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# Medicare

## State Operations Manual

### Provider Certification

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Department of Health and Human Services (DHHS)

HEALTH CARE FINANCING ADMINISTRATION (HCFA)

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<u>HEADER SECTION NUMBERS</u>	<u>PAGES TO INSERT</u>	<u>PAGES TO DELETE</u>
Table of Contents - Chapter 2	2-1 - 2-2 (2 pp.)	2-1 - 2-2 (2 pp.)
2168 - 2200	2-47 - 2-62.2 (30 pp.)	2-47 - 2-62 (16 pp.)
Chapter 9 - List of Exhibits	9-xiii - 9-xiv (2 pp.)	9-xiii - 9-xiv (2 pp.)
Exhibit 284	9-817 (1 p.)	-----
Appendix R	R-43 - R-44 (2 pp.)	R-41 (1p.)

#### **NEW/REVISED MATERIAL--*EFFECTIVE DATE*: April 15, 2001**

This revision incorporates our current home health survey and certification policy issues which have been included in various program memoranda, policy memos, and regulations.

Section 2180, HHA - Citations and Description, revised to specify that only the non-profit Visiting Nurse Associations would be considered an example of non-profit agencies, and to add the word "qualifying" to service(s) that must be provided directly.

Section 2182, Organization of HHA, revised to add language that reflects the statutory requirement for the parent to meet and continue to meet the definition of an HHA; to direct the surveyor to select records and/or schedule home visits to patients who are served by each branch office; and to include the regulatory definition of a subunit.

Section 2182.1, Characteristics Differentiating Branches From Subunits of HHAs, has been given a new section number.

Section 2182.2, Guidelines for Determining Parent, Branch, or Subunit, includes our policy on determining if a proposed location is a parent, branch or subunit.

Section 2182.3, Processing Change from Branch to Subunit, manualizes our current policy on this issue.

Section 2182.4, HCFA Approval Necessary for Non-Parent Locations, manualizes our current policy on this issue.

Section 2183, Separate Entities, clarifies our current policy on approving separate entities.

Section 2183.1, Operation of the HHA, clarifies our current policy on the operation of the HHA.

Section 2183.2, Consumer Awareness, clarifies our current policy on consumer awareness.

Section 2183.3, Staff Awareness, clarifies our current policy on staff awareness.

Section 2184, Operation of HHAs Across State Lines, manualizes our current policy on this issue.

Section 2194, Surveying Health Maintenance Organization (HMO)-Operated HHAs, revised to specify that HMOs who contract for HHA services must use HHAs that have a provider agreement with Medicare.

Section 2195, Guidelines for Determining Survey Frequency, manualizes our current policy on survey frequency.

Section 2196, HHA Survey Process for Determining Quality of Care, revised the first sentence by replacing to the phrase "consists of" with the phrase "provides for."

Section 2196.1, Definitions, adds a separate section number for the definitions of standard, partial extended and extended surveys.

Section 2196.2, Home Health Functional Assessment Instrument (FAI), adds a separate section number for the FAI.

Section 2196.3, Outcome and Assessment Information Set (OASIS) Requirements, outlines the new OASIS regulations that were published as a part of the CoP.

Section 2196.4, Clinical Laboratory Improvement Amendments, adds a separate section number for the CLIA amendments and reflects the changes that were made in response to comments from the final CLIA regulation.

Section 2198, Standard Survey - Structure, includes two OASIS related regulations as a part of the standard survey and adds directions to the surveyors to routinely conduct recertification surveys at a branch location when that location serves more patients than the parent.

Section 2200, Survey Tasks, includes the survey tasks and remove the requirement for the case-mix stratified sample to be randomly drawn.

Section 2202, Conducting Home Vists, has been **deleted**.

Section 2204, Assessing Compliance and Recording Information, has been **deleted**.

Section 2206, Exit Conference, has been **deleted**.

Appendix R, Part III, Resident Assessment Protocols, was inadvertently deleted on Transmittal 22, dated December 8, 2000. Part III is still current and no changes have been made.

**DISCLAIMER: The revision date and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.**

## CHAPTER 2

### THE CERTIFICATION PROCESS

#### Identification of Providers and Suppliers, and Related Presurvey Activities

	<u>Section</u>
Certification Surveys - Citations and Responsibilities .....	2000
Meaning of Providers and Suppliers.....	2002
SA Identification of Potential Providers and Suppliers .....	2003
Provider Based Designation.....	2004
Medicare Health Care Provider/Supplier Enrollment.....	2005
Prioritizing SA Survey Workload - Initial Surveys and Recertifications .....	2008
Ascertaining Compliance With the Civil Rights Requirements .....	2010
SA Identifying Eligible Providers and Suppliers.....	2012
Statement of Financial Solvency (Form HCFA-2572).....	2014
Readmission to the Medicare or Medicaid Program After Involuntary Termination - Reasonable Assurance .....	2016
Readmission Following Voluntary Termination of Program Participation.....	2017
Reinstatement Following Termination of Swing-Bed Approval.....	2018

#### Hospitals

Hospitals - Definition and Citations .....	2020
Hospitals Accredited by the Joint Commission or AOA.....	2022
Hospital Merger/Multiple Campus Criteria .....	2024
Certification of Parts of Institutions as Hospitals .....	2026
Temporary Waivers Applicable to Rural Hospitals.....	2030
Time Limit on Temporary Waiver.....	2034
Hospital Providers of Extended Care Services ("Swing-Beds") – Citations and Description.....	2036
Requirements Assessed Prior to Survey for Swing-Bed Approval.....	2038
Survey Procedures for Swing-Bed Approval.....	2040
Post Survey Procedures for Swing-Bed Hospitals .....	2041
RO Approval Procedures for Swing-Bed Approval.....	2041.1
Psychiatric Hospitals.....	2042
Accredited Hospitals Not Deemed to Meet Special CoPs.....	2044
Distinct Part Psychiatric Hospitals.....	2048
Medical-Surgical Unit of Psychiatric Hospitals .....	2050
Nonparticipating Emergency Hospitals .....	2052
Religious Nonmedical Healthcare Institutions (RNHCIs).....	2054
Certification of Religious Nonmedical Healthcare Institutions (RNHCIs).....	2054.1

#### Hospices

Hospice - Citations and Description.....	2080
Hospice - Multiple Locations.....	2081
Election of Hospice Benefit by Resident of a SNF, NF, ICF/MR, or Non-Certified Facility.....	2082
Hospice Regulations and Non-Medicare Patients.....	2083
Hospice Inpatient Services Furnished Directly or Furnished Under Arrangements.....	2084
Operation of a Hospice Across State Lines .....	2085
Hospice Home Visits .....	2086
Compliance With Advance Directives.....	2087
ICFs/MR -- Citations and Description.....	2130
Distinct Part ICF/MR.....	2134
Approval Procedures for ICFs/MR.....	2138

Section

Assessment of ICFs/MR Based on CoPs for Active Treatment .....2139  
Waiver and/or Variance of ICF/MR Requirements .....2140  
Time Limited Certifications - ICF/MR.....2141

Spell of Illness Certifications

Purpose of Certifying 1861(e)(1) and 1819(a)(1) Status of Hospitals and SNFs.....2160  
Defining Hospital for Spell of Illness, DME, and Home Health Benefit Purposes.....2162  
When to Make Spell of Illness Certification.....2164  
Criteria for Certifying 1819(a)(1) of the Act Status of LTC Facilities Other than SNFs...2166  
Additional Development Required for Spell of Illness Certifications .....2168

Home Health Agencies (HHAs)

HHA - Citations and Description.....2180  
Organization of HHA.....2182  
Characteristics Differentiating Branches from Subunits of HHAs.....2182.1  
Guidelines for Determining Parent, Branch, or Subunit.....2182.2  
Processing Change from Branch to Subunit .....2182.3  
HCFA Approval Necessary for Non-Parent Locations .....2182.4  
Separate Entities.....2183  
Operation of the HHA.....2183.1  
Consumer Awareness.....2183.2  
Staff Awareness .....2183.3  
Operation of HHAs Across State Lines .....2184  
Health Facility-Based HHAs .....2186  
Survey of State-Operated HHAs.....2188  
Surveying Health Maintenance Organization (HMO)-Operated HHAs.....2194  
Guidelines for Determining Survey Frequency.....2195  
HHA Survey Process for Determining Quality of Care.....2196  
Definitions.....2196.1  
Home Health Functional Assessment Instrument (FAI).....2196.2  
Outcome and Assessment Information Set (OASIS) Requirements.....2196.3  
Clinical Laboratory Improvement Amendments .....2196.4  
Standard Survey - Structure .....2198  
Survey Tasks.....2200

Ambulatory Surgical Centers

ASCs - Citations and Description.....2210

Rural Health Clinics

RHCs -- Citations and Description.....2240  
Conditions to be Assessed Prior to Scheduling RHC Survey.....2242  
Preparing for the RHC Survey.....2244  
Clinic's Request to Provide Visiting Nurse Services .....2246  
Clinic's Request for Waiver of Staffing Requirements.....2248  
RO Notification of RHC Approval.....2249

Community Mental Health Centers

Community Mental Health Centers (CMHC) - Citations and Descriptions .....2250  
Certification Process .....2252

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:

- o Is primarily engaged in providing skilled nursing services and other therapeutic services;
- o 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;
- o Provides for supervision of above-mentioned services by a physician or registered professional nurse;
- o Maintains clinical records on all patients;
- o Is licensed pursuant to State or local law, or has approval as meeting the standards established for licensing by the State or locality;
- o Has in effect an overall plan and budget for institutional planning;
- o Meets the CoPs in the interest of the health and safety of individuals who are furnished services by the HHA; and
- o 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:

- o Protect and promote the rights of each individual under its care;
- o Disclose ownership and management information required under the Act;
- o 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;
- o Operate and provide services in compliance with all applicable Federal, State, and local laws and regulations (including the requirements of §1124 of the Act);
- o Operate and provide services in compliance with accepted professional standards and principles which apply to professionals providing items and services for the HHA;
- o 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
- o 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:

- o Patients are accepted for care only by the primary HHA;
- o The services to be furnished under the contract or agreement;
- o 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 1 1/2 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:

- o Address and phone number of the branch/subunit;
- o Organizational lines under the parent;

- o How supervision will occur;
- o Services provided directly and under arrangement; and
- o 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:

- o Operation of the HHA;
- o Consumer awareness; and
- o 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:

- o Separate policies and procedures for admission to the HHA, including separate consent forms;
- o Separate clinical records for all patients receiving HHA services;

- o 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 HCFA 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 HCFA 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 HCFA 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 HCFA ROs, the HCFA 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 HCFA RO in a particular case, it is the HCFA 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 HHAs

HMOs which contract with Medicare to furnish HHA services may provide such services either directly or through Medicare-approved HHAs that have a provider agreement/number with Medicare. (See 42 CFR Part 417.416.) If an HMO provides home health services directly as an integral part of the HMO, it is referred to as an HMO-operated HHA, and the HMO itself must meet the HHA CoPs. Conduct an unannounced standard survey of these facilities. The HMO-operated HHA is not required to:

- o Have a Medicare provider number;
- o Enter into a provider agreement with the Secretary; or
- o Meet other certification requirements (other than the CoPs) 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 HCFA 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 to ascertain whether they continue to meet the HHA CoPs.

## 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.

<b>SURVEY FREQUENCY GUIDELINES</b>	
<b>Frequency</b>	<b>Requirements</b>
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:

- o Patient rights (42 CFR Part 484.10);
- o Release of Patient Identifiable OASIS Information (42 CFR Part 484.11);
- o 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);
- o Coordination of patient services (42 CFR Part 484.14(g));
- o Acceptance of patients, PoC, and medical supervision (42 CFR Part 484.18);
- o Home health aide services (42 CFR Part 484.36);
- o Clinical records (42 CFR Part 484.48); and
- o 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:

- o 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
- o 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);
- o Release of patient identifiable OASIS information (42 CFR Part 484.11);
- o 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);
- o Coordination of patient services (42 CFR Part 484.14(g));
- o Acceptance of patients, PoC, and medical supervision (42 CFR 484.18);
- o Home health aide services (42 CFR Part 484.36);
- o Clinical records (42 CFR Part 484.48); and
- o 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:

- o 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;
- o 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
- o 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.
  - o Present identification and introduce the survey team members.
  - o Request a meeting with appropriate staff based on the organizational characteristics of the HHA. Request a copy of the organization chart, if available.
  - o Inform the HHA administrator, director, or supervisor of the purpose of the survey.
  - o Ask the administrator to explain the organization, services provided (directly and under arrangement) and the relationship to any corporate structure.
  - o Explain the survey process, and estimate the number of days onsite.
  - o Be aware that the unannounced survey may be disruptive to the normal daily activities of the HHA.
  - o Discuss the extent to which the HHA staff may be involved during the survey.
  - o Set up the schedules for any necessary interviews with staff.
  - o 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:
  - o HHA location (including any branches);
  - o Access to patient list, clinical records, personnel files, policies, and procedures;
  - o Documentation of home health aide training and/or competency evaluations;

- o Information concerning services not provided directly;
- o Number of unduplicated patients admitted receiving skilled services during recent 12-month period;
- o List of patients scheduled for a home visit during the survey;
- o List of current employees;
- o CLIA certificate (if applicable);
- o Forms to complete: Forms HCFA 1513 and 1572;
- o Names of key staff (i.e., staff persons most knowledgeable about the home health aides, in-service training, clinical supervision);
- o Clinical staff person who will be the primary resource to respond to the surveyor's questions; and
- o 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:
  - o Reviewing how the HHA performs the comprehensive assessment of patients incorporating the OASIS items;
  - o Determining if the comprehensive assessment accurately reflects the patient's status;
  - o Reviewing how the HHA determines the appropriate care, services, and treatments for patients to achieve desired health outcomes;
  - o Reviewing how the HHA delivers care to patients and measures needed and desired patient outcomes;
  - o Evaluating patient satisfaction with the HHA's services;
  - o Reviewing how the HHA uses OBQM and OBQI reports available from the OASIS data;
  - o 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;
  - o Determining if the HHA provides care to patients that assists patients to attain and maintain their highest practicable functional capacity;
  - o Determining if the PoC is consistently implemented, evaluated, and reviewed based on the response, outcomes and needs of the patients;

- o Selecting a sample for record reviews with home visit;
  - o Selecting a sample for record reviews without home visit;
  - o Arranging for and conducting home visits;
  - o 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:

- o **The sample includes a range of primary admitting diagnoses (stratification); and**
- o **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:

<u>All Patients Requiring Skilled Services Admitted During Recent 12 Month Period</u>	<u>Record Reviews With Home Visit to Patients Requiring Skilled Services Admitted During Recent 12-Month Period</u>
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:

- o 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:

<u>All Patients Requiring Skilled Services Admitted During Recent 12 Month Period</u>	<u>Record Reviews of All Patients Requiring Skilled Services Admitted During Recent 12 Month Period</u>
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, in your judgement, it appears to be in the patient's best interest to end the interview; or
- o Conditions in the patient's 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.

LIST OF EXHIBITS (Cont.)

- 245 CLIA Adverse Action Extract, HCFA-462A/B Reserved
- 246 Model Letter: Regional Office Notifying a State-Operated Laboratory of Cited Deficiencies and Requesting a Plan of Correction
- 247 Notice of (Limitation or) Revocation of a Laboratory's CLIA Certificate - No Immediate Jeopardy
- 248 Notice of Proposed Limitation, Suspension, or Revocation of the CLIA Certificate; Opportunity for a Hearing - No Immediate Jeopardy
- 249 Model Letter: Send to the Laboratory in Conjunction With the Notice of Sanction, In Order to Officially Inform the Laboratory that the Responsibility Lies With the Laboratory to Achieve Compliance, Even if They Have Successfully Completed the Directed Plan of Correction
- 250 Notice of the Reissuance of a CLIA Certificate In Order to Keep a Laboratory Operational if it is Due to Expire Prior to the Administrative Hearing
- 251 Model Letter: Offering the Opportunity for a Reconsideration of the Addition of Specialties or Subspecialties by a Laboratory is Denied by HCFA
- 252 Model Letter: To Laboratory Director to Accompany the AQAS Instrument
- 253 Reserved for SAQIP
- 254 Model Letter: Notification to Applicant that Medicare General Enrollment Health Care Provider/Supplier Application Has Been Denied
- 255A Model Letter: Notification of Pending Involuntary Termination Based on CHOW Review of the Medicare General Enrollment Health Care Provider/Supplier Application
- 255B Model Letter - Notification of Involuntary Termination Based on CHOW Review of the Medicare General Enrollment Health Care Provider/Supplier Application
- 256 Form HCFA-855 - Medicare and Other Federal Health Care Program General Enrollment Health Care Provider/Supplier Application
- 257 Form HCFA-855C - Medicare and Other Federal Health Care Program Change of Information Health Care Provider/Supplier Application
- 258 Form HCFA-855R - Medicare and Other Federal Health Care Program Individual Reassignment of Benefits Health Care Provider/Supplier Application
- 259 Minimum Data Set Automation Contract/Agreement Approval RO Checklist
- 260 MDS 2.0 Discharge and Reentry Flowchart
- 261 Privacy Act Statement - Health Care Records
- 262 Correction Policy Flowchart
- 263 Submission Timeframe for MDS Records
- 264 HCFA-672 - Resident Census and Conditions of Residents

LIST OF EXHIBITS (Cont.)

- 265 HCFA-802 - Roster/Sample Matrix
- 266 HCFA-802P - Roster/Sample Matrix Provider Instructions (use with Form HCFA-802)
- 267 HCFA-802S - Roster/Sample Matrix Instructions for Surveyors (Use with Form HCFA-802)
- 268 Facility Characteristics
- 269 Facility Quality Indicator Profile
- 270 Resident Level Summary
- 271 Quality Indicator Matrix
- 272 Overview of MDS Submission Record
- 273 Correction Policy Summary Matrix
- 274 Definition of Selected Dates in the RAI Process
- 275 Attestation Statement for CMHCs
- 276 Health Insurance Benefit Agreement for CMHCs
- 277 Fiscal Intermediary (FI) Provider Billing Number Deactivation Letter Used by FI
- 278 Model Denial Letter for CMHC Applicants—State Restrictions on Screening
- 279 Model Letter – Notice of Findings for Non-Compliance for CMHCs
- 280 Model Letter – Notice of Termination of Provider Agreement for CMHCs
- 281 Model Letter – CMHC That Has Ceased Operating
- 282 Model Letter – Participation in Medicare as a CMHC Providing Partial Hospitalization Services (Including Threshold and Service Requirements)
- 283 Model Letter – Notice of Failure to Meet Threshold and Service Requirements, CMHCs
- | 284 Model Denial Letter – To a Home Health Agency (HHA) That Requested a Branch Office

Exhibit 284

Model Denial Letter  
To a Home Health Agency (HHA) that Requested a Branch Office

Dear HHA Administrator:

This is to inform you of the Health Care Financing Administration's (HCFA's) decision to deny your request to establish a branch office in (City, County, State).

In order to be approved as a branch office of a parent HHA, an entity must meet the regulatory requirements for a branch. These requirements are found at 42 CFR Part 484.2. The branch must also meet applicable licensing or certification requirements for a branch in the State in which it is located and the State in which the parent is located, if different. The 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 regulations require that a branch be "sufficiently close" to the parent to share administration, supervision, and services in a manner that makes it unnecessary for the branch to meet the conditions of participation on its own. To accomplish this, the parent agency must be physically located so that the sharing of administration, supervision, and services with the branch can occur on a daily basis.

After a careful review, HCFA has determined that the location you propose as a branch does not meet the regulatory requirements. This is because:

- o The proposed location provides services in a different geographic area from the parent HHA;
- o The proposed location is not sufficiently close to the parent to share administration, supervision and services on a daily basis;
- o The proposed location does not meet State licensure or certification requirements for a branch; or
- o The involved State agencies were unable to come to reciprocal agreement concerning surveys of the branch office.

If you wish to request that this location be considered as a subunit, please contact (name of contact).

Sincerely yours,

Associate Regional Administrator  
(or its equivalent)

cc:  
State Survey Agency

## RESIDENT ASSESSMENT INSTRUMENT FOR LONG TERM CARE FACILITIES

AT7 Attestation of Accuracy and Signatures of Persons Who Correct a Portion of Assessment or Tracking Information: Individuals who correct any portion of an MDS record or complete any portion of the MDS Correction Request Form must sign and date a hard copy of the MDS Correction Request form, indicating their title beside their signature. Signature certifies the completion and accuracy of information they corrected, and the portion(s) of the MDS Correction Request Form they completed.

### PART III - RESIDENT ASSESSMENT PROTOCOLS

Part of the utilization guidelines, the resident assessment protocols (RAPs) are problem-oriented frameworks for additional assessment and problem identification that form the final linkage to decisions about care planning. There are 18 RAPs in version 2.0 of the RAI. The RAPs in HCFA's RAI cover approximately 90 - 95% of the areas that are addressed in a typical nursing home resident's care plan. Each RAP has 4 parts: (1) the Statement of Problem, (2) Triggers, (3) Guidelines, and (4) the RAP key. Upon completing the triggered RAPs for a resident, staff will have:

- o Identified the unique problems the resident has that may adversely affect his/her highest practicable physical, mental, and psychosocial functioning;
- o Identified factors that place the resident's highest practicable physical, mental, and psychosocial functioning at risk;
- o Considered whether the identified potential problems could be prevented or reversed, or risk factors minimized, and evaluated the extent to which the resident is able to attain a higher level of well-being and functional independence; and
- o Evaluated ongoing care practices for that resident by, for example, considering alternative therapies and the need for medical consultation, or consultation(s) by other health professionals such as occupational or physical therapists.

The RAPs must be completed whenever a full assessment is required, unless the facility uses the full MDS as its quarterly review (i.e., the facility must complete the RAPs upon admission, significant change, and annual reassessment).

To use RAPs, long term care facility staff shall follow these steps:

- o Review the completed MDS to identify triggered RAPs. This may be performed automatically by software in automated systems or manually by using the RAP Trigger Legend.
- o In the left-hand column of the RAP Summary form next to the RAPs, "Check if triggered," place a checkmark next to each triggered RAP.
- o For each triggered RAP, review the RAP Guidelines. This review process assists the assessor to collect and analyze additional relevant information regarding the triggered condition. The Guidelines also help the assessor examine causal factors that affect the resident's condition and offer suggestions regarding how factors contributing to the resident's problems can be eliminated or minimized.
  - o Describe the following key information:
    - Nature of the condition (may include presence or lack of objective data or subjective complaints);
    - Complications and risk factors, which include the presence of causal factors, that may be identified by the Guidelines;
    - Factors that must be considered in developing individualized care plans;

## RESIDENT ASSESSMENT INSTRUMENT FOR LONG TERM CARE FACILITIES

- The need for referrals to appropriate health professionals; and
- The reasons for deciding to proceed or not to proceed with care planning for triggered problems.

It is not necessary to document findings for each issue or question in the Guidelines. Documentation for each triggered RAP should address the nature of the problem(s) as evidenced by objective findings and subjective complaints of the resident. If the triggered RAP is not a problem for the resident, documentation should include what clinical factors from the RAP review process support that decision.

- o In the "Location of Information" column of the RAP Summary form, indicate where the assessment information is documented. Indicating that the problem is included in the care plan is not enough. If the facility references the care plan as the location of information, all information listed above would have to be documented in the care plan.

- o Complete the "Care Planning Decision" column last. This indicates whether the RAP area was care planned. It must be completed within seven days of the completion of the comprehensive assessment (i.e., within the regulatory timeframe for the completion of the care plan).

The RN coordinator must sign the MDS and the RAP Summary form to signify completion of the assessment. There is no Federal requirement that each staff member completing a RAP sign and date the RAP Summary form to certify its accuracy. They may wish to indicate which RAP(s) they completed, list any credentials, and the date it was completed. If they desire to do so, other staff members may sign the form wherever there is room to do so in a legible manner.

The staff person entering the care planning decision information must also sign and date the RAP Summary form. The facility has 7 days after completing the assessment to complete the care plan. The date for entering of the care plan information may be up to 7 days after the RAPs are completed (i.e., the date on which the RN Coordinator signed to indicate completion of the RAP assessment process).

HCFA will develop additional RAPs in the future. States may also develop additional RAPs and request approval to include them in the State specified RAI.