTIPs)

2350. OOT AND OTIPs - CITATIONS

Section 9337 of the Omnibus Budget Reconciliation Act of 1986 (OBRA) (P.L. 99-509) added §1861(g) to the Act to extend Medicare Part B benefits to include OOT services furnished by providers and OTIPs effective July 1, 1987.

2351. PROVIDERS OF OOT

A. General.--Sections 2290-2346 and the requirements contained in Form HCFA-1893 are applicable to clinics, rehabilitation agencies, and public health agencies applying as providers of OOT services. The SA must modify Form HCFA-1893 as necessary and appropriate to include OOT services. When an OPT/OSP provider adds OOT services to its program, a new survey is not required. In accordance with 42 CFR Part 485.38, HHAs may qualify to provide OOT services if they meet the applicable health and safety requirements in 42 CFR Part 485, Subpart H. The SA completes the OPT Crucial Data Sheet (Form HCFA-1893E, see Exhibit 14H), to show that the facility provides OOT services. Also, the SA must include the number of full-time outpatient occupational therapists who are employed directly by the facility or under arrangement.

B. New OOT Providers.--When a facility which does not otherwise participate requests initial participation in the Medicare program as an OOT provider, the SA includes copies of the following in the certification kit mailed to the provider (see §2004):

- Model letter (see Exhibit 76);
- Subpart Q CoPs: Clinics, Rehabilitation Agencies, and Public Health Agencies; and
- Form HCFA-1856 (see Exhibit 21) (substitute or add "occupational therapy" where necessary and appropriate).

The SA conducts an on-site survey using Form HCFA-1893 which must be modified to include occupational therapy as necessary and appropriate. OOT facilities are required to meet the CoPs except those conditions that apply specifically to physical therapy or speech pathology services. There are currently no CoPs written specifically for OOT services, and an "adequate program" for occupational therapy services has not been defined. Also, OOT providers are exempt from the following:

- 42 CFR Part 485.713 CoPs, Physical Therapy Services; and
- 42 CFR Part 485.715 CoPs, Speech Pathology Services.

The SA surveys all other conditions for compliance by adding or substituting the words "occupational therapy" or "occupational therapist" for "physical therapy" or "physical therapist" as appropriate. The SA uses the Appendix E interpretive guidelines in conducting the survey, substituting occupational therapy for physical therapy where applicable.

C. OPT/OSP Providers Adding OOT Services.--A SA on-site survey of the OPT/OSP provider adding OOT services is not required even if the provider will be providing OOT at a location not previously surveyed, i.e., an extension site.

However, when an OPT/OSP provider requests to add OOT services at an extension site, the services must also be provided at the primary location. Locations not surveyed during the current certification process may be surveyed during the next scheduled survey cycle. The SA mails the OPT/OSP provider requesting OOT services copies of the:

- Model letter (see Exhibit 77); and
- 42 CFR Part 484.4

The provider must furnish documentation that the OOT services are provided by occupational therapists who meet the occupational therapist definition in 42 CFR Part 484.4. If occupational therapist assistants provide services, they must meet the occupational therapist assistant definition in 42 CFR Part 484.4. In addition, OOT services must be provided in accordance with the requirements in 42 CFR Part 485.713(c) and (d). The term "outpatient occupational therapy services" has the same meaning given the term "outpatient physical therapy services," therefore, substitute "occupational" each place "physical" appears in the regulation. Although compliance with these requirements cannot be confirmed because no onsite survey is required, the provider is expected to adhere to them. This is pointed out in the model letter.

2352. OCCUPATIONAL THERAPY SERVICES PROVIDED BY OTIPs

A. General.--OTIPs may participate in the Medicare program in the same manner as, and subject to the same certification requirements as, PTIPs. (See §§2330-2346.) OTIPs must meet the requirements contained in Form HCFA-3042, which must be modified to include "occupational therapy/therapist" where applicable.

B. OTIP.--When an occupational therapist applies as an independent practitioner, the SA includes the following in the initial certification kit mailed to the therapist:

- Model letter to occupational therapist (see Exhibit 79);
- Conditions For Coverage; OPT services furnished by PTIPs; and
- Request to Establish Eligibility, Form HCFA-262 (see Exhibit 22), with appropriate modifications to include OOT services.

An OTIP must meet all the Conditions for Coverage for PTIPs except for:

- 42 CFR Part 486.150(b) - definition of a PT; and
- 42 CFR Part 486.157 - standard: adequate program.

The terms "adequate program" and "necessary equipment" have not been defined for occupational therapy services for the OTIP survey and certification process. All other conditions must be surveyed for compliance by substituting the words "occupational therapy" or "occupational therapist" for "physical therapy" or "physical therapists" as appropriate. The SA uses the interpretive guidelines for PTIPs in Appendix F in conducting surveys of OTIPs by substituting occupational therapy for physical therapy where applicable.

Comprehensive Outpatient Rehabilitation Facilities (CORFs)

2360. CORF - CITATIONS AND DESCRIPTION

The statutory basis for CORFs is §1861(cc) of 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. Although another institution may establish and operate a distinct entity that can be certified as a CORF, such a CORF must be functionally and operationally independent. (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 5 years as governed by 42 CFR Part 485.56(f) (formerly 42 CFR Part 488.56(f)).

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 certification as a CORF meets the requirements for such certification and that the costs of different Medicare providers are clearly identified, segregated, and attributed to the proper provider.

2362. SCOPE AND SITE OF SERVICES

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 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.

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

When certifying a CORF, it is important to understand the relationship of space, equipment, and employees shared with other providers and suppliers.

A. Shared Space With Another Provider or Supplier.--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 (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.

B. Sharing of Equipment.--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.

C. Employee Sharing.--CORF services may be provided by CORF employees or others 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

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

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

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 certified 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 which 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

A. Labeling Requirements.--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 l, 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 which 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.

B. Request For and Review of Labeling Information.--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

The Act defines the term "physician" to include chiropractors who 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) which 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

A. Chiropractors Qualified Prior to July 1, 1974.--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 3 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.

B. Individuals Commencing Their Studies in Chiropractic College After June 30, 1974.--These individuals must meet the following requirements in addition to those in subsection A (see Exhibit 39).

- Satisfactory completion of 2 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

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

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. HCFA 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

A. Background.--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 1985 edition of the LSC. However, the regulations contain a "grandfather clause" which permits facilities in compliance with an earlier edition of the Code to continue to comply with that edition so long as compliance is maintained. Facilities with waivers of the health occupancy provisions of the LSC or with an acceptable PoC are considered "in compliance." Hospitals, NFs, and ICFs/MR may be "grandfathered" under the 1967 or 1981 LSC. SNFs may be grandfathered under the 1967, 1973, or 1981 LSC.

B. Citations For Application to Provider Facilities.--The LSC is applied to hospitals under authority of §1861(e)(9) of the Act and by 42 CFR Part 482.41(b). SNFs and NFs must meet 42 CFR Part 483.70(a) which 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 Part 483.470(j). It is applied to hospices furnishing inpatient care pursuant to 42 CFR Part 418.100(d) and to (ASCs) under 42 CFR Part 416.44(b). (See Appendix I for interpretive guidelines.)

C. Citations For Application to ASCs.--ASCs wishing to participate in the Medicare program must comply with the 1985 edition of the LSC, as it applies to ambulatory health care centers regardless of size. The requirements for ASCs are contained in Chapter 12, Section 12-6 for new facilities, and in Chapter 13, Section 13-6 for existing facilities. Section 12-6 also requires that ASCs comply with Chapter 26. Section 13-6 requires that ASCs comply with Chapter 27 (Business Occupancies) in certain instances, such as where high-rise buildings must be sprinklered if they contain ASCs. The ASC may be grandfathered under the 1981 LSC if it first applied for admission to the program prior to May 9, 1988.

D. Special Application in ICFs/MR.--All ICFs/MR must meet the 1985 edition of the LSC. There is "grandfathering" of ICFs/MR under earlier editions of the Code only if they are surveyed under the health care chapter.

E. Substitution of State Fire Code For LSC.--The LSC is not applicable where HCFA finds that a State has in effect a fire and safety code imposed by State law which adequately protects patients in health care facilities, except for small ICFs/MR surveyed under the Residential Board and Care Chapter (Chapter 21). (See §1863 of the Act.)

The State submits requests that State codes be utilized in lieu of the LSC to the HCFA/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 affords a degree of safety comparable to that afforded by the LSC.

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 HCFA has no authority to accept them in lieu of the LSC.

2472. LSC SURVEYS

A. "Authority to Grant Waivers" For LSC Surveys.--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 Part 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 HCFA 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 HCFA 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.

B. Subagreements With State Fire Authorities.--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 Marshall'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 nonaccredited hospitals, hospices, ASCs, SNFs, NFs, 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 fire hazard;
- Complete the appropriate Fire Safety Survey Report (Form HCFA-2786);
- Prepare statements of deficiencies and review PoCs (Form HCFA-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.

C. Coordinating LSC Survey.--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. Most States require an initial LSC survey before admitting patients prior to becoming operational. Irregardless of the timing of the LSC survey, the SA should schedule it so that all certification actions are completed timely.

D. ASC Surveys.--The SA uses Form HCFA-2786H to survey ASCs. The SA lists any LSC deficiencies found during an ASC survey on Form HCFA-2567 and requests a PoC as with any LSC survey of a health care facility.

E. Involvement of SA Surveyors in LSC Surveys.--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 (HCFA-2786C) 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 HCFA-2786M) for each resident which 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.

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 HCFA-2786 SERIES)

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

1. Form HCFA 2786A, 1967 LSC;
2. Form HCFA 2786B, 1973 LSC;
3. Form HCFA 2786C, Fire Safety Survey Report - Short Form;
4. Form HCFA 2786D, FSES Evaluation Form;
5. Form HCFA-2786E, Crucial Data Extract Sheet - LSC;
6. Form HCFA-2786F, 1981 LSC;
7. Form HCFA-2786G, FSES Evaluation Form, 1981 Code;
8. Form HCFA-2786H, ASC LSC Survey Report;
9. Form HCFA-2786J, Fire Safety Survey Report, 1985 LSC ICF/MR small;
10. Form HCFA-2786K, Fire Safety Survey Report, 1985 LSC ICF/MR large;
11. Form HCFA-2686M, Fire Safety Survey Report, 1985 LSC, ICF/MR Rating Resident, Chapter 21;
12. Form HCFA-2786P, Fire Safety Survey Report, 1985 Code - Health Care; and
13. Form HCFA-2786Q, FSES Evaluation Form, 1985 Code.

Forms HCFA-2786 A, B, F, and P are used only by the fire authority when conducting a complete fire safety survey. They each contain four parts:

I. LSC requirements - New and Existing;
II. Other Federal requirements;
III. Alternative provisions for sprinklers; and
IV. Waiver recommendation form.

2476. FIRE SAFETY SURVEY REPORT - SHORT FORM, FORM HCFA-2786C

A. Background.--The Fire Safety Survey Report - Short Form (Form HCFA-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 8 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 marshall, and can be capably performed by the SA surveyor.

B. When to Use Short Form.--Except as outlined in subsection C, the SA uses Form HCFA-2786C to survey non-JCAHO hospitals, SNFs, and NFs for compliance with the LSC.

C. When NOT to Use Short Form.--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 HCFA-2786):

- 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;
- ICFs/MR;
- ASCs; or
- Surveys preceded by two successive certification surveys in which the Short Form was used.

D. Results of LSC Screening Process - SA Review of Completed Form HCFA-2786C.--

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.

E. 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.)

F. Waivers.--Items which 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 or NFs, however, HCFA must grant the waiver, not the State. The fire authority may grant waivers for ICFs/MR surveyed under the Health Care Requirements. 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)

A. General.--The FSES was developed by the National Bureau of Standards 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 HCFA-2786.

B. Application of System.--The State fire authority uses the FSES in conjunction with Form HCFA-2786 in facilities where the surveyor or the provider feels that the application of the system is beneficial to the facility.

C. Survey Completion.--Whenever an FSES evaluation is conducted, the fire authority completes a:

- Fire Safety Survey Report (Form HCFA-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 HCFA-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 HCFA-2786. The SA marks item 7A of the cover sheet of Form HCFA-2786 "FSES." FSES files are forwarded by the RO to a specialist for a thorough technical review.

D. Certification of Compliance With FSES.--When an FSES evaluation is performed by the fire authority, 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 HCFA-2786, it must indicate its proposed correction in the space adjacent to each deficiency recorded on Form HCFA-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.

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

A. General.--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 which 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 which, while not in strict conformity with the LSC, nevertheless provide an equivalent degree of protection. In such circumstances, a waiver could 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.

B. Meeting Intent of LSC.--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:

6. Staffing considerations such as staff-patient ratios, staffing patterns, and scope of staff training to handle fire emergencies;

7. Availability and adequacy of compartment and horizontal exits, such as areas to hold patients during a fire emergency;

8. Location and number of ambulatory and nonambulatory patients;

9. Availability, extent, and type of automatic fire detection and fire extinguishment systems provided in the facility;

10. Means for notifying the fire department in case of fire; and

11. 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.

C. Waiver Criteria For Sprinkler Requirement In Wood-Frame Buildings.--No waiver of the sprinkler requirement may be granted in unprotected woodframe facilities or protected or unprotected multi-story woodframe facilities.

Before a waiver can be granted for one-story protected woodframe facilities, four specific criteria must be met:

- All hazardous areas are sprinklered;.

- Automatic fire detection devices are installed in all areas that the LSC requires be protected by an automatic sprinkler system. The detection system is currently listed with a nationally recognized testing laboratory, such as Underwriters Laboratory or Factory Mutual. The system closes all fire doors in barrier partitions and is hooked into the local fire department or central system. At a minimum, the detection system must activate an alarm system inside and outside the building;

- Patient rooms are separated from each other and from all other areas by construction having at least a one-hour fire resistance rating; and

- The response time and capability of the local fire department are adequate in the judgment of the State fire authority to provide an acceptable level of protection for an unsprinklered facility.

These specific criteria need not be met in other types of construction. They are, nevertheless, relevant to buildings other than protected wood frame and are to be considered in establishing the basis for waiver of the sprinkler requirement in these other types of construction.

Send a model letter (Exhibit 32) to facilities that do not meet one or more of the above criteria.

D. Elements Considered In Determination of Unreasonable Hardship.--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

A. Technical Codes And Standards Committee Charter and Functions.--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

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 HCFA-1539. The RO will refer the matter to Office of Civil Rights (OCR) for resolution.

Utilization Review

2496. UTILIZATION REVIEW (UR)

A. Definition.--Utilization Review is the process by which the care and services provided to Medicare/Medicaid beneficiaries are reviewed for appropriateness, medical necessity, and whether the services meet professionally recognized standards of health care.

B. Hospitals.--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 Part 482.30, CoPs - Utilization Review.

Under Medicare, the Peer Review Organization (PRO) performs the UR function for hospitals. 42 CFR Part 466.78 requires that beginning November 15, 1984, every hospital seeking payment for services provided to Medicare beneficiaries maintain a written agreement with a PRO operating in the area in which the hospital is located.

C. SMAs.--Section 1902(d) of the Act allows SMAs the option of contracting with a PRO 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.

D. Background and Scope of Work.--PROs 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 PRO 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.

1. Extent of PRO Review.--To participate in the Medicare program, every hospital must have an agreement with a PRO 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 PRO. This agreement allows PROs 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 PRO then responds to beneficiary complaints about the quality of care given by SNFs, HHAs, and hospitals (including HOPDs). PROs also have agreements with ASCs to review a sample of Medicare surgical records for medical necessity. For hospitals certified as swing-bed providers, the PRO reviews a sample of cases to determine the medical necessity of the stay and the appropriateness of the setting.

42 CFR Part 488.14 indicates that when a PRO 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 PRO review activity will also be in lieu of survey, compliance, and assistance activities required of SAs under §1864(a) of the Act.

2. Availability/Disclosure of PRO Information.--As a result of their review activities, PROs have information related to practitioners and institutions that may be helpful to the SA. 42 CFR Part 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 PRO 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 Part 476.105(b)(2) requires disclosure to conform with notice of disclosure requirements. In general, a PRO 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 PRO 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 PRO information are prohibited from disclosing the information unless specifically provided for in Federal regulation. For example, in accordance with 42 CFR Part 476.107(e), if the PRO 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 PROs 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 PRO, the SA contacts the RO.

E. Action When a PRO Ceases Utilization Review.--The SA instructs hospitals and SNFs to forward a copy of their UR plan to it within 90 days of a PRO's cessation of review activity in that area. If the plan does not meet the requirements, the SA returns it for necessary revisions.

F. Including UR in Next Scheduled Resurvey.--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 HCFA-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 HCFA-1539, e.g., name of facility is in compliance with UR requirements," or "Acceptable Plan of Correction for UR has been submitted."

2700. CONDUCTING INITIAL SURVEYS AND SCHEDULED RESURVEYS

A. Unannounced Surveys.--It is HCFA policy to have unannounced surveys for all providers (including psychiatric hospitals) and suppliers (other than hospitals and laboratories), except as indicated. 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 survey problems, 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 2 working days before an impending survey) if the following two 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.)

B. SA Schedule For Conducting Health and Safety Resurveys.--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 3 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 compliance status may necessitate adjustment of the SA survey interval. (See §2702.)

C. Coordinating LSC Surveys.--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 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.

2702. SA CONDUCTING UNSCHEDULED SURVEYS

A. Survey Due To Unanticipated Events.--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 validation survey of an accredited hospital;
- 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 complete 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.)

B. Change of Size or Location of Provider Institution.--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. 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

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. This information is helpful in determining composition of the survey team and the time required for the survey or resurvey.

If an on-site survey is necessary, the SA schedules the survey in a manner that results in the most efficient and effective utilization 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, 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. For example, hospitals wishing to qualify as "swing-bed" hospitals and RHCs must be located in rural areas. The SA develops this before the survey begins.

2705. SA SURVEY TEAM WORKLOAD

The Survey Team Composition and Workload Report (Form HCFA-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 utilization applicable to survey activity of all Medicare and/or Medicaid providers and suppliers and CLIA laboratories. Exhibit 74 also contains instructions for completing Form HCFA-670.

In addition to the instructions in Exhibit 74, the SA follows these guidelines:

o If a survey does not include an on-site visit, do not enter arrival, departure, on-site, and travel dates or times on Form HCFA-670. Enter all other appropriate fields. (See Form HCFA-670 edits);

o Include on Form HCFA-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;

o Report only direct, survey-related time on Form HCFA-670. This includes data entry and supervisory review time. Do NOT include general administrative time, such as time spent logging onto the HCFA Data Center;

o The Type of Survey and Extent of Survey boxes are not required for data entry. However, complete these boxes on Form HCFA-670 since the information may be helpful;

o 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);

o Do not complete Form HCFA-670 for visits conducted solely for licensure purposes;

o Treat multiple complaints investigated at the same time as one complaint survey and enter on one Form HCFA-670;

o If complaints are conducted concurrently with a recertification survey or follow up, report the complaint on a separate Form HCFA-670;

o Include in Column D time spent reviewing complaints in-office as pre-survey preparation hours if a complaint survey is subsequently conducted;

o Prospective Payment System (PPS) surveys are not entered into OSCAR. Therefore, do not complete Form HCFA-670 for PPS surveys;

o Prepare separate Form HCFA-670s for all health, LSC, complaint investigation, and Federal Monitoring Surveys (FMS);

o In cases where the same surveyor performs both health and LSC work, time that cannot be specifically attributed to one survey or the other must be equally split between the two Form HCFA-670s (one for health and one for LSC);

o Supervisory review time reported on Form HCFA-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;

o Do not record time spent tracking nurse aide training and competency reviews on Form HCFA-670;

o In computing travel time, report the lesser of time spent in travel from either the surveyor's home to site or office to site;

o Enter on Form HCFA-670 under the appropriate surveyor ID number the time supervisors spend participating in a survey (conducting reviews, exit conferences, etc.);

o Assign SA consultants identification numbers in the event that they participate in surveys. Their time should be included on Form HCFA-670 if they participate;

o 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;

o If errors are made in data entry, change the information by accessing ODIE's "update" mode;

o 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;

o Do not enter PRO staff on Form HCFA-670 since they are not part of the survey staff;

o Use Form HCFA-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 HCFA-670; and

o Record travel to a patient's home as well as time spent in the patient's home on an HHA survey as on-site time, not travel time.

2706. SA SURVEY TEAM COMPOSITION

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 of teams is governed by the size and type of the provider/supplier. 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

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. (See 42 CFR Part 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 Part 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 HCFA 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 Part 488.6(c) and 489.53(a)(4).)

2710. REVIEWING FORMS AT BEGINNING OF SURVEY

A. Request To Establish Eligibility.--One of the purposes of the "Request to Establish Eligibility" (or the equivalent application form such as Form HCFA-671, Form HCFA-3070G, or Form HCFA-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.

B. Disclosure of Ownership and Control.--Disclosure of financial interest and control information is a prerequisite to participation and payment under programs established by titles V, XVIII, XIX, and XX of the Act and §353 of the Public Health Service Act (CLIA). Failure to provide this information will result in denial or termination of participation and loss of eligibility for payment.

The SA collects information on the Ownership and Control Interest Disclosure Statement (Form HCFA-1513, see Exhibit 6.) The SA mails the form to every party interested in participating in the Medicare or Medicaid programs (initial applicants) for completion according to instructions provided with the forms.

NOTE Most surveys are required to be unannounced either by law or HCFA procedures. Therefore, the SA does not routinely mail these forms to providers in advance of a routine annual resurvey, since doing so might result in "announcing" the survey. (See §2700.A.)

1. Review at Initial Certification.--The SA reviews the form for completeness, not for validity. If there are obvious inconsistencies, the SA returns it to the institution and request that necessary corrections be made. For example, if the institution is organized as a corporation, the SA ensures that officers and directors, as well as those individuals owning five percent or more of the stock, are listed. If this information is incomplete, the SA returns the form. Questions relating to content are referred by the SA to the RO for resolution.

2. Updating at Time of Resurvey.--At the conclusion of the resurvey, the SA leaves a copy of Form HCFA-1513 with the administrator for completion, and request that it be returned to the SA within 30 days.

If there has been no change in the ownership information, it is acceptable for the provider or supplier representative to complete Parts I, II, and III of the form, enter "No Change" in Part IV, and sign and date it on the appropriate lines.

3. Transmission of Forms.--The SA transmits the original Form HCFA-1513 with the certification packet. The first carbon copy is retained by the disclosing entity. The second copy is for the SAs file. The last copy is transmitted to the SMA, if appropriate.

C. RO Processing of Form HCFA-1513

1. Review of Completed Form HCFA-1513.--The RO reviews Form HCFA-1513 for completeness and for positive responses in Section II and the "Remarks" section on page 2 for the provider's comments. The RO always completes Section Ib and makes sure the form is signed. Sections I--VII apply to all types of providers (although in subsequent certifications, Section IIIa may be completed with the remark "No change from prior report"). Section IV-VIII may or may not be applicable to a given situation. Section IIIc applies only to corporations.

2. Routine Processing of Form HCFA-1513.--After ensuring that Form HCFA-1513 has been properly completed and none of the questions in Section II have been answered "yes," the RO adjudicates the certification.

When a provider or supplier undergoes a CHOW and for initial provider certifications, the RO sends Form HCFA-1513 to the intermediary. For provider-based HHAs and hospices, the RO sends Form HCFA-1513 to the auditing intermediary and the regional intermediary. (See §2300.)

3. Forwarding Form HCFA-1513 to OIG.--The RO forwards Form HCFA-1513s with "Yes" responses to questions A and B in Section II and the action it has taken on the request or application for review to the OIG, Office of Inspections (OIG/OI) Investigation Field Office servicing the area in which the provider/supplier is located as required by 42 CFR Part 420.204 and 455.106.

The RO proceeds with its certification action in the usual manner unless it determines that a determination by the OIG is necessary in order to properly adjudicate the certification. In that case, the RO defers its adjudication of the certification until a determination from the OIG is received. In making this decision, the RO considers the facts and circumstances of the specific case, including the nature and severity of the crime, penalty, or sanction, and the extent to which it adversely affected beneficiaries and the programs involved.

4. Incorrect or Missing Information.--If review of Form HCFA-1513 shows that responses on the form are in obvious error or information is missing, the RO contacts the institution and specifies what information is needed to complete the form. The RO stresses that Form HCFA-1513 is a requirement for participation per §1124 of the Act and 42 CFR 420, Subpart C. The RO continues the certification processing in the usual manner, but does not adjudicate an initial certification or a CHOW until the information has been received. The RO forwards to the OIG/OI, if appropriate. If the requested information has not been received, the RO follows the procedures in subsection 5.

5. Failure to Disclose Ownership and Financial Information.--If a provider or supplier is withholding or refusing to fully and accurately disclose ownership and financial information, a termination or initial denial is required. The RO continues any other certification development, and processes Form HCFA-2567.

If a Medicaid-only NF or an ICF/MR fails to disclose ownership or control information as required, FFP is not available in payments made to that provider or to its fiscal agency in accordance with 42 CFR Part 455.104(d).

The RO sends the institution a letter (see Exhibit 215) (certified mail, return receipt requested) together with a blank form HCFA-1513, warning that disclosure of financial ownership and control information is required for participation in Medicare and Medicaid, and that failure to submit requested information will result in denial or termination.

2712. USE OF SURVEY PROTOCOL IN THE SURVEY PROCESS

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 which 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 merely 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:

o Requirement: The comprehensive functional assessment must identify the client's specificdevelopmental and behavioral management needs.

o 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.

o Statement of deficiency: 42 CFR Part 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:

o 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, but are not limited to:

o 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

A. Accompanying Surveyors.--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.

B. Physical Contact With Patients/Residents.--A surveyor is not to touch or examine a patient by themselves. However, in certain circumstances it is permissible and necessary to determine the physical condition of residents. 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. A surveyor should request that a staff member of the facility interact with the individual as necessary. The health and dignity of the resident is always of paramount concern. A surveyor should respect an individual's refusal to be observed.

2714. INTERVIEWING KEY PERSONNEL

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 these roles are assumed by one person.) 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. A surveyor should not 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 may 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 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?"

A 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

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. This means that the surveyors may review the care of private pay patients/residents when surveying a Medicare/Medicaid certified 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, consult the RO.

Also, certain provisions of regulations in 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 Part 486.155(b)(4).) SNF/NF requirements in 42 CFR Part 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

The surveyors interview residents, family members, or legal guardians to evaluate their feelings 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

Appendix N describes the procedure(s) which must be applied when surveying a SNF/NF or ICF/MR for errors in medication dosage, administration, and recording. When detecting irregularities in pharmaceutical recordkeeping, the surveyor should begin a probe into the matter immediately to determine if the errors go beyond recordkeeping 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

A. Use of HCFA Surveyors.--To participate in Medicare and Medicaid, a psychiatric hospital must meet the special medical records and special staffing requirements. (See 42 CFR Part 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, HCFA strongly encourages utilizing the services of specialist surveyors who are under contract with HCFA. All State-owned and operated psychiatric hospitals are to be surveyed by HCFA 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); and
- Date of last survey;
- Name and telephone number of the SA person responsible for coordinating the survey (a SA surveyor should accompany the HCFA 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.

B. CO Responsibility.--HCFA 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 HCFA surveyors, and hotel accommodations.

C. Survey Responsibility.--HCFA surveyors are responsible for the opening conference, the survey of the two special Conditions, 42 CFR Part 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.

HCFA surveyors forward the Psychiatric Hospital Survey Report (Form HCFA 724), and all necessary documentation for recertifications, follow-up visits, and initial certifications to CO.

The completed report is sent by the HCFA 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 utilizing HCFA 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.

In those instances when HCFA surveyors find either of the two psychiatric special conditions out of compliance, they will telephone the findings to CO. CO will telephone the RO.

D. RO Responsibility.--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 HCFA 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 HCFA 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 HCFA mental health surveyors directly.

In most cases, if HCFA surveyors cite deficiencies that result in a termination action being initiated, the HCFA 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

A. Traditional SRF.--The traditional Medicare/Medicaid SRF is a booklet that is utilized as a "check list" during the on-site 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 hospitals, hospices, ASCs, ESRDs, CORFs, OPTs, PTIPs, 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.) 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 HCFA-2567). However, the surveyor should continue to record any information on the SRF that is not being collected on Form HCFA-2567. This is especially important on initial surveys and adverse actions. However, surveyors do not duplicate information that is on Form HCFA-2567. Instead, surveyors cross-refer to Form HCFA-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 traditional 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 utilize 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.

B. Specific Items To Consider When Completing SRF.--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 "No"s or "Not Met"s 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."

C. Completing ICF/MR Survey Report.--Form HCFA-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 HCFA-3070G) is the vehicle for direct data entry into OSCAR about pertinent facility, individual, and survey-related data. The first page of Form HCFA-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 HCFA-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 HCFA-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.

D. Completing HHA and SNF/NF Survey Reports.--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. (See §§2196, 2198, 2202, 2204, and 2206, and Exhibits 103 and 104A and 104B for HHAs. (See Appendix P and Exhibits 85-97 for SNFs/NFs.)

2722. PREPARATION FOR EXIT CONFERENCE (EXCLUDING SNFs AND NFs)

Surveyors hold a pre-exit survey team conference at the conclusion of the survey prior to the exit conference and come to an agreed judgement 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 judgement as to the significance of a deficiency:

- A deficiency exists if the "No" column is checked for a particular requirement; and

- A deficiency is significant if it affects the ability of the institution to provide adequate care. A Standard or an element (within a CoP) not in compliance may or may not be a significant deficiency.

2723. CITING DEFICIENCIES IN SNFs AND NFs

Refer to Appendix P for instructions.

2724. EXIT CONFERENCE

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 HCFA's 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 lawyer tries 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. Video taping 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 video taping 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:

A. Introductory Remarks.--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 HCFA-2567 and will be forwarded to the provider within 10 calendar days. Indicate that the provider will in turn have 10 calendar days to submit a PoC. (See §2728.)

B. Ground Rules.--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 HCFA-2567.)

C. Presentation of Findings.--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.

D. Closure.--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 HCFA-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

Following are summaries of eight SA steps of the post-survey certification process:

1. Prepare survey documents for eventual public disclosure.

2. Send Form HCFA-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) which 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

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 HCFA-2567

Form HCFA-2567 (see Exhibit 7) serves several of the following important functions:

o It is the basic document disclosed to the public about the entity's deficiencies and what is being done to remedy them;

o It documents the specific deficiencies cited;

o It documents any promises made by the provider/supplier, i.e., the provider/supplier's plans for correction and timeframes; and

o 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 HCFA-2567. However, Form HCFA-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 U, "Principles of Documentation", for specific guidance on preparing this statement.

The SA mails the provider/supplier a copy of Form HCFA-2567 within 10 calendar days after the survey. If there are deficiencies, the SA allows the provider/supplier 10 days to complete and return the PoC. Requirements pertaining to submittal of the PoC can be found in subsection B.

A. Statement of Deficiencies.--The surveyor prepares Form HCFA-2567 using the instructions provided in Appendix U, "Principles of Documentation". For each Requirement not met, the surveyor makes a citation which includes the following:

o The prefix and data tag number;

o 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

o The evidence to support the deficiency.

If the ASPEN computer database program is utilized to generate Form HCFA-2567s, the statement of deficiencies will automatically be generated in the general format required by Appendix U, Principles of Documentation, 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 HCFA-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 the Principles of Documentation.

B. PoC.--Regulations in 42 CFR Part 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 Part 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 days after the survey depending on the circumstances of the deficiency. The SA should not accept dates for correction routinely for 60 days when the deficiency can reasonably be corrected well before 60 days. On the other hand, a provider may reasonably require more time than 60 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 Part 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 HCFA-2567 and submit a PoC;
- Record objections to the cited deficiencies on Form HCFA-2567 and submit a PoC; or
- Record objections to cited deficiencies on Form HCFA-2567, do not submit a PoC, and provide convincing arguments and documented evidence that the deficiencies are invalid.

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 judgement 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 in a noncompliance case, the SA reviews the documentation submitted by the provider. If the provider provides the SA with indisputable documented evidence that the deficiencies which are the basis for noncompliance are invalid, the SA revises Form HCFA-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 HCFA-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 HCFA-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 HCFA-2567

must be made available for disclosure to the public within 90 days of the last day of the survey. (See 42 CFR Part 401.133.) For SNFs and NFs, §§1819(g)(5) and 1919(g)(5) of the Act require disclosure of Form HCFA-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 HCFA-2567 and return the original copy to the SA within 10 days of receipt. If a multi-copied Form HCFA-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 HCFA-2567. If so, the SA try 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 HCFA-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 §§ and 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 HCFA-2567. When this occurs, such statements must be removed and an amended PoC obtained by the SA.

C. Review of PoCs by SA.--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 Form HCFA-2567s are used, the SA retains the fourth copy of Form HCFA-2567 in the SA file and associate the remaining copies with the certification packet.

D. Modifications of PoCs.--Evidence of correction or a modified PoC may be submitted to the SA by the provider or supplier 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.

E. Rejection of Unacceptable PoCs.--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 HCFA-2567, and then submit the change to the provider.

F. Major Deficiencies Requiring Long-Term Correction in Hospitals, SNFs, NFs, SNF/NFs, and ICFs/MR.--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 1 year for hospitals and ICFs/MR, the following procedure should be followed:

o A LSC waiver should be recommended for the length of time to correct the deficiency including time for design and construction;

o 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

o 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

A. Post-Survey Revisit.--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 on-site 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 on-site 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 HCFA-2567B).

While most surveys should only require one revisit, if more revisits are necessary, the SA obtains permission from the RO to conduct additional visits.

B. Form HCFA-2567B (See Exhibit 8).--At the time of the follow-up visit to verify corrections of deficiencies previously cited on Form HCFA-2567 and/or when corrections are verifiable by telephone contact or mail, the SA completes Form HCFA-2567B for the corrections which 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 HCFA-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 HCFA-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 HCFA-2567 with Form HCFA-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.

C. Notifying Governing Bodies of Continuing Deficiencies.--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

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. Certifications are made by the SA director or his/her designee. Thus, compliance with program requirements is an official finding made by or for the SA director.

A. Conditions For Certifying Compliance.--

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 HCFA or the SA, which is usually 60 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.

B. Certifying Noncompliance.--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

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).

Processing Certifications

2760. FORWARDING CERTIFICATIONS TO RO

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 63.) 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 days after the exit interview. The SA is not to delay the certification process beyond the certification due date when having to follow-up on Form HCFA-1513. Instead, the SA writes the reason why the Form HCFA-1513 is missing on Form HCFA-1539 when the certification file is sent to the RO, and forwards Form HCFA-1513 as soon as possible.

2762. MEDICARE/MEDICAID CERTIFICATION AND TRANSMITTAL, FORM HCFA-1539

A. Purpose of Form HCFA-1539.--The SA uses Form HCFA-1539 to certify findings to the RO or SMA with respect to a facility's compliance with health and safety requirements. Form HCFA-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 HCFA-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 HCFA-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.

B. Definitions of Terms Used on Form HCFA-1539.--

1. Facility.--For Form HCFA-1539 purposes, facility means the provider entity or the business establishment of a provider or supplier which 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 HCFA-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 HCFA 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 HCFA-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. A hospital-based SNF is by definition a distinct part. 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 which 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.

C. Distributing Form HCFA-1539.--The SA completes the five copies of Form HCFA-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, this copy is intended to be transmitted to the RO by the SMA to indicate the issuance of a provider agreement.

If Form HCFA-1539 is computer generated, copies are distributed the same as above.

D. Amended Certifications.--Should the additional information requested via the Regional Office Request for Additional Information (Form HCFA-1666, see §2776) result in any changes in the certification, the SA prepares a new Form HCFA-1539 incorporating the additional documentation and any resulting changes in the certification. The SA draws a line through the original Form HCFA-1539 and note at the top of this form, "See amended certification dated ____." The SA forwards Form HCFA-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 HCFA-1539 (EXHIBIT 9)

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

NOTE : Within each item on Form HCFA-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 HCFA-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 Form HCFA-1539s 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 Form HCFA-1539s 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 Form HCFA-1539s 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 HCFA-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 HCFA-1539.

Item 2 STATE VENDOR OR MEDICAID NUMBER

The SA completes this item only for those States which 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 (On-site Visit).--The SA selects this code for an on-site inspection of a facility for some other reason not outlined above. Examples include:

1. On-site revisit to verify that the deficiencies cited on the original survey are corrected and a Form HCFA-2567B is completed;

2. On-site visit to verify that a hospital meets the criteria for hospitals operating with multiple components; and

3. On-site 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 HCFA-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 which 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 HCFA-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

A. In Compliance With Program Requirements.--If "A" is entered in the first block and the facility is not in full compliance with the program requirements, all conditional aspects are coded in the blocks following "A". For example, the SA enters A126 when a hospital is in compliance with the program requirements based on an acceptable PoC, recommended waivers for technical personnel, and limited scope of service.

NOTE: A1 applies to all provider/suppliers with an acceptable PoC.
A2 and A6 apply to hospitals only.
A3 applies to hospitals, SNFs, and NFs only.
A4 is no longer applicable.
A8 and A9 apply to all LTC facilities.
A5 applies to all facilities which undergo a fire safety survey.
A7 no longer applies to SNFs.

B. Not in Compliance With Program Requirements (Termination Development).-- If "B" is entered in the first block, the documentation supporting the termination action must accompany Form HCFA-1539 and be referenced in Item 16 of Remarks. Item "B" is also selected when an accredited hospital is not in compliance with one or more of the CoPs surveyed during the sample validation survey or complaint investigation.

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

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.

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

NOTE: In all cases, the appropriate SA documentation must accompany Form HCFA-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 HCFA-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 HCFA-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 HCFA-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
HCFA-1513 Missing Because _____	§2760
Denial of Payments Is Recommended	§§3006, 7506

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 Form HCFA-1539s 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 Form HCFA-1539s 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 Form HCFA-1539s 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 HCFA-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 HCFA-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 HCFA-1539

The main purpose of Form HCFA-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:

A. 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.

B. 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 which indicates that the provider is not eligible to participate. For Medicare Part B suppliers not requiring OCR clearance to participate, enter a 3 which indicates not applicable.

C. Item 21: Statement of Financial Solvency.--In the block provided, enter code 1, 2, or 3, if appropriate. Enter code 1 when the provider has completed and submitted the Statement of Financial Solvency, Form HCFA-2572. (See §2002.) Enter code 2 when the Ownership and Control Interest Disclosure Statement, Form HCFA-1513, is completed and reviewed. (See §1016.) When both forms are submitted, enter code 3.

D. 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 Part 489.13 for Medicare and 42 CFR Part 442.13 for Medicaid.

E. 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 HCFA-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.

F. 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:

o Medicare SNF or dually-participating SNF/NF elects to participate in the Medicaid program only;

o Medicaid NF elects to participate in the Medicare or Medicare and Medicaid programs; and

o 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.)

G. 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 HCFA-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 Part 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 HCFA-462L, AAdverse Action Extract for SNFs and NFs.

H. Item 28 - Termination Date.--Enter the effective date of the termination action specified in Item 26.

I. Item 29 - Intermediary/Carrier Number.--Enter the five-digit number assigned to the intermediary or carrier servicing the provider or supplier of health services.

J. 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 HCFA-1539."

K. Item 31 - RO Receipt of Form HCFA-1539.--Enter the date that a certification package is received.

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

L. Item 32 - Determination Approval.--Following review of the certification documents, an authorized HCFA or SMA representative must sign and date Form HCFA-1539.

2765. INTERMEDIARY TIE-IN ACTIVITIES

The SA maintains a list of the intermediaries available (Intermediary Manual, Part 2, §2807) to serve providers in the area. The SA includes this list in the initial mailing kit sent to new provider candidates. This list contains the 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, HCFA-1539A (EXHIBIT 10)

A. Form(s) to Use.--The SA completes both a HCFA-1539 and Spell of Illness Supplement, HCFA-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 HCFA-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 HCFA-1539 and prepares §1819(a)(1) certification(s) on Form HCFA-1539A. If "Does not meet §1819(a)(1)" is checked on Form HCFA-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 HCFA-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 HCFA-1539, and provides explanation in Item 17. The SA prepares §1819(a)(1) certification(s) on Form HCFA-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 HCFA-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 Iitem 14(c)(1) of Form HCFA-1539 and prepares Form HCFA-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 HCFA-1539; prepares HCFA -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 HCFA-1539; provides explanation in Item 17; prepares Form HCFA-1539A.

Situation - Nursing facility with no SNF and no termination involvement.

Action - Prepare Form HCFA-1539 and Form HCFA-1539A.

B. Items on Form HCFA-1539A.--

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

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 HCFA-1539 or Form HCFA-1540. The SA assembles the materials in the order listed in the exhibit.

2774. ROUTING OF MEDICAID-ONLY CERTIFICATIONS

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 HCFA review. In the event prescribed forms, regulations, and procedures were not followed, HCFA could disallow FFP in Medicaid payments to the SMA for the involved facilities, i.e., old look behind.

2776. RO REQUESTS FOR ADDITIONAL INFORMATION

The Regional Office Request for Additional Information or Other Action (Form HCFA-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 HCFA-1666 in the provider/supplier file for its records.

Form HCFA-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 HCFA-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 HCFA-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

A. Medicaid-Only Certifications.--With the exception of State-operated NFs, which are certified by HCFA, 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.

B. State-Operated Medicaid NFs.--These facilities are certified by the HCFA RO.

C. Medicare Certifications.--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 which 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.

D. Change In Certification.--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

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 HCFA-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 Part 442.12(d).)

Certification documents are official statements of the SA which may not to be altered. The RO uses the Request for Additional Information, Form HCFA-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 HCFA-2567 or the Post-Certification Revisit Report, Form HCFA-2567B, as appropriate. If the deficiencies have not been corrected at the time of the revisit, they are shown on a new Form HCFA-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 HCFA-2567 and Form HCFA-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 HCFA CO for resolution.

2779. RO ASSIGNMENT OF PROVIDER AND SUPPLIER IDENTIFICATION NUMBERS

A. Numbering System For Medicare Providers and Suppliers of Service.--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.

1. Provider Identification Numbers.--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	Continuation of Subunits of Nonprofit and Proprietary Home Health Agencies (7300-7399) Series 3/
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)

1/ These facilities (SPRDFs) will be assigned the same provider number whenever they are recertified.

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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)
7000-7299	Home Health Agencies 2/
7300-7399	Subunits of "Nonprofit" and "Proprietary" Home Health Agencies 3/
7400-7799	Continuation of Home Health Agencies (7000-7299) Series
7800-7999	Subunits of State and Local Governmental Home Health Agencies 3/
8000-8499	Continuation of Home Health Agencies (7400-7799) 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
9000-9499	Continuation of Home Health Agencies (8000-8499) Series
9500-9999	Reserved for Future Use

Before the reserved numbers identified above are used, obtain clearance from CO.

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 alpha-numeric 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.

2. Supplier Identification Numbers.--Suppliers that are paid by Part B carriers have a ten digit alpha-numeric 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
J	-	Physical Therapists in Independent Practice/Occupational Therapists in Independent Practice
X	-	X-Ray Facilities

2/ In Virginia (49) the series 7100-7299 has been reserved for Statewide Subunit Components of the Virginia State HHAs.

3/ Parent agency must have a number in the 7000-7299 or 7400-7799, 8000-8499 or 9000-9999 series.

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
PTIP	- 14J0000001
X-Ray	- 21X0009807

B. Numbering System For Medicaid Providers.-- For certification purposes, title XIX-only providers are identified by a six digit alpha-numeric 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 alpha-numeric 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

C. Special Numbering System For Units of Hospitals That Are Excluded From Prospective Payment System (PPS) and Hospitals With SNF Swing-Bed Designation.--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

D. Assigning LTC Provider Numbers.--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 alpha-numeric 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-A000 or XX-E000	XX-G000

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

FACILITY TYPE	18/19 SNF/NF Dually participating	18 SNF or 18/19 Dually participating with SNF or NF DP	18 or 18/19 Dually participating with SNF or NF DP
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.

E. Assigning Emergency Hospital Identification Numbers (Non-Participating Hospitals).--The identification number for emergency hospitals is a six-position alpha-numeric 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.

F. Merger of Facilities or CHOW.--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 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, the Division of Medicare 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.

G. Notification of Change In Identification Number.--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 HCFA-2007. Follow the procedure in §2783 noting in Item V of HCFA-2007 the reason for the number change.

H. Retirement of Identification Numbers.--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 HCFA-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.

I. Control of Identification Numbers.--The RO gives 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 looseleaf 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.

J. ESRD Identification Numbers.--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 SOM §2779 A.1.

ESRD facilities and their identification numbers are as follows:

Hospital-Based Renal Dialysis Facilities	2300-2499
Hospital-Based Renal Dialysis Satellite Facilities	3500-3699
Hospital-Based Special Purpose Renal Dialysis Facilities	3700-3799
Independent Renal Dialysis Facilities	2500-2899
Independent Special Purpose Renal Dialysis Facilities	2900-2999

1. Hospital-Based Renal Dialysis Facilities, 2300-2499.--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 Part 413.174, and SOM §2287. Please note that in accordance with 42 CFR Part 413.174(d)(3), "In determining whether a facility is hospital-based, CMS will not consider . . . the physical location of a facility on the premises of a hospital." The reason for this is because some ESRD facilities on the hospital's premises merely lease space from the hospital and would not meet the regulatory criteria to be hospital-based.

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 Part 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. 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 SOM §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 Part CFR 405.2102, and the requirements at 42 Part 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.

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 SOM §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 SOM §3222.)

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 the 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 HCFA-855 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, HCFA-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 Form HCFA-1539s that report changes in provider status to its data entry section for input into the OSCAR/ODIE data system.

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

2780. EFFECTIVE DATE OF PROVIDER AGREEMENT, FORM HCFA-1561

The earliest that Form HCFA-1561 (see Exhibit 4A) can be effective is the date the onsite health and safety survey is completed (42 CFR Part 489.13). Whether the agreement is made effective on that date or at a later date is determined by the survey findings and the provider's subsequent actions. This also applies to the Rural Health Clinic Benefits Agreement (Form HCFA-1561A). (See Exhibit 4B.) Note: The entity must be operational prior to survey.

A. Compliance With All Requirements.--The agreement is effective on the date the onsite survey is 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 HCFA.

B. All Requirements Are Not Met on the Day of the Survey.--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.

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

After determining that all title XVIII and appropriate civil rights requirements are met, the RO signs the Health Insurance Benefits Agreement (Form HCFA-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

The RO transmits a letter of acceptance (Exhibit 165) to the provider and encloses a copy of the completed Form HCFA-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 HCFA-2007)

A. Purpose.--Form HCFA-2007 (Exhibit 156) is the official notice to the intermediary of changes in its list of providers (additions, deletions, corrections, recertifications, and terminations).

B. RO Responsibility For Form HCFA-2007 Completion.--The RO completes a Form HCFA-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.

C. RO Completion of Form HCFA-2007.--

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 solicit the aid of the intermediary or SA 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 allow 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 HCFA-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."

D. Distribution.--Form HCFA-2007 is a five-part multicolored snapout form. The RO distributes copies as follows:

1. White Copy - Intermediary.--Whenever there is a change to Form HCFA-2007 (new provider, CHOW, change in intermediary, or termination) the RO forwards the white copy to the provider's servicing intermediary.

Refer to the HCFA Intermediary and Carrier Directory, HCFA 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

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 Part 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 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 and enclose the appropriate Health Insurance Benefits Agreement Form, Form HCFA-1561A (Exhibit 4B), or Form HCFA-370 (Exhibit 65), respectively.

The RO notifies Part B carriers of the effective dates of coverage for all suppliers.

2800. STRIKES AT PARTICIPATING FACILITIES

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

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 OPTN is operated by the United Network for Organ Sharing (UNOS) 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

Certification or recertification means a HCFA determination that an entity meets the standards for a qualified OPO at 42 CFR Part 486.304 and is eligible for designation if it meets the additional conditions for coverage in 42 CFR Part 486.306 and 486.310.

Designation or redesignation means HCFA 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 HCFA 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 encompass 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

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 HCFA-576, OPO Request for Designation as an OPO (Exhibit 167), and Form HCFA-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 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 which 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 Part 486.304 through 486.310 which are listed in Exhibit 168.

2812. OPO INITIAL DESIGNATION REQUIREMENTS

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 Part 486.304--General Qualifications, 42 CFR Part 486.306--Qualifications for Designation, and 42 CFR Part 486.308--Participation in the OPTN. The OPO is not required to demonstrate compliance with the standards at 42 CFR Parts 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 Part 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

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

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 HCFA of any OPO that fails to meet those requirements. No OPTN policy will be considered a rule or requirement of the OPTN unless it has been formally approved by the Secretary. No Medicare or Medicaid hospital or OPO is considered out of compliance with §1138(b)(1)(D) of the Act unless HCFA 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

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 Part 486.316.

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

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

The RO terminates OPOs which are not in compliance with the following conditions for coverage: 42 CFR Part 486.304 (OPO Designations - General); 42 CFR Part 486.306 (Qualifications required of an organization for it to be a designated OPO); 42 CFR Part 486.308 (Organ Procurement and Transplantation Network Participation); and 42 CFR Part 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 Part 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 termination 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 Part 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

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

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). An OPO designated by HCFA for a service area will be exempt from meeting the performance standards at 42 CFR Part 486.310(b)(1) through (3) for the first two years after initially being designated. All subsequent redesignations are for 2 year periods if the OPO is found to be in full compliance.

2815. OPOs OPERATING IN A NONCONTIGUOUS U.S. STATE

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 Part 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 Part 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

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 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

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 HCFA 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

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

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

A. Citations.--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 which 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.

B. Description.--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

A. General.--The SA survey and certification process does not apply to FQHCs. HRSA will supply HCA 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 FQHC intermediary (one intermediary services all independent FQHCs).

The RO investigates complaints that allege an FQHC does not meet applicable Medicare requirements.

B. Request to Participate.--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;

o A completed FQHC crucial data extract sheet (Exhibit 178).

C. Information To Be Sent To Applicant by the RO.--Mail applicants copies of:

o Model letter to FQHC applicants (Exhibit 179);

o FQHC Crucial Data Extract (Exhibit 178);

o Attestation Statement for FQHCs (Exhibit 177); and

o The statutory requirements (§1861(aa)(4)).

D. Processing Requests.--The RO verifies that the applicant's attestation statement is complete, and that the applicant's enrollment information has been verified by the fiscal intermediary, United Government Services.

o 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.

o 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.

E. RO Assigning Applicants an FQHC Provider Number.--

o The RO assigns each entity approved as an FQHC an identification number using the 1800-1989 series. This includes RHCs converting to FQHCs.

o 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.

F. RO Completion of Forms.--

o 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.

o The RO completes appropriate blocks of Part I and Part II of Form CMS-1539. Annotate Item 7 by assigning Code 21 for FQHCs.

o 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.

G. Complaint Investigations.--The RO uses the instructions in the SOM §3281, the Act, FQHC regulations, and the appropriate sections of the Interpretive Guidelines for RHCs (Appendix G) in making determinations whether Medicare requirements are met.

H. Effective Date.--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 SOM §2004.) The FI will send you notification when it has verified the information contained in Form CMS-855.