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Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 14-14-HHA

DATE: **March 14, 2014**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Home Health Agency (HHA) State Operations Manual (SOM) revisions: Appendix B, HHA Enforcement Guidance and revisions to Chapter 2, Certification Process

Memorandum Summary

- **Appendix B – Guidance to Surveyors: Home Health Agencies –** Recent establishment of survey and enforcement regulations as well as changes to other HHA policies have necessitated revisions to previously published survey guidance.
- **HHA Survey and Enforcement regulations –** The final rule on available alternative sanctions for HHAs with condition-level deficiencies was published in 2012. Among other things, this rule allows for the imposition of civil money penalties (CMP), directed in-service training, directed plan of correction, suspension of payment, and temporary management. The Centers for Medicare & Medicaid Services (CMS) has developed a new SOM chapter 9 to guide State Agencies (SAs) and Regional Offices (ROs) on imposing these sanctions, as well as on the procedures regarding an informal dispute resolution process (IDR).
- **SOM, Chapter 2, Certification, Sections 2180-2202.19 –** Survey protocols, HHA enforcement regulations, changes to Outcome and Assessment Information Set (OASIS) data transmission and other policy changes have resulted in the need to update the HHA sections of Chapter 2.

A. Background

On February 11, 2011, CMS published guidance, S&C 11-11, for HHA surveyors on revisions to survey protocols. These protocols revised the survey process for HHAs, including Level 1 and Level 2 standards and guidance for deficiency citations. These revised protocols became effective in May 2011. On November 8, 2012, we published the final rule "Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2013, Hospice Quality Reporting Requirements, and Survey and Enforcement Requirements for Home Health Agencies" (77 Fed. Reg. 67068). This rule codified the requirements for unannounced, standard, and extended surveys of HHAs and set forth alternative sanctions that can be imposed instead or, or in addition to, termination of an HHA's participation. Under this rule, CMS now has the authority to impose the alternative sanctions of civil money penalties directed in-service

training, directed plans of correction, suspension of payment for new admissions, and temporary management on HHAs that are found to have condition level deficiencies. The rule also allows for an IDR process. The enforcement sanctions and new IDR process for HHAs are similar to those for nursing homes.

The SOM, Chapter 2, Sections 2182-2202 had not been revised since 2005 and changes were needed. Policy changes, including policies related to CMS OASIS data transmission and other minor changes have now been completed.

To aid SAs and ROs in selecting and imposing the alternative sanctions, CMS Central Office (CO) has developed a new SOM Chapter 9 pertaining to HHA enforcement. Furthermore, Chapter 2 and Appendix B of the SOM are being updated as well to reflect the new alternative sanctions, the modifications to survey protocols in the final rule, as well as updating guidance related to branches and enrollment modifications to HHA policy.

B. Request

Please review the guidance and familiarize yourself with the processes therein. The guidance should also be distributed to all appropriate personnel.

C. Additional Information

Training on imposing the alternative sanctions was provided on August 7, 2013. This webinar will be posted on the CMS website along with guidance in this letter. Additional guidance related to Automated Survey Processing Environment (ASPEN) Enforcement Management will also be available later in the year.

Questions concerning this chapter or memo may be addressed to Pat Sevast at patricia.sevast@cms.hhs.gov.

Effective Date: The regulations pertaining to directed in-service training, temporary management, and directed plans of correction became effective on July 1, 2013, therefore the guidance related to those provisions will be effective immediately. The provisions pertaining to the imposition of CMPs and suspension of payment for new admissions as well as the provisions for the IDR process will become effective on July 2, 2014.

/s/
Thomas E. Hamilton

Attachments – Chapter 2: The Certification Process;
Chapter 9: Survey and Enforcement for Home Health Agencies;
Appendix B: Guidance to Surveyors: Home Health Agencies

cc: Survey and Certification Regional Office Management

Excerpt from CMS State Operations Manual
Chapter 2 – The Certification Process

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

2180A - Citations
(Rev.)

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 Investigative Procedures and Interpretive Guidance for surveyors.

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

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

2180B - Types of Agencies
(Rev.)

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

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

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

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

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

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

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

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

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

- Maintains clinical records on all patients;

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

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

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

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

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

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

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

- Disclose ownership and management information required under the Act;

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

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

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

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

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

2180D - Services Provided
Rev.

All HHAs must provide skilled nursing services and at least one of the following other therapeutic services: physical therapy, speech language pathology, or occupational therapy, medical social services, or home health aide services in a place of residence used as a patient's home. The HHA must provide at least one of these services (i.e., skilled nursing, physical therapy, speech language pathology, occupational therapy, medical social services,

or home health aide services) directly and in its entirety by employees of the HHA. The other therapeutic services and any additional services may be provided either directly or under arrangement.

An HHA is considered to provide a service "directly" when the person providing the service for the HHA is an HHA employee. For the purpose of meeting 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 met, as though the HHA was furnishing the services directly.

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

- Patients are accepted for care only by the primary HHA;
- The services to be furnished under the contract or agreement;
- The necessity to conform to all applicable agency policies, including personnel qualifications;
- The responsibility for participating in development of plans of care;
- The manner in which services will be controlled, coordinated, and evaluated by the primary HHA;
- The procedures for submitting clinical and progress notes, scheduling of visits, periodic patient evaluation; and
- The procedures for payment for services furnished under the agreement or contract.

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

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

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

In addition to promoting the health and safety of individuals, §1891(b) of the Social Security Act also directs the Secretary to ensure that requirements "promote the effective and efficient use of public moneys." This statutory direction is especially pertinent in the question of whether expenses ought always to be incurred for a comprehensive assessment and care plan when the only service requested from an HHA by an individual is a chore or other clearly non-medical service. When this is the case, we will not consider the individual to be a patient of the HHA in the traditional sense of the term, and requirements that must apply to patients will not be required in such limited situations (e.g., the requirement for a comprehensive assessment under 42 CFR Part 484.55 will not apply).

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

CMS considers as a medical service any hands-on service, personal care service, cueing, or activity that is in any way involved in monitoring the patient's health condition. As soon as the HHA provides any Medicare service to an individual, or any standard service permitted by Federal law under the Medicaid State Plan (such as personal care), we will consider the individual to be receiving medical care. The CoPs will apply for all services rendered to such an individual. For example, the CoPs would apply in the case of an individual who received both chore services and personal care (regardless of funding source), but would not apply in the case of an individual receiving only chore services from the HHA.

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

HHAs may develop their own comprehensive assessment for each required time point under the regulations at 42 CFR Part 484.55 for those patients receiving personal care services only regardless of payor source. The assessment may be performed any time up to and including the 60th day from the most recently completed assessment.

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

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

2182 - Organization of HHA
(Rev.)

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

Subdivisions

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

Parent HHA

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

Branch Offices

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

Subunits

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

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

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

The subunit must submit an initial enrollment application Form CMS-855A and undergo an onsite initial survey from the State Agency (SA) or a National Accreditation Organization (AO) with deeming authority, before it is approved to participate in Medicare. The *SA* completes *the* Form CMS-2567, or the AO completes the equivalent, and all other applicable documents for the parent organization and each subunit. The SA *or AO* does not conduct the initial survey of a subunit prior to the initial survey of the parent agency. *The CMS certification numbers (CCNs) are assigned numerically by the Regional Office (RO).*

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

2182.1 - Characteristics Differentiating Branches From Subunits of HHAs (Rev.)

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

Administrative Functions (Relationship with Parent Agency)

Branch - Not autonomous. Is part of the HHA and shares administration, supervision and services with the parent agency on a daily basis. The administration at the parent agency is aware of the staffing, patient census and any issues/matters affecting the operation of any given branch. The branch location provides *the same* services *as the parent* within a portion of the total geographic area served by the parent agency.

Subunit - Semi-autonomous *and l*ocated 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 *must* convert to a subunit.

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

Administrator (See 42 CFR Part 484.4.)

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

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

Supervising Physician or RN (See 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. *(See 2182.4B)*

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

Personnel Policies (See 42 CFR Part 484.14(e).)

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

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

Coordination of Patient Services (See 42 CFR Part 484.14(g).)

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

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

Services Under Arrangements (See 42 CFR Part 484.14(h).)

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

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

Group of Professional Personnel (See 42 CFR Part 484.16.)

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

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

Clinical Records (See 42 CFR Part 484.48.)

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

Subunit - Maintains clinical records on all its patients.

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

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

A. Supervision

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

Supervision of services requires that a qualified person be physically present to directly supervise the provision of services by any individual who does not meet the qualifications specified at 42 CFR Part 484.4. For individuals that do meet the qualifications specified at 42 CFR Part 484.4, the supervisor does not have to be physically present during the provision of all services. The use of telephones, pagers, facsimile machines, or other electronic devices

does not eliminate the requirement for the physical presence of the supervisor. The parent may appoint an effective full time branch supervisor or manager as long as this individual is and remains under the supervision of the parent.

B. Distance

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

C. Geographic Area

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

D. Sharing Administration, Supervision, and Services

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

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

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

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

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

State licensure laws that define parent, branch, and/or subunit are a consideration in making non-parent determinations, but it is the definitions in the Federal regulations (42 CFR Part 484.2) that must be satisfied in making parent, branch, or subunit determinations. If an HHA operates across State lines, follow the instructions in §2184 of the State Operations Manual.

The SA in the State in which the parent is located should take the lead in coordinating with the adjacent State to resolve parent and non-parent issues.

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

2182.3- Processing A Change From Branch to Subunit
(Rev.)

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

2182.4 - CMS Approval Necessary for Non-Parent Locations
(Rev.)

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

The Form CMS-855A applications are used to gather information on providers for the purpose establishing eligibility to furnish services to Medicare beneficiaries. 42 CFR Part 424.540(a)(2) requires a provider or supplier to update its enrollment information, and recertify its accuracy when any changes are made. Additionally, 42 CFR Part 424.515 requires revalidation of the enrollment information by providers and suppliers every 5 years and (every 3 years for suppliers of durable medical equipment, prosthetics, orthotics and suppliers) or when determined by CMS policy.

See also Chapter 10 and 15 of the Program Integrity Manual which can be found at:
http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c10.pdf
and
http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c15.pdf

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

2182.4A - Notification by HHA to Add a Branch
(Rev.)

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

- *Address and phone number of the branch;*
- *Organizational chart delineating lines of authority, professional and administrative control for the HHA, including the branch;*
- *Defined geographic service area (counties, cities, zip codes), and any intention to cross State lines (which would require a reciprocal agreement between the affected States as well as RO approval);*
- *Services shared with the HHA parent;*
- *Services provided directly and under arrangement;*
- *Contracts for any services provided under arrangement;*
- *Identification of any high-tech services provided (e.g., infusion therapies such as artificial nutrition and hydration, or chemotherapy, mechanical ventilation, tracheostomy care, etc.);*
- *Names of all branch staff and their job descriptions;*
- *Proof of branch staff qualifications (resume, licensure, aide training, etc.);*
- *Explanation of how supervision by the HHA parent will occur;*
- *Identification of the person who will resolve patient care issues at the branch;*

Explanation of how staff will coordinate care and services;

- *Policies for addressing clinical and other emergency situations;*
- *Plans for addressing staff absenteeism; and*
- *State issued certificate of need, if applicable.*

2182.4B - SA Review of Request for Branch Determination
(Rev.)

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

The SA reviews the ability of the branch location to meet the definition of a branch as provided in 42 CFR Part 484.2. The regulations require the branch to be within the HHA parent's geographical service area and sufficiently close enough to the HHA parent to share administration, supervision, and services on a daily basis.

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

Administration, Supervision and Services:

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

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

- *Supervision means authoritative procedural guidance by a qualified person for the accomplishment of a function or activity. Supervision at the branch must be adequate to support the care needs of the patients. The HHA's supervising nurse or physician, as required by 42 CFR Part 484.14(d), is available at all times by phone or other means of communication during operating hours for individuals who meet the qualifications specified at 42 CFR Part 484.4. Supervision of services requires that a qualified person be physically present to directly supervise the provision of services by any individual who does not meet the qualifications specified at 42 CFR Part 484.4. The HHA may formally appoint a supervisor or manager who is under the direct supervision of the HHA parent to assist with supervision at the branch. (The HHA parent may use technological means for supervision in conjunction with periodic onsite visits. However, the use of telephones, pagers, facsimile machines, or other technological or electronic devices does not eliminate the requirement for the physical presence of the supervisor when required.)*

- *The group of professional personnel required by 42 CFR Part 484.16 reviews the agency's policies and service delivery throughout the entire agency, both parent and any branch(es).*

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

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

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

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

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

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

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

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

Distance

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

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

Geographic area

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

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

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

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

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

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

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

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

2182.4C - Onsite Monitoring of Approved Branches by the SA
(Rev.)

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

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

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

- A copy of the HHA's policies and procedures is maintained in each branch. Branch office personnel should be knowledgeable of the policies and consistently apply them;
- Methods of communication between HHA parent and branch assure that all patients receive the necessary care and services identified through the comprehensive assessment and plan of care;
- The branch retains the active clinical records for its patients. Duplicate clinical records need not be maintained at the HHA parent, but must be available to the surveyor upon request;
- Patients are receiving appropriate care and services at the branch, and

- *The HHA is in compliance with OASIS submission requirements.*

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

2182.4D - Drop Sites
(Rev.)

Where permitted by state and local law, an HHA may utilize a drop site for field staff convenience. These drop sites are not considered branches and should not meet the Medicare definition of a branch or operate as such. HHAs that allow these locations to cross the line from drop site to branch are out of compliance with the Medicare requirements. The HHA should not assign staff to these locations, accept referrals at these locations, advertise them as a part of the HHA, or operate them in any other way as branches of the HHA. HHAs that are unsure if the location meets the definition of a branch may seek advice from the SA. If the location does meet the definition of a branch, it must request CMS approval before providing services from this location. The HHA's policies on drop sites should reflect current Federal and State requirements, including compliance with the Health Insurance Portability and Accountability Act of 1996 privacy requirements. While these sites would not be subject to routine surveys, they may be subject to state or RO inspection at any time. Any violation would be addressed by the SA and referred to the CMS RO for any necessary program integrity investigation and follow up.

2182.5 - Branch Identification Numbers
(Rev.)

CMS assigns an identification number to every *Medicare approved HHA* branch *(of either a parent or subunit).* The identification system uniquely identifies every branch of every HHA certified to participate in the Medicare home health program. It also links the parent or subunit to the branch. Having a system to identify branches gives CMS the capability of associating *quality outcome* results with individual HHA branches. Also, submission of branch identification numbers on Outcome and Assessment Information Set (OASIS) assessments provide*s* the capability of developing outcome reports that will help HHAs differentiate and monitor the quality of care delivered by their agencies down to the branch level.

ROs are responsible for assigning branch identification numbers according to the RO's existing policies and HHAs and their respective branches are informed of their assigned branch identification number(s). A sample letter is available at Exhibit 290. HHAs will need to enter this branch identification number on OASIS item M0016 (Branch ID). Detailed instructions for completion of M0016 by parent HHAs, subunits, branches, and HHAs and subunits without branches are included in M0016 Branch ID in Chapter 3 of the OASIS Guidance Manual.

Each branch is numbered with the same Federally assigned *CCN* as the parent or subunit with two modifications. There is a "Q" between the state code and four-digit provider designation plus three more digits for a 10-character branch identifier. Branch identification numbers are to be used only once. In the event that an HHA branch closes, its unique branch identification number is terminated and not re-used to identify another branch of that HHA or subunit.

EXAMPLE:

- ABC Home Health Agency in Alabama has three branches.
- ABC Home Health Agency in Alabama = *CCN* number 017001.
- ABC's branches would be assigned the branch identification numbers 01Q7001001, 01Q7001002, and 01Q7001003.

Collection Of Branch Information During Survey

The Form CMS-1572, the Home Health Agency Survey and Deficiencies Report, captures survey and deficiency information and requests branch information at field G17 that includes the HHA's total number of branches and name and address of each branch location. This information should be entered into ASPEN after every survey as part of the survey kit. As surveys are conducted, SAs should verify that the information they have on branch locations is current and accurate.

Branch Identification Numbers *and MACs*

The RO notifies the MACs of the branch identification information when it is assigned. This communication may occur electronically or through a written letter to the provider.

2183- Separate Entities (Separate Lines of Business)

(Rev.)

The surveyor must be able to identify the *corporate, when applicable*, and *organizational* boundaries of the entity seeking certification or recertification. The Medicare CoPs apply to the HHA as an entire entity and in accordance with §1861(o)(6) of the Act, are applicable to all individuals served by the HHA and not just *to* Medicare beneficiaries. While the purpose of the CoPs is to help ensure proper care for Medicare beneficiaries, the CoPs do this by defining the standards for an HHA in which Medicare beneficiaries may be treated, instead of establishing requirements applicable only to Medicare beneficiaries served by the HHA. *If however, the HHA is able to demonstrate that it operates a "separate entity" or separate line of business to which the CoPs do not apply, it must provide the surveyor with the information to differentiate the separate line of business from the HHA.*

Neither the Act nor the Medicare regulations define a "separate entity" with respect to HHAs that Medicare approves as an HHA in accordance with the Act and the CoPs. *When an HHA alleges that it is operating a separate line of business to which the CoPs do not apply, ask the HHA to produce information to enable the surveyor to differentiate between it and the HHA.*

Use the following guidelines, on a case-by-case basis, to assist in determining if a separate entity exists. The following criteria should be considered in making a decision regarding a separate entity:

- Operation of the HHA;
- Consumer awareness; and
- Staff awareness.

2183.1 Operation of the HHA
(Rev. 1, 05-21-04)

Ask the HHA administrator to describe the organizational, functional, and clinical boundaries of the Medicare-certified program in relation to any other programs the larger organization offers. Other programs should be separate and distinct from the HHA. Ensure that the HHA has:

- Separate policies and procedures for admission to the HHA, including separate consent forms;
- Separate clinical records for all patients receiving HHA services;
- Current licensure, in accordance with State requirements. In States which license HHAs, review if the State has licensed separately the approved HHA and the separate entity, or has licensed the separate entity as another type of provider or supplier;
- Current listing of staff employed by or contracted to the HHA;
- Personnel records;
- Time sheets or other records to demonstrate distinct assignment of personnel to the HHA; and
- Separate budgets.

2183.2 Consumer Awareness
(Rev. 1, 05-21-04)

The organization should differentiate the services of the HHA from other services offered by the larger organization. Ask the HHA for a copy of any brochure the HHA uses to describe itself to the community. Any applicable brochures should identify the HHA services as separate and distinct from other programs, departments, or entities operated by the HHA. The HHA should be differentiated from other programs, departments or entities of the organization in listings, advertisements, etc. Written material should clearly identify the HHA as separate and distinct from other programs, departments or entities of the organization.

2183.3 Staff Awareness
(Rev.)

The HHA staff should be knowledgeable about the HHA's policies and procedures, the regulatory requirements related to their role in the delivery of care in an HHA, and be able to identify the difference in services they provide for the HHA and other programs, departments, or entities of the organization.

Personnel who divide time between the separate entity and the HHA must be appropriately trained to deliver HHA services. The HHA maintains separate time sheets for each individual's assigned time to the HHA.

If the SA determines, based on the information provided by the HHA or for other reasons, that the HHA does not have a separate entity, or if the HHA or parent organization is unable or unwilling to provide the information, inform the HHA that:

- It is in violation of the provisions of §§1861(o) and 1891 of the Act which require compliance with the CoPs, particularly those conditions that relate to clinical records and disclosure of the ownership of the HHA;

- It is in violation of its agreement with the Secretary under §1866 of the Act and the regulations related to this agreement (42 CFR Part 489.53(a)) because it has failed to provide information about ownership and information concerning clinical records;

- It is in violation of §1128(b)(12)(A) of the Act because it has denied access to records to determine compliance with the CoPs, including those that relate to the OASIS requirements; and

- It may be in violation of various requirements related to its Medicare cost reports, which mandate information about all of the HHA's clients in order to properly pay Medicare costs, and that the HHA's *MAC* 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 *must* report these separate entity situations to the CMS RO, along with any recommendations the State has concerning the operation of two distinct entities. The State *must* also indicate whether the HHA refused access to records or information that make it impossible for the surveyor to make a determination concerning whether the applicant or approved HHA complies with the HHA CoPs.

The surveyor *will* inform the approved HHA that the SA must report the alleged separate entity to the CMS RO that in turn must report this information to the *MAC* and, if necessary, to the State Medicaid Director.

2184 - Operation of HHAs Across State Lines
(Rev.)

When an HHA provides services across State lines, whether through its own personnel, or a branch, or subunit, each respective SA must be aware of and approve the action. Each SA must verify that applicable State licensure, personnel licensure, and other requirements are met in its respective State. Any branch or subunit of the HHA must meet applicable State and local laws in the State that it is serving.

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

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

The CMS RO will review the required reciprocal agreement between the States to assure that the SA in which the branch resides is assuming responsibility for any necessary surveys of the branch. If the SAs involved are unable to come to *an acceptable arrangement on*

assuring the necessary surveys of the branch, even though there may be an existing reciprocal agreement between the States, or if the reciprocal agreement *cannot* assure the necessary surveys, the branch should not be approved. The provision of interstate service without a written reciprocal agreement could severely undermine a State's ability to fulfill its statutory responsibilities under §1864 of the Act to enforce Medicare's health and safety requirements. It is at the discretion of the States to decide whether entering into reciprocal agreements is in the best interest of their residents, provider markets, and quality assurance and oversight systems.

Exhibit *289* contains a model reciprocal agreement document that States may use to assist them in fulfilling their statutory responsibilities under §1864 of the Act to enforce Medicare's health and safety requirements when an HHA provides services across State lines. In those States that have a reciprocal agreement, providers are not required to be separately approved in each State; consequently they would not have to obtain a separate Medicare provider agreement/number in each State. Providers residing in a State that does not have a written reciprocal survey agreement with a contiguous State are precluded from providing services across State lines.

If a State does not have a written reciprocal agreement with other States, the HHA must establish a separate parent agency or subunit in the State in which it wishes to provide services.

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

A *CMS approved* branch office may be physically located in a neighboring State if the SAs responsible for certification in each State approve the operation.

Subunits of an HHA may be physically located in more than one State. A separate certification is made by the SA where each subunit is located.

While the HHA may notify the SA of its proposal to provide services on an interstate basis, and the SA may make a recommendation to the CMS RO in a particular case, it is the CMS RO that has the Medicare approval authority of the parent HHA and assumes final responsibility for approval of the operation across State lines.

2185– HHA Change of Address
(Rev.)

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

When an existing HHA intends to move from its surveyed and certified location to a new site or location that is within the current approved geographic area, it notifies its MAC within 30 days of the move, and submits all required documentation including an amended Form CMS -855A. The RHHI reviews the form and makes a recommendation to the RO. The RO then makes the final decision to approve the change of location. The provider notifies CMS either

directly or through the SA, and, if it is a provider deemed to meet the requirements, it notifies its AO, in writing of the change of location.

Upon receipt of the MAC's approval notice, the RO will carefully evaluate the information, together with any supporting documentation from the provider and any other relevant information known to the RO in making its decision. If a decision can be made on the written application and supporting documentation, CMS may grant or deny an approval without requiring an onsite survey. See §2702B regarding when a resurvey is necessary based on change of a provider's size or location.

CMS generally will not approve a change of location of an HHA with one or more previously approved branches if the new location increases the distance between the parent HHA and its previously approved branch(es) to a point that prevents the HHA from exerting the supervision and control necessary to assure the provision of quality care for the patients served by the branch. If the location change is not approved, the provider may consider applying for a new provider number at the new location. CMS will consider the information contained in section 2182.4B in its assessment of the parent's ability to supervise the branch before approving or denying the request.

2185.1– Move after Certification Survey and Before Final Medicare Approval
(Rev.)

Requests for initial certification cannot be processed to completion if a prospective provider moves to a new location after it has been surveyed but before the entity receives a determination from the RO to participate in Medicare. If a prospective provider moves from its reported location after that location has been surveyed and/or accredited but prior to signing a provider agreement with CMS, the prospective provider's application for initial certification becomes incomplete. Absent a survey of the new location to which the prospective provider has moved, CMS is unable to determine whether applicable program requirements are met at the new location, and therefore is prevented from completing its review of the pending application. In these circumstances, CMS advises the prospective provider that its application is incomplete and is denied.

2186 - Health Facility-Based HHAs
(Rev.)

An HHA based to a hospital, SNF, hospice, or rehabilitation facility is expected to be an integral but subordinate part of the institution. Administrative and fiscal controls may be exercised over the HHA. However, the HHA's policies, personnel files, and clinical records must be separate and identifiable. Time records must be maintained for all personnel who provide home health services and must be identifiable as home health regardless of whether they are part-time or full-time. The HHA's use of personnel *who are also concurrently* employed by a hospital, SNF, hospice, or rehabilitation facility is acceptable provided the HHA's operating hours are definite and not arbitrarily subject to the operation of the other institution, and provided the other institution's operation does not interfere with the HHA's maintaining compliance with the CoPs.

An HHA's services must be supervised by an employee of the HHA. If members of the institution's governing body serve the HHA as the group of professional personnel, minutes must reflect meetings of this group. Clinical records may be maintained in the record room or department. However, the clinical records must contain information pertinent only to the delivery of home health services, and should be readily available for either claims review or review by the SA.

In surveying the health facility-based HHA, the SA *or AO* considers the institution's ability to share its administrative structure and personnel in fulfilling the needs and requirements of the HHA on a continuing basis. The CoPs for HHAs must be applied and met independently.

2188 - Survey of State-Operated HHAs
(Rev. 1, 05-21-04)

The same general procedures applicable to surveying other types of HHAs apply to HHAs operated by a state. However, individuals associated with the HHA in an administrative, supervisory, or service capacity must not be involved in the certification and consultation functions of the SA.

2194 - Surveying Health Maintenance Organization (HMO)-Operated Home Health Agencies (HHAs) Providing Home Health Services Through Medicare Survey and Certification Process
(Rev. 1, 05-21-04)

The HMOs (Medicare+Choice) which contract with Medicare to furnish HHA services may provide such services either directly by the HMO or through Medicare-approved HHAs that have a provider agreement/number with Medicare. (See 42 CFR Part 417.416(a) and 42 CFR Part 422.20(b)(3).)

If an HMO provides home health services directly as an integral part of the HMO, the HHA is still required to meet the HHA CoPs, including the OASIS requirements, have a Medicare provider number, enter into a provider agreement with the Secretary, and meet other survey and certification requirements, including Office of Civil Rights and enrollment requirements, that an HHA approved under 42 CFR Part 484.1 would have to comply with.

When the SA receives a request to survey an HMO-operated HHA for compliance with the HHA CoPs, it schedules an unannounced standard survey. The SA conducts the survey, and documents its findings on Form CMS-1572. The SA completes Form CMS-2567, obtains a PoC when necessary, and sends this information along with a completed Form CMS-1539 to the CMS RO.

The SA resurveys approved HMO-operated HHAs according to the survey frequency allowed by the Secretary and determined by the SA to assure quality care and to ascertain whether they continue to meet the HHA CoPs. In essence, these HHAs are surveyed and certified the same as any other Medicare-approved HHAs.

2195 – Guidelines for Determining Standard Survey Frequency
(Rev.)

Section 1891(c)(2)(A) of the Act states that standard surveys will occur not later than 36 months after the previous standard survey, and that the Secretary shall establish a frequency for surveys within this 36-month interval commensurate with the need to assure the delivery of quality home health services.

CMS will identify HHAs to be surveyed each fiscal year according to specific criteria and budget allowances. This list will contain the names of HHAs that have not been surveyed for 24 months or longer, and that are due for survey during the coming fiscal year. CMS will send this list to the State Survey Agencies each year. The annual budget criteria also specify the priority for complaint surveys, validation surveys and any other targeted surveys for the upcoming fiscal year.

***NOTE*: The survey process guidance is now found in Part I of Appendix B.**

2197 – Surveyor Worksheets
(Rev.)

The following surveyor worksheets are used during each home health survey to assist the surveyor's determination of the agency's compliance with the home health conditions of participation.

HHA Survey Investigation Worksheet 1 – Patient Sample:
Complete one patient sample investigation worksheet for each patient record and home visit selected. Use the worksheet to collect and record patient information and findings related to record review and home visit information to determine the appropriateness of care or **services being furnished. Note interviews with clinicians, record review findings and** *observations. In addition to completing the worksheet, it may be appropriate to request the HHA to copy the most current plan of care for each patient in the survey sample that identifies baseline medical information for attachment to the patient's worksheet. Additional documentation, including assessments, medication profiles, visit notes, aide plans or orders may be copied to support findings. Complete each section with comments related to potential tags identified or indicate "Not Applicable/NA."*

HHA Survey Investigation Worksheet 2 – Agency Summary:
Use the survey investigation worksheet 2 to record a summary of any deficient practices identified during the survey. Also record the type of survey(s) performed, the number of agency admissions in the previous 12 months as well as the number of records reviewed and home visits completed.

HHA Survey Investigation Calendar Worksheet :
Use the Calendar Worksheet to determine compliance with 42 CFR 484.18(a) and (b) and 42 CFR 484.55 regarding compliance with orders for service and the findings of the comprehensive assessment. Services ordered can be compared to services provided to determine compliance with visits.

2202 - Outcome and Assessment Information Set (OASIS) Requirements
(Rev.)

The home health regulations *at 42 CFR Part 484.55* require that each patient receive from the HHA a patient-specific, comprehensive assessment. *As p*art of the comprehensive assessment *of adult skilled patients,* HHAs *are required to* use a standard core assessment data set, the OASIS. *See note below for information regarding collection of OASIS data on the non-Medicare/non-Medicaid patients of an HHA.*

The regulations also require that OASIS data be electronically transmitted to the SA or CMS OASIS contractor. These requirements are detailed at *42 CFR Part 484.20*. This regulation is referred to as the "reporting regulation."

The CMS uses the data to achieve broad-based improvements in the quality of care furnished, through measurement of that care, as well as to maintain a home health prospective payment system.

In addition to requiring the reporting of OASIS data, the OASIS regulations *at 42 CFR Part 484.11* require HHAs to maintain privacy of their OASIS *data and not release patient*

identifiable OASIS information to the public. Regulations concerning State survey, certification, and enforcement responsibilities are found at 42 CFR Part 488.68.

Effective July 19, 1999, all HHAs participating in the Medicare/Medicaid program have been required to comply with the comprehensive assessment and OASIS reporting regulations.

NOTE: *HHAs must comply with the comprehensive assessment regulation at 42 CFR Part 484.55 for all its patients. However, until further notice, HHAs are not required to incorporate OASIS items into their patient-specific comprehensive assessment for the HHA's (1) non-Medicare/non-Medicaid patients, (2) patients under the age of 18, (3) patients receiving maternity services, or (4) patients receiving personal care services only (regardless of payer source). (See additional information in section 2180E.)*

- The collection of OASIS data on the non-Medicare/non-Medicaid patients of an HHA was temporarily suspended on December 8, 2003, as a provision of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. HHAs must continue to comply with the aspects of the regulation at 42 CFR Part 484.55 regarding the comprehensive assessment of patients. HHAs must provide **each** agency patient, regardless of payment source, with a patient-specific comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward the achievement of desired outcomes. The comprehensive assessment must also identify the patient's continuing need for home care, medical, nursing, rehabilitative, social, and discharge planning needs.

- HHAs may continue to collect OASIS data on their non-Medicare/non-Medicaid patients for their own use.

- Surveyors must continue to examine the completeness of the comprehensive assessment for all patients during a survey. However, surveyors must not investigate whether the HHA included the specific OASIS items in its patient-specific comprehensive assessments of non-Medicare/non-Medicaid patients, nor cite deficiencies based solely on this finding.

- HHAs must continue to collect, encode, and transmit OASIS data for their non-maternity Medicare and Medicaid patients that are age 18 and over and receiving skilled services.

2202.1 - OASIS Related Definitions
(Rev.)

OASIS ***– Outcome and Assessment Information Set*** **-** Scientifically tested data items developed for the purpose of measuring outcomes (and patient risk factors that affect outcomes) for HHA patients. These data items alone do not constitute a comprehensive assessment; they must be collected as part of the assessment process at various time points during a patient's admission to an HHA.

CMSnet *(formerly known as Medicare Data Communications Network-MDCN)* ***-*** *A private communications network CMS purchased to ensure the security of OASIS and Minimum Data Set (MDS) data transmissions to the state. This system replaces the previous process of direct dial-up by public telephone lines to the SA and reflects the latest technology available for securing the privacy of data during transmission. In addition to increased security, another benefit of the CMSnet is that it is provided at no cost to the HHAs. HHAs may also*

apply for a CMSnet user identification and password for each of their branches for direct transmissions from their branches. Use of the CMSnet allows for all data submitted to the CMS OASIS State System to be encrypted during the transmission process precluding any unauthorized sources from intercepting identifiable data. Similarly, data reports, which are sent by the OASIS State System to the HHA across the CMSnet, are also automatically encrypted and decoded. This network encryption occurs automatically when the HHA uses the CMSnet and requires no special action on the part of the HHA other than using browser software that supports industry standard encryption.

Comprehensive Assessment - An assessment of a patient's condition that accurately and completely reflects the patient's current health status at the time of the evaluation. This assessment must identify the patient's continuing need for home care and must meet the patient's medical, nursing, rehabilitative, social, and discharge planning needs. An HHA must include the collection of specific OASIS data items at specific time points during a patient's admission as part of its comprehensive assessment process for all *adult* Medicare and Medicaid patients *receiving skilled care unrelated to pregnancy or delivery.* The specific OASIS items associated with each assessment time point are summarized in each version of the OASIS data set. The required OASIS data set and its time point related versions include (1) Start of Care *(SOC)/*Resumption of Care *(ROC),* (2) Follow-up, (3) Transfer, and (4) Discharge. HHAs must use the most current version of the OASIS. The most current version of OASIS is available on the OASIS Web site.

Encode - To enter OASIS data into a computer using the Home Assessment and Validation Entry (HAVEN) software (provided by CMS) or other HAVEN-like software (developed by private vendors). HAVEN-like software must meet CMS' data and edit specification requirements.

Encryption - A system to translate plain text into scrambled code. Encryption offers a higher level of security when electronically transmitting information. The sender "locks" the data before transmitting. The receiver "unlocks" the data upon receipt.

HAVEN – Home Assessment and Validation Entry - A software program provided by CMS, free of charge, for use by HHAs to encode their OASIS data and save as electronic files for electronic transmission to the SA. The HAVEN software automatically applies date range and consistency checks according to CMS' published data specifications, which serve as an electronic safety net to preclude the transmission of erroneous or inconsistent information.

Header Record - Contains basic information that identifies the HHA submitting OASIS data, as well as, contact persons and telephone numbers to be used in the event the file is in error.

Initial Assessment - The HHA's first visit to the patient after referral. In the absence of a specified start of care date, the initial visit is the first visit made to the patient within 48 hours of the referral. If the physician specifies a particular start of care date, then the initial visit is the date specified by the physician *and includes performance of the skilled care ordered.* In accordance with the regulations, the initial visit must be made by a registered nurse *except* for therapy-only cases, *in which the initial assessment visit can be made by* a qualified therapist.

Incorporate/Integrate - Incorporating/integrating the OASIS data items into an agency's assessment process means replacing similar questions on the agency's existing assessment tool with the corresponding OASIS data items. Agencies must merge the OASIS data items into their existing assessment process rather than simply appending them without considering which OASIS items could replace similar items on the agency's assessment tool. Simply appending the OASIS items adds time to the assessment process and renders it burdensome

and duplicative. Since the OASIS items are not intended to constitute a complete comprehensive assessment, agencies should gather other pertinent assessment information not included in the OASIS data items in order to create a comprehensive assessment. Except as required to meet other Federal, State, or accreditation standards, agencies are at liberty to determine what other information they require as part of the comprehensive assessment.

Late Assessment - An assessment transmitted after the specific time frames defined in the regulations. *42 CFR 484.20(a) requires the HHA to transmit the assessment within30 days of completing the assessment.*

Masking - A term used to describe software that conceals individually identifiable data elements. When required, HHAs will mask these data elements prior to transmission and keep the masked identifiers and the original data in their records. *Private Pay assessments are no longer accepted by the State System. If M0150 items 1, 2, 3 and 4 are all equal to '0' unchecked, the state system rejects the record. Any private pay assessment entered into HAVEN will be marked as 'Complete' and is excluded from the export process in HAVEN.*

Outcome - Changes in a patient's health status between two or more time points.

Outcome-Based Quality Improvement (OBQI) - Performance improvement based on outcome measurement and reporting.

Outcome-Based Quality Monitoring (OBQM) Reports - The OBQM reports include the *agency patient-related characteristics report* and *potentially avoidable events* outcome reports.

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

Process Based Quality Improvement (PBQI) *- Evaluating or investigating the use of specific best care processes (such as conducting falls risk assessments or providing drug education) by reviewing the care provided to determine any needed changes in care delivery.*

Quality Improvement and Evaluation System (QIES) - *An online system that supports the CMS mission and initiatives to improve the quality of care for Medicare beneficiaries (Providers: Skilled Nursing Home, Home Health Agencies, as well as State Survey Agencies). (Includes CASPER, MDS, OASIS, RAVEN, HAVEN, and ASPEN).*

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

Resumption of Care (*ROC*) – *T*he day that care resumes after an inpatient stay. T*he HHA must complete an OASIS assessment and obtain the necessary physician change orders reflecting the change in the treatment approach in the patient's plan of care.* The ROC is to be done within 48 hours of the patient's return home. If the physician's order requests that the HHA resume care at a point later than 48 hours or if the patient refuses a visit within this 48-hour period, a note to this effect should be documented in the patient's chart for future reference.

Significant Change in Condition (SCIC) - A SCIC is defined as a significant change in the patient's condition during a 60-day episode that was not envisioned in the original plan of care. *While this no longer creates a new case-mix for payment, the HHA must complete an OASIS assessment and obtain the necessary physician change orders reflecting the*

significant change in the treatment approach in the patient's plan of care. The SCIC relates to the OASIS data set "other" Follow-Up (RFA5).

Start of Care (*SOC*)* – *The day care begins after the referral is received. SOC currently relates to the "first billable visit." The "first billable visit" approach was selected largely because of the Medicare payment requirements and the fact that the first billable visit defines SOC and start of the episode for Medicare purposes.

Time Points - Specific times during an episode of care when collection of OASIS data items is required as part of a comprehensive assessment. They are *start of care, resumption of care, recertification,* follow-up, *and* transfer to an inpatient facility, *death at home*, and discharge from agency.

Trailer Record - Indicates the end of the submission file. The trailer record includes a count of the total records in the file, including the header and trailer records.

2202.2 - History of OASIS

(Rev. 1, 05-21-04)

The OASIS is a group of data items developed, tested, and refined over the past decade for the purpose of enabling the systematic measurement of HHA patient care outcomes. Initially, the OASIS was a 79-item data set first published in 1994 by the Center for Health Services and Policy Research at the University of Colorado. Over the years, it has been modified as a result of input from a variety of home care experts, including representatives of all home health care disciplines. Future modifications to the OASIS are expected as we learn more about outcome measurement as well as determine what information would best serve the continued maintenance of a case-mix adjusted home health PPS.

Relative to OASIS, the definition of outcomes is very specific: outcomes measure changes in a patient's health status between two or more time points. The data are collected at specific time points following a patient's admission to an HHA to determine whether appropriate progress toward desired outcomes is being achieved. These data items must be incorporated into the agency's overall patient assessment process as OASIS was not developed to be a complete comprehensive assessment instrument. HHAs will find it necessary to integrate the OASIS items into their own process in order to comprehensively assess the health status and care needs of their own patient population. Effective, January 1, 2010, the OASIS data set was significantly modified to include process measures. Some points to remember about the uses of OASIS data items into an HHA's assessment process can be found in Appendix C of the OASIS-C Guidance Manual.

2202.2A - Current Version of OASIS
(Rev.)

The current version of OASIS and the Guidance manual is found on the CMS Web site at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIOASISUserManual.html.

2202.2B - OASIS as Part of the HHA's Comprehensive Assessment
(Rev.)

OASIS data items are not meant to be the only items included in an agency's assessment process for Medicare and Medicaid patients. They are standardized assessment items that must be incorporated into an agency's own existing assessment policies process. An example

of a comprehensive assessment showing an integration of the OASIS data items with other agency assessment items can be found in Appendix C: Sample Clinical Records Incorporating OASIS Data Set, in the OASIS User's Manual. For a therapy-only case, the comprehensive assessment should include OASIS data items as well as other assessment data items the agency currently collects for therapy-only cases.

2202.2C - Incorporation of OASIS Data Items Into the Comprehensive Assessment (Refer to 42 CFR 484.55(e))
(Rev.)

In accordance with the regulations, agencies MUST incorporate the language of OASIS data items **exactly** as they are written into their own assessment process. Agencies are expected to replace similar items/questions on their current assessment as opposed to simply adding the OASIS items at the end of their existing assessment tool. For agencies electronically collecting assessment data using software that does not accommodate bolding or underlining for emphasis of words in the same manner as the current OASIS data set, capitalizing these words is acceptable. It is also recommended that HHAs include the data set numbers (M numbers) when incorporating the OASIS. In this way, the clinician will know that the M labeled items are items that MUST be assessed, completed, and reported. This will minimize delays in encoding due to incomplete OASIS data items. Agencies may wish to incorporate the assessment categories (e.g., Activities of Daily Living (ADLs)/Instrumental Activities of Daily Living (IADLs), Medications, etc.) into their own assessment process in a different order than presented on the OASIS form. While HHAs are encouraged to integrate the OASIS data items into their own assessment instrument in the sequence presented on the OASIS form for efficiency in data entry, they are not precluded from doing so in a sequence other than that presented on the OASIS form. However, this is not recommended because of the skip patterns built into the OASIS form.

2202.3 – Applicability

(Rev. 1, 05-21-04)

2202.3A - Medicare and Medicaid Patients

(Rev. 1, 05-21-04)

In general, the comprehensive assessment and reporting regulations apply to any HHA required to meet the Medicare CoPs for any reason and are applied to all patients of that HHA unless otherwise specified. This includes Medicare, Medicaid, Medicare and Medicaid Managed Care, and private pay patients served by the agency. It also includes Medicaid waiver and State plan patients to the extent they do not fall into one of the exception categories listed below, and are required by the State to meet Medicare CoPs. HHAs providing services under Medicaid's home health benefit must meet the CoPs for Medicare, as specified at 42 CFR Part 440.70(d). As such, HHAs servicing only Medicaid patients (Medicaid-only HHAs) must meet Medicare CoPs, including the comprehensive assessment and OASIS reporting requirements.

Health maintenance organizations serving Medicare/Medicaid patients can either provide home health services themselves or can contract out for those services. If they provide home health services themselves, they must meet the Medicare home health CoPs. If they contract out for home health services, they must contract with a Medicare-approved HHA in order to serve Medicare/Medicaid patients. (See 42 CFR Part 417.416 and §2194.)

The HHA's requirement to conduct comprehensive assessments that **include** OASIS data items applies to each patient of the agency receiving home health services with certain exceptions:

- Patients under the age of 18;
- Patients receiving maternity services;
- Patients receiving housekeeping or chore services only; and
- Patients receiving personal care services only.
- Patients for whom Medicare or Medicaid insurance is not billed.

The comprehensive assessment and reporting regulations to patients receiving personal care only services, regardless of payor source is not applicable.

2202.3B - OASIS and the Medicare Home Health Benefit

(Rev.)

The comprehensive assessment and OASIS data collection requirements apply to Medicare beneficiaries as described below:

- Medicare beneficiaries, using the Medicare home health benefit provided under either Part A, Part B, or Part C;
- Medicare beneficiaries who require therapy services provided outside the home for special equipment needs, and who are using the Medicare home health benefit.

If a Medicare beneficiary is under a home health plan of care, all therapy services, that is physical therapy, occupational therapy, speech language pathology (PT, OT, SLP), delivered under the home health benefit whether they are furnished directly by the HHA or under arrangement on behalf of the HHA are bundled into the PPS payment rate as part of the consolidated billing requirements.

The consolidated billing governs Medicare home health PPS effective October 1, 2000 and requires that payment for home health services (including medical supplies described in §1861(m)(5) of the Act, but excluding DME to the extent provided for in §1861(m)(5)) furnished to an individual who (at the time the item or service was furnished) is under a plan of care of a HHA, be made to the agency (without regard to whether or not the item or service was furnished by the agency, by others under arrangement with them made by the agency, or under any other contracting or consulting arrangement, or otherwise). The services included in the consolidated billing governing home health PPS are:

- Part-time or intermittent skilled nursing services;
- Part-time or intermittent home health aide services;
- Physical therapy;
- Speech-language pathology services;
- Occupational therapy;

- Medical social services;
- Routine and non-routine medical supplies;
- Covered osteoporosis drug as defined in §1861(kk) of the Act, but excluding other drugs and biologicals; and
- Home health services defined in §1861(m) provided under arrangement at hospitals, SNFs or rehabilitation centers when they involve equipment too cumbersome to bring to the home or are furnished while the patient is at the facility to receive such services.

If a Medicare beneficiary under a home health plan of care is receiving therapy services from another provider (either an inpatient or outpatient provider) under arrangement made by the HHA as part of the home health benefit simply because the required equipment cannot be made available at the patient's home, the Medicare CoPs apply, including the comprehensive assessment and collection and reporting of OASIS data by the HHA.

1. Medicare *Advantage Plans.*

Medicare Advantage Plans are health plan options that are part of the Medicare program. Medicare beneficiaries who elect to have Medicare services provided by *a Medicare Advantage Plan* are entitled to all the Medicare-covered services that are available to beneficiaries residing in the plan's geographic area.

Medicare Advantage Plans, like a Medicare Health Maintenance Organization (HMO) or Preferred Provider Organization (PPO), which contract with Medicare to furnish HHA services may provide such services either directly by the Plan or through Medicare-approved HHAs that have a provider agreement and CCN with Medicare. (See 42 CFR Part 417.416(a)). If the Medicare Advantage Plan provides home health services directly as an integral part of the Plan, the HHA is still required to meet the HHA CoPs, including the OASIS requirements, have a Medicare CCN, enter into a provider agreement with the Secretary, and meet other survey and certification requirements, including Office of Civil Rights and enrollment requirements, with which an HHA certified under 42 CFR Part 484.1 would have to comply.

When the SA receives a request to survey an HMO-operated HHA for compliance with the HHA CoPs, it schedules an unannounced standard survey. The SA conducts the survey, completes the Form CMS-2567, obtains a PoC when necessary, and sends this information along with a completed Form CMS-1539 to the CMS RO.

The SA resurveys approved HMO-operated HHAs according to the survey frequency allowed by the Secretary and determined by the SA to assure quality care and to ascertain whether they continue to meet the HHA CoPs. In essence, these HHAs are surveyed and certified the same as any other Medicare-approved HHAs.

2. Medicaid Home Health Programs/Medicaid Waiver Programs

The comprehensive assessment regulations apply to HHAs that are required to meet the Medicare home health CoPs. An HHA that currently must meet the Medicare CoPs under Federal and/or State law must meet the Medicare CoPs related to OASIS and comprehensive assessment and reporting. If an HHA provides skilled services to individuals under Medicaid, then OASIS applies. If the patient is not receiving skilled nursing, physical

therapy, occupational therapy, or speech language pathology services, then OASIS does not apply. The requirement to collect OASIS on patients receiving only personal care services has been delayed until further notice.

3. Medicare Hospice Benefit

The comprehensive assessment and OASIS data collection requirements do not apply to any individual receiving hospice services from a Medicare-approved hospice. A hospice patient may receive covered home health services for a condition unrelated to the treatment of the terminal condition for which hospice care was elected. This type of patient would be subject to the regulations governing the HHA services, including OASIS collection and reporting.

4. Outpatient Therapy Benefit

If a Medicare beneficiary not under a home health plan of care is receiving therapy services under the Medicare Part B outpatient benefit from another Medicare provider, the OASIS collection and reporting requirements do not apply.

5. SNF or Inpatient Hospital Benefit

The comprehensive assessment and OASIS data collection requirements do not apply to Medicare beneficiaries who are inpatients at a SNF or a hospital because these services are not considered home health services and the OASIS comprehensive assessment does not need to be conducted. The MDS is required in certified skilled nursing facilities.

The following table summarizes the type of Medicare/Medicaid service and the application of the Federal OASIS requirements:

Type of Medicare/*Medicaid* Service	**Further Description**	**Application of OASIS**
Home Health Benefit	Part A	Yes
Home Health Benefit	Part B	Yes
Home Health Benefit	Terminal Care	Yes
Home Health Benefit	Therapy services provided either directly or under arrangement while under a home health PoC during an open episode.	Yes
Medicare Home Health under a Medicare Advantage plan	The selected HHA must be Medicare approved	Yes
Medicaid Home Health Benefit	Skilled services provided including expanded home health services, that are skilled, provided under a Home and Community–based Waiver	Yes
Medicaid Home Health Benefit	Waiver service or home health aide services only provided without skilled services	No
Medicare Hospice Benefit	Inpatient or at home	No
Outpatient Therapy Benefit (patient not under a home health plan of care)	Provided in a clinic, rehabilitation agency, a public health agency or other provider of services	No
Skilled Nursing Facility, Hospital	Inpatient services	No

The guidance above applies to all HHAs that participate in Medicare and to HHAs that are required to meet the Medicare CoPs, including Medicaid HHAs.

2202.3C - Non-Medicare/Non-Medicaid Patients

(Rev.)

The collection, encoding, and transmission requirement for non-Medicare and non-Medicaid patients receiving skilled care is temporarily suspended. While HHAs are not required to collect OASIS for non-Medicare/non-Medicaid patients, HHAs may continue to collect OASIS data for their own use *but they may not submit the data for these patients to the state. The state system will reject any assessment with a M0150 value of '0' (unchecked) for items*

1, 2, 3 and 4. Also, HAVEN will not include these assessments in the submission file, but will mark them as complete.

2202.3D - Skilled Versus Non-skilled Care

(Rev. 1, 05-21-04)

Until the comprehensive assessment and reporting requirement resumes for all patients, regardless of type of care provided, the following definitions apply for determining skilled versus non-skilled care for comprehensive assessment purposes only:

- Skilled Services for Medicare Patients - The provision of skilled service is a pre-condition for Medicare payment for home health care. Therefore, all patients receiving Medicare (traditional) home health services are, by definition, receiving skilled care.

- Skilled Services for Non-Medicare Patients - For comprehensive assessment purposes, skilled services are services which can only be provided by a registered nurse (RN) (or a licensed practical nurse under the supervision of an RN), a physical therapist (PT), occupational therapist (OT), or a speech language pathologist (SLP), licensed by the State. Most States define the kind of care that is allowed by these practitioners under State practice acts.

The former requirement to conduct an initial evaluation of a patient is expanded in the comprehensive assessment regulations. The regulations now require that, in addition to an initial evaluation, the agency must also conduct a comprehensive assessment of a patient with updates at certain time points. These updates include different combinations of OASIS data items. An agency that currently must meet the Medicare CoPs under Federal and/or State law will need to meet the comprehensive assessment and OASIS encoding and reporting CoPs and apply them to each patient of the agency for whom home health services are rendered, with the exceptions listed in A. above.

2202.3E - Agencies Serving Medicaid Waiver and State Plan Patients

(Rev. 1, 05-21-04)

If home care is provided by an entity required to meet the Medicare CoPs for any reason, then the entity must apply all the requirements of the CoPs, including the comprehensive assessment and OASIS data reporting requirements, to all patients of the agency, including patients treated under a Medicaid waiver or State plan, as applicable. The same exceptions apply as listed in section 2202.3A above, i.e., patients under the age of 18; patients receiving maternity services; patients receiving housekeeping or chore services only; and until sometime in the future, patients receiving personal care services only.

If home care is provided by an entity that is not required to meet the Medicare CoPs, then the provider must comply with only those requirements imposed under State or local law. In this case if the provider treats patients under a Medicaid waiver or State plan, then none of the Medicare CoPs for HHAs, including the comprehensive assessment and OASIS data reporting requirements, apply. See §2183 for information on separate entities.

2202.3F- Patients Turning 18

(Rev.)

A patient who is under age 18 and turns 18 while under the care of an HHA is to receive a comprehensive assessment (including OASIS, if Medicare or Medicaid is billed) at the next appropriate time point. Any assessments due under the regulations at the time the patient turns 18 would be conducted, including the collection and reporting of OASIS data, if Medicare or Medicaid is billed.

EXAMPLE

If on 1/5/20*13* a patient under the care of the agency turns 18 and is transferred to an inpatient facility on or after 1/5/20*13*, a transfer assessment with the corresponding OASIS data items must be collected. If the patient was discharged on his/her 18th birthday, a discharge assessment with the corresponding OASIS data items must be collected.

From the day the patient turns 18, any assessment required per the regulations at the next particular time point is required. Agencies are not expected to collect and report start of care OASIS data on patients admitted to the agency prior to turning 18.

2202.3G - Patients Receiving Maternity Services

(Rev. 1, 05-21-04)

The HHA should not collect data on patients receiving maternity services, i.e., prenatal, antepartum, and postpartum. The patient is not exempt from OASIS data collection if under the care of a physician for a condition unrelated to pregnancy or delivery.

2202.4 - Comprehensive Assessment and OASIS Reporting (Refer to 42 CFR Parts 484.20 and 484.55)

(Rev.)

*A*ll HHAs participating in the Medicare/Medicaid program are required to comply with the comprehensive assessment and OASIS reporting regulations as summarized in the following chart.

PATIENT CLASSIFICATION	COLLECT	ENCODE	TRANSMIT
SKILLED Medicare (traditional fee-for service) Medicare (HMO/Managed Care) Medicaid (traditional fee-for-service) Medicaid (HMO/Managed Care)	*Yes*	*Yes*	*Yes*
SKILLED Non-Medicare/Non-Medicaid: Workers' Compensation Title Programs Other Government Private insurance Private *pay patients under a* HMO*/*	*No* Tempora*rily* Suspen*ded*	*No*	*No*

PATIENT CLASSIFICATION	COLLECT	ENCODE	TRANSMIT
PPO/Managed *Care plan* Self-pay; other; unknown			
PERSONAL CARE ONLY Medicaid (traditional fee-for service) Non-Medicaid: Workers' Compensation Title Programs Other Government Private insurance Private HMO/Managed Care Self-pay; other; unknown	*No*	*No*	*No*
Patients under age 18; Patients receiving pre and postpartum maternity services; Patients receiving only chore and housekeeping services	*No*	*No*	*No*

2202.4A - Comprehensive Assessment and OASIS Collection

(Rev.)

The comprehensive assessment regulations require a comprehensive assessment (that includes certain OASIS data items) be conducted at specific time points during a patient's admission. Those specific times are:

1. SOC

After admission to the HHA, the SOC comprehensive assessment should be completed in a timely manner consistent with the patient's immediate needs but no later than 5 calendar days after the SOC.

2. ROC

The comprehensive assessment is completed within 48 hours of the patient's return to the place of residence *or of the HHA's knowledge of the patient's return* after an inpatient admission of 24 hours or more for any reason other than diagnostic tests. This applies when the patient was not discharged from the HHA during the inpatient admission. If the physician's order requests that the HHA resume care at a point later than 48 hours or if the patient refuses a visit within this 48-hour period, a note to this effect should be documented in the patient's chart for future reference.

3. Follow-Up - The comprehensive assessment that is performed at the end of the current 60-day period. This assessment must be performed within the last 5 days of the current 60-day episode. For example:

Start of Care	Certification Period	Follow-Up Assessment Due
1/15/20*xx*	1/15/20*xx* - 3/14/20*xx*	3/10/20xx - 3/14/20*xx*
1/15/20*xx*	3/15/20*xx* - 5/13/20*xx*	5/09/20xx - 5/13/20*xx*
1/15/20*xx*	5/14/20*xx* - 7/12/20*xx*	7/08/20xx - 7/12/20*xx*

4. Transfer to an Inpatient Facility

An assessment update is performed when a patient is transferred to an inpatient facility for 24 hours or more for any reason except diagnostic testing, regardless of whether the patient is discharged from the HHA at that time. The update must be completed within 48 hours of the patient's transfer to the inpatient facility or within 48 hours after the HHA becomes aware of the transfer and includes a limited number of OASIS items.

5. Discharge

The comprehensive assessment is performed when a patient is discharged from home care. These updates must be completed within 48 hours of the discharge/death or within 48 hours after the HHA becomes aware of the discharge/death.

2202.4B - OASIS Encoding

(Rev.)

HHAs should use HAVEN or HAVEN-like software to encode or enter OASIS data into their computers. HAVEN will accommodate data entry of OASIS items from all required time points. Regardless of the time point, OASIS data items should be encoded, *and* checked for errors *using HAVEN or HAVEN-like software, and made export/transmission-ready*.

1. Availability of HAVEN

The HAVEN software is available for downloading free of charge *from the CMS OASIS and QIES Technical Support (QTSO) Web site. See https://www.qtso.com/havendownload.html*

The HAVEN help line can be reached at: 1-877-201-4721.

Specific information describing how to operate the HAVEN software can be found at https://www.qtso.com/download/haven/hhahelp32.pdf.

2. Errors and Warnings in Encoding

See Error Messages and Description Guide -- **https://www.qtso.com/download/Guides/hha/errors/Errors_sec2.pdf**

HHAs may experience two types of messages at completion of data entry.

a. Error Message.

If the HHA uses HAVEN for data entry, an error message may occur if a mandatory field is left blank. The HHA will receive an error that the field must be filled in

before the assessment can be marked as complete. HHAs should correct their errors before an assessment may exported to the OASIS Data Management System. Along with the error message is the name of the window tab where the error was detected.

b. Warning Message

If the HHA uses HAVEN for data entry, a warning message may occur if timing criteria for date fields do not match OASIS data specifications. These messages are informational only and do not preclude an HHA's assessment from being exported. Along with the warning message is an explanation of that message and direction on where the discrepancy was detected.

2202.4C - OASIS Reporting (Refer to 42 CFR 484.20)

(Rev.)

1. HHA Submissions

HHAs must submit their OASIS data within 30 days of the M0090 date, date assessment completed. Data received outside of *this* time *frame* is considered overdue. Specific information describing how HHAs are to transmit OASIS data to the SA is in the OASIS *System Users Guide.*

2. Errors and Warnings in OASIS Reporting

When submitting OASIS records, a fatal error message may occur if the HHA's data record layout does not follow OASIS data specifications. This message should not occur if the HHA is using the HAVEN software to encode the OASIS items.

3. SA Access

In States where the non-long term care agency is in a location separate from the OASIS State System (where the MDS Data System resides and is not under the direct jurisdiction of the home health survey agency), CMS provides access to the OASIS State System by installing a computer work station at the home health survey agency address to link to the OASIS State System.

The CMS will provide additional support to the SA to access and operate the off-site server by providing appropriate software, and technical assistance from CMS and the CMS OASIS contractors.

2202.5 - Outcome-Based Quality Improvement (OBQI)

(Rev.)

OBQI is a systematic approach that HHAs can implement and follow in order to continuously improve the quality of care they provide. *OBQI manuals are available on the CMS Home Health Quality website.* Under OBQI, quality is measured against the ultimate yardstick - patient outcomes. OBQI is fundamentally a two-stage process that requires the collection of OASIS data for all patients in the agency, *except those excluded by exemption.*

The first stage of OBQI is outcome analysis based on the OASIS data. The analysis is based on an agency-level report showing the agency's present performance regarding patient outcomes relative to a national measure of HHA patients. Outcome reports are generated at

the SA and retrieved by the HHA through the same communication process the HHA uses to transmit OASIS data. Subsequent outcome reports contain comparisons of an agency's present patient outcomes performance relative to the preceding time period for the agency and relative to a national measure of HHA patients. From these reports, HHAs can target areas for improvement as part of their overall quality assurance process.

The second stage of OBQI is outcome enhancement, whereby the agency, using the data from its outcome analysis, identifies opportunities to improve care and develops plans. HHAs are provided with reports on a series of outcomes for their patients in the current year that compares its performance to the prior year and to the national reference (i.e., benchmarking) values.

2202.5A - Using Outcome Based Quality Monitoring (OBQM) and Risk Adjusted OBQI Reports in the Survey Process

(Rev.)

The OBQM reports consist of the patient-related characteristics and potentially avoidable event outcome reports, which are derived from the OASIS data that HHAs submit to the State. The *agency patient-related characteristics* and *potentially avoidable event reports* can be used by HHAs for quality monitoring and improvement purposes. The risk-adjusted OBQI reports provide measures of patient care based on all of the OASIS data items. These reports allow an HHA to proceed to outcome enhancement. It is the outcome enhancement activities that allow an HHA to focus its quality (or performance) improvement activities on select target outcomes, to investigate the care processes that contributed to these outcomes, and to make agency-specific changes in clinical actions that will lead to improved patient outcomes. Using these reports is a first step toward full implementation of the OBQI program. As a part of the pre-survey preparation, surveyors should access and review the OBQM and OBQI reports before surveying an HHA. These reports contain valuable information that may assist surveyors in identifying areas to review during the survey and possibly identify individuals or types of patients to include in the sample selection when on site following guidance provided in the Home Health Survey Protocol Enhancements, effective May 1, 2003 published February 13, 2003 as S&C Memorandum 03-13. The OBQM Manual, (titled "Quality Monitoring Using Case-Mix and Adverse Event Outcome Report" available on the OASIS Web site), provides examples of possible surveyor actions related to adverse event outcomes. The OBQI Manual (titled Outcome-Based Quality Improvement Implementation Manual provides guidance to HHAs for establishing a quality improvement program using the risk-adjusted OBQI reports. This manual is also available on the OASIS Web site.

1. Agency Patient-Related Characteristics Report

The *agency patient-related characteristics report* presents a picture, or snapshot, of an HHA's patients at the beginning of a care episode for the time period selected for the report. The beginning of a care episode is marked by either a SOC assessment or a ROC assessment. The body of the case-mix report describes the characteristics of an HHA's Medicare and Medicaid patients receiving skilled services compared to the rest of the Medicare and Medicaid patients receiving skilled home health services across the country during the same time period. Surveyors should review the case-mix outcome report as described in the OBQM Manual and the Appendix titled "Guidelines for Reviewing *Agency Patient-Related Characteristics and Potentially Avoidable Event Reports*." Any significant results should be identified after reviewing the report, and highlights noted. This will allow surveyors to begin to identify potential clinical groups of patients that can be included in the case-mix stratified sample for record review and home visits, as part of the onsite survey.

2. Potentially Avoidable Event Reports

The *Potentially Avoidable Event Report* displays incidence rates for untoward events (or outcomes) comparing one HHA's patients to patients in the CMS OASIS National repository for the same time period.

Potentially avoidable events serve as markers for potential problems in care because of their negative nature and relatively low frequency. The Patient Listing can be used to investigate the care processes that contributed to these outcomes and to make agency-specific changes in clinical actions that will lead to improved patient outcomes. As a part of the pre-survey preparation, surveyors should access and review the OBQM and OBQI reports before surveying an HHA. These reports contain valuable information that may assist surveyors in identifying areas to review during the survey.

Surveyors do not look at the potentially avoidable event report in a vacuum. They review this report in light of the actual circumstances surrounding the delivery of care to the specific patients.

As a part of the CoPs (42 CFR 484.16, Group of Professional Personnel and 42 CFR 484.52, Evaluation of the Agency's Program), HHAs are required to conduct an annual evaluation of their total program, including patient services. HHAs are also required to conduct quarterly clinical record reviews to evaluate the care provided under the HHA's policies. The CoPs require an agency to have policies and procedures to promote patient care that are appropriate, adequate, effective and efficient. HHAs have access to the OBQM reports and the OBQI reports and may incorporate a review and investigation of these reports into their evaluation and patient care review programs and include them as part of their quarterly record review.

3. Risk Adjusted OBQI Reports

The risk adjusted OBQI reports are the third and final of the OASIS-based reports. These agency-level reports allow individual HHAs to assess their own performance with respect to patient outcomes and compare their performance to a national reference or benchmark. In addition, HHAs can use the OBQI data to target and develop plans of action to improve or maintain HHA performance and patient outcomes. The risk adjusted OBQI reports became available to all HHAs in February 2002.

CMS anticipates that HHAs will choose to use the OBQI reports for quality improvement and for consumer education. In CMS-sponsored demonstrations where the OBQI process has been tested, many HHAs have demonstrated significant improvements in targeted patient outcomes. These data rich reports now represent a decade of benchmarking that is risk adjusted for each HHA. This means that every HHA can be compared to the national reference values, regardless of the types of patients it serves, when compared to another HHA. Therefore, an HHA that strives to provide quality care services to its patients will be able to determine its performance and to identify areas for improvement or reinforcement with the quality reports available to them.

Process Measures were added to the OASIS in 2010. For further information, refer to the PBQI Manual which is located at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/PBQIProcessMeasures.html

The OASIS C Process Measure Reports are now available in the CASPER Reporting System. The reports are located in the OASIS C - Quality Improvement report category.

Resources are located on the following CMS websites:

- *PBQI – http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/PBQIProcessMeasures.html*
- *OBQI - http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIOASISOBQI.html*
- *OBQM http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIOASISOBQM.html*

2202.5B - Case-Mix Stratified Sample

(Rev. 1, 05-21-04)

Surveyors will continue to select a case-mix stratified sample for record reviews and home visits since this requirement is explicitly referenced in §1891 of the Act. For example, surveyors will continue to routinely assess the ability of the HHA to provide quality care by conducting the following activities:

- Evaluating the current status of the patient as reflected in the comprehensive assessment, plan of care and visit notes;
- Verifying that all drugs and treatments are provided according to a physician's order and that the HHA has reviewed all drugs for potential adverse effects and drug reactions;
- Reviewing the plan of care to identify whether the HHA used the comprehensive assessment to make sound care planning decisions appropriate to the patient's needs;
- Reviewing the timeliness of services provided to the patient;
- Evaluating the HHA's ability to coordinate care and services;
- Reviewing the patient's progress toward the achievement of desired outcomes;
- Verifying that any changes in the patient's medical condition were reported to the physician and recorded, including documentation of verbal orders with written confirmation; and
- Evaluating the appropriateness of patient's continuation of services or discharge at the time of record review.

However, the scope of patients eligible for the case-mix stratified sample may include both current and discharged patients. Surveyors may also identify clinical areas and select patients for review on site as part of their off-site survey preparation. The outcome reports may point to concerns that surveyors need to address during the survey and surveyors will now be able to include in the sample patients representing the identified concerns.

The surveyor should continue to use the HHA's current visit schedule (or plans for visits) during the week that the surveyor(s) is on site to develop the sample for clinical record review with home visits. The sample for clinical record review without home visits may include records of patients that have been discharged by the HHA.

2202.5C - Privacy Act Requirements

(Rev.)

1. SA/RO Use of OASIS Data

Each SA or RO user authorized to access and use the OASIS data or reports derived from OASIS data must comply with the provisions governing the privacy and security of this Federal information system. Each user with authorized access to the system, records, and reports must agree to *effectively maintain CMS approved administrative, technical, procedural, and physical safeguards to ensure protection of the confidentiality of the patient identifiable data and to prevent unauthorized access to the data.* Each user is required to *have individual* valid *user identification* and a secure password. Each user is obligated to protect the confidentiality of the OASIS data. As noted in the June 18, 1999, December 27, 2001, *and November 13, 2007* "Federal Register" notices of the OASIS system of records: "No user shall disclose, release, reveal, show, sell, rent, lease, loan or otherwise grant access to the data to any person." The Federal Privacy Act of 1974 provides criminal penalties and fines for certain violations. *The November 13, 2007 Notice describes routine uses*.

2. HHA Use of OASIS Data

The HHAs are required, as a part of the CoPs to maintain the confidentiality of all patient identifiable information contained in the clinical record, including OASIS data and reports, and may not release patient identifiable OASIS information to the public. Therefore, neither the State nor the HHA may release any of the OBQM or OBQI reports or the information contained in them.

2202.5D – Accessing the OBQM, OBQI, and Process Based Quality Improvement (PBQI) Reports

(Rev.)

The authorized SA and RO user needing access to these reports must have a valid user identification and a secure password. These are obtained by submitting a request to the CMS Central Office via the State system coordinator through the CMS RO. Approved requests will be assigned the required user identification and password. SAs and ROs will access the OBQI, *PQBI* and OBQM reports from the Certification and Survey Provider Enhanced Reports (CASPER) link located under the CASPER title on the QIES to Success Web site. The CASPER Home page will display, requiring entry of the login ID and password necessary to access the reporting tool. For most SA and RO users, this login ID and password are the same that are currently used when accessing the OBQM Reports. HHAs access their OBQI and OBQM reports in the same way they access their OASIS validation reports, by connecting to the OASIS State System via the *CMSnet* and selecting the applicable menu option.

The CASPER Reporting User's Guide is located on the state OASIS Welcome page.

2202.5E - Role of the OASIS Coordinators in OBQI

(Rev. 1, 05-21-04)

The OASIS coordinators work directly with the HHAs to help them access the OBQM, risk-adjusted OBQI, and Data Management System reports. In addition, the OASIS Coordinators support and train State surveyors to access and interpret the reports as needed. States do not advise HHAs on which outcomes to target nor do they provide advice on care practices.

2202.6 - OASIS Instructions

(Rev. 1, 05-21-04)

2202.6A - OASIS Guidance Manual

(*Rev*.)

The OASIS Manual *was* intended for use by HHAs in implementing the regulations for comprehensive patient assessments, including data collection and reporting using the OASIS. *The original OASIS User's Manual, "Implementing OASIS at an HHA to Improve Patient Outcomes," has been archived and can be found at the following web address: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIArchives.html*

The current OASIS manual is the OASIS Guidance Manual and can be found at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIOASISUserManual.html.

The OASIS Guidance Manual provides guidance for HHAs on how to ensure the collection of high-quality (accurate) OASIS-C data. It includes both general data collection conventions and item-specific guidance, as well as links to quality-related resources for agencies. It is a streamlined and updated version of the original OASIS Implementation Manual. It covers the overall OASIS implementation process from a clinical and management perspective and includes detailed information needed to train HHA clinical staff to use OASIS as part of the comprehensive assessment and materials to assist operationally in the implementation of OASIS data collection and data reporting. While the manual has been revised several times over the past decade to reflect changes to the OASIS, the basic structure of the manual has not changed. It provides:

- *Specific item-by-item information on completion of each OASIS item;*
- *General information relevant to OASIS data collection versions of OASIS-C for each OASIS data collection time point;*
- *Sample pages of clinical record forms for OASIS data time points illustrating how the relevant OASIS items can be integrated;*
- *Relevant resources for HHAs, with hyperlinks when available;*
- *Information on OBQI;*
- *Home health care regulations related to OASIS data collection; and*
- *Recommendations for ensuring accuracy of OASIS data.*

Additional Manuals associated with OASIS:

- ***The Outcome-Based Quality Monitoring (OBQM) Manual*** *can be used in the agency's quality improvement program. The two reports discussed in this manual have been renamed. The Agency Patient-Related Characteristics Report (formerly*

the Case Mix Report) presents characteristics of the agency's patients at the start or resumption of care. Potentially Avoidable Event Reports, (formerly the Adverse Event Outcome Report) displays incidence rates for infrequently occurring untoward events (outcomes).

- ***The Outcome-based Quality Improvement (OBQI) Manual*** *is written for agencies wishing to implement activities to improve or maintain OASIS outcomes.*

- ***The Process Based Quality Improvement (PBQI) Manual*** *is written to assist agencies with the use of the process measure reports which can be used in their annual program evaluation or internal quality improvement activities. This could include the development of and use of best practices within the agency.*

- **OASIS National Automation Project: HHA System User's Guide** covers the data submission process for HHAs, including how they are to access the OASIS State System, procedures for electronically submitting data (including corrections of previously submitted data), and interpretation of feedback reports from the OASIS State System. *Materials are updated as needed. Updates are posted on both the CMS and the QIES Technical Support Office (QTSO) websites.*

- **OASIS HAVEN System Reference Manual** covers the use of HAVEN software, which was developed to provide HHAs with software for data entry, editing, and validation of OASIS data. It includes information on setting up the software, defining agency and employee information, entering patient and assessment data, and data management functions. This manual, in electronic form, is also included with the HAVEN software. *These are updated as needed and updates are posted on both the CMS and QTSO websites.*

As updates are made to the OASIS Manuals, *States are notified through the CMS contractor of any updates.* In addition, all updates to the manuals are posted on the *CMS and QTSO* Web site.

2202.6B - Other Manuals

(Rev.)

For SAs only, there is a detailed User's Manual for SA System Administrators who, pursuant to the regulations, are required to administer and maintain the OASIS system at the State level. This manual includes an overview of the components of the OASIS State System and provides the instructions necessary to administer and maintain them.

- *OASIS Validation Report Messages and Descriptions (December 2009). This updated manual provides the HHAs with guidance which describes the types of reports and messages they can expect to see in response to their electronic submission of OASIS data. This manual is based on version 2.00 data specifications, available in HAVEN 10.0. This manual assists HHAs in interpreting their feedback reports.*

- *OASIS-B1 HAVEN System Reference Manual (December 2007). This manual addresses the use of the current recommended version of the Home Assessment Validation and Entry (HAVEN) System software which is available online. This manual includes information on setting up the software, defining agency and employee information, entering patient and assessment data, and data management functions.*

2202.6C - Other Teaching Tools

(*Rev.*)

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

- ***OASIS-C Educational Resources -*** http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/EducationalResources.html

- ***CMS Sponsored Calls -*** *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/EducationalResources.html*

- ***OASIS Training -*** *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/Training.html and*
http://surveyortraining.cms.hhs.gov/index.aspx

- **QIES QTSO Web site** - In addition to the above sources of information available to help States implement OASIS, IFMC's QTSO Web site contains current and relative OASIS information, training manuals, HAVEN software, software patches, slides from past OASIS conferences and video files that can be viewed on line at http://www.qtso.com/

- **OASIS Web site** - *(http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/index.html)* - The CMS OASIS Web site stores and *disseminates* policy and technical information related to OASIS for use by the home health community. The information posted on the OASIS Web site is intended to assist HHAs, SAs, software vendors, professional associations, and other Federal agencies in implementing and maintaining OASIS as efficiently as possible. CMS continually updates and modifies the OASIS Web site in an effort to provide HHAs and other principals with information necessary to understand and implement OASIS.

- **OASIS Help Lines** - In addition to the OASIS Web site, QTSO Web site, OASIS User's Manual, OASIS Training Manual and CBT modules available through each SA, HHAs can access help through telephone and e-mail hot lines:

    - The telephone hotline for assistance with HAVEN and OASIS data submission is: 1-877-201-4721. This is a toll-free number available from 7a.m. - 7 p.m. Central Time. After hours, a voice-mail box is available to record inquiries.

    - The e-mail address for assistance with HAVEN and OASIS data submission is. *help@qtso.com*

    - SA and RO OASIS staff have different telephone, FAX, and e-mail hot lines in place for assistance with their clinical questions concerning HAVEN and OASIS data submission. These hot lines are designed for use by SA and RO staff only. SA personnel should contact their State OASIS Coordinator, RO OASIS Coordinator, or central office OASIS staff for this information.

- ***HAVEN System Reference Manual*** *- This manual includes information on setting up the software and data management functions.*

- *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/HAVEN.html or*
- *https://www.qtso.com/havendownload.html*

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

(Rev.)

The home health PPS helps to ensure appropriate reimbursements for quality, efficient home health care. *Under prospective payments, Medicare pays HHAs a predetermined base payment. This payment is adjusted for the health condition and care needs of the beneficiary. The payment is also adjusted for the geographic differences in wages for HHAs across the country.*

This and other PPS information is available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/index.html*.

The following are highlights of the home health PPS system:

- *Episode* - Medicare pays HHAs for each covered 60-day episode of care. As long as beneficiaries continue to remain eligible for home health services and episodes are not overlapping and are medically necessary, they may receive an unlimited number of episodes of care. Payments cover skilled nursing, home health aide visits, covered therapy, medical social services and routine and non-routine medical supplies.

- *Home Health Resource Groups (HHRG) -* A case mix methodology adjusts payment rates based on characteristics of the patient and his/her corresponding resource needs (e.g., diagnosis, clinical factors, functional factors, and service needs, etc.). The 60-day episode rates are adjusted by case mix methodology based on *payment policy* data elements from the OASIS. The data elements of the case mix adjustment methodology are organized *into several* dimensions *such as* clinical severity factors, functional severity factors, and service utilization *factors resulting in Home Health Resource Groups (HHRG), a patient payment classification described as* case mix.

- *Request for anticipated payment (RAP) -* To ensure adequate cash flow to HHAs, the home health PPS has set forth a split percentage payment approach to the 60-day episode. The split percentage occurs through the request for anticipated payment (RAP) at the start of the episode and the final claim at the end of the episode. For the initial episode, there *is* a 60/40-split percentage payment. An initial percentage payment of 60 percent of the episode *is* paid at the beginning of the episode and a final percentage payment of 40 percent will be paid at the end of the episode, unless there is an applicable adjustment. For all subsequent episodes for beneficiaries who receive continuous home health care, the episodes *are* paid at a 50/50 percentage payment split.

- *Outlier - Additional payments will be made to the 60-day case-mix adjusted episode payments for beneficiaries who incur unusually large costs. These outlier payments will be made for episodes whose imputed cost exceeds a threshold amount for each case-mix group. The amount of the outlier payment will be a proportion of the amount of imputed costs beyond the threshold. Total national outlier payments for home health services annually will be no more than a fixed percent of estimated total payments under home health PPS.*

- *Partial episode payment (PEP) - The partial episode payment allows the 60-day episode clock to end and a new clock to begin if a beneficiary transfers to another HHA or is discharged with goals met but returns because of a decline in their condition to the same HHA within the 60-day episode. When a new 60-day episode begins, a new plan of care and a new assessment are necessary. The original 60-day episode payment is proportionally adjusted to reflect the length of time the beneficiary remained under the agency's care before the intervening event. The new episode is paid an initial episode payment rate. The 60 day clock is restarted.*

- *Consolidated billing - Under the PPS a HHA must bill for all Medicare home health services which includes nursing and therapy services, routine and non-routine medical supplies, home health aide and medical social services, except durable medical equipment (DME). DME is excluded from the consolidated billing requirement. The law requires that all home health services paid on a cost basis be included in the PPS rate. Therefore, the PPS rate will include all nursing and therapy services, routine and non-routine medical supplies, and home health aide and medical social services.*

- *Low Utilization Payment Adjustment," (LUPA)* - An episode with four or fewer visits is paid as a LUPA, which is the national per visit amount by discipline adjusted by the appropriate wage index based on the site of service of the beneficiary. Such episodes of four or fewer visits are paid the wage adjusted per visit amount for each of the visits rendered instead of the full episode amount. *Beginning January 1, 2008, an additional payment is made for the first visit in a LUPA episode.* Payment rule refinements often impact policy and are published annually at: *http://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html*.

Exceptions to OASIS Collection and Reporting Procedures Under PPS

There are some exceptions to the general OASIS collection and reporting procedures that are unique to Medicare PPS patients. There is information on the OASIS Web site that is provided to help HHAs integrate the home health PPS into their existing OASIS data collection procedures. A summary of that information with regard to OASIS data collection and the appropriate M0100 (Reason for Assessment) and M*2200* (Therapy Need) response selection is provided below.

A - PPS Start-up

For new patients after October 1, 2000, *any* applicable (skilled care) patients (not just Medicare patients) accepted for care on or after October 1, 2000, are assessed according to the established time points at 42 CFR Part 484.

EXAMPLE: A patient whose SOC date is October 15 would be re-assessed for the need to continue services for another certification period during the last 5 days of the current 60-day certification period. In this example, the follow-up assessment would be conducted during the period 12/9/00 through 12/13/00.

B. First 60-day Episode

SOC: M0100 = RFA 1 and M*2200* = 0-No or 1-Yes.

C. New 60-day Episode Resulting From Discharge With All Goals Met and Return to Same HHA During the 60-Day Episode. (PEP Adjustment)

SOC: M0100 = RFA 1 and M*2200* = 0-No or 1-Yes.

D. New 60-Day Episode Resulting From Transfer to HHA With No Common Ownership (PEP Adjustment to Original HHA)

PEP Adjustment does not apply if patient transfers to HHA with common ownership during a 60-day episode. Receiving HHA completes OASIS, as applicable, on behalf of transferring HHA. Transferring HHA serves as the billing agent for the receiving HHA. Transferring HHA may continue to serve as the billing agent for receiving HHA or conduct a discharge assessment at end of episode. Receiving HHA starts new episode with SOC (if original HHA discharges at end of episode): M0100 = RFA 1 and M0825 = 0-No or 1-Yes.

E Subsequent 60-Day Episode Due to the Need for Continuous Home Health Care After an Initial 60-Day Episode

Recertification (Follow-up): (M0100) = RFA 4 and (M2200) select 0-No or 1-Yes.

F. Patient's Inpatient Stay Extends Beyond the End of the Current Certification Period. (Patient Returns to Agency After Day 60 of the Previous Certification Period)

SOC: M0100 = RFA 1 and M2200 = 0-No or 1-Yes. When patient returns home, new orders and plan of care are necessary.

At time of transfer to an inpatient facility, the HHA completes the transfer. If transferred without discharging, a new episode is started and a new SOC assessment is completed when the patient returns home.

2202.8 - Surveying for the OASIS Requirements

(Rev. 1, 05-21-04)

The comprehensive assessment regulation requires that HHAs use a standard core data set, i.e., OASIS, when evaluating adult, non-maternity Medicare and Medicaid patients (except those receiving exclusively homemaker or chore services.) The OASIS meets the condition specified in §1891(d) of the Act, which requires the Secretary to designate an assessment instrument in order to evaluate the extent to which the quality and scope of services furnished by the HHA attained and maintained the highest practicable functional capacity of the patient as reflected in the plan of care. These regulatory changes are an integral part of CMS' efforts to achieve broad-based improvements in the quality of care furnished through Federal programs and in the measurement of that care.

Since the requirement to report OASIS data to the OASIS State System is not part of the standard survey process, while determining compliance with the comprehensive assessment of patients is, both offsite and onsite monitoring are required to determine compliance with the OASIS CoPs. The State OASIS Educational and Automation Coordinators can assist with the offsite monitoring for OASIS compliance and in providing available OASIS reports, (e.g., data management, quality monitoring and quality improvement reports) to surveyors. HHAs that do not collect and report accurate and complete OASIS data for all applicable HHA patients risk citations at the standard and condition levels. HHAs found not to be in compliance may be subject to enforcement actions and/or termination from the Medicare program.

2202.8A - Condition of Participation: Comprehensive Assessment of Patients (See 42 CFR 484.55)

(Rev.)

This CoP states that a comprehensive assessment of the patient, in which patient needs are identified, is a crucial step in the establishment of a plan of care. In addition, a comprehensive assessment identifies patient progress toward desired outcomes or goals of the care plan. HHAs complete the OASIS items as part of the clinician's total assessment process. This process is not based solely on interviewing the patient. Conducting a patient's comprehensive assessment involves both observation and interview. These data collection techniques complement each other. Many HHA clinicians begin the assessment process with an interview by sequencing questions to build rapport and trust. Others choose to begin the assessment process with a familiar procedure such as taking vital signs in order to demonstrate clinical competence to the patient before proceeding to the interview. HHAs are expected to complete all OASIS items as accurately as possible while minimizing burden and intrusion on the patient.

HHAs should not force patients to cooperate with the assessment process; rather, they must do the best they can to assess patients who do not fully cooperate with the assessment process. Since collecting OASIS information rarely depends solely on patient interview, HHAs are expected to complete, encode, and transmit all OASIS data items. If patients refuse to answer some questions that are part of the OASIS assessment, HHAs may still deliver care to the patient as long as they complete and submit the OASIS assessment to the best of their ability.

States may advise HHAs that seem to report difficulty with specific OASIS items to review the processes of performing a comprehensive assessment with their staff. Sometimes such difficulties indicate that staff might benefit from additional training or retraining in assessment skills. The OASIS Web-based Training Internet site provides additional guidance on "OASIS and the Comprehensive Assessment" and "How to effectively conduct a comprehensive assessment" for clinicians who are challenged by these activities.

- As stated in the CoPs, each patient (except those under 18; receiving maternity services; receiving only services such as homemaker or chore services; or, until sometime in the future, receive personal care services only), regardless of payor source, is expected to receive from the HHA a comprehensive assessment that accurately reflects the patient's current health status and incorporates the exact language of the OASIS data items required for the time points specified in this condition.

- The requirement to collect OASIS data as part of the comprehensive assessment for non-Medicare /non-Medicaid patients is temporarily suspended, effective December 8, 2003, as a provision of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. HHAs must continue to comply with the aspects of the regulation at 42 CFR Part 484.55 regarding the comprehensive assessment of patients. HHAs must provide **each** agency patient, regardless of payment source, with a patient-specific comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward the achievement of desired outcomes. The comprehensive assessment must also identify the patient's continuing need for home care, medical, nursing, rehabilitative, social, and discharge planning needs.

- HHAs may continue to collect OASIS data on their non-Medicare/non-Medicaid patients for their own use.

- Surveyors must continue to examine the completeness of the comprehensive assessment for all patients during a survey. However, surveyors must not investigate whether the HHA included the specific OASIS items in its patient-specific comprehensive assessments of non-Medicare/non-Medicaid patients, nor cite deficiencies based solely on this finding.

The CoP is comprised of the following five standards.

1. Initial Assessment Visit

This standard requires that an initial visit be performed to determine the immediate care and support needs of the patient. *The initial assessment visit requirement is intended to confirm beneficiary eligibility, to ensure that the patient's most critical needs for home care services are identified and met in a timely fashion, and to perform the skilled care that was ordered.* It is not required that a SOC comprehensive assessment be completed at this visit, although the HHA may choose to do so. If the HHA does not complete the SOC comprehensive assessment during the initial visit, then the comprehensive assessment must be completed and updated according to the required time points.

- The initial assessment visit is conducted by a registered nurse and must occur either within 48 hours of referral or within 48 hours of the patient's return home from a hospital stay of 24 hours or more for any reason other than diagnostic testing, or on the SOC date ordered by the physician.

- For Medicare patients, the initial assessment visit must include a determination of the patient's eligibility for the home health benefit. Verification of a patient's eligibility for the Medicare home health benefit including homebound status does not apply to Medicaid patients, beneficiaries receiving Medicare outpatient services, or private pay patients.

- When rehabilitation therapy (speech-language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate rehabilitation professional. For the purpose of the initial visit, a therapy case that includes knowledge of skilled nursing for a one-time visit to remove sutures or draw blood is not considered a therapy-only case. The initial visit must be conducted by the qualified registered nurse.

NOTE: While Medicare pays for occupational therapy, eligibility for the Medicare home health benefit cannot be established based solely on the need for that service. The need for occupational therapy does not establish eligibility for the Medicare home health benefit. However, the Medicare home health patient with multiple service needs can retain eligibility if, over time, the only remaining need is for occupational therapy. Therefore, under the Medicare benefit, the *occupational* therapist (OT) cannot conduct the initial assessment. An OT can conduct the Follow-Up assessment and those associated with transfers and discharges. Occupational therapy, could, however, establish eligibility, in some States, under the Medicaid program. In the case of Medicaid patients (or Medicare patients receiving therapy services), if the need for a single therapy service either establishes eligibility or allows eligibility to continue once it is otherwise established, the corresponding practitioner, (including a PT, SLP, or OT) can conduct any of the designated assessments.

2. Completion of the Comprehensive Assessment

- When a patient is first admitted to the HHA, a comprehensive assessment must be completed no later than 5 calendar days after the SOC date. The comprehensive assessment for all Medicare and Medicaid patients receiving skilled services must include OASIS data. OASIS data is not required for non-Medicare/non-Medicaid patients at this time. However, HHAs may include OASIS data if they choose. Additional comprehensive assessments are required throughout a patient's course of treatment.

- A registered nurse must complete the comprehensive assessment and, for Medicare patients, confirm eligibility for the Medicare home health benefit.

- When physical therapy or speech-language pathology is the only service ordered by the physician, the PT or SLP may complete the comprehensive assessment. For the purpose of the SOC comprehensive assessment, a therapy case that includes skilled nursing for a one-time visit to remove sutures is not considered a therapy-only case. The SOC assessment in this case should be conducted by the qualified registered nurse but may be completed by the qualified therapist at subsequent time points. The same discipline is not required to complete the subsequent assessments at every required time point. The HHA can decide how best to approach the assessment process at the required time points. For other than Medicare, OTs may complete the SOC assessment when the need for occupational therapy establishes program eligibility. (See **NOTE** above concerning eligibility for the home health benefit and occupational therapy services.)

- The SOC comprehensive assessment may be completed in more than one visit as long as it is completed within the 5-day time frame required by the regulations.

- Non-clinical staff, i.e., those not qualified by current regulation, may not assess patients or complete assessment items; however, non-clinical staff or data entry operators may enter the OASIS data collected by the qualified skilled professional into the computer. Many elements in the Clinical Records Items section (which identifies the patient) of each OASIS data set may be completed initially by clerical staff as part of the intake/referral process; but should be verified by the qualified clinician doing the assessment.

Master of Social Work Only Evaluations

Visits for medical social work assistance only are frequently requested by case managers. A visit for medical social work in order to evaluate the patient's need or eligibility for community services generally is not considered a visit to conduct a comprehensive assessment of the patient *and would not solely qualify a patient for Medicare home care eligibility.* If a physical assessment of the patient is conducted, as is required by the comprehensive assessment regulations, it must be done by a qualified person. In this case, that qualified person must be an RN, PT, SLP or OT (as applicable).

Drug Regimen Review

The drug regimen review requirement was moved from the previous plan of care requirements to the new comprehensive assessment requirement to reflect the true nature and purpose of this activity. The comprehensive assessment must include a review of all medications the patient is currently using in order to determine compliance with drug therapy,

significant side effects and drug interactions, potential adverse effects and drug interactions, ineffective drug therapy, and duplicate drug therapy.

The previous requirements for drug regimen review were modified by eliminating the actual identification of "adverse actions" and "contraindicated medications" and substituting the requirement to review drug therapy compliance, drug interactions, and duplicative drug therapy.

3. Update of the Comprehensive Assessment

In order to have data that is comparable across HHAs, OASIS data must be collected at uniformly defined time points including recertification. This requirement is not expected to add to the number of skilled visits provided by the HHA. Many HHAs arrange visit schedules to accommodate home health aide supervisory requirements and patient and care giver schedules. HHAs are expected to similarly adjust the patient's visit schedule in order to accommodate OASIS time points. OASIS reassessment visits that are not part of a treatment visit are overhead/administrative costs and not separately billable visits. They do not require a physician order.

The comprehensive assessment, which includes the OASIS data items for Medicare and Medicaid patients, should be updated and revised no less frequently than:

- During the last 5 calendar days of the current 60-day certification period beginning with the SOC date (Follow-up OASIS data set); *or within 48 hours of (or knowledge of) the patient's return home from a hospital stay of 24 hours or more for any reason except diagnostic tests (ROC OASIS data set). If these two assessment time periods fall within the five day window, only the ROC assessment must be completed;*

- Within 48 hours of (or knowledge of) transfer to an inpatient facility (Transfer to an Inpatient Facility OASIS data set, with or without agency discharge);

- Within 48 hours of (or knowledge of) the patient's return home from an inpatient stay other than a hospital. (See major decline or improvement in the patient's health at 4. below;)

- Within 48 hours of (or knowledge of) discharge to the community or death at home (Discharge OASIS data set); and

- For non-Medicare/non-Medicaid patients, HHAs must provide each agency patient with a patient-specific comprehensive assessment at the above time points to accurately reflect the patient's current health status and the patient's progress toward achievement of desired outcomes.

In a case involving more than one discipline, the SOC assessment should be conducted by the qualified registered nurse but may be conducted by the qualified therapist at subsequent time points. The same discipline is not required to complete the subsequent assessments at every required time point. The comprehensive assessment updates should include the appropriate OASIS items as indicated on the data set for the respective time points, (i.e., SOC, ROC, Follow-Up, transfer to inpatient facility with or without discharge, discharge, and death at home).

If home health care is resumed after an inpatient stay, the comprehensive assessment must include the OASIS items appropriate for assessment after an inpatient stay. If the patient is

not formally discharged at the time of transfer to an inpatient facility, the agency completes a comprehensive assessment that includes the ROC OASIS data items.

If the patient is formally discharged from the HHA, the data collection proceeds on the basis of a new agency SOC date that follows the inpatient stay; therefore, a SOC comprehensive assessment is conducted. The ROC and SOC (minus the Patient Tracking Sheet) OASIS data sets are actually the same data set. For purposes of OASIS data collection, the HHA can establish its own internal policies regarding criteria for formal discharge versus interrupting home care services but maintaining the patient on the HHA admission roster, i.e., placing the patient on "hold" status. (See OASIS and the Home Health Prospective Payment System for exceptions to this general rule.)

If the patient is under the care of the HHA and is not formally discharged prior to the end of the current 60-day period, the HHA conducts the next comprehensive assessment during the last 5 days of the current 60-day period beginning with the original SOC date. For example, if the SOC date were June 25, 20*xx*, the patient would be reassessed between August 18 and August 22, 20*xx*.

If the HHA transfers a patient to an inpatient facility and places the patient on "hold" status, no further assessments are conducted and no data is collected while the patient is in the inpatient facility. The HHA is not providing care while the patient is on "hold" during the inpatient stay. At the time the patient is transferred to the inpatient facility, a transfer assessment (response 6 selected for M0100) is completed. When the patient returns to home care, the HHA completes the ROC assessment (response 3 selected for M0100). (See OASIS and Home Health Prospective Payment System for exceptions to this general rule.)

The ROC assessment is required within 48 hours of the patient's return home from the inpatient facility unless otherwise determined by physician's orders. The Follow-up assessment is required during the last 5 days of the current 60-day (recertification) period. It is possible for these two time periods to overlap. If they do, M0100, ROC (response 3), should be marked. If these two periods DO NOT overlap, two comprehensive assessments should be completed in accordance with the regulations. One assessment is done for the ROC while the other is done for the follow-up time point. (See OASIS and Home Health Prospective Payment System for exceptions to this general rule.)

4. Major Decline or Improvement in the Patient's Health Status

The OASIS regulations require that assessments with OASIS data collection be performed at certain time points. In the event an HHA determines that a patient's condition has improved or deteriorated significantly at a point in the episode of care that is not already captured at a required time point, the HHA should collect and report additional assessment information. Each HHA should define major declines or improvements in the patient's health status. Thus, the term "major decline or improvement in the patient's health status" is the impetus for collecting and reporting OASIS data to:

- Assess a patient on return from an inpatient facility other than a hospital, if the patient was not discharged upon transfer (ROC OASIS data set); and

- As defined by the HHA (Other Follow-up OASIS data set).

5. Incorporation of OASIS Data Items

Integrating the OASIS items into the HHA's own assessment system in the order presented on the OASIS data set facilitates data entry of the items into the data collection and reporting

software. Agencies may integrate the items in such a way that best suits their assessment system. Some agencies may wish to electronically collect their OASIS data and upload it for transmission to the State. As long as the HHA can format an output file for transmission to the State (that is, in the 1448-byte data string format specified by CMS), it doesn't matter in what order it is collected; however, this is not recommended because of the skip patterns *that are* built into the OASIS data set. In accordance with the regulations, data MUST be transmitted in the sequence presented on the OASIS data set. The HAVEN software will prompt HHAs to enter data in a format that will correctly sequence it and ultimately be acceptable for transmission.

HHAs collecting data in hard copy or electronic form must incorporate the OASIS data items into their own assessment instrument using the exact language of the items. Agencies are expected to replace similar items/questions on their existing assessment tool as opposed to simply adding the OASIS items at the end. For agencies using software that does not accommodate bolding or underlining for emphasis of words in the same manner as the current OASIS data set, software that capitalizes these words is acceptable, including the M numbers when integrating is also recommended. In this way, the HHA will know that the M labeled items are items that MUST be assessed and completed. This will minimize delays in encoding due to *incomplete* OASIS data items.

HHAs may wish to incorporate the assessment categories (e.g., ADLs/IADLs, Medications, etc.) into their own assessment instrument in a different order than *what is* presented on the OASIS data set; however, as stated above, the agency must consider any skip instructions contained within the questions in the assessment categories and provide the proper instructions.

2202.8B - Record Keeping

(Rev.)

Since the OASIS data set is incorporated into the HHA's comprehensive assessment, the clinical record must be maintained according to existing CoPs for clinical records. Records of both active and discharged patients must be readily retrievable for use by SA staff.

Surveyors may need to ask for orientation to the HHA Electronic Health Record, as providers have the right to use whatever system of medical records they choose. Surveyors will cooperate and work with facilities that use Electronic Health Records. During the entrance conference, surveyors will establish with the agency the process they will follow in order to have unrestricted access to the medical record. Electronic access to records will not eliminate the need for a surveyor to print a paper copy or to request a paper copy of certain parts of a record. However, the surveyor shall make reasonable efforts to avoid, where possible, the printing of entire records. The surveyor should print or request a paper copy of only those parts of records that are needed to support findings of noncompliance, unless protocols for particular types of surveys require otherwise.

Although not required, it is recommended that the HHA print hard copies of the electronic validation records received from *CASPER and store the validation records in an electronic format for twelve months, until the next set of OBQI reports are available. The validation reports may be needed as evidence if the HHA receives a denial from the MAC for missing OASIS assessments.*

The OASIS Activity Report in CASPER provides a list of assessments that were submitted and accepted by a HHA in the previous calendar month. Information provided in these activity reports includes Patient ID, SSN, Patient Name, RFA, Effective Date and Submission Date.

This report is generated automatically on the 5th of each month. Rejected records are not reported within the Activity Report as the patient information is not stored for rejected records.

The activity reports can be found with the validation reports under the naming convention of ARmmyyyy.txt. For example reports completed with data submitted and accepted in the month of September 2010 will display as AR092010.txt.

Note: The Activity Reports are deleted from the state servers on the same cycle as the validation reports, therefore it is essential to either save the reports to a secured network as a text file OR print and save the report.

2202.8C - Condition of Participation: Reporting OASIS Information

(Rev.)

Except as specified in the June 18, 1999 notice, HHAs must report OASIS data on all patients (except those under 18, those receiving maternity services, and those receiving housekeeping or chore services only) in a format that meets CMS specifications. HHAs or contracted entities acting on behalf of the HHA can report OASIS data to the SA using the HAVEN software CMS provides or by using HAVEN-like software that conforms to the same specifications used to develop HAVEN. Once reported to a CMS central database, the compiled, aggregate OASIS data (i.e., outcome reports) can be used by the HHA to determine how it is performing in terms of patient outcomes compared with other HHAs.

1. Encoding OASIS Data

   HHAs must encode (that is, enter OASIS data into a computer using HAVEN or HAVEN-like software) and finalize *(make export ready)* data entry for all applicable patients in the agency within *30* days of the *M0090* date of an OASIS data set.

   Once the OASIS data set has been collected at the specified time points described above, HHAs may take up to *30* calendar days after the *M0090* date of collection to enter the assessment into their computer systems. For example, if the comprehensive assessment is completed on May *1*, the data must be encoded by May *31*. (HHAs should consider implementing a tracking system that considers the window for correcting OASIS assessments that need corrections before *submission*.) HHAs will enter their OASIS data into their computers using HAVEN or HAVEN-like software.

   HAVEN will automatically review the data for accuracy and consistency; it will alert the HHA to make any necessary changes in order to finalize or lock the data. The locking mechanism is necessary to ensure the accuracy of the patient assessment at the point in time that the assessment took place. The locking mechanism will prevent the override of current assessment information with future information. HHAs will be prompted by HAVEN to export and store encoded data into an electronic file. The export file is transmitted to the State by the HHA.

2. Accuracy of Encoded OASIS Data

   Encoded OASIS data must accurately reflect the patient's status at the time the information was collected. In preparation for transmission to the State, the HHA should ensure that data encoded into the computer is identical to the OASIS data items completed by the skilled professional. HHAs should, therefore, develop systems to ensure that encoded data matches the OASIS data items completed by the

skilled professional. Such a monitoring system could include staff appointed to audit sample OASIS records after data is encoded as part of the agency's overall quality assurance program.

3. Transmission of OASIS Data

After being exported to a transmission-ready file, the *export ready* data should be transmitted to the State or CMS contractor. HHAs transmit OASIS data at least monthly. By the last day of each month, HHAs should electronically transmit all OASIS data *made export* ready during the previous month for each patient (as applicable *based on M0090 date*) to the SA.

NOTE: CMS requires the encoding and transmission of OASIS information only on patients who are receiving Medicare/Medicaid benefits. This means that for patients with pay*e*r source (1) Medicare (traditional fee-for-service), (2) Medicare (HMO/Managed Care), (3) Medicaid (traditional fee-for-service), or (4) Medicaid (HMO/Managed Care) on OASIS item M0150, the HHA must collect, encode and transmit all required OASIS information to the SA. If Medicare/Medicaid is contributing to the payment of the patient's episode of care, the patient is considered a Medicare/Medicaid patient. The pay*e*r source for services provided as part of a Medicaid waiver or home and community-based waiver program by a Medicare-approved HHA are coded as (3) Medicaid (traditional fee-for-service) at item M0150.

For non-Medicare/non-Medicaid patients (patients with only pay sources other than M0150 response 1, 2, 3, or 4, the HHA is not required to assess and collect OASIS as part of the comprehensive assessment and agency medical record. Alternatively, the HHA must use its own comprehensive assessment as the requirement to collect OASIS data is temporarily suspended. Non-Medicare/non-Medicaid payer sources include private insurance, private HMO/Managed Care, self pay, programs funded under the Act: for example, Title III, V, XX, or other Government programs.

HHAs must have a computer system that supports transmission of OASIS data via the *CMSnet* to the SA (or other designated location), transmits the export file, and receives validation information. CMS provides HHAs access to the *CMSnet*, a private communications network CMS purchased to ensure the security of OASIS data transmissions to the State. Use of the *CMSnet* allows for all data submitted to the OASIS State System to be encrypted during the transmission process precluding any unauthorized sources from intercepting identifiable data. Similarly, data reports, which are sent by the OASIS State System to the HHA across the *CMSnet* are also automatically encrypted and decoded. This network encryption occurs automatically when the HHA uses the *CMSnet* and requires no special action on the part of the HHA other than using browser software that supports industry standard encryption.

HHAs need two different sets of user identification numbers and passwords; one set to access the *CMSnet* and one set to access the OASIS System. *User identifications and Passwords to access the OASIS State System to submit assessments or obtain CASPER reports are now specific to individuals(2) and should not be shared.* The *CMSnet* is how HHAs transmit their OASIS data. HHAs must install the communications software, which is separate from the HAVEN software, which will allow them to access the *CMSnet*.

1.) *The supported version of the dialer/CMS vendor is posted on the CMSNet page on https://www.qtso.com/mdcn.html. The helpdesk that supports the CMS vendor is the CMSnet Help Desk. Their phone number is: 1-800-905-2069 Opt 2.*

In the event that CMS changes telecommunication vendors, updates to requirements will be made known on the All State Technical Call and on the QTSO website.

2.) Instructions for downloading and installing this software are available on the OASIS Web site. Alternatively, HHAs can call the HAVEN help desk at 1-877-201-4721 for help in obtaining and installing this software.

When the OASIS System receives a transmission file, it validates the reported information while the HHA remains on-line to ensure that some basic elements conform to CMS requirements, such as proper format and HHA information. Once these file checks are complete, a message indicating whether the file has been accepted or rejected is automatically sent back to the HHA's computer via the agency's communication link. If the submission is rejected, an informative message is sent to the HHA.

A file may be rejected for a variety of reasons. For example, the HHA *Facility ID in the header record may be incorrect and not match the Facility ID at the State, or the number* of records indicated in the trailer record *is different from* the actual number of records submitted. The HHA needs to make the corrections and re-submit the file to the State. If the submission passes the initial validation check, the file is checked further for errors or exceptions to the data specifications and a Final Validation Report is generated up to 48 hours later.

4. Data Format

The format used for encoding and transmitting OASIS data should conform with software available from CMS or other software that conforms to the CMS standard layout, edit specifications, and data dictionary including the OASIS data set. Details regarding these specifications are available on the OASIS Web site. The software must also include the most current version of the OASIS data items which will be available on the OASIS Web site at all times. *CMS provides registered HAVEN users with instructions for any revised HAVEN software.*

HAVEN will prompt the user to enter the data items associated with a required time point by providing the user with the correct screens for the specific type of assessment data required. HHAs will be able to use HAVEN to encode OASIS data, maintain agency and patient-specific OASIS information, and create export files to submit OASIS data to the OASIS System. HAVEN provides comprehensive on-line help for encoding, editing, and transmitting these data sets. Additionally, the HAVEN help line (1-877-201-4721) is available to HHAs with questions concerning the installation and use of HAVEN.

The export function in HAVEN produces an ASCII text file from the HAVEN database. The file meets the OASIS data specifications that must be transmitted to the system. The OASIS System will reject all assessments with a non-Medicare/non-Medicaid payment source; *therefore HAVEN will not include these assessments in the export file.*

The following chart summarizes the required time points and time frames outlined in the regulations for collection, encoding, and reporting OASIS data.

OASIS ASSESSMENT REFERENCE SHEET

RFA = Reason For Assessment

RFA Type	RFA Description	Assessment Completed	Locked Date	Submission Timing
01	SOC - further visits planned	Within 5 calendar days following the SOC Date (M0030)	*Effective 6/21/2006* *No required lock date*	*Effective 6/21/2006* *Transmission required within 30 calendar days of completing the assessment (M0090)*
02	SOC - no further visits planned	Within 5 calendar days following the SOC Date (M0030)		
03	ROC - after inpatient stay	Within 2 calendar days following the ROC Date (M0032)		
04	Recertification - Follow-up	Completed (M0090) every 60 days following SOC: no earlier than day 56 and no later than the day (day 60) on which the certification period ends		
05	Other Follow-up	Complete assessment (M0090) within 2 calendar days following identification of significant change of patient's condition		
06	Transferred to inpatient facility - not discharged from agency	Within 2 calendar days following or knowledge of disch/trans/death date (M0906)		
07	Transferred to inpatient facility - discharged from agency	Within 2 calendar days following or knowledge of disch/trans/death date (M0906)		
08	Died at home	Within 2 calendar days following or knowledge of disch/trans/death date (M0906)		
09	Discharged from agency: Not to inpatient facility	Within 2 calendar days following or knowledge of disch/trans/death date (M0906)		

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

(Rev.)

This CoP states that an agent acting on behalf of the agency, in accordance with a written contract, must ensure the confidentiality of all patient identifiable information contained in the clinical record, and may not release it to the public.

The purpose of this provision is to ensure that access to all OASIS data (hard copy as well as electronic data) is secured and controlled by the HHA. This requirement mandates that the HHA ensures the confidentiality of all patient identifiable OASIS information contained in the clinical record and may not release it for any reason other than for what it is intended, which is to transmit to the SA for the development of outcome reports. The HHA's policies should include assignment and maintenance of secure passwords required for encoding and transmitting OASIS data. Policies should narrowly define the qualifications of individuals having access to the OASIS software. For security reasons, passwords are required in the HHA for access to the agency's computer system. A separate password is required for transmitting the OASIS data files to the SA. Privacy and confidentiality of OASIS data are extremely important. Coverage under the Federal Privacy Act of 1974 begins when the data reaches the SA. The Privacy Act protects OASIS data from unauthorized use and disclosure and has been effective in ensuring confidentiality of Medicare data.

HHAs may choose to encode and transmit OASIS data to the SA themselves, or may contract with an outside entity (agent) to fulfill these requirements. Agents acting on behalf of the HHA, such as a data entry and submission vendor or contractor, guided by a written contract, are bound by the same confidentiality rules. The HHA is ultimately responsible for compliance with the confidentiality requirements and is the responsible party if the contractor does not meet the requirements. HHAs using HAVEN are prompted to enter agent information during set up of the HAVEN program.

Data in the hands of an entity contracted by the HHA for data transmission is not covered by the protections of the Privacy Act, therefore policies related to the security of the OASIS data set are required. HHAs contracting with outside entities for data submission are ultimately responsible for the confidentiality and use of that data. Agreements between HHAs and their contractors should specify that the data is only to be used for *its intended* purpose, that is, to create outcome reports. As such, identifiable data must be treated in accordance with State law and must not be disclosed without patient consent. Violations of data confidentiality by an entity contracted by the HHA are the responsibility of the HHA and would constitute condition-level non-compliance.

Agents must be aware of the requirements and security policies of the HHA and the SA concerning passwords, as well as the requirements of the OASIS System of Records and the Privacy Act.

2202.9 - Patient Notification of OASIS Collection and Reporting

(Rev. 1, 05-21-04)

Under existing patient rights regulations (42 CFR Parts 484.10(a) and (d), the HHA must provide the patient with a written notice of the patient's rights to confidentiality of medical records in advance of furnishing care to the patient. As part of the patient's rights, the HHA

is required to notify the patient of its policies and procedures for disclosure (confidentiality) of clinical records at the time of admission. The HHA must maintain documentation showing that this requirement has been completed; therefore, HHAs must develop admission policies that encourage patient compliance with assessment procedures. Failure to collect and report accurate and complete OASIS data on all applicable patients places the HHA at risk of losing its Medicare certification. States will be able to monitor whether HHAs are submitting the required OASIS information through the use of data management reports. While patients have the right to refuse to answer questions posed by the HHA, very few OASIS data items rely solely on direct patient questioning. Therefore, HHAs must complete all OASIS data items as best they can, using their assessment skills.

2202.9A - Informing Patients of OASIS Collection and Reporting

(Rev. 1, 05-21-04)

On or after July 19, 1999, HHAs were required to provide existing patients with privacy notifications. To properly inform patients of their rights under the Privacy Act, the provider must furnish each patient with information required by the Privacy Act. Under the authority of the Privacy Act, notices must contain the following information:

- The right to be informed that OASIS information will be collected and the purpose of collection;
- The right to have the information kept confidential and secure;
- The right to be informed that OASIS information will not be disclosed except for legitimate purposes allowed by the Federal Privacy Act;
- The right to refuse to answer questions; and
- The right to see, review, and request changes on their assessment.

The statements of patient privacy rights with regard to the OASIS collection (one for Medicare/Medicaid patients, one for all other patients served by the HHA) are available on the OASIS Web site as part of the June 18, 1999, "Federal Register" notice. HHAs must include these statements as part of their admission information. Effective December 8, 2003, HHAs who choose to collect OASIS data on their non-Medicare/non-Medicaid patients must continue to comply with informing patients with privacy notifications. HHAs that do not collect OASIS data on non-Medicare/non-Medicaid patients are no longer required to provide the Privacy Act notification.

2202.9B - Right to See, Review, and Request Changes

(Rev. 1, 05-21-04)

The "Federal Register" notice of June 18, 1999, requires that, under the Privacy Act, Medicare/Medicaid patients have the right to see, review, and request changes in their assessments. HHAs must accommodate patients (or their representative), who request this review. If the patient disputes OASIS information collected as part of a comprehensive assessment, the HHA has two options; it can agree or disagree with the dispute.

1. The HHA Agrees.--If the HHA agrees with the patient's request, it accepts the request, and changes the applicable OASIS data item(s) on the assessment. A corrected

assessment can be submitted to the State, using the terms of the OASIS correction policy.

2. The HHA Disagrees.--If the HHA disagrees with the patient's request, the patient should request written documentation that the disputed information will not be changed by the HHA including the reason(s) why.

If a patient chooses to pursue his/her request at the Federal level, he/she may contact CMS at 1-800-Medicare, toll free, for further review of the disputed issue. The individual contesting a record will be advised to write to the Privacy Officer, CMS, 7500 Security Boulevard, Baltimore, Maryland, 21244-1850, identify the record, and specify the information being contested. This correspondence must include the HHA's written documentation refusing the change. It must also state the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with the Department's regulations (45 CFR 5b.7.) To preserve the privacy of the OASIS/HHA system of records, the Privacy Act Privacy Officer may require that the individual provide the following information for verification purposes: The system name, health insurance claim number, and, for verification purposes, the individual's name (woman's maiden name, if applicable), social security number, address, date of birth, and sex. (Furnishing the social security number is voluntary, but it may make searching for a record easier and prevent delay.) This information must be notarized to preserve the confidentiality of this process.

The HHA Medicare/Medicaid patient who wants to know if there is a record belonging to him/her in the OASIS/HHA system of records, or wants to review the record contained in the CMS OASIS/HHA system of records repository would follow the same process. The patient can contact CMS toll free at 1-800-Medicare to get instructions for how to pursue his/her request.

2202.10 - OASIS and HHAs Seeking Initial Certification

(Rev.)

Prior to receiving Medicare approval, HHAs must meet certain requirements, including enrollment and capitalization, and must provide skilled home health services to a minimum of 10 patients (not necessarily Medicare patients) that is consistent with the Medicare home health CoPs. This includes compliance with the OASIS collection and transmission requirements. New HHAs must demonstrate *that* they can transmit OASIS data prior to the initial certification survey. Specifically, new HHAs must apply for *a user identification* number and password from the State OASIS automation coordinator in order to *register for an individual user identification and password which is used to* electronically transmit to the OASIS System any encoded and locked SOC or ROC OASIS assessment record(s) for applicable Medicare and Medicaid patients in a test mode. HHA survey staff must communicate with the OASIS coordinators to determine this aspect of compliance prior to the initial onsite survey. SAs and AOs *with deeming authority* should not schedule initial surveys until the SA or AO has determined the HHA's status with the OASIS transmission requirement. AOs may contact the state directly to determine the status of the new HHA's activities concerning the OASIS transmission process prior to scheduling the onsite survey. The names and phone numbers of the State OASIS contacts are found on the OASIS Web site.

*To acquire an HHA personal login ID, agencies will be required to complete and submit the OASIS Individual User Account Request form. This form is available on the QIES Technical Support Office website (*www.qtso.com*).* To meet the OASIS transmission requirements prior to the initial certification survey, new HHAs need two different sets of temporary user

identification numbers and passwords; one set to access the *CMSnet* and one set to access the OASIS System.

The OASIS automation coordinator in each SA should assist the new HHA in obtaining the user identification numbers and passwords *and guide HHAs through registration for an individual user identification and password* prior to the initial certification survey. Once the communications software and access are in place, the new HHA must demonstrate that it can transmit OASIS data to the OASIS System by (1) making a test transmission of any SOC or ROC OASIS data that passes CMS edit checks; and (2) receiving validation reports back from the OASIS System confirming data transmission. Once Medicare approval has been determined*, the HHA must apply for* permanent user identification number*s* and password*s* for access to the *CMSnet* by contacting the help desk at 1-800-905-2069.

Transmissions of test data prior to the OASIS system *successfully uploading the certification kit in ASPEN will result in any submission file being processed as a test submission. The user will receive a final validation report showing any warning and fatal error messages associated with each record. However no data will be stored on the database until the initial certification kit has been successfully uploaded. Unless submitted as a test, once the certification kit is successfully uploaded all assessment data will be treated as live data and stored on the database.*

2202.10A - Determining Compliance with the OASIS Transmission Requirements

(Rev.)

Depending on the method of transmission the HHA chooses, the SA needs to determine compliance in one of the following ways:

- If the new HHA chooses to independently transmit OASIS data from its own office, the State HHA survey team and OASIS coordinator must communicate with each other to establish that the new HHA has successfully transmitted test OASIS data using the appropriate user identification numbers and passwords, prior to onsite survey. The HHA should maintain all copies of validation reports for its records.

- If the new HHA chooses to use a software vendor to meet the OASIS encoding and/or transmission requirement on its behalf, the HHA must still establish connectivity to the OASIS System via the software vendor. The HHA should have a written contract that describes this arrangement. *The vendor and/or other certified HHA will need to apply for access to this agency as a Third Party Submitter. Forms are available on QTSO at: https://www.qtso.com/accesshha.html.*

- The HHA or its software vendor must apply for the applicable user identification numbers and passwords from the SA in order to establish connectivity with the OASIS System. As described above, the HHA survey team and OASIS coordinator must communicate with each other to establish that the software vendor, on behalf of the new HHA, has successfully transmitted test OASIS data using the appropriate user identification numbers and passwords, prior to onsite survey. The HHA should obtain copies of all validation reports from its software vendor for its records.

- If the new HHA chooses to use another certified HHA to meet its transmission requirements, for example, another established HHA in the chain or other established but non-related HHA, the HHA must still demonstrate connectivity to the OASIS System via the other established certified HHA. The new HHA or other HHA must

apply for user identification numbers and passwords, unique to the new agency, from the SA, in order to establish connectivity with the OASIS System. The new HHA must have clearly written policies outlining the procedures in place with the other HHA with regard to OASIS collection, encoding and submission to the OASIS State System and the sharing of feedback reports from the OASIS System with the new HHA.

2202.10B - HHAs Seeking Initial Certification Through an AO with Deeming Authority

(Rev.)

An HHA may choose to obtain initial Medicare certification by electing the deemed status option through an approved AO that has been granted deeming authority for Medicare requirements for HHAs. There are currently *three* AOs with deeming authority *for HHAs* - the Joint Commission (*TJC*), the Community Health Accreditation Program (CHAP), *and the Accreditation Commission for Health Care, Inc.* HHAs seeking initial certification through the deemed status option must still apply to the SA for user identification numbers *and register as an individual* in order to demonstrate compliance with OASIS submission requirements prior to approval.

When the SA receives a request from an HHA interested in seeking Medicare deemed status through accreditation by *an AO with deeming authority*, the State ensures that the HHA understands its obligation to meet the OASIS requirements, even when the AO conducts the initial certification survey. This includes compliance with the OASIS collection and transmission requirements.

If the SA receives a certification packet from an HHA seeking Medicare certification based on its accreditation through a deemed status program, it is the SA's responsibility to determine that the HHA meets its OASIS transmission responsibilities. The OASIS transmission responsibility may be met in one of the three ways described above.

2202.10C - Exceptions to Demonstrating Compliance with OASIS Submission Requirements Prior to Approval

(Rev.)

New HHAs that intend to admit or treat only patients to whom OASIS currently does not apply, i.e., patients under 18, maternity, and patients receiving only unskilled care or chore services are not expected to demonstrate compliance with OASIS submission requirements prior to approval.

These HHAs must attest this intention to the SA. After certification, if there is a change in the HHA's policies that includes the acceptance of patients to whom OASIS applies, the HHA is expected to install the necessary communications software and contact the SA and CMS*net* for the applicable user identification numbers and passwords.

2202.10D - Compliance Dates and PPS

(Rev.)

Compliance with the rest of the CoPs is determined via an onsite survey by the SA and any applicable subsequent actions or revisions required of the HHA following the initial survey. After survey, the new HHA cannot bill Medicare for payment of services to Medicare

beneficiaries until the effective date for Medicare participation has been determined by the CMS RO.

Realistically, notification of the effective date may come many weeks after the initial survey of the HHA. In addition, the date of official compliance may vary depending on the outcome of the onsite survey. As described in §2780, the date of compliance is either:

1. The date the onsite survey is completed if, on the date of the survey the HHA meets all CoPs and any other requirements required by CMS; or

2. If the HHA fails to meet any of the requirements as a result of the onsite survey, compliance is the earlier of:

    - The date the HHA meets all *enrollment* requirements; or

    - The date the HHA meets all the CoPs and submits an acceptable plan of correction for standard level deficiencies.

Payment under Medicare for services provided prior to the effective date for Medicare participation is not permitted. As such, it is important that new HHAs seeking payment under Medicare establish the required 60-day episode on or after the effective date of their Medicare participation.

2202.10E - Instructions for Handling Medicare Patients in HHAs Seeking Initial Certification

***(Rev.*)**

The Medicare OASIS submission and billing process cannot begin until the effective date of the HHA's CCN, which is assigned after the RO has done the review of the initial survey findings, plan of correction if one was necessary, documentation on whether the HHA has met the enrollment requirements, and documentation that the MAC has completed the second capitalization review. Enrollment requirements include completion of the CMS Form 855A, first capitalization review, completion of a survey by a SA or RO with the HHA in compliance with the CoPs, additional development by the MAC and second capitalization review by the MAC. After it is assigned its CMS certification number (CCN) by the RO, the HHA should do a new SOC assessment (RFA 1) on each of its Medicare eligible patients. This assessment visit date should be consistent with the first billable visit date after Medicare participation becomes effective.

Once the CCN has been assigned, the HHA can go back and encode the collected OASIS information, obtain the necessary payment system codes for billing under PPS, and transmit the information to the OASIS State System as production (i.e., "live") data. The date of this assessment will become day 1 of the HHA's first 60-day episode under Medicare, as long as the assessment was done in conjunction with a billable visit. Warning messages related to noncompliance with timing requirements are unavoidable and are to be expected in this situation.

If compliance (i.e., the effective date) is not the date of the onsite survey, it will be based on D.2. above, as further outlined in §2780. The HHA should, again, do a new SOC assessment (RFA 1) on each of its Medicare patients at the first billable visit after the anticipated date of compliance, delay encoding and transmitting the assessment until the CCN is assigned, and continue as outlined in the paragraph above. That is, the HHA should go back and encode the

collected OASIS information, obtain the necessary payment codes for billing under PPS, and transmit the information to the OASIS State System as production data. As above, warning messages related to noncompliance with timing requirements are unavoidable and are to be expected in this situation.

If the new HHA did not conduct a SOC (RFA 1), ROC (RFA 3), or Follow-up (RFA 4) OASIS assessment during the time between the effective date for Medicare participation and the date the HHA learns of its approval, the HHA should conduct a SOC assessment, as soon as possible. This assessment can be used to generate the payment code used for billing under Medicare. The SOC date should reflect a date that is consistent with the first billable visit after the effective date for Medicare participation, as stated above.

2202.10F - Instructions to New HHAs Concerning all Other Patients

(Rev.)

Non-Medicare and Non-Medicaid patients do not require OASIS collection or transmission. For all other patients treated by the HHA (i.e., non-Medicare *or non-Medicaid* patients), if a new start of care date is not required by the patient's payer source, the HHA should encode and transmit all OASIS assessments as required by current regulation that were collected after the effective date of Medicare participation. These assessments should be submitted in the production mode using the newly assigned provider number. The HHA should continue with the OASIS assessment schedule already established based on the patient's admission date.

2202.11 - Correction Policy

(Rev.)

HHAs have the ability to electronically correct nearly all errors found in their production OASIS submissions. SAs should not be accepting requests for manual key field changes. Instead, HHAs should use the inactivation procedures to correct assessments containing key field errors. HAVEN 5.0 and above will give HHAs the ability to electronically correct nearly any kind of assessment errors.

CMS strongly recommends that all HHAs install the most updated version of HAVEN. OASIS HAVEN software may be adjusted over time to incorporate changes in system components as well as incorporate bug fixes. Adjustments will be posted to the HAVEN Data Entry Software web page on the CMS Web site at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/index.html?redirect=/oasis/and on the OASIS State Systems.

Key Fields and Non-Key Fields

A description of key fields is below. Non-key fields are all other fields making up the OASIS data set that are not key fields.

KEY FIELDS	
Patient Identifiers:	
M0040_PAT_LNAME	Patient last name
M0040_PAT_FNAME	Patient first name
M0064_SSN	Patient social security number
M0066_PAT_BIRTH_DT	Patient date of birth
M0069_PAT_GENDER	Patient gender
HHA Identifiers:	
HHA_AGENCY_ID	Unique Agency ID code
Assessment Event Identifiers:	
M0100_ASSMT_REASON	Reason for completing assessment
M0090_INFO_COMPLETED_DT	Date assessment information completed (This is a key field only on recertification or follow-up assessments where RFA = 04 or 05)
M0030_START_CARE_DT	SOC date (This is a key field only on SOC assessments where RFA = 01)
M0032_ROC_DT	ROC date (This is a key field only on ROC assessments where RFA = 03)
M0906_DC_TRAN_DTH_DT	Discharge, transfer, death date (This is a key field only on transfer to inpatient facility assessments where RFA = 06 or 07, death at home assessments where RFA = 08 and discharge assessments where RFA = 09)

HHAs can electronically correct key field errors in production records in addition to non-key field errors and also remove erroneous records using an automated methodology called inactivation. With the ability to inactivate erroneous OASIS assessments, as described below, HHAs will be able to remove assessments from the OASIS State System's active database that have been submitted in error. These records are not actually deleted, but are moved from the active database to a history database that contains records that have been modified or inactivated. This approach keeps an audit trail of modified and inactivated records, but "hides" them from the normal OASIS State System reporting procedures.

2202.11A - Determining When to Inactivate an Assessment

(Rev.)

If an error has been made in one or more key fields, or if an assessment was submitted in error, the HHA should electronically inactivate it. Use of the inactivation procedure is not applicable to correcting assessments with only non-key field errors. In other words, if an assessment contains errors in only non-key fields, then correction type 3 described at C.3. below should be used. In order to determine whether to submit an inactivation request, the user should apply the following rules:

1. Assessment Submitted in Error

If an assessment was submitted in error (i.e., it should never have been submitted), it must be inactivated. For example, if a discharge assessment was submitted by the therapist; however, the patient is still being visited by the nurse, an inactivation request must be submitted for the erroneous discharge record. Another reason to inactivate an assessment would be if the submitted assessment contained the wrong patient name.

2. Error in Key Field

If an assessment was submitted which contained an error in any of the key fields listed above, then an inactivation request must be submitted. Normally, the HHA will also submit a new, corrected assessment in this situation. For example, if the HHA discovers that the patient's last name on the SOC assessment is spelled "Smyth," while on the Follow-up assessment it is spelled "Smith," it needs to make the appropriate correction. When the HHA determines the discrepancy, the incorrect record must be inactivated and a new corrected record must be submitted.

3. Submission of Incorrect Format

Private Pay assessments are now rejected upon submission and do not require inactivation.

NOTE: There is no automatic mechanism to reactivate a record that has been inactivated. Consider the case where a discharge assessment is submitted to the OASIS State System for a patient, but is inadvertently inactivated. There is no means to "undo" the inactivation and thereby "reactivate" this discharge. Instead the HHA must submit the discharge record again. An inactivated record can only be "undone" by the re-submission of the record.

2202.11B - Deleting Assessments

(Rev)

In certain infrequent situations, inactivation is not sufficient to correct assessment errors since inactivation alone does not remove the assessment record from the OASIS System. Two situations require deletion of an erroneous assessment, rather than inactivation. States will *need to* continue to submit deletion requests on behalf of HHAs, upon request, *to the CMS Division of National Systems (DNS) contractor* when the following situations occur.

1. Assessment Deletion

The HHA submits identifiable data on patients not defined by the OASIS system of records. The OASIS repository is limited to the collection of identifiable data on patients who are Medicare and/or Medicaid patients receiving skilled care with certain exceptions, i.e., under 18 and maternity patients. In instances where the OASIS System has received OASIS data on patients not included as part of the OASIS System of Records, the data needs to be deleted.

EXAMPLE: The HHA checks Response 1, 2, 3, and/or 4 in the Current Payment Source (M0150 field) for that assessment record **and it should not have**. The record is transmitted to the OASIS System and accepted. The HHA determines that the response for M0150 is in error. The patient was not a Medicare or Medicaid patient; therefore, this data should not be stored on the *OASIS* database.

EXAMPLE: The HHA submits an incorrect birth date on a patient who is a year old, which was accepted because the birth year identified the patient as being over 18. The patient was actually under 18 and the assessment should be deleted.

Deletion Request forms are located on the State password protected Page of the QTSO website. CMS requires the signature of the agency administrator and of the SA before the deletion will be processed.

The HHA must send the Deletion Request Form in writing to the State OASIS coordinator to request deletion of an assessment. The State will then send in writing to DNS contractor, the reason this data should be removed from the State's database.

*Effective dates are:

M0030_START_CARE_DT for RFA types 01;

M0032_ROC_DT for RFA type 03;

M0090_INFO_COMPLETED_DT for RFA types 04 & 05; and

M0906_DC_TRAN_DTH_DT for RFA types 06, 07, 08, & 09.

2. File Deletion

The HHA submits a file as "Production" data instead of "Test" data. The State must verify the HHA's claim of "Production" data versus "Test" data. The HHA must send the following information in writing to the State coordinator to request deletion of a file:

- HHA Name;
- HHA ID;
- Submission Date/Time;
- Submission Batch ID; and
- Reason this data should be removed from the State's database.

The State will then send in writing to *the CMS contractor* following information to request deletion of a file:

- HHA Name;
- HHA ID;
- Submission Date/Time;
- Submission Batch ID; and
- Reason this data should be removed from the State's database.

The following events will then take place:

The CMS DNS Contractor will create a report from the above listed information. This report will be sent to the State OASIS Coordinator for him/her to verify the accuracy of assessment(s) to be deleted from the State's database.

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

The deletion request information should be communicated *to the CMS DNS contractor* by one of the following methods *of communication:*

The Deletion Request Form directs states to forward the signed form to the CMS DNS contractor via certified mail to the address on the form.

The deletion request sheets must be submitted to *the CMS DNS contractor* by the State. Requests received directly from HHA will not be accepted.

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

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

(Rev.)

HAVEN offers the following menu of corrections an HHA can make:

1. Assessment was Submitted to the State and was Rejected

The HHA can unlock the assessment, make the necessary changes, and re-submit it. Because of the built-in edit checks, HHAs using the HAVEN software should not expect records to be rejected by the OASIS System for this reason. Note that the following examples are provided for illustration purposes to troubleshoot HAVEN-like software, but **cannot** occur in HAVEN.

EXAMPLE 1: The HHA Agency ID field in one or more assessment records does not match the HHA Agency ID in the header record of the submission file. The entire submission file is rejected and no data is loaded into the state database.

EXAMPLE 2: The patient's last name was missing from the assessment file (data record). The HHA may have inadvertently left this field blank. The OASIS System must have the patient's last name. The data record in this example would be rejected and no data from this record would be loaded into the state database.

In these examples, the HHA would make the necessary corrections and re-submit the record. Since the OASIS System never accepted the original assessment, the correction

number field IS NOT incremented in this situation. HHAs may still receive a warning if submission/timing guidelines have been exceeded.

2. Assessment was Submitted to the State and was Accepted. Correction to Key Fields is Necessary

With the implementation of the OASIS System update, this option will display in HAVEN but will no longer be available and is disabled in the HAVEN software. To correct an assessment with key field errors, first inactivate the assessment, then create a new assessment for re-submission, as applicable. See correction type 4 below.

3. Assessment was Submitted to the State and was Accepted. Correction to Non-Key Fields is Necessary

If an HHA determines that a correction(s) must be made to non-key fields only (i.e., any fields in the OASIS data set not contained in the key fields listed above), the HHA should re-open the assessment, revise the targeted non-key fields, and re-lock and re-submit the corrected record. The lock date changes to reflect the date the correction was made.

NOTE: "CORRECTION_NUM" is a counter field contained in the programming of the HAVEN software used to track corrections made to an assessment record. The counter field is set to 00 when an assessment record is initially locked. The counter field is incremented in this case. Both the original assessment and the corrected assessment will be stored in the state database.

4. Assessment was Submitted to the State and was Accepted. Inactivation of the Assessment is Necessary

This is an option in HAVEN that allows HHAs to correct key field errors by inactivating the assessment(s) containing key field errors and re-submitting a new, corrected assessment. Unlike making non-key field changes, as described in correction type 3 above, the HHA does not simply unlock the assessment record, make the necessary key field changes, re-lock the record, and re-submit it. Instead, the HHA is taken directly to the assessment in question where it can be viewed in a read-only format. While in read-only mode, when the HHA confirms that the assessment should be inactivated, HAVEN will ask the HHA to commit to this selection. The correction number field on the HAVEN Management screen displays an "X" and the assessment status is set to Export Ready." The *"value of '99'"* indicates that this assessment has been *inactivated.*

When the HHA selects this correction type, a copy of the original assessment record is created. To re-submit the assessment with the necessary corrections, the HHA first exports the assessment that is being inactivated. From the HAVEN Management screen, the HHA then selects the inactivated record in question and clicks on the "Correct Assessment" button. *A pop-up box will appear asking if the HHA wants to create a new assessment containing data from the inactivated assessment.* When the HHA clicks on the "OK" button, a copy of the original assessment appears. The HHA makes the necessary changes and re-submits the assessment. The correction number for this assessment is reset to 00.

2202.11D - Documentation of Corrected Assessments

(Rev. 1, 05-21-04)

When a comprehensive assessment is corrected, the HHA must maintain the original assessment record as well as all subsequent corrected assessments in the patient's clinical record in accordance with current clinical record requirements at 42 CFR Part 484. If maintained electronically, the HHA must be capable of retrieving and reproducing a hard copy of these assessments upon request. It is acceptable to have multiple corrected assessments for an OASIS assessment, as long as the OASIS and the clinical record are documented in accordance with the clinical record requirements at 42 CFR Part 484.

2202.11E - Clinical Implications of Corrected Assessment Records

(Rev. 1, 05-21-04)

When corrections are made to an assessment already submitted to the OASIS System, the HHA must determine if there is an impact on the patient's current care plan. If there is an impact, in addition to the correction made to the assessment, the HHA must make corresponding changes to the current care plan. If there are any other records where the correction has an impact, for example, the Home Health Resource Group, the Plan of Treatment or the Request for Anticipated Payment, the agency should make corresponding changes to that record, as applicable. The agency should establish a procedure to review the impact of any corrections made to assessment records and make corresponding changes to other records that are affected.

2202.11F - Regarding Corrections in Lieu of Required Assessments

(Rev. 1, 05-21-04)

Collection and submission of information on SOC, ROC, Follow-up, Other Follow-up, transfer, and discharge assessments are required by the comprehensive assessment requirements at 42 CFR Part 484. The correction process described here does not preclude the need for accurate patient assessment at the required time points.

The inactivation of an assessment and subsequent correction and re-submission of a new assessment, or a correction to a non-key field cannot be used in lieu of the appropriate OASIS assessment for documenting an unanticipated change in patient condition that was not envisioned in the original plan of care. If there is an unexpected change in the patient's clinical condition due to a major decline or improvement in health status that warrants a change in plan of treatment, the appropriate OASIS assessment is expected to document the change, i.e., the ROC or Other Follow-up assessment, as appropriate. This is in keeping with the regulation at 42 CFR Part 484.20(b) for accuracy of encoded OASIS data that states, "The encoded OASIS data must accurately reflect the patient's status at the time of assessment." The HHA should have one document for the patient's assessment, care planning, and payment purposes.

2202.11G - Timeliness of Corrections

(Rev.)

HHAs are urged to make corrections and/or submit inactivations as quickly as possible after errors are identified so the state system will be as current and accurate as possible *prior to*

HHA submission of the RAP. This *also* affects the data used to calculate the HHA's OBQI and OBQM reports.

2202.11H - Multiple Corrections in a Record

(Rev. 1, 05-21-04)

Correcting assessments with key field errors can only be done by inactivating the incorrect assessments and replacing them with the corrected assessments, as previously described above. Correcting assessments with non-key field errors can only be done by re-opening the assessment, revising the targeted non-key fields, and re-submitting the assessment, as previously described above. "CORRECTION_NUM" (the counter field) is implemented in non-key field changes. For more specific information concerning the process of correction and inactivation, refer to the OASIS data specification notes on the OASIS web site.

2202.12 - OASIS State System

(Rev)

The purpose of the OASIS State System is to provide computerized storage, access, and analysis of the OASIS data on patients in HHAs across the nation. The OASIS State System is intended to create a standard, nationwide system for connecting HHAs to their respective SAs for the purpose of electronic interchange of data, reports, and other information. The automated OASIS system is a critical component of SA and CMS operations. It is a key part of a fully integrated system of clinical data, facility demographics, survey findings, and SA operations information. The OASIS State System also provides the means for transmission of assessment data to CMS for validating payments under prospective payment for HHAs.

The OASIS State System implementation involved a CMS-funded installation of standardized computer hardware and data management software at each SA to allow electronic transfer of OASIS data elements from all HHAs to the State. The data management software:

- Validates the basic accuracy of the data and rejects submission files (batches) with fatal file errors, such as a missing or invalid agency ID, incorrect record length, or missing headers or trailers;

- Validates individual assessment records and rejects those records with fatal record errors;

- Stores and reports non-fatal or warning errors on records that are accepted by the database; and

- Builds a database of OASIS information for all applicable patients of each HHA in the State.

In accordance with the regulations, HHAs will collect SOC, ROC, follow-up, discharge to the community, transfer to an inpatient facility (with or without discharge), and death at home OASIS data on all patients (except those under 18; those receiving maternity services; and patients receiving only housekeeping or chore services) under the care of the HHA as of July 19, 1999, as applicable. The requirements for OASIS collection, encoding, and transmission apply to all Medicare and Medicaid patients, including Medicare and Medicaid HMO/Managed Care patients (with the exception of those listed above) receiving skilled services. The applicability of the comprehensive assessment and reporting regulations to

patients receiving personal care only services, regardless of payer source, has been delayed until further notice. In addition, the collection, encoding and transmission requirement for non-Medicare and non-Medicaid patients receiving skilled care is also temporarily suspended until further notice. Until collection and submission of non-Medicare/non-Medicaid patient assessments is required, HHAs must meet all other requirements of the comprehensive assessment regulation including conducting SOC comprehensive assessments and updates at the required time points on all non-Medicare and non-Medicaid patients receiving skilled services, although the OASIS data items are not required. This means that only the requirement to collect, encode and transmit OASIS data is delayed. The *completion of the* comprehensive assessment and updates at the required time points is required in order to ensure quality of care for all patients and to encourage the use of OASIS as the basis for care planning.

Effective August 24, 1999, and at least monthly thereafter, HHAs should transmit to the SA all applicable OASIS data collected and encoded from July 19, 1999, and monthly thereafter. Monthly transmissions should include all OASIS data encoded in the previous month.

OASIS activities will provide enhanced analytical capabilities at the SAs; electronic transmission from the State databases to a national repository; integration with performance indicators for quality oversight and survey planning by the SA; a basis for maintaining prospective payment of HHAs; research directed at improving quality of care; feedback to providers; and dissemination of information to purchasers, beneficiaries, and others.

2202.12A - System Description

(Rev.)

The CMS has provided each State with an OASIS State System composed of standardized hardware and software platforms scaled to meet each State's anticipated processing volumes, and a standardized operating system. The hardware is comprised of a communications server, database server, the local area network, and other peripheral devices.

The OASIS State System deployed to each State was specifically engineered and purchased to fulfill the OASIS requirements of 42 CFR Parts 484 and 488, *as well as to incorporate* additional CMS provider assessment processes as they become effective, and operational support of Medicare and Medicaid Survey and Certification pursuant to §1864 of the Act. The system was designed with an emphasis on flexibility and integration, so that additional software components could be easily added to provide the States with new related functionality (such as outcome measures and expanded analytical reports), as well as applications that support future assessment processes for other provider types, and new capabilities to support survey and certification operations. Since each State's OASIS system was specifically sized to accommodate these planned functions, the SA should not add other non-CMS prescribed applications or databases to it.

2202.12B - Administration Requirements

(Rev.)

The OASIS State System in each State is part of a comprehensive, Quality Improvement and Evaluation System that will not only fulfill OASIS administration requirements, but also grow to support other assessment-based programs; quality and performance indicators; and new, integrated survey and certification data systems. The State should use the OASIS State System for editing, storing, and processing OASIS data to support CMS' OASIS operating requirements within the State and to transmit the required OASIS data to the CMS OASIS

repository. As noted above, the State may not add additional software applications to the OASIS system without a specific directive from CMS.

The States are directly responsible for fulfilling requirements to operate the OASIS State System. However, the State may enter into an agreement with the State Medicaid agency, another State component, or a private contractor to perform day-to-day operations of the system.

The State must obtain RO approval prior to entering into an agreement with another agency**.** Such agreements should address the following provisions:

1. Meets confidentiality requirements: Federal Privacy Act, 5 U.S.C. §522a; HIAA of 1996; other applicable Federal data acts; §1902(a)(7) of the Act; applicable State standards; and industry security standards;

2. Gives the SA real-time access to the system to fully support all OASIS-driven functions which will be required of the survey agency (e.g., quality indicator reporting, survey targeting, etc.), or if a contractor is performing analysis for SA contract, provides the details on how this is to be conducted;

3. Complies with *the* need for high capacity, fault-tolerant network connections to ensure reliable support for the SAs, CMS' national database, and any other daily operations (e.g. Intermediary Medical Case Review, Office of the Inspector General or Department of Justice Fraud and Abuse activities), which will be affected by this system. Assures hardware will be properly maintained and upgraded as necessary to meet any future CMS or SA requirements. Assures adequate backup of all data;

4. Includes SA responsibilities for reporting OASIS data to a central repository at CMS. Designates responsibilities for edits and "cleanness" of data:

   - Designates responsibilities for generating and communicating facility error reports.

   - Describes what kinds of communication will be established, e.g., a State-specific Internet and/or Intranet web pages, newsletters, etc., their content, and who will produce/maintain/distribute these communications.

   If there is a separate database, designates who is responsible for operating and maintaining the CMS-provided equipment and who will assure the viability of the CMS database;

5. Lists responsibilities of contractor and/or State for training and support operations: Includes at least who will provide facility and OASIS software vendor startup training, and on-going customer/facility support/troubleshooting; provide internal training and daily user support within the SA; work with program staff to integrate the OASIS system into SA functions; train SA staff on aspects of analytical system (e.g., ASPEN upgrades and "performance measure/quality indicator" linked reports); handle System Operations - functions associated with transmission logging, error tracking and resolution, system archival, and process reporting; and designate who is responsible for determining facility transmission schedules;

6. Delineates how State will fund the monthly line charges associated with installation, maintenance, and transmission of the OASIS data from the facilities to the contractor and between the contractor and State, e.g., built into contract costs or is an outside ongoing cost to the SA; and

7. Specifies whether it is the contractor's or the SA's responsibility for systems maintenance for commercial "off-the-shelf" OASIS hardware and software components.

NOTE: Standardized OASIS software components that are developed and distributed by CMS will be maintained and upgraded centrally by CMS.

Under any such arrangement, the State must be guaranteed real-time, priority access to this system to fully support all OASIS functions. All CMS privacy and confidentiality requirements must be met. Off-site operation of the OASIS State System will require high capacity, fault-tolerant network connections to ensure reliable support for the State's daily operations that will be affected by this system. The State also must use the OASIS State System for reporting OASIS data to the CMS central repository.

To promote national consistency in OASIS system operations and troubleshooting, each State should designate one individual as the OASIS automation project coordinator. This person is CMS' key contact within each State for managing OASIS State System issues and must be familiar with the use of the OASIS automation and transmission process. Technical knowledge of information systems is useful but far less critical than an understanding of the OASIS processes, good communication and project management skills, and the ability to educate and work with providers and vendors to ensure successful implementation of an automated process for all providers. The State should designate additional staff, including a System Administrator, to manage the technical aspects of running the OASIS State System and support staff to assist in processing corrections, answering routine user questions, assigning passwords, etc.

With respect to systems maintenance, the OASIS State System installed in each State is comprised of commercial, off-the-shelf hardware, and software components that are generally covered under typical umbrella service agreements that the State may already have in place for maintenance of data processing equipment. Those OASIS software components that are developed and distributed by CMS will be maintained and upgraded centrally by CMS. The State will not be responsible for these software upgrades.

To the extent that the State has developed customized external applications for using information obtained from the OASIS database (e.g., to support Medicaid payment), the costs of developing and maintaining these additional software applications (and any related hardware components) will not be funded through the survey and certification budget.

2202.12C - Validation and Editing Process

(Rev.)

Each time an HHA accesses the OASIS State System and transmits an assessment file, it performs a series of three levels of validations:

1. Fatal File Errors

   - The first check examines the basic structure and integrity of the submission file. If there are fatal flaws in the file (batch of records), then the entire file is rejected and the HHA is notified of the reason for rejection in the "Initial Feedback Report." In the event that a batch is rejected due to fatal file errors, the HHA will not receive a "Final Validation Report." Fatal file errors are listed in the data

specifications, which can be found on the OASIS Web site. Rejected files must be corrected and retransmitted.

2. Fatal Record Errors

- If the file structure is acceptable, then each record in the file is examined individually for fatal record errors. These errors may cause an individual assessment within a submission to be rejected. Assessments that have fatal records are not stored in the database. *The HHA is informed of fatal record errors on the "Final Validation Report."* OASIS data specifications outline the valid data requirements and are posted on the OASIS Web site.

The Initial Feedback and Final Validation reports are available shortly following the submission of a file.

3. Non-Fatal or Warning Errors

If there are no fatal record errors, the record is loaded into the State database and the record is further examined for non-fatal errors. Any non-fatal errors are reported to the facility in the "Final Validation Report." Non-fatal errors include missing or questionable data of a non-critical nature, record sequencing, field consistency errors, invalid value, and range errors.

The Initial Feedback Report is available immediately following the submission of a file. *The HHA should obtain this report before logging off to ensure the submission has been processed.* Since the Final Validation Report is not available for up to 48 hours after the Initial Feedback Report, the HHA may, based on experience, choose to obtain this report on a subsequent log on.

The validations and edits described above fulfill all of CMS' editing requirements under 42 CFR Part 488.68. Also, States may not modify any aspect of the CMS OASIS standard system, including these validations and edits, the Standard Record Layout, and the software code and specifications on which the system is based.

States that use OASIS data for Medicaid payment may require additional assessment information not required by CMS' OASIS system. Some States may impose additional edits on Medicaid assessments. However, a State may not interfere with, modify, or delay the transmission of records meeting CMS edit standards from a Medicare-certified or Medicaid-approved agency to the CMS OASIS standard system. Furthermore, the State may not impose any requirements that modify the clinical accuracy of CMS prescribed OASIS records, reports, or calculations.

2202.12D - Reports

(Rev.)

The OASIS State System provides reports to both the State and the provider. These reports, which focus on errors in OASIS submissions, are particularly key to working with agencies to ensure successful transmission of OASIS data. Refer to the State OASIS Administration Manual available on the QTSO Web site (http://www.qtso.com/) for information about specific reports provided. *Monthly validation of OASIS submission is highly recommended*

for both states and providers as OASIS is required for payment, pay for reporting, and medical review.

2202.12E - Replication to the CMS Repository

(Rev.)

Each State's OASIS database will be transmitted to the CMS central repository at least monthly using a data replication process initiated by CMS. Since the process will be managed by CMS through an automatic polling process, the States will not actually have to transmit the data. However, the State must ensure that the CMS data line established for this purpose is accessible to CMS at all times for testing and monitoring purposes. Actual access to the Oracle assessment data tables may be controlled by the States but in such cases, *CMS* recommends that a fixed schedule be established with CMS central office.

The OASIS State System and CMS data line meet all industry security standards. However, if the State is concerned about security, it may establish a firewall (an electronic block) to restrict access to the State's portion of the network. Access must not be restricted to the CMS-supplied OASIS System.

2202.12F - System Security

(Rev.)

As distinguished from confidentiality and privacy, which primarily focuses on the rules for release of information when it is authorized, security relates to the means by which the information is protected from "unauthorized" access, disclosure, and misuse. As part of the new requirements under 42 CFR Part 488.68, States must ensure that electronic data in the OASIS State System are protected to the same degree that paper records containing any identifiable data must be safeguarded. Additionally, any printed copies of reports from the system must be maintained in a secure locked area while they are needed and properly disposed of when no longer needed. States must issue a policy that defines and limits the qualifications for an individual to access the OASIS State System. The System Administrator must issue passwords and user *identifications* in strict adherence to those requirements. State personnel who receive passwords must be aware of the requirements of the State's security policies and those of the System of Records and the Privacy Act. Passwords must be protected by the System Administrator and those receiving passwords. Passwords must be disabled at the time an individual exits a position requiring OASIS State System access. SAs are likewise reminded of the secure nature of passwords for the HHAs and must use due process to ensure the security of those passwords.

State personnel should not leave the OASIS State System in a logged-in status when leaving the area. If possible, the system hardware should be located in an enclosed area, preferably with a door having interior hinges that can be locked. Keys or a combination lock should be available to only a minimum group of individuals with need for access to the system.

In addition to the specific guidance above, the safeguards must provide a level of security at least equivalent to that required by the Office of Management and Budget Circular A-130 (revised), Appendix III, Security of Federal Automated Information Resources.

2202.12G - Security of Transmission

(Rev.)

OASIS data is encoded and transmitted from HHAs to SAs via the *CMSnet*, a private communications network CMS purchased to ensure the security of OASIS and MDS transmissions to the State. This system replaces the previous process of direct dial-up by public telephone lines to the SA and reflects the latest technology available for securing the privacy of data during transmission. Standard industry authentication is employed at each SA. Further security is provided at the SA by isolation of the receiving communications server from the actual storage site at the State (the MDS/OASIS Database Server). This serves effectively as a security firewall. Transmission of OASIS data from the SAs to CMS occurs via *the* CMS Virtual Private Network (VPN), which allows only authorized CMS staff access within this secure CMS infrastructure.

The CMS has determined that the transmission of OASIS data through the process described above is fully compliant with all current Federal, Department of Health and Human Services, and CMS information system's security requirements. The applicable Federal guidelines include The Computer Security Act of 1987, Federal Information Processing Standards promulgated by the National Institute of Standards and Technology pursuant to the Computer Security Act of 1987, the Office of Management and Budget Circular A-130 (revised), and Appendix III, Security of Federal Automated Information Resources.

Per CMS policy, in the CMS Information Systems Security Policy, Standards and Guidelines Handbook, it is a violation of the CMS Security policy to send via email or fax: patient personally identifiable information, IP addresses, and both ID and password in the same document. CMS Security policy prohibits saving the login information in the Internet browser or sharing the personal login ID or the password with anyone else.

2202.12H - Provider Relations

(Rev. 1, 05-21-04)

With CMS technical support and guidance, the States work closely with the provider community and their OASIS software vendors in providing information on specific requirements related to the submission of OASIS assessments to the OASIS State System.

The CMS expects that some vendors will provide primary support to HHAs in terms of OASIS encoding and transmission to the State repository. The State, however, must work with HHAs and software vendors in educating them about this process. The States must also provide training and technical assistance in interpretation of OASIS reports provided to HHAs.

2202.13 - Protection of the Confidentiality of OASIS Data

(Rev. 1, 05-21-04)

2202.13A - OASIS System of Records

(Rev.)

The OASIS database is operated and maintained by States or CMS contractors as a Federal database and, as such, is subject to the requirements of the Federal Privacy Act. In general, the only records subject to the Privacy Act are records that are maintained in a system of

records (SOR). The idea of a "system of records" is unique to the Privacy Act and requires explanation.

The Act defines a "record" to include most personal information maintained by an agency about an individual. A record contains individually identifiable information, including but not limited to information about education, financial transactions, medical history, criminal history, or employment history. A SOR is a group of records from which information is actually retrieved by name, social security number, or other identifying symbol assigned to an individual.

The text of the SOR notice for the OASIS database describes the legal requirements regarding privacy and disclosure of information by CMS or the State. *The assigned identifying number for this system is: System No. 09-70-0522.*

The CMS established a new SOR, published June 18, 1999, in the "Federal Register" (64 FR 32992) containing data on the physical, mental, functional, and psychosocial status of patients receiving the services of HHAs that are approved to participate in the Medicare and/or Medicaid programs. The purpose of the system is to aid in the administration of the survey and certification of Medicare/Medicaid HHAs and to study the effectiveness and quality of care given by those agencies. This system also supports regulatory, reimbursement, policy, and research functions, and enables CMS to provide HHAs with outcome data for providers' internal quality improvement activities.

The OASIS SOR was modified and published on December 27, 2001, (66 FR 66903) to allow a new routine use authorizing disclosure to national accrediting organizations that have been approved by CMS for deeming authority for Medicare requirements for home health services. This SOR notice replaces the SOR notice published June 18, 1999. *The SOR was again updated November 13, 2007.*

The HHA SOR contains individually identifiable clinical assessment information (OASIS records) for all Medicare/Medicaid patients receiving the services of a Medicare and/or Medicaid approved HHA, except prepartum and postpartum patients; patients under 18 years of age; patients receiving only housekeeping services and/or chore services exclusively; and, until sometime in the future, patients receiving only personal care services. The CMS established the system in accordance with the principles and requirements of the Privacy Act.

2202.13B - Protection of Confidentiality Under the Privacy Act of 1974

(Rev.)

OASIS data are generally protected under the provisions of the Privacy Act of 1974. The Privacy Act of 1974 protects the confidentiality of person-specific records that are maintained by the Federal Government and retrieved by a unique indicator. It contains 12 conditions of disclosure under which these records may be released without the written consent of the individual.

The system notice for the OASIS repository (HHA OASIS) was originally published in the "Federal Register" on June 18, 1999, and modified on December 27, 2001 *and November 13, 2007.* The system notice contains a listing of the prescribed limited circumstances under which person-specific records contained in that system may be released. These circumstances are called routine uses. Routine uses must be compatible with the purpose for which the records are collected and maintained. The OASIS system notice now contains nine routine uses.

Requests submitted to CMS for release of OASIS data are forwarded to the appropriate data release authority. The authority to release data from the OASIS national repository is limited to the System Manager and his or her designees. The OASIS System Manager is the Director of the *Survey and Certification Group at CMS*, and as such has the sole authority to grant or deny a request for access to, or disclosure of data contained in the HHA OASIS system of records. It is the responsibility of the data release authority to review these requests for adherence to Privacy Act requirements. Release of data from any system is discretionary.

Release of data from the OASIS repository follows CMS policy and procedure for data release. It is CMS policy that each requestor of Privacy Act protected data must sign a CMS approved Data Use Agreement (DUA). A DUA is not required by the Privacy Act, however; it is one safeguard CMS has instituted in order to protect the confidentiality of identifiable data. DUAs are an integral part of the data use approval process. The agreements delineate the confidentiality requirements of the Privacy Act and CMS' data use policies. The agreement serves as both a means of informing data users of these requirements and a means of obtaining their agreement to abide by these requirements. Additionally, the agreements serve as a control mechanism through which CMS can track the location of its data and the reason for the release of the data. CMS' Office of Information Systems carries the functional responsibility to control guidelines and policies for the language in the agreements and coordinates the requests for release of data.

2202.14 - SA and RO Roles and Responsibilities

(Rev. 1, 05-21-04)

2202.14A - State

(Rev. 1, 05-21-04)

The CMS expects the SA to play a key role in providing the educational and technical resources to HHAs in each State concerning OASIS. States must designate an OASIS Automation Coordinator and OASIS Educational Coordinator to function as resources for the HHAs in each State. These positions are funded by CMS through the Medicare Survey and Certification program.

Each State Automation Coordinator must have the ability, through education, training, or experience, to provide for the statewide administration of the OASIS project. The State Automation Coordinator provides systems operations and technical support for the HHAs, vendors, and SA staff. The State OASIS Educational Coordinator must be a member of any professional discipline operating in the home health environment, that is, a social worker, registered nurse, occupational therapist, or physical therapist. Together, the functions of these two positions include providing training and educational support to HHAs in the administration of OASIS for:

- Integrating the OASIS items into the HHA assessment process;
- Answering questions on the clinical aspects of OASIS;
- Training HHAs on the OASIS data set administration;
- Providing information about hardware and software requirements for HHAs to consider when automating OASIS;

- Training HHAs on submission of OASIS data to the State and interpreting validation reports, including providing support for transmission of test data during start-up, supporting callers requesting technical assistance, providing passwords to HHAs, and answering questions about computer edits and reports;

- Submit an annual training report of the state-wide OASIS training and other activities in the Home Health Training Worksheet available in Casper reports of the QIES system by October 15 following each Federal Fiscal Year.

- Using the outcome reports generated by the OASIS data;

- Using OASIS data in survey tasks;

- Training other SA staff, as applicable;

- Providing information from OASIS to determine prospective payment rates for HHA patients; and

- Participating in training updates on OASIS and related home health issues.

2202.14B - Regional Office

(Rev.)

ROs also have *OASIS* coordinators for the implementation *updates* and automation of OASIS. Designated RO *staff provides* information about OASIS in the region, *act as a resource to the provider and a consultant to the SA. They also administer survey and certification funds, and other aspects of the OASIS project.* At least one RO staff person, knowledgeable about home health survey and certification issues, and/or knowledgeable about MDS automation coordination should be assigned to these OASIS related roles. ROs must provide the States with the program guidance and technical assistance critical to the successful implementation of OASIS and ensure that the States have the necessary resources to accomplish these goals.

The following activities are performed by the RO:

1. Budget Process

   The RO reviews each SA's budget request and the required OASIS Implementation Plans in accordance with the SCG Budget *instructions.* The RO must monitor for a reasonable and prudent expenditure of funds to ensure that States receive a fair and reasonable allocation. The RO must monitor Quarterly Expenditure Reports against the States' allocation.

2. Review State Implementation Plans

   The RO annually reviews all State OASIS Implementation Plans to ensure States have reasonable plans for assisting HHAs with the technical information, training, and assistance needed to comply with requirements for OASIS submission, accuracy, privacy, and security. The RO must assess whether States are monitoring HHA compliance with the OASIS requirements.

3. Review Contracts and Agreements

The RO ensures that the SA has executed an agreement with any other entity if that other entity is operating the OASIS system on behalf of the SA. The RO must use the criteria in §2202.12.B in performing this review.

4. Provide Training and Technical Assistance

The RO *supports CO in* training and technical assistance to the States in OASIS *and ASPEN* requirements and *supports OASIS continuing education and program requirements.*

5. Perform Focused Reviews/Federal Surveys

The RO uses the OASIS Repository and outcome data to select HHAs for focused reviews, and in preparation for Federal surveys.

6. Take Enforcement Action.

The RO processes and carries out enforcement actions for non-compliance with OASIS requirements (as reported by SAs).

2202.15 - OASIS Education and Training

(Rev. 1, 05-21-04)

2202.15A - State

(Rev.)

The OASIS Educational and Automation Coordinators *(OEC/OAC)* participate in various training programs concerning OASIS, monthly *All State* teleconferences to discuss OASIS issues, and meetings for OASIS updates and other matters related to home health services, as necessary. State support is provided by CMS central office, ROs, the OASIS Web site, and clinical and technical Help Desks supported by CMS contractors. *The State OACs and OECs are considered the subject matter experts who provide training to State Agency staff and act as a resource to providers.*

The OASIS Education Coordinators (by state) can be found at:- http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/EducationCoord.html.

The OASIS Automation Coordinators (by state) can be found at: - http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/AutomationCoord.html.

2202.15B - RO

(Rev.)

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

2202.15C - HHAs

(Rev.)

All HHAs, both existing and prospective, are trained on the implementation and automation of OASIS by each State's OASIS Educational and Automation Coordinators. HHAs with clinical, technical and regulations-related questions should contact the State OASIS Educational or Automation Coordinator about OASIS. A current list of the State OASIS Educational Coordinators is found on the OASIS Web site. Support is also available for HHAs via the OASIS Help Desk. The Help Desk can be accessed toll-free by telephone on (877) 201-4721 between the hours *of 7:00 a*.m. and 7*:00* p.m. Central Time and by electronic mail at HAVEN_help@IMFC.org.

The SA provides support to HHAs by providing OASIS presentations at meetings sponsored by the SA, HHA provider associations, or other entities.

Updates to existing software and training manuals which support OASIS *updates*, HAVEN, and the OASIS State System, are distributed via the OASIS *and QTSO* Web site.

2202.16 - Fax Transmission of OASIS or Other Patient Identifiable Information

(Rev.)

OASIS assessment data is personal information about home health recipients that HHAs are required to collect and keep confidential in accordance with federal law. The use of electronic means of communication is acceptable in HHAs, if appropriate safeguards are in place. The fax machine provides a fast and inexpensive method to send and receive patient specific information, such as patient referrals and physician orders. However, the use of fax transmission can open up the possibility that confidential patient information can be transmitted or handled in a manner that is not secure and does not protect the patient's confidential health information. For example, the use of an incorrect fax number can allow the material being transmitted to persons who are not legally authorized to have this information. CMS takes its responsibility seriously to protect patient specific information once it has been transmitted to the State, and *CMS* expects HHAs to provide the same protections to OASIS data while it is maintained at the HHA.

SAs must follow Federal requirements for systems that retain "Federal data" e.g., MDS data, OASIS data. Additional information on information security (IS) can be found on the CMS Information Security web pages at http://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/InformationSecurity/index.html?redirect=/informationsecurity in the CMS Policy for the Information Security Program (PISP) and the CMS IS Acceptable Risk Safeguards (ARS) found under "Policies" and "Standards."

The home health CoP at 42 CFR Part 484.11, Release of Patient Identifiable OASIS information, requires that HHAs and agents acting on behalf of the HHA in accordance with a written contract must ensure the confidentiality of all patient identifiable information contained in the clinical record, including OASIS data, and may not release patient identifiable information to the public.

It is the responsibility of the HHA to make sure that it has a written contract providing its agent with the legal authority to encode and transmit OASIS assessment data. The contract should also ensure that the agent holds all OASIS data confidential. Each HHA that uses fax transmission of OASIS information should develop its own policies and procedures to assure

confidentiality of patient information, as well as, comply with legal, regulatory and accreditation requirements. It is also the responsibility of the HHA to make sure that OASIS assessment data is transmitted to its agent by a secure method.

If the HHA chooses to use facsimile transmission of OASIS data, guidelines for use of facsimile transmission of OASIS data are provided below:

- The HHA or agent should place fax machines in a secure area and limit access to them.

- The HHA should identify one person in a department or unit to monitor incoming documents on a fax machine, or to deliver the document information directly into a secured data base system.

- The HHA should outline appropriate written policies that safeguard that transmitted OASIS information is sent to the appropriate person and verify the correct facsimile number to which the OASIS data is being transmitted. This should include:

  (a) Use of the of a cover sheet, either electronic or hard copy, accompanying the faxed information that specifies that the OASIS information is confidential and limits its use to the terms of the written contract;

  (b) That the person who is the legal authority for the receipt of the OASIS information is prohibited from disclosing this information to any other party, any may use the data only for the purposes outlined in the written contract; and

  (c) The HHA should contact the agent to verify the correct fax number to use prior to faxing.

The HHA should develop and enforce procedures to be followed in the case of a misdirected transmission. This should include:

(a) A notice on the cover sheet that prohibits the disclosure, copying, or distribution of the information by the unintentional receiver of the fax;

(b) A notice to the unintentional receiver of the fax to notify the sender immediately if they have received this information in error to arrange for the return of the information; and

(c) The name and phone number of the sender to contact.

HHAs shall only use or disclose patient identifiable records as permitted or required by law.

State survey agencies should follow the *CMS* guidelines when sending and receiving requests to correct errors to the OASIS data base.

2202.17 - Change of Ownership (CHOW), Merger, and Termination Procedures Affecting HHAs and OASIS Requirements

(Rev.)

It is imperative that the Medicare *CCN* be accurately reported on the OASIS assessments in all reports, including when HHAs undergo change of ownership, merger, or termination.

Change of Ownership - Mergers

In accordance with 42 CFR Part 489.18 and §3210, the merger of a provider corporation into another corporation constitutes a change of ownership. In the case of the merger of Agency A into Agency B, Agency A's provider agreement and its associated *CCN* are terminated. Agency B retains its existing provider agreement and *CCN*. Agency A should provide the OASIS discharge comprehensive assessment for each discharged patient prior to or at the effective date of the merger. The surviving HHA (Agency B) should provide a Start of Care (SOC) comprehensive assessment for all persons it admits after the merger at the next skilled visit after the official merger date. The SOC assessment will allow eligibility for the home health benefit to be verified and care planning for the individual to proceed under Agency B. Subsequently, the assessments for all individuals being accepted for care by Agency B will be linked to the correct provider number to enable the agency to engage in quality improvement efforts with accurate OBQI reports.

In accordance with 42 CFR Part 489.18 and §3210, when there is a *permissible* change in ownership *under 42 CFR Part 424.550(b)(2)*, as described below and the new owner *does not reject automatic* assignment of the existing provider agreement *under 42 CFR Part 489.18(c),* the new owner is subject to all the terms and conditions under which the existing agreement was issued, including compliance with the comprehensive assessment of patients condition of participation. The *CCN* remains the same if the new HHA owner accepts assignment of the existing provider agreement. The new owner is responsible for continuing to complete updates to the comprehensive assessment at the next scheduled time points.

Change of Ownership without Assignment

In accordance with 42 CFR Part 489.18 and §3210, when there is change of ownership and the new owner rejects this *automatic* assignment of the provider agreement, the provider agreement and provider number of the former owner should be terminated.

The HHA that is terminating its provider agreement and provider number should provide an OASIS discharge comprehensive assessment for each patient subject to OASIS standards prior to the effective date of the termination, according to 42 CFR Part 484. The new HHA will not be able to participate in the Medicare program without going through the same process as any new provider, which includes an initial survey. The HHA should meet all the Federal requirements, including applicable OASIS requirements as specified in the regulations, for all persons it accepts for care in order to participate in the Medicare program. This means that the HHA should provide a new SOC comprehensive assessment at the first skilled visit once it becomes Medicare-approved. In addition, updates to the comprehensive assessment should be provided at the other OASIS time points, in accordance with 42 CFR Part 484, for all patients of the former owner it accepts for care.

NOTE: The "Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2011; Changes in Certification Requirements for Home Health Agencies and Hospices; Final Rule"(75 FR 70372) (also referred to as CMS-1510-F) published on November 17, 2010, revised certain policies related to the prohibition of the sale or the transfer of HHA billing privileges at §424.550(b)(1), defined "change in majority ownership" at §424.502, and provided several exceptions to the new "36-month rule." Specifically, the final rule provided that, effective January 1, 2011, and in accordance with §424.550(b)(1), if there is a change in majority ownership of an HHA by sale (including asset sales, stock transfers, mergers, and consolidations) within 36 months after the effective date of the HHA's initial enrollment in Medicare or within 36 months after the HHA's most recent

*change in majority ownership, the provider agreement and Medicare billing privileges do **not** convey to the new owner.*

Section §424.502 defines the term "Change in Majority Ownership" as a transaction in which an individual or organization acquires more than a 50 percent direct ownership interest in an HHA during the 36 months following the HHA's initial enrollment into the Medicare program or the 36 months following the HHA's most recent change in majority ownership (including asset sales, stock transfers, mergers, and consolidations). This includes an individual or organization that acquires majority ownership in an HHA through the cumulative effect of asset sales, stock transfers, consolidations, or mergers during the 36-month period after Medicare billing privileges are conveyed or the 36-month period following the HHA's most recent change in majority ownership.

If the CMS RO or SA receives an inquiry from the provider regarding procedures for a change in majority ownership pursuant to §424.550(b) (1), it should refer the provider to its Medicare Administrative Contractor (MAC). The MAC will review the applicable time frames, exceptions and any other pertinent enrollment requirements, and will determine if the facility has had a majority ownership change within 36 months of its initial certification or within 36 months of another majority ownership change.

If the proposed HHA change of ownership meets the revised HHA change in majority ownership definition, it must:

- *Enroll in the Medicare program as a new (initial) HHA under the provisions of 42 CFR Part 424.510;*
- *Obtain a State survey or an accreditation from an approved accreditation organization with deeming authority; and*
- *Sign a new Medicare provider agreement and receive a newly assigned CMS Certification Number (CCN).*

CMS will deactivate the HHA's old Medicare billing number if the sale has already occurred.

Scheduling of an initial certification survey is initiated by a recommendation from the MAC to the RO/SA. The SAs and ROs will follow the current established processes and policies for initial certification. The initial surveys required under the change in majority ownership guidelines will be considered Tier IV as per CMS's Mission Priority Document (MPD). The HHA may utilize an approved AO for an initial survey if it is seeking deemed status through accreditation. It is the responsibility of the HHA to arrange the initial Medicare survey with the AO.

Upon successful completion of the enrollment and survey process, the new HHA will have a new effective date of Medicare participation and a new CCN.

Questions from the provider community about the definitions for a change in majority ownership and specifics regarding participation dates, exceptions, etc., should be directed to the applicable MAC.

An existing HHA that has engaged in a transaction that meets the definition of change in majority ownership is considered to have voluntarily terminated its participation under its original provider agreement. The requirements for a provider/supplier to terminate voluntarily from participation in the Medicare program are set forth at 42 CFR Part 489.52. The RO should follow the usual procedure regarding voluntary termination, using the date of the ownership change as determined by the MAC as the effective date of voluntary termination.

There are a four allowable exceptions to the sale or transfer prohibition at 42 CFR Part 424.550(b)(2). Specifically, the provisions of 42 CFR Part 424.550(b)(1) do not apply if:

- *The HHA submitted two consecutive years of full cost reports (which are not low utilization or no utilization cost reports);*
- *The HHA parent company is undergoing an internal corporate restructuring, such as a merger or consolidation;*
- *The owners of an existing HHA are changing the HHA's existing business structure and the owners remain the same; or*
- *An individual owner of an HHA dies.*

Note: 42 CFR Part 424.550(b)(1) does not apply to "indirect" changes in majority ownership (e.g., changes to the ownership of a holding company that owns and operates HHAs through subsidiaries).

Voluntary Terminations

In accordance with 42 CFR Part 489.52 and §*2005 and* §3046, a Medicare approved HHA may voluntarily terminate its provider agreement by filing a written notice of its intention to the State Agency who, in turn, notifies the RO. *The provider/supplier must also submit a Form CMS-855A or CMS-855B to voluntarily terminate its Medicare billing privileges.* .

NOTE: According to Pub. 100-08, chapter 10, section 7.3: In the event the HHA notifies the MAC of its intent *to voluntarily terminate*, the MAC *shall notify the State and RO. This notification can be made via letter, e-mail, or fax, no later than 3 business days after the contractor has finished processing the termination.*

CMS recommends *that an HHA provide a discharge comprehensive assessment for each patient prior to the effective date of the termination of its provider agreement.*

The former HHA that meets the 2010 revised HHA CHOW definition is considered to have voluntarily terminated the original provider agreement. The State should follow usual procedures regarding voluntary termination, using the date of the CHOW as the effective date of voluntary termination. Electronic communication with the MAC should occur between all interested parties.

Involuntary Terminations

The RO may terminate *the provider* agreement with an HHA, in accordance with *42 CFR Part 489.53*. *Revocation of billing privileges in the Medicare program may be initiated by the MAC at 42 CFR Part 424.535, which results in termination of the provider agreement. When revocation of billing privileges also results in the termination of a corresponding provider agreement, the provider may appeal CMS's decision under 42 CFR Part 498, where a final decision applies to both the billing privileges and the provider agreement. See 42 CFR Part 424.545.*

CMS will work with the HHA on a case-by-case basis to provide for the safe and orderly transfer of patients to another Medicare-approved HHA if appropriate.

Deactivation of billing privileges

Under 42 CFR Part 424.540, a provider or supplier who does not submit any Medicare claims for 12 consecutive calendar months will have its Medicare billing privileges

deactivated. The 12 month period begins on the 1st day of the 1st month without claims submission through the last day of the 12th month without a submitted claim. Deactivated agencies are not terminated and are still required to be surveyed every 36 months by the SA or AO, if deemed.

Effective January 1, 2010, if an HHA's billing privileges are deactivated, the HHA must also undergo a Medicare survey in order for its billing privileges to be reactivated. This applies to all applications for reactivation that were received after December 31, 2009.

In order for its billing privileges to be reactivated, a HHA must first submit a Form CMS-855 update (re-activation application) to the MAC. The MAC will conduct its preliminary review of the application and either deny the application or notify the RO, AO or SA that a survey may be scheduled. The MAC will notify the provider that the preliminary review is complete and that the SA has been notified.

Once the RO/SA receives notification from the MAC, surveys of deactivated HHAs are scheduled as a low survey priority. In circumstances of demonstrated access to care issues, the RO may change the survey priority and determine if an earlier recertification survey is indicated.

If an HHA chooses to have a deemed status survey by an AO, it is the responsibility of the HHA to arrange the Medicare recertification or initial survey with the AO. The AO shall perform a recertification survey for existing clients when billing privileges have been deactivated and the agency has subsequently requested reactivation. In the event the HHA wishes to use the AO to conduct a reactivation survey when it formerly was under the jurisdiction of the SA, the AO would conduct this as an initial survey. The AO must notify the RO of the survey findings and the deeming recommendation. The RO retains the responsibility to notify the MAC that the agency passed the requirements of the Medicare survey.

A standard survey is conducted and entered into the ASPEN system as a recertification survey along with a note that this is an early recertification due to a request for reactivation of Medicare billing. The SA must notify the RO of the survey activity. If the survey finds condition level non-compliance, routine enforcement procedures should be followed. If the survey finds substantial compliance, the RO should forward Form CMS-2007 to the MAC with the date the provider was determined to be in compliance with the CoPs in the remarks section. The HHA will retain its existing CMS CCN.

2202.18 - Wound Ostomy Continence Nurses Society (WOCN) and the National Pressure Ulcer Advisory Panel (NPUAP) OASIS Guidance

(Rev.)

The CMS collaborates with clinical wound care experts from the *WOCN and the NPUAP* to clarify OASIS wound items. The clarifications are intended to be helpful to home health agency (HHA) clinicians as they complete their patient assessments. For more information about the WOCN guidelines and for answers to questions about the WOCN guidelines, please contact the WOCN web site at *www.wocn.org.*

HHA clinicians are encouraged to use the *WOCN and the NPUAP* guidance to assist with clinical assessments of patient wounds. The WOCN OASIS Guidance *is located at*: *http://www.wocn.org/pdfs/GuidanceOASIS-C.pdf (www.wocn.org) and the NPUAP website is located at www.npuap.org.*

2202.19 - OASIS Collection on Private Pay (Non-Medicare/Non-Medicaid) Patients

(Rev. 1, 05-21-04)

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 includes a provision regarding the collection of OASIS data for non-Medicare/non-Medicaid (private pay) patients. Specifically, section 704 of this Act temporarily suspends the requirement that Medicare-approved HHAs collect OASIS data on non-Medicare/non-Medicaid patients, effective December 8, 2003.

State Operations Manual

Chapter 9 – Survey and Enforcement Process for Home Health Agencies

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9000 Introduction

Chapter 9 implements the home health agency (HHA) survey, certification, and enforcement regulations at 42 CFR Part 488. No provisions contained in this chapter are intended to create any rights or sanctions not otherwise provided in law or regulation.

To participate as an HHA in the Medicare program, an agency or organization must meet the definition of an HHA as defined in section 1861(o) of the Social Security Act (the Act). Additionally, HHAs must meet the requirements in section 1891(a) of the Act. The regulations implementing sections 1861(o) and 1891(a) of the Act are known as health and safety standards, or conditions of participation (CoPs), for HHAs and are codified in §484.

The Secretary has the responsibility to promote quality of care and the health and safety of patients receiving services through Medicare certified HHAs by ensuring that providers maintain compliance with the CoPs. The survey and certification process provides a method for CMS to evaluate HHA compliance with the CoPs, ensuring that patient services provided meet the minimum health and safety standards and a basic level of quality. This process is explained in Appendix B of this manual.

9000.1 Expectations of the Regulations

The HHA survey, certification, and enforcement provisions of the Act and regulations establish several expectations. The first is that providers remain in substantial compliance with Medicare program requirements as well as State law. The regulation emphasizes the need for continued, rather than cyclical compliance. The enforcement processes require that policies and procedures be established to correct deficient practices and to ensure that correction is lasting; specifically, that HHAs take the initiative and responsibility for continuously monitoring their own performance to sustain compliance.

The second expectation is that all deficiencies will be addressed promptly. The standard for program participation mandated by the regulation is substantial compliance, which is defined at §488.705 as compliance with all condition-level requirements, as determined by CMS or the State. The State and the CMS regional office will take steps to bring about compliance quickly. In accordance with 42 CFR §488.800 – §488.865, in addition to termination of the HHA's provider agreement, sanctions such as civil money penalties, suspension of payment for all new admissions, temporary management, directed plans of correction, directed in-service training, and/or additional State alternative sanctions recommended and approved by CMS can be imposed when HHAs are out of compliance with Federal requirements. See also section 1891(f)(2)(B) of the Act.

The third expectation is that the individuals under the care of the HHA will receive the care and services they need to attain and maintain their highest practicable functional capacity. The process detailed in these sections provides incentives to HHAs for the continued compliance needed to enable these individuals to reach these goals.

Throughout this chapter, references to the State would be applicable, as appropriate, to the CMS RO when the CMS RO is the surveying entity. Alternative sanctions are recommended by the SA and the CMS RO reviews the recommendation to ensure that it is supported by the SA findings.

It should be noted that failure of CMS or the State to act timely does not invalidate otherwise legitimate survey and enforcement determinations. It should also be noted that in cases where the State is authorized by CMS, the State may provide notice of imposition of certain sanctions on CMS's behalf, within applicable notice requirements.

The Automated Survey Processing Environment (ASPEN) Enforcement Manager (AEM) is the data system used by CMS and all States for data entry and reporting on home health survey and enforcement activities.

9001 Definitions and Acronyms

Abbreviated standard survey means a focused survey other than a standard survey that gathers information on an HHA's compliance with fewer specific standards or conditions of participation. An abbreviated standard survey may be based on complaints received, a change of ownership or management, or other indicators of specific concern such as reapplication for Medicare billing privileges following a deactivation. (42 CFR §488.705)

An abbreviated standard survey is a focused survey that examines any standard(s) related to the reason for the survey.

AEM – ASPEN Enforcement Manager.

AO – national Accreditation Organization whose program is approved by CMS.

ASPEN – Automated Survey Processing Environment.

Certification of Compliance means that the HHA is in at least substantial compliance and is eligible to participate in the Medicare and Medicaid programs. (42 CFR §488.740)

Certification of Noncompliance means that the HHA is not in substantial compliance and is not eligible to participate in in the Medicare and Medicaid programs. (42 CFR §488.740)

CFR - Code of Federal Regulations.

CMP - Civil money penalty.

Complaint survey means a survey that is conducted to investigate specific allegations of noncompliance. (42 CFR §488.705)

Condition-level deficiency means noncompliance as described in 42 CFR §488.24 of this part. A condition-level deficiency is any deficiency of such character that substantially limits the provider's or supplier's capacity to furnish adequate care or which adversely affects the health or

safety of patients. SAs and ROs should refer to the State Operations Manual (SOM), Appendix B for further guidance on how surveyors determine condition-level and standard-level deficiencies. (42 CFR §488.705)

Credible allegation of compliance is a statement or documentation that is realistic in terms of the possibility of the corrective action being accomplished between the exit conference and the date of the allegation; and that indicates resolution of the problems. (See §3016A)

Deficiency is a violation of the Act and regulations contained in §484, subparts A through C of this chapter, is determined as part of a survey, and can be either standard or condition-level. (42 CFR §488.705)

Directed plan of correction means CMS or the temporary manager (with CMS/SA approval) may direct the HHA to take specific corrective action to achieve specific outcomes within specific timeframes. If a temporary manager establishes a plan of correction, then this is considered a directed plan of correction and the imposition of this sanction needs to be entered into AEM. (42 CFR §488.805)

Enforcement action means the process of imposing one or more of the following remedies: termination of a provider agreement; denial of participation; suspension of payment for all new admissions; temporary manager; civil money penalty; directed plan of correction; directed in-service training; transfer of patients; closure of the agency and transfer of patients; or other CMS-approved alternative State remedies.

Extended survey means a survey that reviews additional conditions of participation not examined during a standard survey. It may be conducted at any time but must be conducted when substandard care is identified. (42 CFR §488.705)

Immediate jeopardy means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause serious injury, harm, impairment, or death to a patient(s). (42 CFR §488.805)

New admission means an individual who becomes a patient or is readmitted to the HHA on or after the effective date of a suspension of payment sanction. (42 CFR §488.805)

Noncompliance means any deficiency found at the condition-level or standard-level. (42 CFR §488.705)

Partial extended survey means a survey conducted to determine if deficiencies and/or deficient practice(s) exist that were not fully examined during the standard survey. The surveyors may review any additional requirements which would assist in making a compliance finding. (42 CFR §488.705)

Per instance means a single event of noncompliance identified and corrected through a survey, for which the Act authorizes CMS to impose a sanction. (42 CFR §488.805)

Plan of correction means a plan developed by the HHA and approved by CMS that is the HHA's written response to survey findings detailing corrective actions to cited deficiencies and specifies the date by which those deficiencies will be corrected. (42 CFR §488.805)

Repeat deficiency means a condition-level citation that is cited on the current survey and is substantially the same as or similar to, a finding of a standard-level or condition-level deficiency cited on the most recent previous standard survey or on any intervening survey since the most recent standard survey. (42 CFR §488.805)

Standard-level deficiency means noncompliance with one or more of the standards that make up each condition of participation for HHAs. SAs and ROs should refer to the State Operations Manual (SOM), Appendix B for further guidance on how surveyors determine condition-level and standard-level deficiencies. (42 CFR §488.705)

Standard survey means a survey conducted in which the surveyor reviews the HHA's compliance with a select number of standards and/or conditions of participation in order to determine the quality of care and services furnished by an HHA as measured by indicators related to medical, nursing, and rehabilitative care. (42 CFR §488.705)

State survey agency (SA) means the entity responsible for conducting most surveys to certify compliance with the Medicare and Medicaid participation requirements.

Substandard care means noncompliance with one or more conditions of participation identified on a standard survey, including deficiencies which could result in actual or potential harm to patients of an HHA. (42 CFR §488.705)

Substantial compliance means compliance with all condition-level requirements, as determined by CMS or the State. SAs and ROs should refer to the State Operations Manual (SOM), Appendix B for further guidance on how surveyors determine condition-level and standard-level deficiencies. (42 CFR §488.705)

Temporary management means the temporary appointment by CMS or by a CMS authorized agent, of a substitute manager or administrator based upon qualifications described in §484.4 and §484.14(c). The HHA's governing body must ensure that the temporary manager has authority to hire, terminate or reassign staff, obligate funds, alter procedures, and manage the HHA to correct deficiencies identified in the HHA's operation. (42 CFR §488.805)

9002 Home Health Agencies – Citations and Description

9002.1 Citations

A HHA is defined in section 1861(o) of the Act. The conditions of participation for HHAs are found at 42 CFR 484.10 – 484.55.

9002.2 Description

An HHA is a public agency or private organization or a subdivision of such an agency or organization, which:

(1) is primarily engaged in providing skilled nursing services and other therapeutic services;

(2) has policies, established by a group of professional personnel (associated with the agency or organization), including one or more physicians and one or more registered professional nurses, to govern the services (referred to in paragraph (1)) which it provides, and provides for supervision of such services by a physician or registered professional nurse;

(3) maintains clinical records on all patients;

(4) in the case of an agency or organization in any State in which State or applicable local law provides for the licensing of agencies or organizations of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing agencies or organizations of this nature, as meeting the standards established for such licensing;

(5) has in effect an overall plan and budget that meets the requirements of subsection (z);

(6) meets the conditions of participation specified in section 1891(a) and such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such agency or organization;

(7) provides the Secretary with a surety bond—

(A) effective for a period of 4 years (as specified by the Secretary) or in the case of a change in the ownership or control of the agency (as determined by the Secretary) during or after such 4-year period, an additional period of time that the Secretary determines appropriate, such additional period not to exceed 4 years from the date of such change in ownership or control;

(B) in a form specified by the Secretary; and

(C) for a year in the period described in subparagraph (A) in an amount that is equal to the lesser of $50,000 or 10 percent of the aggregate amount of payments to the agency under this title and title XIX for that year, as estimated by the Secretary that Secretary determines is commensurate with the volume of the billing of the supplier; and

(8) meets such additional requirements (including conditions relating to bonding or establishing of escrow accounts as the Secretary finds necessary for the financial security of the program) as the Secretary finds necessary for the effective and efficient operation of the program;

except that for purposes of part A such term shall not include any agency or organization which is primarily for the care and treatment of mental diseases. The Secretary may waive the

requirement of a surety bond under paragraph (7) in the case of an agency or organization that provides a comparable surety bond under State law.

NOTE: The surety bond requirement in the above paragraph is currently on hold.

9002.3 Home Health Services

Home health services are covered for the elderly and disabled under the Hospital Insurance (Part A) and Supplemental Medical Insurance (Part B) benefits of the Medicare program. Section 1861(m) o the Act defines the term "home health services" as items or services furnished to an individual, who is under the care of a physician, that must be furnished by, or under arrangement with, an HHA that participates in the Medicare program, under a plan (for furnishing such items and services to such individual) established and periodically reviewed by a physician, and must be provided on a visiting basis to the individual's home (unless provided on an outpatient basis, under arrangement by the HHA, at a hospital or skilled nursing facility, or at a rehabilitation center). Such items and services may include the following:

- Part-time or intermittent skilled nursing care furnished by or under the supervision of a registered nurse.
- Physical therapy, speech-language pathology, and occupational therapy.
- Medical social services under the direction of a physician.
- Part-time or intermittent home health aide services who have successfully completed an approved training program.
- Medical supplies (other than drugs and biologicals – unless osteoporosis drugs) and durable medical equipment.
- Medical services of interns and residents if the HHA is owned by or affiliated with a hospital that has an approved medical education program.
- Services at hospitals, skilled nursing facilities, or rehabilitation centers when they involve equipment too cumbersome to bring to the home.

Survey Process

9003 Emphasis, Components, and Applicability

Home health agencies must be in compliance with the requirements in 42 CFR Part 484, Subparts A, B, and C to receive payment under Medicare. To certify a HHA, surveyors follow the procedures in Appendix B of this manual.

9003.1 Introduction

The Secretary is authorized to enter into an agreement with a State survey agency (SA) under section 1864(a) of the Act or a CMS-approved national accreditation organization (AO) under section 1865(a) of the Act, with oversight by CMS ROs, to determine whether HHAs meet the Federal participation requirements for Medicare. Sections 1902(a)(9) and (33)(B) of the Act

provides for SAs to perform the same survey tasks for facilities participating in or seeking to participate in the Medicaid program. The results of Medicare and Medicaid-related surveys are used by CMS and the Medicaid State Agency, respectively, as the basis for a decision to enter into, deny, or terminate a provider agreement with the agency. To assess compliance with Federal participation requirements, surveyors conduct onsite inspections (surveys) of agencies. In the survey process, surveyors directly observe the actual provision of care and services to patients and the effect or possible effects of that care to assess whether the care provided meets the assessed needs of individual patients. A SA periodically surveys HHAs and certifies its findings to CMS and to the State Medicaid Agency if the HHA is seeking to acquire or maintain Medicare or Medicaid certification, respectively. The general requirements regarding the survey and certification process are codified at 42 CFR Part 488 and specific survey instructions are detailed in the SOM, Chapter 2, sections 2180- 2202, Appendix B and in policy transmittals.

Certain providers and suppliers, including HHAs, can be deemed by CMS to meet the Federal requirements for participation if they are accredited and recommended for participation in Medicare by an AO whose program is approved by CMS to meet or exceed Federal requirements under section 1865(a) of the Act. These deemed providers and suppliers are subject to complaint and validation surveys under §488.7.

9003.2 Survey and Certification Responsibility

Surveyors conduct the HHA survey in accordance with the applicable protocols. They look to the requirements in the statute and regulations to determine whether a deficiency citation of non-compliance is appropriate. Surveyors should base any deficiency on a violation of the statute or regulations, which is identified through clinical record reviews, interviews with the HHA's patients, staff, and others as appropriate and direct observations of the HHA's performance and practices. (See §2712.)

9004 Survey Team

9004.1 Survey Team Size

Survey team size will vary, depending primarily on the size of the agency being surveyed. The SA or CMS for Regional Office (RO) surveys determines how many members will be on the survey team. Survey team size is normally based upon the following factors:

- The average patient census of the agency to be surveyed;
- Whether the agency has a historical pattern of serious deficiencies or complaints;
- Whether the agency has branches; and
- Whether new surveyors are to accompany a team as part of their training.

9004.2 Survey Team Composition

Each home health survey team should include at least one RN with home health survey experience. Other qualified surveyors who have the expertise to determine whether the HHA is in compliance may be used as needed.

9004.3 Length of Survey

The length of a survey in terms of person hours is expected to vary, based on the actual patient census, presence of branches, number of home visits and travel time, and the number and complexity of concerns that need to be investigated.

9004.4 Surveyor Qualifications

Section 1891(c)(2)(C)(iii) of the Act requires that "an individual who meets the minimum qualifications established by the Secretary" to conduct a survey of an HHA. This means that each individual on a survey team must meet certain minimum qualifications. CMS criteria for surveyor minimum qualifications as well as circumstances that would disqualify a surveyor from surveying a particular agency are found at §488.735. In addition, before any State or Federal surveyor may serve on an HHA survey team (except as a trainee), he/she must have successfully completed the relevant CMS-sponsored Basic HHA Surveyor Training Course and any associated course prerequisites as determined by current CMS policy. New surveyors may accompany the team, in an observational role only, as part of their training prior to completing the CMS Basic HHA Surveyor Training Course.

9005 Conflicts of Interest for Federal and State Employees

9005.1 Introduction

Conflicts of interest may arise within the Medicare certification and survey process when public employees' duties give them the potential for private gain (monetary or otherwise) or the opportunity to secure unfair advantages for outside associates. This includes all Federal and State surveyors and their supervisors. There are a number of Federal and State laws setting forth criminal penalties for abuses of privileged information, abuses of influence, and other abuses of public trust. Federal employees are required to make a declaration of any outside interests and to update it whenever such interests are acquired. The same should be required of State employees whose positions may produce possible conflicts of interest. Both CMS and the State are responsible for evaluating the need for preventive measures to protect the integrity of the certification program. When survey and certification work is performed by agencies other than CMS or the State, the State administrators and the sub-agency administrators have a shared responsibility for this surveillance.

In the case of States, it is not necessary to inform CMS of all potential conflict situations. However, if an overt abuse requires corrective action, the CMS RO must be informed.

9005.2 Conflicts of Interest

Section 488.735(b) sets out the circumstances that would disqualify a surveyor from surveying a particular HHA. A surveyor is prohibited from surveying an HHA if the surveyor currently works, or within the past two years has worked for the HHA to be surveyed. Specifically, the surveyor could not have been a direct employee, employment agency staff at the HHA, or an officer, consultant or agent for the surveyed HHA regarding compliance with CoPs. A surveyor

would also be prohibited from surveying an HHA if he or she has a financial interest or an ownership interest in that HHA. A financial interest is defined as salary, fees, commissions, honoraria, or any other source of income. The surveyor would also be disqualified if he or she has a family member who has a financial interest or ownership interest with the HHA to be surveyed or has an immediate family member who is a patient of the HHA to be surveyed. An immediate family member is defined in §488.301 as husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

9005.3 Examples of Potential Conflicts of Interest

CMS and the States must consider all relevant circumstances that may exist beyond the benchmarks given in this section to ensure that the integrity of the survey process is preserved. For example, a surveyor may not have worked for the agency to be surveyed for more than two years, but may have left the HHA under unpleasant circumstances, or, may not currently have an immediate family member who receives services from, but may have recently received services from the HHA who the surveyor considers to have received inadequate care.

The following are typical of situations that may raise a question of possible conflicts of interest for Federal or State employees; however, they do not necessarily constitute conflicts of interest:

i. Participation in ownership of an HHA located within the employing State;
ii. Service as a director or trustee of an HHA;
iii. Service on a utilization review committee for an HHA;
iv. Private acceptance of fees or payments from a health facility or group of health facilities or association of health facility officers for personal appearances, personal services, consultant services, contract services, referral services, or for furnishing supplies to a health facility;
v. Participation in a news service disseminating trade information to a segment of the health industry; and
vi. Having members of one's immediate family engaged in any of the above activities.

9005.4 Report and Investigation of Improper Acts

Any acts of employees in violation of Federal or State laws or regulations regarding conflicts of interest should be handled in accordance with applicable Federal or State procedures. In the case of State employees, conflicts of interest violations must be reported to the CMS RO, and the CMS RO must be kept advised of the corrective actions. States should ask for assistance or advice from CMS in the case of any impropriety involving a conflict of interest that cannot be handled immediately under an applicable State procedure. The regional office of the Inspector General, along with the CMS RO, will then work in close cooperation with the responsible State officials until the matter is resolved.

9006 Survey Protocol

9006.1 Introduction

Surveys conducted on a HHA must be based upon protocols developed, tested, and validated by the Secretary under section 1891(c)(2)(C)(ii) of the Act. Survey protocols are established to provide guidance to surveyors of HHAs. They serve to clarify and/or explain the intent of the regulations. The purpose of the protocols and guidelines is to direct the surveyor's attention to avenues of investigation in preparing for the survey, conducting the survey, and evaluating the survey findings. All surveyors are required to reference the protocols in assessing compliance with Federal requirements.

These protocols represent the policies of CMS on relevant issues that must be inspected or reviewed under each requirement. The use of these protocols promotes consistency in the survey process. The protocols assure that a HHA's compliance with the requirements is reviewed in a thorough, efficient, and consistent manner to produce sufficient information to make compliance decisions. The survey protocols are found in Appendix B of this manual.

9006.2 Types of Surveys

Sections 1891(c)(1)-(2) of the Act specify the requirements for types and frequency of surveys, identifying standard, and abbreviated standard, partial extended, and extended surveys. These surveys are generally defined in §488.705.

9006.3 Standard Survey

A standard survey is conducted not later than 36 months after the date of the previous standard survey, as is specified in section 1891(c)(2)(A) of the Act. A standard survey may also be conducted within 2 months of any change of ownership, administration, or management of the HHA to determine whether the change has resulted in any decline in the quality of care furnished by the HHA and it shall be conducted within 2 months of when a significant number of complaints have been reported as specified in section 1891 (c)(2)(B)(i) and (ii). Section 1891(c)(2)(C) of the Act requires that a standard survey, to the extent practicable, reviews a case-mix stratified sample of individuals to whom the HHA furnishes services. Actual visits to the homes of sampled patients must be conducted and a survey of the quality of services being provided as measured by indicators of medical, nursing, and rehabilitative care must be conducted. Minimum requirements for standard surveys are specified in §488.710.

Standard surveys are conducted for initial certifications and for re-certifications. During a standard survey, the surveyor reviews compliance with Level I standards as designated in the SOM Appendix B.

Deficiency findings of any Level I standard will trigger a partial extended survey. Deficiencies at the condition-level will trigger an extended survey.

9006.4 Initial Certification Surveys

All HHAs are required to successfully complete an initial standard survey before they can be certified as meeting the Medicare requirements. The initial Medicare certification survey begins as a standard survey. Before this initial Medicare survey takes place, the prospective HHA must send written documentation to the SA requesting an initial certification survey. Follow Appendix B - Guidance to Surveyors: Home Health Agencies for conducting initial certification surveys.

9006.5 Recertification of Participating Facilities

An HHA is subject to a recertification survey no later than 36 months from the previous recertification survey. All recertification surveys begin (and may end) as a standard survey, unless a problem is identified with a Level 1 standard as described in Appendix B of this manual. Each State must follow CMS instructions for survey frequency within this 36-month interval commensurate with the need to assure the delivery of quality home health services. Follow Appendix B - Guidance to Surveyors: Home Health Agencies for standard surveys.

9006.6 Post Survey Revisit (Follow-Up)

The SA follows up on all deficiencies cited in PoCs. In some cases, the cited deficiencies may be of a nature that a mail or telephone contact will suffice in lieu of an onsite visit (e.g., the HHA amended its written policies). A mail or telephone contact is acceptable as long as the SA has no reason to question the validity of the reported corrections. However, an onsite visit is generally required for deficiencies concerning quality of care.

If the SA has cited condition level deficiencies, they must conduct a post survey revisit to determine if the HHA now meets the CoPs.

At the time of the follow-up visit to verify corrections of deficiencies previously cited on Form CMS-2567 and/or when corrections are verifiable by telephone contact or mail, the SA completes Form CMS-2567B for the corrections that have been completed. The SA enters:

1. HHA identification information;
2. Date of the revisit or date of verification;
3. Data tag;
4. Corresponding regulatory reference cited on the original Form CMS-2567; and
5. Date the correction was accomplished.

If documentation or onsite verification is warranted, the SA obtains appropriate verification before reporting a deficiency as corrected. The revisit requires that the SA complete a Post-Certification Revisit Report (Form CMS-2567B).

If possible, the revisit is to be conducted by a member(s) of the survey team who cited the original findings. The SA has the completed form initialed by the reviewing official and signed

by the surveyor and retains the fourth copy for its provider file, mails a copy to the HHA, and forwards a copy to the RO or SMA, as appropriate.

If, at the time of the revisit, some deficiencies have not been corrected, follow the instructions at Section 2732B.

9006.7 Abbreviated Standard Survey

An abbreviated standard survey is limited in its scope and does not cover as many aspects of HHA operations and services as are covered in a standard, partial extended, or extended survey but rather concentrates on a particular area of concern(s). This survey focuses on particular tasks that relate, for example, to complaints received, or a change of ownership, management, or administration, or reapplying for Medicare billing privileges following a deactivation. The survey team (or surveyor) may investigate any area of concern and make a compliance decision regarding any regulatory requirement, whether or not it is related to the original purpose of the survey.

9006.7A Complaint Investigations

If the State's review of a complaint allegation(s) identifies possible non-compliance with one or more of the requirements and only a survey can determine whether a deficiency(ies) exist, an abbreviated standard survey will be conducted. During an abbreviated standard survey, the standards identified as being related to the allegations of noncompliance are reviewed. If a condition is found to be out of compliance during the survey, the surveyor should move into a partial extended or extended survey depending on the findings identified. Follow the guidelines in Chapter 5: Complaint Investigations and Appendix B of this manual.

If an accredited HHA is deemed to meet the requirements and a deficiency(ies) is found at the condition level during a complaint or validation survey, the RO will remove deemed status and oversight authority reverts back to the SA until the organization returns to substantial compliance with all requirements or is terminated. Once the HHA is in compliance, the RO will restore deemed status and turn oversight authority back to the AO.

For example, S&C-09-08 (Question V-4) provides for two processes:

1. If the SA finds condition-level noncompliance as a result of a full survey conducted on a representative sample basis and the RO agrees with this finding, the provider/supplier is: notified of the deficiencies via the CMS 2567 and also of the removal of its deemed status; placed under the jurisdiction of the SA; and, placed on track for termination of its provider agreement. The RO also notifies the provider's/supplier's AO of the removal of deemed status and that the facility has been placed on a termination track. CMS will terminate the provider agreement unless the provider/supplier submits an acceptable POC and the SA verifies through a revisit survey that the provider/supplier has come into compliance. The revisit survey focuses on the conditions that were previously deficient. The timeframe for coming into compliance depends on whether the deficiencies posed an immediate jeopardy to patient health and safety. If the provider/supplier fails to make

timely correction of its deficiencies, the RO terminates the provider agreement. If the provider/supplier has been determined to have achieved compliance, the RO notifies the provider/supplier that its deemed status has been reinstated.

2. If the SA finds condition-level noncompliance as a result of a validation survey based on a substantial allegation and the RO agrees with this finding, the provider/supplier is notified of the deficiencies via the CMS-2567 and also of the removal of its deemed status and placement under SA jurisdiction; the RO notifies the AO of its removal of deemed status.

9006.7B Substantial Changes in an HHA's Organization and Management

If an HHA notifies the SA of a change in organization or management, review the change to ensure compliance with the regulations. Request copies of the appropriate documents, e.g. written policies and procedures, personnel qualifications and agreements, etc., if they were not submitted with the notification. If changes in an HHA's organization and management are significant and raise questions of its continued substantial compliance, determine, through a survey, whether deficiencies have resulted. Collect information about changes in the HHA's organization and management on the "Medicare and other Federal Care Program General Enrollment," Form CMS-855A.

9006.8 Partial Extended Survey

The partial extended survey is conducted to determine if a deficiency (ies) and/or deficient practice exists at standard or condition levels in the CoPs that were not fully examined during the standard survey and there are indications that a more comprehensive review of the CoPs would determine if a deficient practice exists. The surveyors may review any additional standards or conditions which would assist in making a compliance decision. Partial extended surveys are also conducted when the surveyor's off-site preparation determines a concern. At that point there is not a determination of a deficient practice. For example, the surveyor may have a concern about the HHA's transmission of OASIS data and want to review that area during the survey.

During the partial extended survey, the surveyor reviews, at a minimum, the Level 2 standards under the same conditions which are related to the Level 1 standard(s) that are out of compliance. The surveyors may review any additional standard(s) under the same condition or other related or unrelated condition(s) which would assist in making a compliance decision. Follow the guidance in Appendix B of this manual.

9006.9 Extended Survey

The extended survey consists of a review of additional conditions of participation not reviewed during a standard survey. At a minimum, review any related conditions of participation or standards to the condition found to be deficient, as defined in Appendix B of the SOM. Extended surveys may be conducted at any time at the discretion of CMS or the SA, and must be conducted when any condition level deficiency is found. This survey also reviews the HHA's policies, procedures, and practices that produced the substandard care. An extended survey must

be conducted not later than 14 calendar days after the completion of a standard survey which found the HHA out of compliance.

9007 Survey Frequency

9007.1 Citation

Section 1891(c)(2) of the Act requires HHAs to be subject to a standard survey not later than every 36 months from the previous standard survey and the frequency of a standard survey to be commensurate with the need to assure the delivery of quality home health services. Surveys may be conducted as often as necessary to ascertain compliance or confirm correction of deficiencies.

9008 Unannounced Surveys

9008.1 Citation

Section 1891(c)(1) of the Act requires that standard surveys be unannounced. Moreover, under §488.725, all HHA surveys must be unannounced, including standard surveys, complaint surveys and onsite revisit surveys.

9008.2 Scheduling Requirements

The SA has the responsibility for keeping surveys unannounced and their timing unpredictable. This gives the SA greater ability to obtain valid information because it increases the probability that the surveys will observe conditions and care practices that are typically present. While the Act and implementing regulations in §488.725 require that standard surveys be unannounced, it is CMS's intention and expectation to not announce **any** type of HHA survey such as an abbreviated standard, complaint, or onsite revisit surveys. Therefore, if CMS conducts standard surveys or validation surveys, the CMS RO must follow the same procedures as required of the SA to not announce surveys.

9008.3 CMS Review of State Scheduling Procedures

Section 1891(c)(1) of the Act requires CMS to review State scheduling and survey procedures to ensure that the agency has taken all reasonable steps to avoid giving notice of impending surveys through these procedures. The CMS RO reviews annually each of its State's procedures for assuring that HHA surveys are not announced through the methods by which they are scheduled or conducted.

9008.4 Penalty for Announcing a Survey

Section 1891(c)(1)of the Act provides that any individual who notifies (or causes to be notified) an HHA of the time or date of the standard survey is subject to a civil money penalty not to exceed $2,000. Section 488.725 reflects these requirements.

If any individual has, in any way, given prior notification to a HHA of the date of a standard survey, the State or CMS is to contact the regional Office of the Inspector General and report the name of the individual and what has occurred. The Office of the Inspector General will further investigate and make a determination as to whether or not a Federal civil money penalty will be imposed. A civil money penalty of up to $2,000 may be imposed. The provisions of section 1128A of the Act, other than subsections (a) and (b), apply to civil money penalties. The imposition of a civil money penalty applies only when a standard survey is announced. See §1005 for policy developed by the Office of the Inspector General regarding administrative appeals of Federal civil money penalties.

9009 Informal Dispute Resolution (IDR)

9009.1 Introduction

Section 488.745 offers HHAs, upon their receipt of the official Form CMS-2567, the option to request an informal opportunity to dispute condition-level survey findings warranting a sanction. This IDR will occur with the agency who conducted the survey. A State does not need to create any new or additional processes if its existing process meets the requirements described in this section. The IDR process, as established by the State or CMS RO, must be in writing so that it is available for review upon request.

If the survey is conducted by the CMS RO, the RO may conduct the IDR.

CMS has adopted the following elements to be incorporated in all cases involving deficiencies cited as a result of Federal surveys. They are designed to clarify and expedite the resolution process. States are free to incorporate these elements into their procedures.

1. Notice to the HHA will indicate that the IDR, including any face-to-face meetings, constitutes an informal administrative process that in no way is to be construed as a formal evidentiary hearing.

2. Notice to the HHA will indicate that counsel may accompany the HHA. If the HHA chooses to be accompanied by counsel, then it must indicate that in its request for IDR, so that CMS may also have counsel present.

3. CMS will verbally advise the HHA of CMS's decision relative to the informal dispute, with written confirmation to follow.

9009.2 Purpose

IDR offers a HHA the opportunity to refute one or more condition level deficiencies cited by the State on the Form CMS-2567 Statement of Deficiencies. An HHA's initiation of the IDR process or failure of CMS or the State, as appropriate, to complete an IDR will not postpone or otherwise delay the effective date of any enforcement action.

9009.3 Mandatory Elements of IDR

Upon their receipt of the official Form CMS-2567, agencies must be offered one informal opportunity, if they request it in writing, to dispute condition level deficiencies. Deficiencies cited at the standard level are not subject to the IDR process.

The following elements must be included in each IDR process offered:

1. Agencies may not use the IDR process to delay the formal imposition of sanctions or to challenge any other aspect of the survey process, including:

- The severity assessment of a deficiency(ies) at the standard level that constitutes substandard care or immediate jeopardy;
- Sanctions imposed by the enforcing agency;
- Alleged failure of the survey team to comply with a requirement of the survey process;
- Alleged inconsistency of the survey team in citing deficiencies among agencies;
- Alleged inadequacy or inaccuracy of the IDR process.

2. HHAs must be notified of the availability of IDR in the letter transmitting the official Form CMS-2567. (See Exhibit 139 in this manual for transmission of Form CMS-2567.) The letter should inform the agency of the following:

- It may request the opportunity for IDR, and that if it requests the opportunity, the request must be submitted in writing.
- The written request must include an explanation of the specific deficiencies that are being disputed.
- The written request must be made within the same 10 calendar day period the HHA has for submitting an acceptable plan of correction to the surveying entity;
- The name and address, e-mail and phone number of the person to contact in order to request the IDR;
- The IDR process that is followed in that State, e.g., telephone conference, written communication, or face-to-face meeting.
- The name and/or position title of the person who will be conducting the IDR, if known.

NOTE: IDR is a process in which State agency officials make determinations of noncompliance. SAs should be aware that CMS holds them accountable for the legitimacy of the process including the accuracy and reliability of conclusions that are drawn with respect to survey findings. This means that while the SA may have the option to involve outside persons or entities they believe to be qualified to participate in this process, it is the SA, not outside individuals or entities that are responsible for IDR decisions. When an outside entity conducts IDR, the results of the IDR process may serve only as a recommendation of noncompliance or compliance to the SA. The SA will then make the IDR decision and notify the HHA of that decision. CMS will look to the SA to assure the viability of these decision-making processes, and holds the SA accountable for them.

Since CMS has ultimate oversight responsibility relative to a SA's performance, it may be appropriate for CMS to examine specific IDR decisions or the overall IDR process to determine whether the decision is consistent with CMS policy. For dually participating or Medicare-only agencies, informal dispute findings are in the manner of recommendations to CMS and, if CMS has reason to disagree with those findings, it may reject the conclusions from IDR and make its own binding determinations of noncompliance.

3. Failure to complete IDR timely will not delay the effective date of any enforcement action against the agency.

4. When an HHA is unsuccessful during the process at demonstrating that a deficiency should not have been cited, the SA must notify the agency in writing that it was unsuccessful.

5. When an HHA is successful during the IDR process at demonstrating that a deficiency should not have been cited or should be revised:

- The deficiency citation should be marked "deleted," or "revised" as appropriate, and signed and dated by a supervisor of the surveying entity; and
- Any enforcement action(s) imposed solely because of that deleted or revised deficiency citation should be rescinded.

NOTE: The HHA has the option to request a clean (new) copy of the Form CMS-2567. However, the clean copy will be the releasable copy only when a clean (new) plan of correction is both provided and signed by the agency. The original Form CMS-2567 is disclosable when a clean plan of correction is not submitted and signed by the agency. Deficiencies pending IDR should be entered into AEM but will not be uploaded to the Certification and Survey Provider Enhanced Reporting system (CASPER) until IDR has been completed.

6. An agency may request IDR for each survey that cites condition-level deficiencies. However, if IDR is requested for deficiencies cited at a subsequent survey, an HHA may not challenge the survey findings of a previous survey for which the HHA either received IDR or had an opportunity for it. Condition-level deficiencies that are not corrected and that are carried forward on a subsequent survey are not eligible for the IDR process. Condition-level deficiencies identified on a subsequent survey that are new are eligible to be reviewed through the IDR process.

Enforcement Process

9010 Alternative Sanctions for Home Health Agencies

9010.1 Statutory Basis

Sections 1891(e)-(f) of the Act authorizes the Secretary to utilize varying enforcement mechanisms to terminate participation and to impose alternative sanctions if HHAs are found out of compliance with the Medicare home health conditions of participation. Prior to the implementation of alternative sanctions, the only sanction that CMS used for enforcement actions of HHAs that were not meeting the participation requirements was termination within 90 days. The imposition of alternative sanctions specified in §488.805 would allow for noncompliant HHAs to have additional time to come into compliance with the CoPs before being terminated.

9010.2 General Provisions

Under section 1891(e)(1) of the Act, if CMS or a SA determines that the HHA's condition-level deficiencies immediately jeopardize the health or safety of its patients, then CMS must take immediate action to notify the HHA of the jeopardy situation and the HHA must correct the deficiencies. If the IJ is not removed because the HHA is unable or unwilling to correct the deficiencies, CMS will terminate the HHA's provider agreement. In addition, CMS may impose one or more specified alternative sanctions, including but not limited to civil money penalties and suspension of all Medicare payments before the effective date of termination. These provisions are incorporated in §488.810. The purpose of enforcement sanctions is to ensure prompt compliance with program requirements in order to protect the health and safety of individuals under the care of an HHA.

Sections 1891(e)(1) and (2) of the Act provide that if CMS finds that an HHA is not in compliance with the Medicare home health CoPs and the deficiencies involved do not immediately jeopardize the health and safety of the individuals to whom the agency furnishes items and services, CMS may terminate the provider agreement, impose an alternative sanction(s), or both. While section 1891(e)(2) of the Act provides for termination of the HHA's provider agreement as an enforcement option in non-immediate jeopardy situations, CMS provides incentives for HHAs to achieve and maintain full compliance with the participation requirements before termination becomes necessary.

The decision to impose one or more sanctions would be based on condition-level deficiencies or repeat deficiencies found in an HHA during a survey. Determinations on deficiencies would not be limited to findings from the mandated surveys specified in the statute or the regulations. Rather, deficiency findings that are based on other reporting or evaluative programs, procedures, or mechanisms, such as OASIS reporting and validated complaints, would be sufficient to determine whether Medicare requirements are met.

Survey agencies should make a recommendation to the RO on which sanction(s) may be effective in prompting the HHA to return to compliance. The RO considers the SA's recommendations and makes a determination to agree with or impose a different sanction(s) for the HHA.

9010.3 Effect of Sanctions on HHAs that participate in Medicare via Deemed Status through an Accrediting Organization

HHAs can acquire certification for participation in Medicare via a SA survey or via deemed status through a CMS-approved AO. Deemed status through a CMS-approved AO is voluntary and not necessary to participate in Medicare. Deemed status HHAs remain under the jurisdiction of their AO rather than SAs for oversight of their ongoing compliance with health and safety standards, unless SAs conducting a validation survey at the direction of CMS find evidence of serious noncompliance. In such case, the HHA is placed under the jurisdiction of the SA.

A deemed HHA loses its deemed status when a condition-level finding is cited on a complaint or validation survey. When a condition-level deficiency (ies) is found, the RO returns oversight of the accredited HHA back to the SA until the HHA can demonstrate compliance with the CoPs. During the time that the SA has jurisdiction over the HHA, the SA, not the AO, will follow the procedures for recommending the imposition of sanctions, if appropriate. Once the HHA returns to compliance with the Medicare conditions and has not been terminated, the RO will restore its deemed status and return oversight to the AO.

In accordance with 42 CFR 488.7, CMS may require a survey of an accredited HHA to validate the AO's accreditation process. There are two types of validation surveys:

- Surveys conducted on a representative sample basis, which may be either comprehensive surveys of all Medicare conditions or focused surveys on a specific condition or conditions; or

- Surveys in response to a "substantial allegation" – generally a complaint. These surveys focus on those Medicare conditions related to the allegations.

SAs conduct validation surveys of accredited providers/suppliers only when they are specifically authorized to do so by the RO. In the case of representative sample surveys, CMS selects the providers/suppliers to be surveyed and the RO assigns the SA to conduct the validation survey within 60 days of the AO survey. In the case of substantial allegations, most complaints are received by the SA, which then forwards to the RO complaints that they believe make substantial allegations of noncompliance with Medicare conditions. The RO reviews the complaint and determines whether it will authorize the SA to conduct a survey, and also determines which conditions the SA should focus its survey on. CMS also receives complaints directly. Information raising substantial allegations of noncompliance may also come to CMS' attention via means other than complaints, such as press reports. In such cases the RO reviews the information and makes a determination as to whether the SA should conduct a validation survey, and of which conditions. (See Section 5100 of the SOM for more details about procedures for substantial allegation surveys of accredited, deemed providers/suppliers).

9010.4 Effect of Sanctions on HHA Branches

An HHA's branch office is part of the HHA and is located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the branch independently to meet the conditions of participation as an HHA. An HHA's branch location may be included in, or be the focus of, the unannounced standard survey of a parent HHA, and any deficiencies found at a branch of the HHA will apply to the entire HHA. Therefore,

regardless of whether the deficiency or deficient practice is identified at the branch or the parent location, all sanctions imposed would apply to the parent HHA and its respective branches. For example, if a deficient practice is found in one branch of an HHA and CMS imposes sanctions, the sanctions would apply to the parent and all branch offices that are affiliated with that HHA. However, these sanctions would not apply to any non-branch subunit that was associated with an HHA since a subunit is independently required to meet the CoPs for HHAs. Such subunit instead could have sanctions imposed on it based on deficient practices found at that subunit. For HHAs that operate branch offices in multiple states, CMS would base enforcement decisions on surveys conducted by the State in which the parent office is located.

Definitions for "parent HHA," "branch office," and "subunit" are found at 42 CFR 484.2. See also section 2182 for additional information on parent, branch and subunit.

9010.5 Available Sanctions

In accordance with §488.820, the following sanctions in addition to termination of the provider agreement are available:

- Civil money penalties;
- Suspension of payment for all new admissions;
- Temporary management of the HHA;
- Directed plan of correction; and
- Directed in-service training.

9010.6 Factors to be considered in selecting sanctions

Consistent with section 1891(f)(3) of the Act, procedures for selecting the appropriate sanction, including the amount of any fines and the severity of each sanction have been designed to minimize the time between the identification of deficiencies and the final imposition of sanctions.

In order to select the appropriate sanction(s) for an agency's noncompliance, the seriousness of the deficiencies must first be assessed and the determination made as to whether the deficiencies pose immediate jeopardy to patient health and safety. The factors CMS considers include:

I. The extent to which the deficiencies pose immediate jeopardy to patient health and safety.
II. The nature, incidence, manner, degree, and duration of the deficiencies or non-compliance.
III. The presence of repeat deficiencies, the HHA's overall compliance history and any history of repeat deficiencies at either the parent or branch location.
IV. The extent to which the deficiencies are directly related to a failure to provide quality patient care.
V. The extent to which the HHA is part of a larger organization with performance problems.
VI. An indication of any system-wide failure to provide quality care.

In addition, CMS reviews other factors including but not limited to the history of the HHA's compliance with the CoPs, specifically with reference to the cited deficiencies.

9011 Action when deficiencies pose immediate jeopardy.

9011.1 Statutory and Regulatory Basis

Sections 1891(e)(1) of the Act and §488.825 provide how situations involving immediate jeopardy will be processed. In addition, Appendix Q of this manual discusses immediate jeopardy.

9011.2 Purpose

Immediate action is required to remove the immediate jeopardy to patient health or safety and to subsequently correct the deficiencies. Termination is required to address immediate jeopardy situations and occurs within 23 days if the immediate jeopardy is not removed. CMS may also choose to impose alternative sanctions in addition to termination. While the use of alternative sanctions in addition to termination is permitted, the Act makes it clear that the enforcement action for noncompliant agencies with immediate jeopardy deficiencies is intended to be swift. The imposition of alternative sanctions in addition to termination would not extend the timeframe that the HHA has to abate the immediate jeopardy situation.

9012 Enforcement Action When Immediate Jeopardy Exists

When the State identifies immediate jeopardy to patient health or safety, the State must notify the RO and follow the procedures in Appendix Q of this manual. When immediate jeopardy exists, the HHA's provider agreement is immediately terminated in accordance with§489.53 and §488.825. In addition to termination, one or more alternative sanctions may be imposed.

9013 Action When Deficiencies are Condition-level But Do Not Pose Immediate Jeopardy.

If the HHA is no longer in compliance with the CoPs, either because the deficiency(ies) substantially limit the HHA's capacity to furnish adequate care but do not pose immediate jeopardy, or because the HHA has repeat noncompliance that results in a condition level deficiency based on the HHA's failure to correct and sustain compliance, CMS will either terminate the provider agreement following the 90 day termination track or impose one or more alternative sanctions as an alternative to termination. If alternative sanctions are imposed, CMS terminates the HHA's provider agreement within 6 months of the last day of the survey if the HHA is not in substantial compliance with the CoPs and the condition level deficiencies are not corrected.

9014 Guidance for Individual Sanctions

The following sections describe each possible alternative sanction and procedures for imposing them. In addition, the CMS RO and SA follow the procedures in Chapter 3 of the SOM if an adverse action is likely to be initiated against a Medicare participating provider.

9015 Temporary Management

9015.1 Introduction

This sanction is established pursuant to §1891 of the Act and §488.835.CMS may choose to impose temporary management in situations where the failure to comply with the CoPs is directly related to poor management or lack of management such that it is likely to impair the HHA's ability to correct deficiencies and return the agency to full compliance within the necessary timeframe.

9015.2 Purpose

A temporary manager may be imposed if it is determined that an agency is not in substantial compliance. The maximum period for use of the temporary manager is six months. It is the temporary manager's responsibility to oversee correction of the deficiencies and assure the health and safety of the agency's patients while the corrections are being made. A temporary manager may also be imposed to oversee orderly closure of an agency including the proper and safe transfer of patients to another local HHA.

9015.3 Authority of Temporary Manager

A temporary manager has the authority to hire, terminate, or reassign staff; obligate agency funds; alter agency policies and procedures; and otherwise manage an agency to correct deficiencies identified in the agency's operation.

9015.4 Selection of Temporary Manager

Each SA should compile a list of individuals who are eligible to serve as temporary managers. When CMS decides to impose this sanction, it considers the SA's recommendation for a temporary manager whose work experience and education qualify the individual to oversee the correction of deficiencies to achieve substantial compliance. The temporary management will not exceed a period of six months.

The SA should reject a candidate who has demonstrated difficulty maintaining compliance in the past.

9015.5 Conditions of Temporary Management

CMS notifies the HHA that a temporary manager is being appointed. The HHA's management must agree to relinquish authority and control to the temporary manager and to pay his/her salary before the temporary manager can be installed in the HHA. A contract or memorandum of understanding should be completed between the temporary manager and the HHA prior to the temporary manager beginning any work or incurring any costs. Failure to relinquish authority and control to the temporary manager will result in termination of the HHA.

The HHA cannot retain final authority to approve changes of personnel or expenditures of HHA funds and be considered to have relinquished control to the temporary manager. The temporary manager must be given access to all HHA bank accounts. If the HHA does not relinquish control to the temporary manager and/or provide access to bank accounts and available assets, the HHA will be terminated. It should be noted that the HHA's governing body remains ultimately responsible for achieving compliance. The responsibility does not transfer to the temporary manager, SA, or CMS.

The temporary manager's salary must be at least equivalent to the prevailing annual salary of HHA administrators in the HHA's geographic area (Geographic Guide by the Department of Labor, BLS Wage Data by Area and Occupation), plus any additional costs that would have reasonably been incurred by the HHA if the temporary manager had been in an employment relationship, e.g., the cost of a benefits package, prorated for the amount of time that the temporary manager spends in the HHA. The HHA is also responsible for any other costs incurred by the temporary manager in furnishing services under such an arrangement or as otherwise set by the State. Failure to pay the salary and other costs is considered a failure to relinquish authority and control to temporary management.

9015.6 Orienting and Supervising Temporary Manager

The State should provide the temporary manager with an appropriate orientation that includes a review of the HHA's deficiencies and compliance history. The State may request that the temporary manager periodically report on the actions taken to achieve compliance and on the expenditures associated with these actions.

9015.7 Notice of Imposition of Temporary Management

A temporary manager may be imposed 15 calendar days after the HHA receives notice in non-immediate jeopardy situations and 2 calendar days after the HHA receives notice in immediate jeopardy situations.

9015.8 Duration of Temporary Management

Temporary management continues until a HHA is terminated, or achieves substantial compliance and is capable of remaining in substantial compliance, or decides to discontinue the sanction and reassume management control before it has achieved substantial compliance. If the HHA reassumes control before achieving substantial compliance, CMS would initiate termination of the provider agreement and could impose additional sanctions during the time period between HHA resumption of management and termination. Temporary management will not exceed six months from the date of the survey identifying noncompliance.

9016 Suspension of Payment for All New Medicare Admissions

9016.1 Introduction

Sections 1891(f)(2)(A)(ii) of the Act and §488.840 provide for the suspension of payment for all new Medicare admissions when a HHA is not in substantial compliance, regardless of whether cited deficiencies pose immediate jeopardy to patient health and safety. This suspension of payment for new admissions may be imposed alone or in combination with other sanctions to encourage prompt compliance.

9016.2 Notice of Sanction

Suspension of payment for new admissions may be imposed anytime a HHA is found to be out of substantial compliance, as long as the HHA is given written notice at least 2 calendar days before the effective date in immediate jeopardy situations and at least 15 calendar days before the effective date in non-immediate jeopardy situations. The notice of suspension of payment for new admissions must include the following: the nature of the non-compliance; the effective date of the sanction; and the right to appeal the determination leading to the sanction. In addition to notifying the HHA of this proposed sanction, CMS will also notify the State Medicaid Agency if the HHA is dually certified.

9016.3 Effect of Sanction on Patients Admitted before the Effective Date of Sanction

The patient's status on the effective date of the suspension of payment sanction is the controlling factor. This sanction would not apply to patients who have been receiving care from the HHA before the effective date of this sanction. This sanction would apply only to new Medicare admissions. CMS will suspend payments for new Medicare patient admissions to the HHA that are made on or after the effective date of the imposition of the sanction for the duration of the sanction. Payments for individuals who are already receiving services could continue. In accordance with §488.805, CMS define a "new admission" as the following:

- A patient who is admitted to the HHA under Medicare on or after the effective date of a suspension of payment sanction; or
- A patient who was admitted and discharged before the effective date of the suspension of payment and is readmitted under Medicare on or after the effective date of suspension of payment sanction.

As part of this sanction, the HHA would be required to notify any new patient admission, before care is initiated, of the fact that Medicare payment would not be available to this HHA because of the imposed suspension. The HHA would be precluded from charging the Medicare patient for those services unless it could show that, before initiating the care, it had notified the patient or representative both orally and in writing in a language that the patient or representative can understand that Medicare payment is not available.

The suspension of payment sanction will end when CMS finds that the HHA is in substantial compliance with all of the CoPs or when the HHA is terminated. That is, the suspension of payment sanction would end when the HHA has corrected all condition-level deficiencies. Any Medicare patients admitted during the suspension of payment time period would require a new

start of care (SOC) date after the suspension of payment for new admissions has ended. This is required for the HHA to begin receiving payments for those patients.

9016.4 Duration

The suspension of payment would end when CMS terminates the provider agreement or when CMS finds, in accordance with section 1891(f)(2)(C) of the Act and §488.840(c), the HHA to be in substantial compliance with all of the CoPs. If CMS terminates the provider agreement or determines that the HHA is in substantial compliance with the CoPs, the HHA would not be able to recoup any payments for services provided to Medicare patients admitted during the time the suspension was in place.

Generally, if the HHA achieves substantial compliance and it is verified by CMS, CMS will resume payments to the HHA prospectively from the date it determines that substantial compliance was achieved. No payments are made to reimburse the HHA for the period of time between the date the sanction was imposed and the date that substantial compliance was achieved. CMS accomplishes the suspension of payment sanction through written instructions to the appropriate Medicare Administrative Contractor (MAC). The RO will send the letter with instructions to the MAC.

9017 Civil Money Penalties

9017.1 Basis for Imposing Civil Money Penalties

Under sections 1891(e) and 1891(f)(2)(A)(i) of the Act and §488.845, CMS may impose a civil money penalty against an HHA that is determined to be out of compliance with one or more CoPs, regardless of whether the HHA's deficiencies pose immediate jeopardy to patient health and safety. CMS may impose a civil money penalty for the number of days that a HHA is not in substantial compliance with one or more CoPs, or for each instance that a HHA is not in substantial compliance. The civil money penalty amount cannot exceed $10,000 for each day of non-compliance.

CMS defines "per instance" in §488.805 as a single event of noncompliance identified and corrected during a survey, for which the statute authorizes CMS to impose a sanction. While there may be a single event which leads to noncompliance, there can also be more than one instance of noncompliance identified and more than one civil money penalty imposed during a survey. For penalties imposed per instance of noncompliance, CMS has established penalties from $500 to $10,000 per instance. The sum of all penalties cannot exceed $10,000 per day. Such penalties would be assessed for one or more singular events of condition-level noncompliance that were identified at the survey and where the noncompliance was corrected during the onsite survey. Since the range of possible deficiencies is great and depends upon the specific circumstances at a particular time, it would be impossible to assign a specific monetary amount for each type of noncompliance that could be found. SAs and ROs may use the chart found in section 9020 of this chapter for guidance in determining a per instance amount.

A per-day and a per instance civil money penalty cannot be used simultaneously for the same deficiency. However, both types of civil money penalties may be used during a noncompliance cycle if more than one survey takes place and the per day penalty was not the civil money penalty initially imposed.

9017.2 Determining Amount of Civil Money Penalty

In determining the amount of the civil money penalty, CMS considers certain factors in addition to those listed in §488.815 which include:

- The size of the agency and its resources.
- Accurate and credible resources such as PECOS and Medicare cost reports and claims information, that provide information on the operations and the resources of the HHA.
- Evidence that the HHA has a built-in, self-regulating quality assessment and performance improvement system to provide proper care, prevent poor outcomes, control patient injury, enhance quality, promote safety, and avoid risks to patients on a sustainable basis that indicates the ability to meet the conditions of participation and to ensure patient health and safety.

When several instances of noncompliance are identified at a survey, more than one per-day or per-instance civil money penalty could be imposed as long as the total civil money penalty did not exceed $10,000 per day.

The regional office consults with the regional attorney's office to ensure compliance with section 1128A of the Act and Department of Justice requirements. Section 1128A of the Act requires CMS to offer a hearing before collecting, but not before imposing, a civil money penalty.

9017.3 Adjustments to penalties

CMS has the discretion to increase or reduce the amount of the civil money penalty during the period of noncompliance depending on whether the level of noncompliance changed at the time of a revisit survey.

CMS may increase a civil money penalty based on the following:

- The HHA's inability or unwillingness to correct deficiencies;
- The presence of a system-wide failure in the provision of quality care; or
- A determination of immediate jeopardy with actual harm versus immediate jeopardy with potential for harm.

CMS may decrease a civil money penalty to the extent that it finds, pursuant to a revisit, that substantial and sustainable improvements have been implemented even though the HHA is not yet in full compliance with the conditions of participation.

No penalty assessment shall exceed $10,000 for each day of noncompliance.

9018 Range of Penalty Amounts

9018.1 Upper range of penalty

Penalties in the upper range of $8,500 to $10,000 per day of noncompliance are imposed for a condition-level deficiency that is immediate jeopardy. The penalty in this range will continue until compliance can be determined. In the event of noncompliance with the CoPs, a "credible allegation of compliance" is required before a revisit is conducted. Once the credible allegation of compliance has been received, the SA will conduct a revisit. If the HHA makes an additional credible allegation that the deficiency(ies) is corrected following an earlier revisit or between the 46th and 90th calendar day prior to the effective date of termination, the RO must be notified by telephone. The SA submits all evidence or documentation regarding the HHA's allegation and its recommendation regarding the HHA's alleged compliance. The RO makes a determination whether a second revisit is appropriate. (See §3016A.)
During the revisit survey, the SA will determine if the immediate jeopardy situation has been abated. If the immediate jeopardy situation has been abated, but condition level deficiencies still exist, the penalty amount may be decreased to the middle or lower range of penalties based on the deficiency. The civil money penalty ranges are set forth in §§488.845(b)(3)(i),(ii), and (iii) and are as follows:

a. $10,000 per day for a deficiency or deficiencies that is determined to be immediate jeopardy and that results in actual harm;

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b. $9,000 per day for a deficiency or deficiencies that is determined to be immediate jeopardy and that result in a potential for harm; and

c. $8,500 per day for an isolated incident of noncompliance that is in violation of established HHA policies and procedures

Note: The following examples contain findings that could become a part of an HHA's immediate jeopardy citation. Please note that the citation of immediate jeopardy is only made after careful investigation of all relevant factors as detailed in Appendix Q. An IJ decision requires a determination that the situation meets all required IJ components.

1. The SA considers recommending a $10,000 per day civil money penalty for a deficiency or deficiencies that is determined to be immediate jeopardy and that results in actual harm. **Examples:** HHA fails to report to physician episodes of severe hyperglycemia, resulting in ketoacidosis and hospitalization of diabetic patient; HHA fails to timely and accurately assess a patient's pressure ulcers, which deteriorate to Stage 4 and sepsis prior to their recognition.

2. The SA considers recommending a $9,000 per day civil money penalty for a deficiency or deficiencies that is determined to be immediate jeopardy and that result in a potential for harm. **Examples:** HHA fails to intervene after patient verbal threats of suicide, resulting in potential for self-harm; HHA fails to administer ordered intravenous antibiotic to patient with diagnosed infection, resulting in potential for development of sepsis

3. The SA considers recommending $8,500 per day for an isolated incident of noncompliance that is in violation of established HHA policies and procedures. **Example:** One of the HHA's nurses did not follow the HHA's infection control policies and procedures when performing wound care. Patient developed infection which could not be controlled at home and hospitalization was needed.

9018.2 Middle range of penalty

Civil money penalties imposed in the range of $1,500 to $8,500 per day of noncompliance are imposed for a repeat and/or condition-level deficiency that does not constitute immediate jeopardy, but is directly related to poor quality patient care outcomes.

9018.3 Lower range of penalty

Civil money penalties in the range of $500 to $4,000 per day of non-compliance are imposed for a repeat and/or condition-level deficiency that does not constitute immediate jeopardy and that is related predominately to structure or process-oriented conditions (such as OASIS submission requirements) rather than directly related to patient care outcomes.

9018.4 Per instance civil money penalty

Penalties imposed per instance of noncompliance may be assessed for one or more singular events or instances of condition-level noncompliance that are identified and where the noncompliance was corrected during the onsite survey. The terminology "per instance" is not used to suggest that only one instance of noncompliance may be the basis to assess a civil money penalty. There can be more than one instance of noncompliance identified during a survey. When penalties are imposed for per instance of noncompliance, or for multiple instances of noncompliance, the penalties will be in the range of $500 to $10,000 per instance, and will not exceed a total of $10,000 for each day of noncompliance.

9018.5 Decreased penalty amounts

If a penalty was imposed in the upper range and the immediate jeopardy is removed or abated but the HHA continues to have condition-level noncompliance that is not immediate jeopardy, CMS will shift the penalty amount imposed per day from the upper range to the middle or lower range based on the conditions that are out of compliance. SAs and ROs should follow the same guidelines above to determine new penalty amount. An earnest effort to correct any systemic causes of deficiencies and sustain improvement must be evident.

9018.6 Increased penalty amounts

Following the imposition of a lower level penalty amount (either the middle range or the lower range), CMS may increase the per day penalty amount for any condition-level deficiency or deficiencies which become sufficiently serious to pose potential harm or immediate jeopardy.

CMS increases the per day penalty amount for deficiencies that are not corrected and found again at the time of revisit survey(s) for which a lower level penalty was imposed.

For repeated noncompliance with the same condition-level deficiency or for uncorrected deficiencies from a prior survey, CMS may impose an increased civil money penalty amount .

9018.7 Considerations in determining the penalty amount

SAs and ROs should review all applicable findings and consider the factors in §488.845 in determining the final amount of the CMP to be imposed.

9019 Suggested Penalty Amounts

9019.1 Upper Range Civil Money Penalties for Immediate Jeopardy Citations

Immediate Jeopardy – results in harm	$10,000
Immediate Jeopardy – results in a potential for harm	$9,000
Immediate Jeopardy – isolated event of non-compliance in violation of an established HHA policy	$8,500

9019.2 Middle Range Penalties for Non-Immediate Jeopardy Citations

	Amount imposed in Recertification Survey	1st Revisit Survey	2nd Revisit Survey
Repeat Deficiency related to direct patient care. Consider citing for the following conditions: **§484.18** Acceptance of patients, plan of care, and medical supervision **§484.30** Skilled Nursing Services	$5,000 - $6,000	$6,000 - $7,000	$8,500

§484.32 Therapy Services **§484.34** Medical Social Services **§484.36** Home Health Aide Services **§484.38** Qualifying to Furnish Outpatient Physical Therapy or Speech Pathology Services **§484.55** Comprehensive Assessment of Patients			
Initial Citation related to direct patient care. Consider citing for the following conditions: **§484.18** Acceptance of patients, plan of care, and medical supervision **§484.30** Skilled Nursing Services **§484.32** Therapy Services **§484.34** Medical Social Services **§484.36** Home Health Aide Services **§484.38** Qualifying to Furnish Outpatient Physical Therapy or Speech Pathology Services **§484.55** Comprehensive Assessment of Patients	$2,000 -$3,000	$3,000 - $4,000	$5,500
Citation for structure or process deficiencies. Consider citing for the following conditions: **§484.10** Patient Rights **§484.12** Compliance with federal, state, and local laws, disclosure and ownership information, and accepted professional standards and principles. **§484.14** Organization, services, and	$1,500 - $2000	$2,000 - $3,000	$3,500

administration **§484.48** Clinical records			

9019.3 Lower Range Penalties for Structure and Process Citations Not Directly Related to Patient Care

	Amount imposed in Recertification Survey	1st Revisit Survey	2nd Revisit Survey
Repeat Deficiency related to structure or process deficiencies. Consider citing for the following conditions: **§484.11** Release of patient identifiable OASIS information **§484.16** Group of professional personnel **§484.20** Reporting OASIS information **§484.52** Evaluation of the agency's program	$2,000	$3,000	$4,000
Initial Citations of structure or process deficiencies. Consider imposing for deficiencies related to CoPs: **§484.11** Release of patient identifiable OASIS information **§484.16** Group of professional personnel **§484.20** Reporting OASIS information **§484.52** Evaluation of the agency's program	$500 - $800	$800 - $1,000	$1,500

9020 Procedures

9020.1 Notice of imposition of civil money penalty

If CMS or the SA imposes a civil money penalty, it provides the HHA with written notice of the intent to impose the sanction, including the amount of the civil money penalty being imposed, the basis for such imposition and the proposed effective date of the sanction. The notice includes:

I. The nature of the noncompliance (regulatory requirements not met);
II. The statutory basis for the civil money penalty;
III. The amount of the penalty per day of noncompliance or the amount of the penalty per instance of noncompliance during a survey;
IV. The factors that were considered in determining the amount of the civil money penalty;
V. The date on which the per day civil money penalty begins to accrue;
VI. A statement that the per day civil money penalty will accrue until substantial compliance is achieved or until termination from participation in the program occurs.
VII. When the civil money penalty is collected;
VIII. Instructions for responding to the notice, including a statement of the HHA's right to a hearing and information about how to request a hearing;
IX. Implications of waiving the right to a hearing and information about how to waive the right to a hearing (see §9021.4 below).

9020.2 Sending the Notice

The notice shall be in writing and shall be addressed directly to the HHA; or to an individual, an officer, managing or general agent, or other agent authorized by appointment or law to receive the notice.

The notice shall be dispatched through first-class mail, or other reliable means. Other reliable means refers to the use of alternatives to the United States mail in sending notices. Electronic communication, such as facsimile transmission or email, is equally reliable and on occasion more convenient than the United States mail. If electronic means are employed to send notice, the sender should maintain a record of the transmission to assure proof of transmission if receipt is denied.

9020.3 Appeal of Noncompliance That Led to Imposition of Civil Money Penalty

Before collecting a civil money penalty, section 1128A of the Act requires the Secretary (CMS) to conduct a hearing for an HHA that properly requests. An HHA may request a hearing with the Administrative Law Judge (ALJ) on the determination of the noncompliance that is the basis for imposition of the civil money penalty. The procedures to request a hearing specified in 42 C.F.R. §498.40 are followed when CMS imposes a civil money penalty on an HHA. Once an appeal hearing is requested, CMS cannot collect the CMP until a final agency determination.

9020.4 HHA Waives Right to a hearing

An HHA may waive the right to a hearing, in writing, within 60 days from the date of the notice imposing the civil money penalty. If an HHA timely waives its right to an appeal hearing within 60 calendar days of their receipt of CMS' notice imposing the civil money penalty, CMS will

approve the waiver and reduce the CMP by thirty five percent (35%). Payment of the reduced CMP must be made within 15 days of the HHA's receipt of CMS's notice approving the waiver and reducing the CMP. If the HHA does not waive its right to an appeal hearing in writing within 60 calendar days of their receipt of CMS original request for payment under §488.845(c)(2)(ii), it will not receive the CMP reduction.

NOTE: Each time a survey is conducted within an already running noncompliance cycle and a civil money penalty is imposed, the HHA is given appeal rights and may exercise its waiver of right to a hearing.

When a per day civil money penalty is imposed and then is increased or decreased at subsequent surveys during an already running noncompliance cycle, an HHA may elect to either appeal each separate imposition of civil money penalty or waive the right to appeal each imposition. Each civil money penalty imposition is computed separately for a set number of days. The final civil money penalty amount is established after the final administrative decision.

Example: An HHA is cited on the original recertification survey for non-compliance with 42 CFR 484.18, Acceptance of patients, plan of care, medical supervision. Findings include evidence that the HHA did not follow the plan of care (G158), the plan of care did not include all pertinent diagnoses (G159) and the HHA failed to notify the physician of changes in the patient's condition (G164). On the first revisit survey, the incidence of these deficiencies increased. On both surveys, the condition is cited as out of compliance and CMPs are imposed. The CMP will be increased following the revisit survey. The HHA may choose to appeal one or both of the citations, or waive one or both citations, or waive one citation and appeal the other.

When several per instance civil money penalties are imposed during a noncompliance cycle, an HHA may choose to appeal or waive the right to appeal one or more of the civil money penalties, in the same manner as illustrated above for the per day civil money penalties.
After the facility achieves substantial compliance or its provider agreement is terminated, it is notified of the revised civil money penalty amount due.

9020.5 Accrual and duration of per day penalty

The per-day civil money penalty would begin to accrue on the last day of the survey that identified the noncompliance and would continue to accrue until the HHA achieves substantial compliance with all requirements or the date of termination, whichever occurs first.

9020.6 Amount of per instance penalty

A civil money penalty is imposed for each instance of noncompliance based on a deficiency(ies) during a specific survey. It is applied to as many instances as is deemed appropriate and in a specific amount for that particular deficiency(ies), with an amount not to exceed $10,000 each day.

Note: The per-day and per-instance CMP would not be imposed simultaneously for the same CoPs in a survey. In no instance will the period of noncompliance be allowed to extend beyond

6 months from the last day of the original survey that determined the HHA's noncompliance. If the HHA has not achieved substantial compliance with all the participation requirements within those 6 months, CMS will terminate the HHA. The accrual of the per day CMP stops on the day the HHA's provider agreement is terminated or the HHA achieves substantial compliance, whichever is earlier.

Example: When the per instance civil money penalty is used on the original survey, the revisit is considered another survey to determine compliance. If noncompliance is identified at the revisit and a civil money penalty is selected as the enforcement response, either the per instance or per day remedy may be selected.

9020.7 Duration of Civil Money Penalty

The per day civil money penalty accrues for the number of days of noncompliance from the date that the deficiency starts until the date that the HHA achieves substantial compliance or, if applicable, the date of termination. For example, if a HHA is found in substantial compliance or its provider agreement is terminated on May 18, the accrual of the civil money penalty stops on May 17.

The per instance civil money penalty is imposed for each instance of noncompliance based on a deficiency during a specific survey. It is applied to as many instances as is deemed appropriate during a specific survey up to a total of $10,000.

EXAMPLE: When the per instance civil money penalty is used on the original survey, the revisit is considered another survey to determine compliance. If noncompliance is identified and a civil money penalty is selected as the enforcement response, either the per instance or per day penalty may be selected.

a. **Revisit Identifies New Noncompliance and Same Data Tag is Selected** - If the same data tag is selected to identify noncompliance, the State (or regional office) could choose to utilize either the per instance or per day civil money penalty. It would not matter whether the same data tag was selected to identify the new noncompliance. The issue is whether noncompliance is present and whether the deficient practice rises to a level that will support selecting a civil money penalty as a sanction. For instance, noncompliance was identified at Tag G100 during the original survey. During the revisit survey, a different problem dealing with the patient rights of three patients was cited at Tag G100. The per instance or per day civil money penalty would be selected for the noncompliance identified at Tag G100. If the per instance civil money penalty was used, the amount of the civil money penalty might be influenced by factors relating to the violations of patient rights. However, only one per instance civil money penalty would be appropriate. It would not be appropriate to assign a separate civil money penalty for each of the violations related to patient rights (findings) identified at Tag G100.

b. **Revisit Identifies New Noncompliance and a Different Data Tag is Selected** - If a revisit identifies new deficiencies at a different data tag, either a per instance or per day civil money penalty could be selected as a sanction.

c. **Noncompliance - Immediate Jeopardy Does Not Exist** - For noncompliance that does not pose immediate jeopardy, the per day civil money penalty is imposed for the days of noncompliance, i.e., from the day the penalty starts (and this may be prior to the notice), until the HHA achieves substantial compliance or the provider agreement is terminated. However, if the HHA has not achieved substantial compliance at the end of 6 months from the last day of the original survey, the regional office terminates the provider agreement. The accrual of the civil money penalty stops on the date that the provider agreement is terminated.

   For noncompliance that does not pose immediate jeopardy, the per instance civil money penalty is imposed for the number of deficiencies during a survey for which the civil money penalty is determined to be an appropriate sanction. For example, Tag G330 and Tag G320 were cited on a survey. A civil money penalty of $2,000 is imposed for Tag 320 and a civil money penalty of $8,000 is imposed for Tag 330. No civil money penalty could then be imposed for additional deficiencies because the total "per instance civil money penalty" may not exceed $10,000 for each survey.

d. **Noncompliance - Immediate Jeopardy Exists** - For noncompliance that poses immediate jeopardy, CMS must terminate the provider agreement within 23 calendar days after the last day of the survey that identified the immediate jeopardy if the immediate jeopardy is not removed. The accrual of the per day civil money penalty stops on the date that the provider agreement is terminated.

9020.8 Duration of per day penalty when there is immediate jeopardy

In the case of noncompliance that poses immediate jeopardy, CMS must terminate the provider agreement within 23 calendar days after the last date of the survey if the immediate jeopardy is not removed.

A penalty imposed per day of noncompliance will stop accruing on the day the provider agreement is terminated or the HHA achieves substantial compliance, whichever occurs first.

9020.9 Duration of penalty when there is no immediate jeopardy

In the case of noncompliance that does not pose immediate jeopardy, the daily accrual of per day civil money penalties is imposed for the days of noncompliance, i.e., from the day the penalty starts (and this may be prior to the notice), until the HHA achieves substantial compliance based on a revisit or the provider agreement is terminated, but for a period of no longer than 6 months following the last day of the survey.

If the HHA has not achieved substantial compliance with all of the conditions of participation, CMS will terminate the provider agreement. The accrual of civil money penalty stops on the day the HHA agreement is terminated or the HHA achieves substantial compliance, whichever is earlier.

9020.10 When Penalty Is Due and Payable

1. After Final Administrative Decision

When CMS imposes a civil money penalty, a final administrative decision includes an Administrative Law Judge decision and review by the Departmental Appeals Board, if the HHA requests a review of the Administrative Law Judge decision. Payment of a civil money penalty is due 15 calendar days **after** a final administrative decision, upholding the imposition of the civil money penalty, when:

a. The HHA achieved substantial compliance before the final administrative decision; or
b. The effective date of termination occurred before the final administrative decision.

2. No Hearing Requested

Payment of a civil money penalty is due 15 calendar days **after** the time period for requesting a hearing has expired and a hearing request was not received when:

a. The HHA achieved substantial compliance before the hearing request was due; or
b. The effective date of termination occurred before the hearing request was due.

3. After Request to Waive Hearing

Payment of a civil money penalty is due 15 calendar days **after** receipt of the HHA's written waiver of a right to a hearing when:

a. The HHA achieved substantial compliance before receipt of the HHA's written waiver of its right to a hearing;
b. A per instance civil money penalty has been imposed. Since no opportunity to correct is available for the noncompliance against which a per instance civil money penalty is imposed, allowing time for the HHA to achieve substantial compliance is not a factor in determining when the civil money penalty is due; or
c. The effective date of termination occurred before receipt of the HHA's written waiver of its right to a hearing.

4. After Substantial Compliance Is Achieved

Payment of a per day civil money penalty is due 15 calendar days after substantial compliance is achieved when:

a. A final administrative decision, upholding the imposition of the civil money penalty, is made before the HHA achieved substantial compliance;
b. The HHA did not file a timely hearing request before it achieved substantial compliance; or
c. The HHA waived its right to a hearing before it achieved substantial compliance. However, the period of noncompliance covered by the civil money penalty may not extend beyond 6 months from the last day of the survey.

5. After Effective Date of Termination

Payment of a civil money penalty is due 15 calendar days **after** the effective date of termination, if before the effective date of termination:

a. The final administrative decision was made upholding the imposition of the civil money penalty;
b. The time for requesting a hearing has expired and the HHA did not request a hearing; or
c. The HHA waived its right to a hearing.

9021 Notice of Amount Due and Collectible

1. Contents of Notice

The following information is included in a notice of the amount due which is sent to the HHA after the final amount due and collectible is determined:

a. The amount of the penalty per day or the amount of the penalty per instance;
b. For the per day civil money penalty, the number of days involved;
c. The total amount due;
d. The due date of the penalty; and
e. The rate of interest to be assessed on the unpaid balance on the due date as follows:

The rate of interest is the higher of either the rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date of the notice of the penalty amount due and this rate is published quarterly in the "Federal Register" by the Department of Health and Human Services under 45 CFR 30.13(a); or the current value of funds rate which is published annually in the "Federal Register" by the Secretary of the Treasury, subject to quarterly revisions. (The regional office contacts CMS Central Office for the rate of interest information.)

2. Method of Payment

a. The civil money penalty is payable by check to CMS if the check is rendered by the due date.
b. After the due date of the penalty, the regional office or the State Medicaid Agency deducts the civil money penalty plus any accrued interest from money owed to the HHA.

9021.2 Computation and notice of total penalty amount

When a civil money penalty is imposed on a per day basis and the HHA achieves compliance with the conditions of participation as determined by a revisit survey, CMS sends a final notice to the HHA containing all of the following information:

- The amount of penalty assessed per day.

- The total number of days of noncompliance.
- The total amount due.
- The due date of the penalty.
- The rate of interest to be assessed on any unpaid balance beginning on the due date. The rate of interest is the higher of either the rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date of the notice of the penalty amount due and this rate is published quarterly in the "Federal Register" by the Department of Health and Human Services under 45 CFR 30.13(a); or the current value of funds rate which is published annually in the "Federal Register" by the Secretary of the Treasury, subject to quarterly revisions. (The regional office contacts CMS Central Office for the rate of interest information.)
- Instructions for submitting payment to CMS CO with the reference number on the check.

When a civil money penalty is assessed per instance of noncompliance, a notice is sent to the HHA containing all of the following information:

- The amount of the penalty or penalties that was assessed.
- The total amount due.
- The due date of the penalty.
- The rate of interest to be assessed on any unpaid balance beginning on the due date. The rate of interest is the higher of either the rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date of the notice of the penalty amount due and this rate is published quarterly in the "Federal Register" by the Department of Health and Human Services under 45 CFR 30.13(a); or the current value of funds rate which is published annually in the "Federal Register" by the Secretary of the Treasury, subject to quarterly revisions. (The regional office contacts CMS Central Office for the rate of interest information.)
- Instructions for submitting payment to CMS CO with the reference number on the check.

9021.3 When a penalty is due and payable

Total civil money penalty amounts are computed after a final administrative decision; that is, after:

I. Compliance is verified;
II. The HHA provider agreement is involuntarily terminated; or
III. Administrative remedies have been exhausted.

When the regional office imposes a civil money penalty, a final administrative decision includes an Administrative Law Judge decision and review by the Departmental Appeals Board, if the facility requests a review of the Administrative Law Judge decision. A civil money penalty is due and payable 15 days from the final administrative decision upholding the imposition of the penalty when (1) the facility achieved substantial compliance before the final administrative decision, or (2) the effective date of termination occurred before the final administrative decision.

Final administrative decision is when:

- The time to request a hearing has expired and a hearing request was not received when the HHA achieved substantial compliance before the hearing request was due or the effective date of termination occurred before the hearing request was due;

- CMS receives a request from the HHA waiving its right to appeal the initial determination and (1) the HHA achieved substantial compliance before CMS's receipt of the request, or (2) a per instance penalty has been imposed and the facility has achieved substantial compliance before CMS's receipt of the request; or (3) the effective date of termination occurred before receipt of the HHA's written request waiving its right to a hearing;

- A final decision of an Administrative Law Judge and/or Departmental Appeals Board Appellate Board upholding the imposition of the penalty; or

- The HHA is terminated from the program and if before the effective date of termination (1) the final administrative decision was made upholding the imposition of the penalty, (2) the time for requesting a hearing has expired and the HHA did not request a hearing, or (3) the HHA waived its right to a hearing.

A request for hearing will not delay the imposition of the civil money penalty, but can only affect the collection of any final amounts due to CMP. If an HHA timely waives its right to a hearing, CMS reduces the final CMP amount by 35%. This reduction would be reflected once the CMP stops accruing: when the HHA achieves substantial compliance before CMS receives its request to waive a hearing; or the effective date of the termination occurs before CMS received the waiver request.

The final penalty receivable amount would be determined when the per-day CMP accrual period ends (either when the HHA achieves substantial compliance or is terminated).

An HHA has two options for action following the imposition of a penalty:

- The HHA could pay the fine in full for all CMPs imposed prior to the date a CMP is due and payable; or
- The HHA could request a hearing based on the determination of noncompliance with Medicare CoPs.

Within 60 days of receipt of the notice of imposition of a penalty, the HHA may file a request directly to the Departmental Appeals Board in the Office of the Secretary, Department of Health and Human Services with a copy to the State and CMS. In accordance with §498.40(b), the HHA's appeal request would identify the specific issues of contention, the findings of fact and conclusions of the law with which the agency disagreed, and the specific basis for contending that the survey findings and determinations were invalid. A hearing would be completed before any penalty was collected. However, sanctions would continue regardless of the timing of any appeals proceedings if the HHA had not met the CoPs. Requesting an appeal would not delay or end the imposition of a sanction. A civil money penalty would begin to accrue on the last day of

the survey which identified the noncompliance. These include penalties imposed on a per day basis, as well as penalties imposed per instance of noncompliance.

9021.4 Method of Payment

The civil money penalty is payable by check to CMS if the check is rendered by the due date. After the due date of the penalty, the regional office deducts the civil money penalty plus any accrued interest from money then or later owed to the HHA by CMS or the State Medicaid Agency (see section 9022 below).

9021.5 Settlement of Civil Money Penalty

The regional office has the authority to settle civil money penalty cases at any time prior to a final administrative decision. If a decision is made to settle, the settlement should not be for a better term than had the HHA opted for a 35 percent reduction.

9021.6 Offsets

If payment was not received by the established due date, CMS will collect the civil money penalty through offset of monies then owed or later owing to the HHA. To initiate such an offset, CMS will instruct the appropriate Medicare Administrative Contractors/Fiscal Intermediaries and, when applicable, the State Medicaid agencies to deduct unpaid civil money penalty balances from any money owed to the agency. To maintain consistency in recovering a civil money penalty among other types of providers who are subject to a civil money penalty, the amount of any penalty can be deducted (offset) from any sum CMS or the State Medicaid Agency owes to the HHA.

Interest would be assessed on the unpaid balance of the penalty beginning on the due date. The rate of interest assessed on any unpaid balance would be based on the Medicare interest rate published quarterly in the Federal Register, as specified in §405.378(d).

Those civil money penalty amounts not recovered due to HHA failure to pay or inadequate funds for offset will be collected through the Debt Collection Improvement Act of 1996 which requires all debt owed to any Federal agency that is more than 180 days delinquent to be transferred to the Department of the Treasury for debt collection services.

9022 Disbursement of Recovered CMP funds

The CMP amounts and any corresponding interest recovered will be divided between the Medicare and Medicaid programs, based on a proportion that is commensurate with the comparative Federal expenditures under Titles XVIII and XIX of the Act, using an average of years 2007 to 2009 based on Medicaid Statistical Information System (MSIS) and HHA Prospective Payment System (PPS) claims. Based on the proportions of HHA claims attributed to Medicare and Medicaid, respectively, for the FY 2007-2009 period, approximately 63 percent of the CMP amounts recovered would be deposited as miscellaneous receipts to the U.S.

Department of the Treasury and approximately 37 percent will be returned to the State Medicaid Agency to improve the quality of care for those who need home-based care. Beginning one year after the effective date of §488.845 (which is July 1, 2014), these proportions shall be updated annually based on the most recent 3-year fiscal period in which the CMP is imposed, for which CMS determined that the Medicare and Medicaid expenditure data were essentially complete. The portion corresponding to Medicare payments is returned to the Department of Treasury as miscellaneous receipts and the portion corresponding to Medicaid payments is returned to the State Medicaid Agency. Penalty funds may not be used for survey and certification operations nor can it be used as the State's Medicaid non-Federal medical assistance or administrative match.

9023 Directed plan of correction

9023.1 Introduction

These procedures implement the regulatory requirements at §488.850 for imposing a directed plan of correction. A directed plan of correction is one of the sanctions that the CMS regional office can select when it finds a HHA out of compliance with Federal requirements.

9023.2 Purpose

The purpose of the directed plan of correction is to achieve correction and continued compliance with Federal requirements. A directed plan of correction is a plan that the State, with RO approval, or the RO develops to require a HHA to take corrective action to achieve specific outcomes within specified time frames.
Whether it has standard-level or condition-level deficiencies, an HHA must submit an acceptable plan of correction to CMS. If the HHA is unable to develop an acceptable plan of correction, CMS may impose a directed plan of correction for condition level deficiencies.

9023.3 Imposition of a Directed Plan of Correction

The HHA's directed plan of correction may be imposed by CMS when the HHA has deficiencies that warrant directing the HHA to take a specific action(s) or when the HHA fails to submit an acceptable plan of correction for condition level deficiencies.

9023.4 Elements of a Directed Plan of Correction

A directed plan of correction should address all of the elements required for a HHA-developed plan of correction. These elements include, but are not limited to, the following:

I. How an HHA has or will correct each deficiency;
II. How the HHA will act to protect patients in similar situations;
III. How the HHA will ensure that each deficiency does not recur;
IV. How the HHA will monitor performance to sustain solutions; and
V. Under what timeframe corrective actions will be taken.

9023.5 Achieving Compliance

Achieving compliance is the agency's responsibility, whether or not a directed plan of correction is followed. If the HHA fails to achieve compliance within the timeframes specified in the directed plan of correction, CMS may impose one or more additional alternative sanctions until the HHA achieves compliance or is terminated from the Medicare program.

9023.6 Notice of Imposition of Directed Plan of Correction

CMS must provide written notification of the intent to impose a directed plan of correction sanction.

A directed plan of correction may be imposed 15 calendar days after the HHA receives notice in non-immediate jeopardy situations and 2 calendar days after the HHA receives notice in immediate jeopardy situations. The date the directed plan of correction is imposed, that is, the date the sanction becomes effective, does not mean that all corrections must be completed by that date.

9024 Directed In-service Training

9024.1 Introduction

These instructions implement §488.855. Directed in-service training is one of the sanctions the SA may recommend and the RO may select when it finds an HHA out of compliance with Federal requirements.

9024.2 Purpose

Directed in-service training is a remedy that may be used when the State, CMS, or the temporary manager believe that education is likely to correct the deficiencies and help the HHA achieve substantial compliance. Directed in-service training requires the staff of the HHA to attend a specific in-service training program. The purpose of directed in-service training is to provide basic knowledge to achieve and remain in compliance with Federal requirements. For example, in circumstances where some, but not all, compliance problems are a result of a lack of knowledge on the part of the health care provider relative to advances in health care technology and expectations of favorable patient outcomes, directed in-service training would benefit the agency. Also, directed in-service could be used in situations where staff performance results in deficient practice. A directed in-service training program would correct this deficient practice through retraining the staff in the use of clinically and professionally sound methods to produce quality outcomes.

9024.3 Appropriate Resources for Directed In-Service Training Programs

Home health agencies should use programs developed by well-established centers of health education and training such as continuing education programs offered by schools of medicine, nursing, public health, community colleges, state health departments, centers for the aging, and other available area centers which have established continuing education programs for health professionals. The programs may also be conducted by consultants with background in education and training with Medicare HHA providers, or as deemed acceptable by CMS and/or the SA (by review of a copy of the curriculum vitas and/or resumes/references in order to determine the educator's qualifications). The SA or RO may also compile a list of resources that can provide directed in-service training and may make this list available to HHAs.

9024.4 Further Responsibilities

The HHA bears the expense of the directed in-service training for its staff. After the training has been completed, the SA will assess whether substantial compliance has been achieved. If directed in-service training was the sanction imposed and the HHA does not achieve substantial compliance, CMS may impose one or more additional sanctions as specified in §488.808.

9024.5 Notice of Imposition of Directed In-Service Training

Directed in-service training may be imposed 15 calendar days after the HHA receives notice in non- immediate jeopardy situations and 2 calendar days after the HHA receives notice in immediate jeopardy situations.

9025 Effect of termination on the HHA's patients

Under the provisions of §§1866(b)(2)(A) and (B) of the Act (also 42 CFR 489.53), the Secretary may terminate an agreement with a provider of services if it is determined that the provider fails to comply substantially with the terms of the provider agreement, the provisions of title XVIII, or regulations promulgated thereunder, and that the provider fails to meet the applicable provisions of section 1861.

Under §488.830 (e), an HHA that has its provider agreement terminated is required to appropriately and safely transfer its patients to another local HHA within 30 days of termination. The HHA is responsible for providing information, assistance and any arrangements necessary for the safe and orderly transfer of its patients. The SA is required to work with all HHAs that are terminated to ensure the safe discharge and orderly transfer of all patients to another Medicare-approved HHA. Payment to terminated HHAs for services for current patients is provided up to 30 days after termination pursuant to §489.55(b).

State Operations Manual
Appendix B - Guidance to Surveyors: Home Health Agencies

(Rev. 12, PUB Date here)

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Part I – Investigative Procedures

I – Introduction

Home health agencies (HHAs) are required to meet the definition of an HHA in section 1861(o) of the Social Security Act (the Act) as well as be in compliance with the Federal requirements set forth in the Medicare Conditions of Participation (CoPs) in order to receive Medicare/Medicaid payment. The goal of the HHA survey is to determine if the agency is in compliance with the CoPs set forth at 42 CFR Part 484.

The survey and certification process provides a method to evaluate HHA compliance with the CoPs, ensuring that patient services provided meet minimum health and safety standards and a basic level of quality. The HHA survey process incorporates an approach that is patient-focused, outcome-oriented, and data-driven, making it more effective and efficient in assessing, monitoring, and evaluating the quality of care delivered by an HHA. Through the survey process, the SA needs to determine if the HHA has the ability to deliver needed patient services and, most importantly, if the delivery of those services impacts the quality of care and results in positive patient outcomes.

The purpose of the survey protocols and interpretive guidelines is to direct the surveyor's attention to avenues of investigation in preparation for the survey, conducting the survey, and evaluating the survey findings.

Surveyors conduct the HHA survey in accordance with the appropriate protocols, which are intended to promote consistency in the survey process. Surveyors should base any deficiency on a violation of the statute or regulations, which, in turn, is to be based on clinical record reviews, interviews with the HHA's patients and staff, and observations of the HHA's performance and practices. (See §2712.)

Surveyors gather information during the entrance interview, HHA patient and staff interviews, home visit observations, and clinical record reviews. Since they gather information from staff interviews as a data source, and focus on those areas of HHA functioning that are most related to the delivery of high-quality patient care, surveyors are able to minimize the review of non-clinical record documentation. During their pre-survey preparation, surveyors also use information available from agency level reports derived from the Outcome and Assessment Information Set (OASIS) data to select HHA patients and records for survey and to increase focus on clinical outcomes in preparing for the survey. This is further outlined in Task One of the Survey Tasks.

Survey Team

The State survey agency (SA), or the CMS Regional Office (RO) for Federal teams, decides the size of the team. Each home health survey team should include at least one RN with home health survey experience. Other surveyors who have the expertise to determine whether the HHA is in compliance may be used as needed.

Surveyor Qualifications

HHA surveyors should have the necessary training and experience to conduct an HHA survey. Each individual on a survey team must meet certain minimum CMS qualifications. Surveyor minimum qualifications are found at §488.735. Before any surveyor can serve on an HHA survey team (except as a trainee), he/she must

successfully complete the relevant CMS-sponsored Basic HHA Surveyor Training Course and any associated course prerequisites. Individuals who have not completed the course but are currently in training may accompany the survey team in an observational role only, as part of their training prior to completing the CMS Basic HHA Surveyor Training Course.

Section 488.735(b) describes the circumstances that would disqualify a surveyor from surveying a particular HHA. A surveyor will be prohibited from surveying an HHA when:

(1) The surveyor currently works for, or, within the past two years, has worked with the HHA to be surveyed as:

(i) A direct employee;

(ii) An employment agency staff at the agency; or

(iii) An officer, consultant, or agent for the agency to be surveyed concerning compliance with conditions of participation specified in or pursuant to sections 1861(o) or 1891(a) of the Act.

(2) The surveyor has a financial interest or an ownership interest in the HHA to be surveyed.

(3) The surveyor has a family member who has a relationship with the HHA to be surveyed.

(4) The surveyor has an immediate family member who is a patient of the HHA to be surveyed.

Unannounced surveys

All HHA surveys must be unannounced and conducted with procedures and scheduling that render the onsite surveys as unpredictable in their timing as possible. SAs make every effort to lessen the predictability of a survey occurring at a specific time, day, or month. CMS reviews state scheduling and survey procedures to ensure that the agency has taken all reasonable steps to avoid giving advance notice to HHAs of impending surveys through these procedures. Any individual who notifies (or causes to be notified) an HHA of the time or date of the standard survey is subject to a civil money penalty not to exceed $2,000 under section 1891(c)(1) of the Act and §488.725.

Frequency of HHA Surveys

In addition to the standard survey conducted at the HHA's initial application for Medicare certification and at its periodic recertification, section 1891(c)(2)(B)(ii)of the Act provides that a standard survey, or abbreviated standard survey, must be conducted of an HHA within 2 months of when a significant number of complaints against the HHA are reported to CMS, the State, the State or local agency responsible for maintaining a toll-free hotline and investigative unit, or any other appropriate Federal, State, or local agency, or as otherwise required to determine compliance with the conditions of participation, such as the investigation of a complaint. See also §488.730.

Section 1891(c)(2)(B(i) provides that a standard survey or an abbreviated standard survey may be conducted at the discretion of CMS or the State within 2 months of a change, or knowledge of a change, of the ownership, administration, or management of

the HHA to determine whether the change has resulted in any decline in the quality of care furnished by the HHA.

Neither CMS nor the Medicare Administrative Contractor (MAC) requires a survey when a new service is added to a Medicare-certified HHA. Rather, the SA directs the HHA to notify the MAC about the added service. Review the new service at the next scheduled survey, unless a complaint is received about the HHA or there are concerns about the ability of the HHA to provide the new service(s).

An HHA may also be subject to a partial extended or extended survey at the discretion of CMS or the State. The specific types of HHA surveys are discussed below.

II - Types of Home Health Surveys

HHAs are subject to the following unannounced surveys:

A. Standard Survey

The standard survey is a survey in which the surveyor reviews the HHA's compliance with a select number of standards and/or conditions of participation in order to determine the quality of care and services furnished by an HHA as measured by indicators related to medical, nursing, and rehabilitative care. This survey is required of all HHAs under section 1891(c)(2)(C)(i)(II) of the Act and §488.710.

During the standard survey, the surveyor reviews, to the extent practicable, a case-mix stratified sample of individuals to whom the HHA furnishes services. The survey includes visits to the homes of sampled patients who have given their consent, either directly or through their guardian or legal representative. The purpose of the home visit is to evaluate the extent to which the quality and scope of services furnished by the HHA has attained and maintained the highest practicable functional capacity of each patient, as reflected in the patient's written plan of care and clinical records. Other forms of communication with patients, such as through telephone calls, could also be used to complete the survey, in addition to home visits, if determined necessary by the SA or CMS.

During the standard survey, the surveyor reviews the HHA's compliance with a select number of regulations (standards) most related to high-quality patient care. These highest priority standards are called Level 1 standards, and cover 9 of the 15 total CoPs for HHAs (see table below for the specific standards reviewed during the standard survey and partial extended survey). These standards include both process standards and administrative standards most closely related to the agency's ability to deliver high-quality patient care. Compliance with these Level 1 highest priority standards is highly likely to affect care delivery and patient outcomes.

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

determine if standard or condition-level deficiencies are present in the CoPs not examined in the standard survey, the standard survey is expanded to a partial extended survey. The partial extended survey reviews Level 2 standards which are additional standards that are considered the next highest priority standards See Table below for a listing of the Level 1 (highest priority) standards which must be reviewed in the standard survey and the Level II (next highest) priority standards which are reviewed during the partial extended survey.

Level 1 and Level 2 Standards

Condition	***Level 1 (Highest Priority Standards)*** *(Standard Survey)*	***Level 2 (Next Highest Priority Standards)****(Partial Extended Survey)*
484.10 Patient Rights	*G107, G109*	*G101, G108, G111, G114*
484.12 Compliance with Federal, State and Local Laws	*G121*	*G118*
484.14 Organization, Services and Administration	*G123, G133, G143, G144*	*G124, G125, G137, G138, G139, G150*
484.18 Acceptance of Patients, Plan of Care, Medical Supervision	*G157, G158, G159, G164, G165, G166*	*G160, G162, G163*
484.30 Skilled Nursing Services	*G170, G172, G173, G174, G175, G176, G177*	*G169, G179*
484.32 Therapy Services	*G186, G187, G188*	*G190, G193*
484.36 Home Health Aide Services	*G224, G229*	*G212, G215, G225, G226, G230, G232*
484.48 Clinical Records	*G236*	*G239*
484.55 Comprehensive Assessment of Patients	*G331, G332, G334, G335, G336, G337, G338, G340*	*G339, G341*

B. Abbreviated standard survey:
The abbreviated standard survey is a focused survey other than a standard survey that gathers information on an HHA's compliance with fewer, specific standards or conditions of participation. An abbreviated standard survey may be based on complaints received, a change of ownership or management, or other indicators of specific concern such as reapplication for Medicare billing privileges following a deactivation.

The abbreviated standard survey focuses on particular tasks that relate, for example, to complaints received, or a change of ownership, or management. It does not cover all the aspects reviewed in the standard survey, but rather concentrates on a particular area or areas of concern. The surveyor may investigate any area of concern and make a compliance decision regarding any regulatory requirement, whether or not it is related to the original purpose of the survey or complaint. The abbreviated standard survey can be

expanded and changed to a standard, partial extended or extended survey when necessary.

C. Complaint survey

The complaint survey is a survey that is conducted to investigate specific allegations of noncompliance. The complaint survey is an example of an abbreviated standard survey.

D. Partial Extended Survey

The partial extended survey is a survey conducted to determine if deficiencies and/or deficient practice(s) exist that were not fully examined during the standard survey. It is conducted when standard-level noncompliance is identified in a Level 1 standard or if a surveyor believes that a deficient practice exists at a standard or condition-level that was not examined during the standard survey. The standard survey is then immediately expanded to become a partial extended survey.

During the partial extended survey, the surveyor reviews, at a minimum, the Level 2 Next Highest Priority standards under the same condition of participation for which the Level 1 standard(s) were determined to be out of compliance. The surveyors may review any additional standards under the same or related conditions which would assist them in making a compliance decision. See Table above for a listing of the Level 2 standards reviewed in the partial extended survey.

E. Extended Survey

Extended survey means a survey that reviews additional conditions of participation not examined during a standard survey. It may be conducted at any time but must be conducted when substandard care is identified. Substandard care means noncompliance with one or more conditions of participation(i.e, at the condition-level) that are identified on a standard survey, including deficiencies which could result in actual or potential harm to patients of an HHA.

The extended survey may review all conditions of participation or a focused number of conditions that were not examined in the standard survey. At a minimum, the surveyor should investigate the HHA's compliance with any other conditions of participation that are related to the condition(s) found to be out of compliance (regardless of the level of seriousness). See chart below for the related conditions that should be investigated, at a minimum, when a particular condition of participation is cited:

Condition Cited	***Related Conditions for Further Investigation***
484.10 Patient Rights	*CoP 484.12: Compliance with Federal, State & Local Laws* *CoP 484.14: Organization, Services & Administration* *CoP 484.18: Acceptance of Patients, Plan of Care, & Medical Supervision*
484.12 Compliance with Federal, State & Local Laws, Disclosure & Ownership Information, & Accepted Professional Standards & Principles	*CoP 484.14: Organization, Services & Administration* *CoP 484.18: Acceptance of Patients, Plan of Care, & Medical Supervision* *CoP 484.30: Skilled Nursing Services* *CoP 484.32: Therapy Services* *CoP 484.34: Medical Social Services* *CoP 484.36: Home Health Aide Services* *CoP 484.48: Clinical Records* *CoP 484.55: Comprehensive Assessment of Patients*
484.14 Organization, Services, & Administration	*CoP 484.12: Compliance with Federal, State & Local Laws* *CoP 484.18: Acceptance of Patients, Plan of Care, & Medical Supervision* *CoP 484.30: Skilled Nursing Services* *CoP 484.32: Therapy Services* *CoP 484.34: Medical Social Services* *CoP 484.36: Home Health Aide Services* *CoP 484.48: Clinical Records* *CoP 484.52: Evaluation of Agency's Program* *CoP 484.55: Comprehensive Assessment of Patients*
484.18 Acceptance of Patients, Plan of Care, & Medical Supervision	*CoP 484.12: Compliance with Federal, State & Local Laws* *CoP 484.14: Organization, Services and Administration* *CoP 484.30: Skilled Nursing Services* *CoP 484.32: Therapy Services* *CoP 484.34: Medical Social Services* *CoP 484.36: Home Health Aide Services* *CoP 484.48: Clinical Records* *CoP 484.52: Evaluation of Agency's Program* *CoP 484.55: Comprehensive Assessment of Patients*

Condition Cited	***Related Conditions for Further Investigation***
484.30 *Skilled Nursing Services*	*CoP 484.12: Compliance with Federal, State & Local Laws* *CoP 484.14: Organization, Services and Administration* *CoP 484.20: Reporting OASIS Information* *CoP 484.32: Therapy Services* *CoP 484.34: Medical Social Services* *CoP 484.36: Home Health Aide Services* *CoP 484.48: Clinical Records* *CoP 484.52: Evaluation of Agency's Program* *CoP 484.55: Comprehensive Assessment of Patients*
484.32 *Therapy Services*	*CoP 484.12: Compliance with Federal, State & Local Laws* *CoP 484.14: Organization, Services and Administration* *CoP 484.30: Skilled Nursing Services* *CoP 484.34: Medical Social Services* *CoP 484.36: Home Health Aide Services* *CoP 484.48: Clinical Records* *CoP 484.52: Evaluation of Agency's Program* *CoP 484.55: Comprehensive Assessment of Patients*
484.36 *Home Health Aide Services*	*CoP 484.12: Compliance with Federal, State & Local Laws* *CoP 484.14: Organization, Services and Administration* *CoP 484.30: Skilled Nursing Services* *CoP 484.32: Therapy services* *CoP 484.48: Clinical Records* *CoP 484.52: Evaluation of Agency's Program* *CoP 484.55: Comprehensive Assessment of Patients*
484.48 *Clinical Records*	*CoP 484.12: Compliance with Federal, State & Local Laws* *CoP 484.14: Organization, Services and Administration* *CoP 484.20: Reporting OASIS Information* *CoP 484.30: Skilled Nursing Services* *CoP 484.32: Therapy services* *CoP 484.34: Medical Social Services* *CoP 484.36: Home Health Aide* *CoP 484.52: Evaluation of Agency's Program* *CoP 484.55: Comprehensive Assessment of Patients*
484.55 *Comprehensive Assessment of Patients*	*Related Conditions for Further Investigation:* *CoP 484.12: Compliance with Federal, State & Local Laws* *CoP 484.14: Organization, Services and Administration* *CoP 484.20 Reporting OASIS Information* *CoP 484.30: Skilled Nursing Services* *CoP 484.32: Therapy services* *CoP 484.48: Clinical records* *CoP 484.52: Evaluation of Agency's Program*

Whether the extended survey examines all, or a focused number, of the conditions of participation not examined during the standard survey is determined on the basis of the nature and extent of serious risk to patients that is identified in the survey.

Under section 1891(c)(2)(D) of the Act, each home health agency that has been found during a standard survey to have provided substandard care shall be subject to an extended survey to review and identify the policies and procedures which produced this substandard care and to determine if the agency is in compliance with the conditions of participation. The extended survey must be conducted not later than 14 calendar days after completion of a standard survey which found the HHA out of compliance with a condition of participation.

F Initial Certification Survey of Prospective HHA Providers

The initial certification survey of a prospective HHA provider seeking to participate in the Medicare program begins (and may end) as a standard survey. As noted above, all standard surveys can be converted to partial extended and extended surveys as appropriate. See guidelines above for standard, partial extended and extended surveys. The SA conducts a standard survey during the initial Medicare certification of an HHA. (see SOM, section 2202.10B) The AO will conduct an extended survey during the initial Medicare certification of an HHA in accordance with the requirements oat 1865 of the Act. Before the initial certification survey, the SA must have received written documentation submitted by the prospective HHA requesting an initial certification survey and MAC initial approval of the 855A application for enrollment. At the time of the certification survey, the prospective HHA must:

1. *Be operational;*
2. *Meet the capitalization requirements;*
3. *Be providing nursing and at least one other therapeutic service (physical therapy, speech language pathology, occupational therapy, medical social services or home health aide) - See §484.14(a);*
4. *Be capable of demonstrating the operational capability of all facets of its operation;*
5. *Have successfully completed an OASIS transmission to the State repository;*
6. *Have provided care to a minimum of 10 patients requiring skilled care (not required to be Medicare patients) that is consistent with the conditions of participation. At least 7 of the 10 required patients should be receiving skilled care from the HHA at the time of the initial Medicare survey. If this is not the case, contact the CMS RO. If the HHA is located in a medically underserved area, as determined by the CMS RO, the CMS RO may reduce the minimum number of patients from 10 to 5. In such situations, at least 2 of the 5 required patients should be receiving skilled care from the HHA at the time of the initial Medicare survey; and*
7. *Have submitted a complete Form CMS-855A to the MAC.*

The MAC will verify the information on the Form CMS-855A enrollment application and provide the SA and RO with written notification, via a recommendation of approval, that the initial certification survey to determine compliance with the conditions of

participation may be conducted. The SA or AO completes the initial survey and makes a recommendation to the RO for certification if the survey has been successful.

The RO reviews the SA or AO recommendation for initial certification, and if it concurs, the RO notifies the MAC via e-mail that the initial survey has been completed, the HHA is in compliance with the conditions of participation and that the RO is awaiting notification from the MAC of the results of its re-review before the certification is processed.

The RO will hold the issuance of a CCN and provider agreement until the MAC has re-reviewed certain Medicare enrollment requirements (e.g., site visit verification, capitalization requirements and Medicare exclusion checks). Criteria for a successful site visit includes a determination that the facility is open and operational, staffed with personnel, and, if applicable, serving customers. If the provider/supplier does not pass the site visit, the contractor must deny its enrollment.

The MAC will conduct its re-review and notify the RO of the results via e-mail. If the re-review indicates that the prospective HHA remains in compliance with all enrollment criteria and the RO concurs, the RO will issue the CCN and the provider agreement and forward a Form CMS-2007 to the MAC with the effective date of participation being the date on which the HHA was determined to be in compliance with the conditions of participation.

If, however, the MAC re-review determines that the prospective HHA is no longer in compliance with the enrollment requirements, the MAC will deny enrollment and notify the prospective HHA of this by letter with a copy sent to the RO. Upon receipt of this recommendation of denial of enrollment, the RO will then issue an initial certification denial letter to the HHA explaining that certification has not been granted due to the HHA's failure to meet the enrollment requirements as described in the MAC letter. The basis for denial contained within the RO denial letter should be §424.530(a)(1). The associated appeal rights will be provided by the MAC through the provider enrollment process to the prospective HHA. The letter should include standard appeals language from the Program Integrity Manual, Chapter 15, Section 15.24.11.

G. Recertification

Once initially certified to participate as an HHA in the Medicare program, all HHAs are subject to periodic recertifications. Under section 1891(c)(2)(A) of the Act, an HHA is subject to an unannounced SA standard survey no later than 36 months from the previous standard survey. These recertification surveys begin (and may end) as a standard survey, but may be converted to a partial extended or extended surveys as appropriate. See guidelines above for standard, partial extended and extended surveys. Under 1865 of the Act, an HHA accredited by AO's approved program is subject to an unannounced AO survey no later than 36 months from the previous extended survey. Each State must follow CMS's instructions for survey frequency within this 36-month interval commensurate with the need to assure the delivery of quality home health services. HHA branch locations should be included in the unannounced standard survey of a parent

HHA. When the recertification standard survey is performed at a branch location of an HHA, or when deficiencies are found at a branch of an HHA, the survey findings apply to the entire HHA. Routinely conduct the recertification survey at a branch location when that location serves more patients than the parent. Include a sample of clinical records from all branches in the record review selection and make every attempt to visit all branch locations during the survey.

III – The Survey Tasks

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

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

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 Ch. 2, §2704. Follow §2710, Reviewing Forms at the Beginning of a Survey. In addition, review any disclosure of information statements (Form CMS-1513), complaint data, previous survey data, and reports generated from the OASIS data. These reports contain valuable information that may assist 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, potentially avoidable event, risk adjusted Outcome-based Quality Improvement (OBQI) reports, or process measure reports).

Use the worksheet in Exhibit 285 *to conduct a review of the following five OASIS reports:*

- *Potentially Avoidable Events Report and Patient Listing Report*
- *OBQI Outcome Report (risk adjusted outcome report)*
- *Patient/Agency Characteristics report (case-mix report)*
- *Submission Statistics by Agency Report*
- *Error Summary Report by HHA*

Outcome-based Quality Monitoring (OBQM) Potentially Avoidable Events Report and Patient Listing

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

Tier 1 Potentially Avoidable Events

The threshold for each Tier 1 potentially avoidable event is one patient. Therefore, the surveyor must—

a. Identify if any agency patients experienced either of the 2 Tier 1 potentially avoidable events:

- *Emergent care for injury caused by a fall at home; or*
- *Emergent care for wound infections, deteriorating wound status.*

b. During the onsite survey, select patient records and home visits that focus on either (or both) potentially avoidable events identified on the report.

Tier 2 Potentially Avoidable Event Outcomes and Patient Listing

There are six Tier 2 Potentially Avoidable Event outcomes for consideration. The following thresholds must be met for a potentially avoidable event in Tier 2 to become a focus area:

a. *There must be patients who experienced the event; and*
b. *The HHA's current incidence rate must be equal to or greater than twice the reference rate.*

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

If, after working through the Tier 2 Potentially Avoidable Event outcomes, none of the outcome rates are greater than or equal to twice the reference rate, surveyors may optionally focus on other potentially avoidable events (not listed on the Pre Survey Outcome Worksheet, exhibit 285) with incidence rates equal to or greater than twice the reference rate.

OBQI Outcome Report

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

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

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

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

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

Patient/Agency Characteristics Report

The Patient/Agency Characteristics report identifies the HHA patient population trends to investigate during the onsite survey. As part of the pre-survey process:

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

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

Submission Statistics by Agency Report

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

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

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

Error Summary Report by HHA

As part of the pre-survey process, focus on the errors listed on the ***Pre-Survey Process and Sample Selection Worksheet for OBQM & OBQI Reports -***

- *Error 262, Inconsistent M0090 date – M0090 is the date the assessment is completed. The recertification assessment must be done on an every 60-day cycle. Investigate if the HHA's percent of assessments with the error is at or above 20 percent.*
- *Error 1003, Inconsistent effective date sequence – This error warns the HHA that the effective date of the assessment it just submitted was earlier than the most current assessment received. Investigate further if the HHA's percent of assessments with this error is at or above 10 percent; and*
- *Error 1002, Inconsistent record sequence – This error warns the HHA that the assessment it just submitted does not logically follow the previous one submitted and may indicate the HHA has missed submitting a record. Investigate further if the HHA's percent of assessments with this error is at or above 10 percent.*

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

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

SAs must not cite any deficiency for an HHA's failure to include the OASIS data set as part of the patient-specific, comprehensive assessment for non-Medicare non-Medicaid patients as required by §484.55.

Task 2 - Entrance Interview

The entrance interview, which sets the tone for the entire survey, is the critical first stage of the onsite survey process. The surveyor must establish rapport with the HHA staff and establish his or her authority as the leader of the survey. Be aware that the unannounced survey may be disruptive to the normal daily activities of the HHA.

Upon arrival at the HHA, complete the following activities.

- *Inform the HHA administrator, director, or supervisor of the purpose of the survey.*
- *Present identification and introduce the survey team members.*
- *Explain the survey process and estimate the number of days onsite.*
- *Discuss the extent to which the HHA staff may be involved during the survey.*
- *Request verbal explanation of organizational structure, lines of authority, delegation of responsibility, and services furnished (both directly and under arrangement) and the HHA's relationship to any corporate structure.*
- *Ask if the HHA is operating any additional locations, including branches.*
- *Request a meeting with appropriate staff based on the organizational characteristics of the HHA. Request a copy of the organization chart, if available.*

- *Ask for the number of unduplicated patients admitted receiving skilled services during a recent 12-month period.*
- *Ask for a list or access to names of patients scheduled for a home visit during the survey. Include all branch locations.*
- *Ask for a list of current (direct and contracted) employees (including name and title).*
- *Request the names of key staff (i.e., staff persons most knowledgeable about the home health aides, in-service training, clinical supervision) and the clinical staff person who will be the primary resource to respond to the surveyor's questions.*
- *Verify the process to follow in order to have unrestricted access to the clinical records.*
- *Request access to all active patient names (Medicare/Medicaid/private pay) receiving skilled services that identifies the start of care (SOC) date, primary diagnosis, and services provided. This will aid in selecting the sample for home visits with record review based on the review of the OBQM and OBQI reports.*
- *Request specific closed records for review from the agency's Potentially Avoidable Event Patient Listing report.*
- *Set up the schedules for any necessary interviews with staff.*
- *Request space to work after the completion of the entrance interview.*

During this entrance interview, begin to gather information from the HHA about its compliance with the Level 1 standards. For example:

- *Ask how complaints are investigated and how the existence, investigation and resolution are documented. Request and review a copy of the HHA documentation of complaint investigation and resolution.*
- *Review patient admission packet for instructions for making a complaint.*
- *Ask how the HHA ensures that all clinical staff members (direct and contractual) follow professional practice standards, laws, HHA policies and procedures.*
- *Ask how the HHA monitors the professional skills of its staff to determine if those skills are appropriate and adequate for the agency's patients (e.g., competency testing, supervisory visits, skills labs, etc.).*
- *Ask if there are any services that the agency sometimes has trouble staffing, and if so, what they do when a patient needing those services is referred.*
- *Ask administrative staff if the HHA has a policy regarding how quickly an order for therapy, medical social worker or an aide will be staffed.*
- *Ask how the HHA staffs RNs and LPNs. If HHA relies primarily on LPNs for most visits, how does HHA ensure that RNs supervise and manage each case?*
- *Ask how the HHA staffs therapists and therapy assistants.*
- *How does the HHA ensure that qualified therapists supervise and manage their patients?*
- *Ask if aides are direct employees of the HHA or provided by arrangement.*
- *Ask what the HHA's system is for tracking aide supervisory visits.*
- *Ask if the HHA accepts electronic signatures by either clinicians or physicians, and what the related policies allow.*

- *Ask how the clinical records are maintained (i.e., all electronic, all paper, or combination), stored, and accessed. How is confidentiality of records maintained out of the office?*
- *Ask what time frame is allowed for clinicians to turn in documentation following a visit. If there is a stated/published policy, is there a monitoring system present? What are results of internal monitoring?*
- *Ask what the HHA's time frame is for documents to be filed in patient record.*
- *Ask where clinicians document aide supervisory visits, case conferences, phone calls, medications, etc.*
- *Ask what the HHA's policy is for making corrections in the clinical record.*
- *Ask what the HHA's policies are for conducting the initial and comprehensive assessments (including whether therapists complete these assessments).*
- *Ask how the HHA ensures that initial assessments are conducted within the required time frame.*
- *If problems with OASIS data submission are evident in the reports reviewed pre-survey, ask the administrative staff to address those issues.*

Arrange a time with clinical managers to ask them the following questions:

- *Describe the HHA's process of drug regimen review, including how this is accomplished when a therapist completes the comprehensive assessment.*
- *How does the HHA address medication discrepancies (e.g., medications in the home differ from orders received) or patient non-compliance?*
- *How does the HHA respond to prescriptions from physicians other than the physician responsible for the patient's home health care?*
- *How does the HHA determine when there has been a "major decline or improvement in the patient's health status" that would warrant an update of the comprehensive assessment?*
- *How does the HHA track due dates for updating the comprehensive assessments?*

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 the CoPs. During the standard survey, activities focus on Level 1 standards unless problems are found. ***Surveyors gather critical information by focusing on home visits, observations, interviews, and clinical record reviews.*** *Non-clinical record materials are not reviewed unless problems are identified through HHA staff interviews, patient/caregiver interviews, home visits, and clinical record reviews. If problems are found with Level 1 standards, surveyors move to a partial extended survey and evaluate Level 2 standards as necessary. If concerns arise during interview, record reviews or home visits, it may be necessary to include a review of additional material as needed, such as personnel records, contracts, policies and procedures, clinical/procedural references, documentation of home health aide training and/or competency evaluation, documentation of complaint investigation and resolution, CLIA waiver, and/or other materials.*

During the standard survey and partial extended surveys, the surveyor's focus is on the Level 1 and Level 2 standards.

Probes for Interviewing Clinical Managers

- *How do clinical managers ensure that physician orders, agency policies, and regulations are being followed in delivering care to each patient (including obtaining interim orders and getting physician signatures)? How are prescriptions from other physicians seeing the patient handled?*
- *How are clinicians (all services) assigned to cases, including case managers?*
- *How are clinicians and aides instructed to maintain clinical record confidentiality outside the office? What is the time frame for submitting completed documentation? How are errors identified and corrected?*
- *How do clinicians ensure that initial assessments are conducted within the required time frame and that all assessments are comprehensive?*
- *Who completes the drug regimen review? How is it documented for therapy-only cases? At follow-up and discharge time points?*
- *How do clinicians determine when there has been a "major decline or improvement in the patient's health status" that would warrant an update of the comprehensive assessment? How does the HHA track due dates for updating the comprehensive assessments?*
- *Where in the clinical records should surveyors find documentation of aide supervisory visits, case conferences, phone calls, medications, wound care and wound measurements, etc?*
- *What resources are available to nurses and therapists for care problems and how do they access the resources when the need is identified?*
- *Who documents patient care instructions for aides and where are the instructions filed? Is a copy left in patient's home?*
- *Who determines whether an aide needs in-home demonstration or instruction in a care procedure? Who does the aide call with patient-specific questions?*

Probes for interviewing case managers and clinical staff members

- *How do clinicians involve patients and their caregivers in planning care?*
- *How do case managers and other clinicians communicate necessary information about patient condition, response to interventions and teaching, changes in the plan of care, and discharge planning to the patient/caregivers? How is this same information shared among the appropriate care providers (including physicians and aides)?*
- *Is the clinical staff member knowledgeable about where to turn for help with difficult clinical problems? Has he/she sought help regarding a specific issue noted on home visit or record review? What response was received?*
- *How do clinicians ensure the safety and confidentiality of patient records when transported for use during home visits?*

- *Is clinician knowledgeable about the correct way to make a correction in a clinical record?*
- *What actions are taken when the medication(s) in the home differs from orders received or when patients are non-compliant with medications, diet or treatments?*
- *How do you handle prescriptions from physicians other than the physician responsible for the patient's home health care?*

Clinical Records

The minimum number of clinical records of patients to be reviewed during the HHA survey will be the sum of the number of clinical records without home visits and the number of clinical records with home visits. More clinical records may be reviewed and more home visits may be made if necessary to assess compliance with the CoPs. See chart below.

Unduplicated Skilled Admissions in Recent 12 months.	*Min # of Record Reviews With No Home Visit*	*Min # of Record Reviews With Home Visit*	*Total Record Reviews*
< 150	*5*	*5*	*10*
150-750	*6*	*6*	*12*
751-1250	*8*	*8*	*16*
1251 or more	*10*	*10*	*20*

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 interventions and skilled therapeutic services by the HHA under a plan of care. "Stratified' means patients selected 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 surgical wound is considered in a different stratum from the patient recuperating from a cerebrovascular accident. Since HHAs treat patients with a wide range of medical conditions, the review is to encompass patients with varying needs and services. The surveyor may also select some patients for review based on OASIS reports reviewed during pre-survey preparation. The OASIS reports only represent Medicare and Medicaid skilled patients. The sample selected for record review with home visits and record review without home visits should include patients from all payment sources. The patients selected through the use of the OBQM and OBQI reports should not replace the entire stratified sample. Additional current patients should be selected for record review with home visits and record review without home visits.

Use the approximate number of unduplicated admissions from all payer sources for skilled services to the HHA (including branches) during the recent 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. Include records from branches in your selection of clinical records.

Use the HHA's current visit schedule (or plans for visits) during the survey week to select the sample for clinical record review with home visits. The sample for clinical record review without home visits may include closed records. The surveyor works with HHA staff to develop, as simply as possible and in the shortest period of time, a survey sample that meets, in its entirety, the following criteria:

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

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 days of the survey. Whenever possible, include (at a minimum) at least one patient who is receiving a "high-tech" service, (e.g., infusion therapies such as artificial nutrition and hydration, or chemotherapy; mechanical ventilation; tracheostomy care, etc.) Also, include a patient from one or more of the HHA's branches when possible. 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. Include patients receiving only home health aide or personal care services to complete the survey sample size if the number of patients receiving skilled care is not available.

Surveyors continue completing the surveyor worksheet and:
Select one or two patients triggered to be "at risk" of Tier 1 potentially avoidable events.
Select one or two patients triggered to be "at risk" for Tier 2 potentially avoidable events of:

a. *Emergent Care for Improper Medication Administration and Side Effects; and*
b. *Emergent care for Hypo/hyperglycemia.*

Select one or two patients with a medical condition relevant to the OBQI outcomes triggered. (For example, if the outcome "Improvement in Urinary Incontinence" is a focus outcome, select one or two patients with or at risk for urinary incontinence.)

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

Number of Unduplicated Skilled Admissions During Recent 12 Months	*Minimum Number of Record Reviews With Home Visits*
Less than 150	*5*
150 – 750	*6*

Number of Unduplicated Skilled Admissions During Recent 12 Months	*Minimum Number of Record Reviews With Home Visits*
751 – 1250	*8*
1,251 or more	*10*

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 still inadequate to provide the samples necessary, include a review all of the standard-level requirements under § 484.14 in addition to the level 1 and level 2 standards as part of the standard survey.

Selecting Sample of Clinical Records of Patients Who Will Not Receive a Home Visit
Select both closed and active clinical records for review based on the potentially avoidable events and OBQI outcome(s) triggered for focus and targeted case mix characteristics. If possible, review of closed clinical records identified on the Potentially Avoidable Event Patient Listing report under any triggered outcomes can begin while the HHA obtains the patient roster and home visit schedule.

- *Select one or two clinical records for review for each Tier 1 potentially avoidable event triggered.*
- *Select one or two clinical records for review for each Tier 2 potentially avoidable event outcome triggered.*

NOTE: Patients experiencing more than one Tier1/Tier2 potentially avoidable events are good candidates for clinical record reviews.

For clinical records without home visits, the surveyor uses the clinical records of any patients not selected for home visits, regardless of payer source. If additional records are needed to complete the sample size, include records of patients visited one to two 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:

Number of Unduplicated Skilled Admissions During Recent 12 Months	*Minimum Number of Record Reviews With No Home Visits*
Less than 150	*5*
150 – 750	*6*
751 – 1250	*8*
1,251 or more	*10*

Clinical Record Review
Ask to see where the clinical records are stored in the agency and how access to records is controlled. 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, ask the HHA staff person recommended by the administrator to guide you through the contents of a clinical record, whether electronic or paper. See how it is organized and where to find key elements.

Use the HHA Survey Investigation Worksheets to note any areas that you want to remember for a particular patient or survey. It is a helpful tool for documenting problems identified and findings from the survey – as well as to use as a review to see if the problems were related to more than one standard. If the survey becomes an extended survey, use the current interpretive guidelines to evaluate those conditions and standards not reviewed in the standard and partial extended surveys. Use additional sheets as necessary to record your findings in the "other" category.

Record Review Guidelines:

- *Review the most recent plan of care for the primary admitting diagnosis, and the goals to be accomplished by the care.*
- *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?*
- *If the initial assessment occurred greater than 48 hours after the referral was received, was the discrepancy explained (physician ordered, patient request, or approved by physician)?*
- *Are comprehensive assessments complete?*
- *Are comprehensive assessments completed on time and by the appropriate clinician during a home visit at start of care, within 48 hours of (or knowledge of) patient's return home from an inpatient stay (or referral or on the physician ordered start date), every 60 days (or more frequently), and at discharge?*
- *Are medications on plan of care, medication list (if applicable), and visit notes the same?*
- *If a record indicates that a patient had a "major decline or improvement," was the comprehensive assessment updated?*
- *Determine how the HHA ensures coordination of services among and between personnel providing services. What evidence do you find in the clinical record(s) that this is occurring?*
- *Determine if the patient's continuation of services or discharge seems appropriate at the time of record review.*
- *If information cannot be found or cannot be interpreted or integrated, ask the HHA staff to either find the information or help you understand its content.*
- *Is there evidence that patients verbalized complaints and how the complaints were addressed?*
- *Is there evidence that the patient/caregiver was informed about and contributed to planning the patient's care?*

- *Are there examples of care provision not in compliance with laws, regulations, accepted professional standards or HHA policies and procedures (e.g., documentation of wound care, wound assessment, or physical assessment)?*
- *Is information about patient condition, response to interventions (e.g., medication side effects, responses to wound therapy, laboratory values, etc.,) and teaching, changes in the plan of care, and discharge planning discussed with or forwarded to the appropriate care providers as applicable, including home health aide and physician?*
- *Are case conferences, informal conferences and phone calls documented?*
- *Did the HHA begin services as ordered within the ordered time frame, at the frequency ordered?*
- *Do plans of care contain all required elements and are they reviewed by the physician at least every 60 days?*
- *Are plans of care patient-specific (i.e., contain measurable goals and instructions for care that are specific to the individual patient) with stated parameters for measurements where appropriate?*
- *Is there evidence that physician orders obtained after the beginning of each 60-day episode of care are documented and implemented?*
- *Do clinicians promptly report patient status changes, including variance from any parameters stated in the plan of care?*
- *Is there evidence of patients denied or not offered needed services?*
- *Review records of patients that have been hospitalized or Medicare low utilization payment adjustment (LUPA) patients to determine if sufficient care is being provided.*
- *Is nursing care provided to each patient as ordered on the plan of care?*
- *For patients with co-morbidities, is there evidence that inter-related factors are addressed in managing the patient's care (e.g., addressing nutrition and skin care in a wound care patient who has diabetes)?*
- *Is there evidence of patient needs that are not addressed in the plan of care or communicated to the physician?*
- *Are therapy visits made at the frequency ordered?*
- *Are assessments & communication with other care providers documented?*
- *Is therapy provided to each patient as ordered?*
- *Is there evidence of patient therapy or equipment needs that are not addressed in the plan of care or communicated to the physician?*
- *Were physical therapy assistants, occupational therapy assistants, and licensed practical nurses appropriately supervised according to State practice acts and the HHA's policies and procedures?*
- *Were home health aide supervisory visits made every two weeks?*
- *Did the RN or therapist ever observe aide's provision of care?*
- *Was aide instructed in any clean dressing changes or other specialized procedures?*
- *Was aide's care provided according to the written instructions and the physician's orders?*
- *Were written instructions provided to the aide specific to the patient?*

- *If record seems incomplete, note the date of the latest filing in records and ask about any documentation waiting to be filed.*
- *Do clinicians consistently document vital signs; insulin injections; blood glucose values; wound appearance, location(s) and treatment; and pain location(s), frequency, severity, interventions, and response to interventions?*
- *How are corrections made in clinical record? Is there evidence of different handwriting in the record signed by the same clinician?*
- *Do records of discharged patients contain discharge summaries?*
- *Do records contain periodic summaries of patient care that were sent to physicians?*
- *Do records show consistency in assessment of patient's status and progress over many visits (e.g., wounds in consistent locations, patient weights seem logical, pain management, presence of Foley catheter, etc.)?*

Home Visits

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 (or family/caretaker consent if the patient is unable to give consent as a result of his or her medical, psychosocial or emotional problems). Patient participation is strictly voluntary. It is important to contact the patient before you arrive at the home or place of residence, if possible, because the first onsite contact may be intimidating to the patient or may generate some fear that would interfere with access to the patient's home or the quality of the interview. In most situations, the HHA representative who provides care or services should contact the patient/family/caretaker to request permission and make the arrangements for the home visit. However, you may choose to contact the patient/family/caretaker directly.

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.

Be sure that the HHA representative (or the surveyor, if appropriate) explains clearly to the patient/family/caretaker that the permission for the RN surveyor home visit (or therapist surveyor home visit for a patient who is only receiving therapy) is voluntary and that refusal to consent to the home visit will not affect his or her Medicare/Medicaid status or coverage, or other health benefits. If a patient refuses to have the RN or therapist surveyor accompany the HHA representative, select an alternate patient care situation from the sample.

Home visits may be made before or after reviewing a patient's clinical record. It is preferable to review the comprehensive assessment and plan of care before meeting the patient since this may assist you in making appropriate observations and asking pertinent questions during the home visit.

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 plan of care. There may be circumstances that should be reviewed during a home visit without the HHA representative being present (for example, concern that the presence of the HHA representative may prevent the patient from speaking freely).

Conducting Home Visits

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 plan of care ordered by his or her physician. The surveyor asks the patient to sign a Consent for Home Visit Form (see Exhibit 104), and leaves a copy of the signed consent form with the patient and a copy of signed consent form is filed in the patient's clinical record. Also, the surveyor maintains a copy of the consent statement in the survey file. A Spanish version of the Consent for Home Visit Form is also available.

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

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

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

During the home visit, surveyors are in a key position to assess the HHA's compliance with requirements related to patient's rights, accepted professional standards of practice, coordination of care, comprehensive assessment of patients, plan of care, services provided, and clinical records. Use the following probes as you gather information during home visits.

Home Visit Probes

- *Are there instances of staff providing care that may not be in accordance with laws, regulations, state practice acts, accepted professional standards or HHA policies/procedures (e.g., wound care procedures, prevention of infection, physical assessment, and medication review)?*
- *How do providers communicate with patient/caregivers and identify the need to communicate with other providers?*
- *When pertinent clinical findings are noted during visit (e.g., changes in patient condition, new medication, lab values, updates to the plan of care, etc.,) how will the provider follow up or share the information with the appropriate care providers? Is there evidence that the communication plan was implemented?*
- *Did the care provider(s) deliver care as ordered and according to accepted professional standards of practice (e.g., CDC guidelines) and agency policy?*

- *Did the care provider report any untoward or unexpected patient changes immediately?*
- *Do clinicians follow CDC infection control guidelines, state practice acts, HHA policies and procedures and accepted clinical standards in providing care?*
- *How does the aide interact with patient/caregiver(s)?*
- *Did the aide provide care as described on written instructions?*
- *Are medications in the home the same as those listed on plan of care, interim orders and the clinical record notes?*
- *Ask the clinical staff about instances of patient care noted in home visits or record reviews that deviated from the physician's orders, accepted professional standards or agency policy.*

Interviewing the Patient/Caregiver

Ask the patient/caregiver(s) the following questions:

- *What care does the aide provide?*
- *Are your needs being met?*
- *Are you satisfied with the care?*
- *What medication are you currently taking? Compare this with the orders and medications in the clinical record.*
- *Have there been setbacks or problems during your episode of home care and how has the HHA has addressed them?*
- *Are you concerned about problems that have not been addressed by HHA staff to your satisfaction?*
- *Have you been able to participate in planning care?*
- *If you had a complaint, would you know who to contact and how?*
- *Is the care being provided as you were told it would be?*

Discontinue the interview if:

- *The patient shows signs of being uncomfortable or seems reluctant to talk, and if, after asking the patient, he or she says they would rather discontinue the discussion;*
- *The patient appears tired, overly concerned, agitated, etc., and would like to end the interview, or, if in your judgment, it appears to be in the patient's best interest to end the interview; or*
- *Conditions in the patient' home, such as safety factors, perceptions of intimidation, etc., are of concern to you or the HHA representative.*

Task 4 - Information Analysis

The information analysis process requires surveyors to review the information gathered during the survey process and to make judgments about the compliance of the HHA. When analyzing information and making determinations about the importance of the findings, the following guidance should be helpful:

Analyze findings relative to each requirement for:

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

Review your findings from the clinical record reviews and home visits. Use the Home Health Agency Survey Investigation Worksheet to review your findings.

Standard and Condition Level Deficiencies

Deficiencies under the home health requirements are cited on the Form CMS-2567 at either the standard level or the condition level. To facilitate documentation of a deficiency citation, data tags are assigned to the HHA conditions and each standard under the condition in the interpretive guidelines. For example, G100 is the condition level tag for the Condition at 484.100, Patient rights; G101 is the tag for the standard to inform, promote and protect patient rights. A data tag assigned to a condition is considered a condition-level data tag. Any data tags that are not a condition level deficiency (e.g., those not placed at the condition) are standard level data tags. A condition level deficiency is identified by citing the condition level tag A standard level deficiency is cited at the standard level tag. If Immediate Jeopardy (IJ) is cited, IJ is cited at the condition level, with any associated standard level tags.

Guidelines for Citing Standard Level deficiencies:

Because the Level 1 highest priority standards are identified as those most related to the delivery of high-quality patient care, a single problematic finding with an actual (or potential) poor outcome(s) would support a determination of noncompliance with a standard tag (e.g., one clinical record finding and/or one home visit finding). Determine if a deficiency exists, and if it does, move to a partial extended survey.

NOTE: *This does not preclude a deficiency citation at a Level 2 standard or any other standard if findings are identified that affect actual or potential negative patient outcomes due to non-compliance with the standard.*

Guidelines for a Partial extended Survey:

The partial extended survey may be conducted at any time, at the discretion of CMS or the SA, but must be conducted when a Level 1 standard level deficiency is identified during a survey. When a Level 1 standard-level deficiency is identified, the survey is expanded to a partial extended survey and the surveyor examines, at a minimum, the Level 2 standards under the same condition and any other standards which the surveyor chooses to examine. This review may or may not result in additional standard level deficiencies. For example, if the surveyor identifies the existence of a problem for the standard G157 (Patients are accepted for treatment with the expectation that the patients' needs can be adequately met by the HHA in patient's residence), the standard survey is expanded to a partial extended survey. Therefore, in addition to evaluating HHA compliance with other Level 1 tags, the surveyors assess compliance with the following Level 2 tags under the same condition as G157 (CoP 484.18 Acceptance of Patients, Plan of Care, and Medical Supervision),G160 (Physician is consulted to

*approve additions or modifications to the plan of care), G162 (Therapist, other personnel participate in developing the plan of care), and G163 (Total plan of care is reviewed by the physician and HHA personnel at least every 60 days). A review of all Level 2 standards that relate to a deficiency of a Level 1 standard is the **minimum** requirement. Surveyors may also identify other standards for investigation as part of a partial extended survey. For example, if, during review of the data sources, additional problems with standards not designated as being Level 1 or Level 2 are found, the surveyor should investigate those problems further as part of a partial extended survey.*

Since the Level 2 next highest priority standards are identified as also being related to the delivery of high-quality patient care, a single problematic finding with an actual (or potential) poor outcome(s) would support a determination of noncompliance with a standard tag (e.g., one clinical record finding and/or one home visit finding).

Guidelines for an Extended Survey

The extended survey means a survey that reviews additional conditions of participation not examined during a standard survey. It may be conducted at any time, at the discretion of CMS or the SA, but will be conducted when substandard care is identified during a survey. Substandard care is defined in §488.705 as noncompliance with one or more conditions of participation at the condition-level. When substandard care is identified, the extended survey reviews and identifies the HHA's policies, procedures, and practices that produced the substandard care. It may also review additional conditions of participation depending on the nature and extent of serious risk to patients that is identified in the standard survey. Additionally, the survey will review any associated activities that might have contributed to the deficient practice.

The extended survey should be conducted immediately after a finding of substandard care (or, if not practical, not later than 2 weeks after the date of completion of the standard survey or partial extended survey). However, if the surveyor identifies or suspects an immediate jeopardy situation, he/she must immediately follow the guidelines in SOM §3010 and in Appendix Q. Immediate jeopardy is interpreted as a crisis situation in which the health and safety of patients is at risk and is defined in §489.3 as "a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident."

Guidelines for Citing Condition Level Deficiencies

According to §488.24, the SA will certify that a provider is not in compliance with the CoPs where the deficiencies are of such character as to substantially limit the provider's capacity to furnish adequate care or which adversely affect the health and safety or patients. A CoP may be considered out of compliance for one or more deficiencies and cited at the condition-level, if, in a surveyor's judgment, the deficiency constitutes a significant or a serious finding that adversely affects, or has the potential to adversely affect, patient outcomes. Surveyors are to use their professional judgment, in concert with the Federal forms, policies and interpretive guidelines in their assessment of an HHA's compliance with the CoPs.

§484.10 Condition of Participation: Patient Rights

Consider citing this condition (i.e., at the condition-level) when:

- *The HHA is found out of compliance with tags G107 or G109 and one additional tag within §484.10.*

§484.12 Compliance With Federal, State and Local Laws, Disclosure and Ownership Information, and Accepted Professional Standards and Principles

Consider citing the condition when:

- *The HHA is out of compliance with G118 and G121; OR*
- *The HHA is out of compliance with G118* ***or*** *G121* ***and*** *two additional tags within §484.12.*

§484.14 Condition of Participation: Organization, Services, and Administration

Consider citing the condition when:

- *Expected outcomes are not met for three of the four Level 1 tags listed (G123, G133, G143, G144); OR*
- *The agency is out of compliance with one of the Level 1 tags plus two additional tags within §484.14.*

§484.18 Condition of Participation: Acceptance of Patients, Plan of Care, and Medical Supervision

Consider citing the condition when:

- *Expected outcomes are not met for three of the six Level 1tags listed (G157, G158, G159, G164, G165, G166); OR*
- *The HHA is out of compliance with one Level 1 tag plus two additional tags within 484.18.*

§484.30 Condition of Participation: Skilled Nursing Services

Consider citing the condition when:

- *Expected outcomes are not met for three of the seven Level 1 tags (G170, G172, G173, G174, G175, G176, G177); OR*
- *The HHA is out of compliance with one Level 1 tag plus two additional tags within §484.30.*

§484.32 Condition of Participation: Therapy Services

Consider citing the condition when:

- *Expected outcomes are not met for two of the Level 1 tags listed (G186, G187, G188); OR*
- *The HHA is out of compliance with one Level 1 tag plus one additional tag within §484.32.*

§484.36 Condition of Participation: Home Health Aide Services

Consider citing the condition when:

- *Expected outcomes are not met for the two Level 1 tags listed (G224, G229); OR*
- *The HHA is out of compliance with one Level 1 tag plus one additional tag within §484.36.*

§484.48 Condition of Participation: Clinical Records

Consider citing the condition when:

- *Expected outcomes are not met for G236; OR*
- *The HHA is out of compliance with G239 plus one additional tag within §484.48.*

§484.55 Condition of Participation: Comprehensive Assessment of Patients

Consider citing the condition when:

- *Expected outcomes are not met for three of the eight Level 1 tags listed (G331, G332, G334, G335, G336, G337, G338, G340); OR*
- *The HHA is out of compliance with one of the Level 1 plus two additional tags within §484.55.*

If the surveyor finds a condition level deficiency with one of the 9 conditions listed above, additional related conditions, including the following 6 conditions listed below, are examined under the extended survey:

§484.11 Condition of Participation: Release of Patient Identifiable OASIS Information

Consider citing the condition when:

Expected outcomes are not met for G310.

§484.16 Condition of Participation: Group of Professional Personnel

Consider citing the condition when:

- *Expected outcomes are not met for G152, G153 and G154.*

§484.20 Condition of Participation: Reporting OASIS Information

Consider citing the condition when:

- *Expected outcomes are not met for G321 and 322.*

§484.34 Condition of Participation: Medical Social Services

Consider citing the condition when:

- *Expected outcomes are not met for G 195, 196 and one additional tag within §484.36.*

§484.38 Condition of Participation: Qualifying to Furnish Outpatient Physical Therapy or Speech Pathology Services

Consider citing the condition when:

- *Expected outcomes are not met for G234*

§484.52 Condition of Participation: Evaluation of the Agency's Program

Consider citing the condition when:

- *Expected outcomes are not met for G 245, 246, and one other tag within §484.52.*

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.*

Because of ongoing dialogue between the surveyor(s) and HHA staff during the survey, there should be few instances of findings where the HHA is not aware of the surveyor concerns prior to the exit conference. Implement the following guidelines during the conference:

- *Conduct the exit conference with the HHA administrator, clinical managers, and other staff invited by the HHA. Clarify and note the names and positions of all HHA personnel or other individuals attending the meeting.*
- *Summarize the facts of the onsite evaluation (e.g., team size, composition, days onsite, the sample size for record review and home visits).*
- *Describe the regulatory requirements that the HHA does not meet and the findings that substantiate these deficiencies. Avoid using data tag numbers when referring to findings.*
- *Present findings regarding citations of deficient practice(s) in a straight forward, understandable way, and in a clear logical sequence. Offer examples to support the findings as appropriate.*
- *Offer the HHA the opportunity to ask questions regarding the findings or provide further pertinent information for the surveyors to consider offsite prior to making formal citation recommendations to CMS on Form CMS-2567.*
- *Respond to any HHA procedural questions with timely and accurate survey process information (e.g., recertification status: the timeframe for receiving Form CMS-2567 and submitting a plan of correction to the SA in response to the written citations). Clarify any areas for which further possible deficiency citations may be made offsite after further analysis with team members or the SA supervisor.*
- *Present the Form CMS-2567 in accordance with the State agency's policy, but no later than 10 working days after the exit conference. A listing of patient identifiers should accompany the CMS-2567.*
- *Provide instructions and time frame for submitting a plan of correction. The plan of correction must be submitted to the SA within 10 calendar days after receipt of the Form CMS-2567.*
- *Refer to SOM §2724 and §2728 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.*

Task 6 - Formation of the Statement of Deficiencies

Use the guidance in Part I - Investigative Procedures and Part II - Interpretive Guidelines in Appendix B to conduct standard, partial extended and extended surveys to determine compliance with HHA requirements. Write the deficiency statement in terms specific enough to allow a reasonably knowledgeable person to understand how the aspects of each requirement are not met. Follow SOM §2728 for preparation of the Statement of Deficiencies and Plan of Correction. Refer to the document "Principles of Documentation for the Statement of Deficiencies" for detailed instructions on completing the Form CMS-2567.

Follow up on all deficiencies cited on the HHA's plan of correction according to the instructions in SOM §2732A and §2732B.

Part II – Interpretive Guidelines

Subpart A - General Provisions

§ 484.1 Basis and scope.

(a) Basis and scope. This part is based on the indicated provisions of the following sections of the Act:

(1) Sections 1861(o) and 1891 establish the conditions that an HHA must meet in order to participate in Medicare.

(2) Section 1861(z) specifies the Institutional planning standards that HHAs must meet.

(3) Section 1895 provides for the establishment of a prospective payment system for home health services covered under Medicare.

(b) This part also sets forth additional requirements that are considered necessary to ensure the health and safety of patients.

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§ 484.2 Definitions.

As used in this part, unless the context indicates otherwise—

Bylaws or equivalent means a set of rules adopted by an HHA for governing the agency's operation.

Branch office means a location or site from which a home health agency provides services within a portion of the total geographic area served by the parent agency. The branch office is part of the home health agency and is located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the branch independently to meet the conditions of participation as a home health agency.

Clinical note means a notation of a contact with a patient that is written and dated by a member of the health team, and that describes signs and symptoms, treatment and drugs administered and the patient's reaction, and any changes in physical or emotional condition.

HHA stands for home health agency.

Nonprofit agency means an agency exempt from Federal income taxation under section 501 of the Internal Revenue Code of 1954.

Parent home health agency means the agency that develops and maintains administrative controls of subunits and/or branch offices.

Primary home health agency means the agency that is responsible for the services furnished to patients and for implementation of the plan of care.

Progress note means a written notation, dated and signed by a member of the health team that summarizes facts about care furnished and the patient's response during a given period of time.

Proprietary agency means a private profit-making agency licensed by the State.

Public agency means an agency operated by a State or local government.

Subdivision means 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 conditions of participation for HHAs. A subdivision that has subunits or branch offices is considered a parent agency.

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

Summary report means the compilation of the pertinent factors of a patient's clinical notes and progress notes that is submitted to the patient's physician.

Supervision means authoritative procedural guidance by a qualified person for the accomplishment of a function or activity. Unless otherwise specified in this part, the supervisor must be on the premises to supervise an individual who does not meet the qualifications specified in §484.4.

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§ 484.4 Personnel qualifications.

Staff required to meet the conditions set forth in this part are staff who meet the qualifications specified in this section.

Administrator, home health agency. A person who:

(a) Is a licensed physician; or

(b) Is a registered nurse; or

(c) Has training and experience in health service administration and at least 1 year of supervisory or administrative experience in home health care or related health programs.

Audiologist. A person who:

(a) Meets the education and experience requirements for a Certificate of Clinical Competence in audiology granted by the American Speech-Language-Hearing Association; or

(b) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

Home health aide. Effective for services furnished after August 14, 1990, a person who has successfully completed a State-established or other training program that meets the requirements of §484.36(a) and a competency evaluation program or State licensure program that meets the requirements of §484.36 (b) or (e), or a competency evaluation program or State licensure program that meets the requirements of §484.36 (b) or (e). An individual is not considered to have completed a training and competency evaluation program, or a competency evaluation program if, since the individual's most recent completion of this program(s), there has been a continuous period of 24 consecutive months during none of which the individual furnished services described in §409.40 of this chapter for compensation.

Occupational therapist. A person who—

(a)(1) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing, unless licensure does not apply;

(2) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA), or successor organizations of ACOTE; and

(3) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(b) On or before December 31, 2009—

(1) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing; or

(2) When licensure or other regulation does not apply—

(i) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or successor organizations of ACOTE; and

(ii) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc., (NBCOT).

(c) On or before January 1, 2008—

(1) Graduated after successful completion of an occupational therapy program accredited jointly by the committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or

(2) Is eligible for the National Registration Examination of the American Occupational Therapy Association or the National Board for Certification in Occupational Therapy.

(d) On or before December 31, 1977—

(1) Had 2 years of appropriate experience as an occupational therapist; and

(2) Had achieved a satisfactory grade on an occupational therapist proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(e) If educated outside the United States, must meet all of the following:

(1) Graduated after successful completion of an occupational therapist education program accredited as substantially equivalent to occupational therapist entry level education in the United States by one of the following:

(i) The Accreditation Council for Occupational Therapy Education (ACOTE).

(ii) Successor organizations of ACOTE.

(iii) The World Federation of Occupational Therapists.

(iv) A credentialing body approved by the American Occupational Therapy Association.

(2) Successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(3) On or before December 31, 2009, is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing.

Occupational therapy assistant. A person who—

(a) Meets all of the following:

(1) Is licensed, unless licensure does not apply, or otherwise regulated, if applicable, as an occupational therapy assistant by the State in which practicing.

(2) Graduated after successful completion of an occupational therapy assistant education program accredited by the Accreditation Council for Occupational Therapy Education, (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or its successor organizations.

(3) Is eligible to take or successfully completed the entry-level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(b) On or before December 31, 2009—

(1) Is licensed or otherwise regulated as an occupational therapy assistant, if applicable, by the State in which practicing; or any qualifications defined by the State in which practicing, unless licensure does not apply; or

(2) Must meet both of the following:

(i) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association.

(ii) After January 1, 2010, meets the requirements in paragraph (a) of this section.

(c) After December 31, 1977 and on or before December 31, 2007—

(1) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association; or

(2) Completed the requirements to practice as an occupational therapy assistant applicable in the State in which practicing.

(d) On or before December 31, 1977—

(1) Had 2 years of appropriate experience as an occupational therapy assistant; and

(2) Had achieved a satisfactory grade on an occupational therapy assistant proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(e) If educated outside the United States, on or after January 1, 2008—

(1) Graduated after successful completion of an occupational therapy assistant education program that is accredited as substantially equivalent to occupational therapist assistant entry level education in the United States by—

(i) The Accreditation Council for Occupational Therapy Education (ACOTE).

(ii) Its successor organizations.

(iii) The World Federation of Occupational Therapists.

(iv) By a credentialing body approved by the American Occupational Therapy Association; and

(2) Successfully completed the entry-level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

Physical therapist. A person who is licensed, if applicable, by the State in which practicing, unless licensure does not apply and meets one of the following requirements:

(a)(1) Graduated after successful completion of a physical therapist education program approved by one of the following:

(i) The Commission on Accreditation in Physical Therapy Education (CAPTE).

(ii) Successor organizations of CAPTE.

(iii) An education program outside the United States determined to be substantially equivalent to physical therapist entry-level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or an organization identified in 8 CFR 212.15(e) as it relates to physical therapists; and

(2) Passed an examination for physical therapists approved by the State in which physical therapy services are provided.

(b) On or before December 31, 2009—

(1) Graduated after successful completion of a physical therapy curriculum approved by the Commission on Accreditation in Physical Therapy Education (CAPTE); or

(2) Meets both of the following:

(i) Graduated after successful completion of an education program determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified in 8 CFR 212.15(e) as it relates to physical therapists.

(ii) Passed an examination for physical therapists approved by the State in which physical therapy services are provided.

(c) Before January 1, 2008—

(1) Graduated from a physical therapy curriculum approved by one of the following:

(i) The American Physical Therapy Association.

(ii) The Committee on Allied Health Education and Accreditation of the American Medical Association.

(iii) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association.

(d) On or before December 31, 1977 was licensed or qualified as a physical therapist and meets both of the following:

(1) Has 2 years of appropriate experience as a physical therapist.

(2) Has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(e) Before January 1, 1966—

(1) Was admitted to membership by the American Physical Therapy Association; or

(2) Was admitted to registration by the American Registry of Physical Therapists; or

(3) Has graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education.

(f) Before January 1, 1966 was licensed or registered, and before January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy.

(g) If trained outside the United States before January 1, 2008, meets the following requirements:

(1) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy.

(2) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.

Physical therapist assistant. A person who is licensed, unless licensure does not apply, registered, or certified as a physical therapist assistant, if applicable, by the State in which practicing, and meets one of the following requirements:

(a)(1) Graduated from a physical therapist assistant curriculum approved by the Commission on Accreditation in Physical Therapy Education of the American Physical Therapy Association; or if educated outside the United States or trained in the United States military, graduated from an education program determined to be substantially equivalent to physical therapist assistant entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified at 8 CFR 212.15(e); and

(2) Passed a national examination for physical therapist assistants.

(b) On or before December 31, 2009, meets one of the following:

(1) Is licensed, or otherwise regulated in the State in which practicing.

(2) In States where licensure or other regulations do not apply, graduated on or before December 31, 2009, from a 2-year college-level program approved by the American Physical Therapy Association and, effective January 1, 2010 meets the requirements of paragraph (a) of this definition.

(c) Before January 1, 2008, where licensure or other regulation does not apply, graduated from a 2-year college-level program approved by the American Physical Therapy Association.

(d) On or before December 31, 1977, was licensed or qualified as a physical therapist assistant and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

Physician. A doctor of medicine, osteopathy or podiatry legally authorized to practice medicine and surgery by the State in which such function or action is performed.

Practical (vocational) nurse. A person who is licensed as a practical (vocational) nurse by the State in which practicing.

Public health nurse. A registered nurse who has completed a baccalaureate degree program approved by the National League for Nursing for public health nursing preparation or post registered nurse study that includes content approved by the National League for Nursing for public health nursing preparation.

Registered nurse (RN). A graduate of an approved school of professional nursing, who is licensed as a registered nurse by the State in which practicing,

Social work assistant. A person who:

(1) Has a baccalaureate degree in social work, psychology, sociology, or other field related to social work, and has had at least 1 year of social work experience in a health care setting; or

(2) Has 2 years of appropriate experience as a social work assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a social work assistant after December 31, 1977.

Social worker. A person who has a master's degree from a school of social work accredited by the Council on Social Work Education, and has 1 year of social work experience in a health care setting.

Speech-language pathologist. A person who meets either of the following requirements:

(a) The education and experience requirements for a Certificate of Clinical Competence in speech-language pathology granted by the American Speech-Language-Hearing Association.

(b) The educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

Subpart B - Administration

The Conditions of Participation for HHAs apply to each individual under its care unless a requirement is specifically limited to Medicare beneficiaries. Section 1861(o) of the Social Security Act (the Act) describes an HHA for purposes of participation in the Medicare program in broadly descriptive terms. All the requirements are stated generally

as applicable to the HHA's overall activity, and not specifically to the Medicare patient. This provision, which was reaffirmed by Congress in the OBRA 1987 amendments to §1891(a) of the Act has been in the law since the inception of the Medicare program, and CMS' interpretation of it has remained the same. Do not attempt to resolve or enforce matters relating to Medicare/Medicaid coverage of services. If you observe what you believe are noncovered services, report this information to the *CMS* Regional Office Medicare or Medicaid Divisions, as appropriate.

Section 1891(c)(2)(C)(i)(II) of the Act requires that the standard survey shall include a survey of the quality of care and services furnished by the agency as measured by indicators of medical, nursing, and rehabilitative care.

G100

§484.10 Condition of Participation: Patient Rights

G101

§484.10 - The patient has the right to be informed of his or her rights. The HHA must protect and promote the exercise of these rights.

Interpretive Guidelines §484.10

The HHA has a responsibility to inform the patient of his or her rights. Patient rights should be explained to **ALL** patients admitted to the HHA. However, HHAs treat patients whose physical, mental, and emotional status varies widely. Overall, there should be evidence that the HHA has conscientiously tried, within the constraints of the individual situation, to inform the patient in writing, and orally (§484.10(e)), of his/her rights. If, in a particular situation, the HHA determines that the patient, despite the HHA's best efforts, is unable to understand these rights, a notation describing the circumstances should be placed in the patient's clinical record. The notation should be consistent with the patient's diagnosis, general state of physical or mental health, and/or other recorded clinical information, environmental information, or observations. Question clear patterns of seemingly routine notations that patients could not understand their rights.

During home visits, ask patients if the HHA informed them of their rights, and, if so, how. They should be able to give, in their own words, examples of how the rights apply to the HHA care being received and any concerns they have about financial implications of the items or services being received. They should also be able to explain how to access information, services, and the HHA hotline.

If the patient is vague in answering questions, ask for written information about his or her rights that the HHA may have given him or her as resource material. Reviewing the

written statement with the patient during the home visit may help the patient remember the HHA's patient rights instructions.

G102

§484.10(a) Standard: Notice of Rights

(1) The HHA must provide the patient with a written notice of the patient's rights in advance of furnishing care to the patient or during the initial evaluation visit before the initiation of treatment.

Interpretive Guidelines §484.10(a)(1)

In the stratified sample of clinical records selected for review, look for notations that a statement of the patient's rights, including the statement concerning the collection and reporting of OASIS information, has been given to the patient by the HHA staff **prior to care being initiated**. This written statement must have been provided during admission, the patient's initial evaluation visit, or the patient's first professional visit.

The OASIS database is subject to the requirements of the Federal Privacy Act of 1974. The Privacy Act allows the disclosure of information from a system of records without an individual's consent if the information is to be used for a purpose that is compatible with the purposes for which the information was collected. However, under the existing patient's rights regulation, the HHA **must** provide the patient with a written notice of this collection of information, i.e., OASIS in advance of furnishing care to the patient.

Before comprehensive assessments (that include collection of OASIS data items) are conducted, the HHA must tell patients about OASIS and explain their rights with respect to the collection and reporting of OASIS information. These rights include:

1. The right to be informed that OASIS information will be collected and for what purpose;
2. The right to have the information kept confidential and secure;
3. The right to be informed that OASIS information will not be disclosed except for legitimate purposes allowed by the Privacy Act;
4. The right to refuse to answer a specific question; and
5. The right to see, review, and request changes on their assessment.

A standard notice to patients that explains these rights in plain language is available in English and Spanish on the OASIS website (http://www.cms.hhs.gov/oasis/). HHAs must present and explain this required notice to beneficiaries before their initial OASIS assessment.

Review HHA admission information to determine if the OASIS Statement of Patient Privacy Rights (for Medicare/Medicaid patients) is included concerning OASIS data collection and transmission.

If the HHA chooses to continue to collect OASIS information from non-Medicare/non-Medicaid patients the patient should be provided with the Notice about Privacy (for non-Medicare/non-Medicaid patients). If a home visit is made, the verification could also include a conversation with the patient and any material on patient rights that the patient has received from the HHA. A notation in the clinical record might also include a statement regarding any limitations the patient had in being able to understand the information.

Probes §484.10(a)(1)

- How do HHA employees, and staff used by the HHA under an arrangement or contract, implement HHA procedures for informing patients of their rights?
- What are the HHA's admission policies concerning the OASIS Privacy Act Statement?
- How does the HHA assure that the patient understands the OASIS Privacy Act Statement? Is the patient given a copy of the OASIS Privacy Act Statement?
- What is the HHA's policy and procedure for requests to see, copy, review, or change assessment information?
- Does the patient receive a written copy of the HHA's response when a change request is not granted?

G103

§484.10(a)(1)(2) -- The HHA must maintain documentation showing that it has complied with the requirements of this section.

The documentation maintained by an HHA to show that the patient was informed of the patient's rights might include a patient rights statement, signed and dated by the patient or some other documentation consistent with the HHA's policies and procedures.

G104

§484.10(b) Standard: Exercise of Rights and Respect for Property and Person

(1) The patient has the right to exercise his or her rights as a patient of the HHA.

(2) The patient's family or guardian may exercise the patient's rights when the patient has been judged incompetent.

G105

§484.10(b)(3) - The patient has the right to have his or her property treated with respect.

G106

§484.10(b)(4) - The patient has the right to voice grievances regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for property by anyone who is furnishing services on behalf of the HHA and must not be subjected to discrimination or reprisal for doing so.

G107

(Rev.)

§484.10(b)(5) - The HHA must investigate complaints made by a patient or the patient's family or guardian regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for the patient's property by anyone furnishing services on behalf of the HHA, and must document both the existence of the complaint and the resolution of the complaint.

Interpretive Guidelines §484.10(b)(4) and (5)

The expected outcome for this Level 1 standard is that all complaints are investigated, resolved and documented by the HHA.

During home visits, ask the patient, the patient's family, guardian or other legal representative under state law, if they have *or had* any comments or concerns *and how they pursued them*, or if they have registered any grievances or complaints about the HHA or its services. *Determine whether the patient/caregiver would know whom and how to contact if they had a complaint or grievance.* Also, note any patient-described problems recorded in the clinical records during your stratified sample clinical record review. *Is there evidence that the patients verbalized complaints and how the complaints were addressed and resolved?*

Review the agency's compliance with its stated procedures for grievance/complaint investigations and resolution. If resolution of the problem was not possible, the actions that were attempted and the outcomes should be documented by the HHA.

Probes §484.10(b)(4) and (5)

- *How does the HHA receive, record, investigate, and resolve patient grievances and complaints?*
- *Who in the HHA is ultimately accountable for receiving and resolving any patient concerns or problems that cannot be resolved at the staff level?*
- *How does the HHA document the existence, investigation and resolution of complaints?*
- *Follow-up on investigation and documentation of complaints noted in home visits or record reviews with administrator, clinical manager, and HHA staff.*

G108

§484.10(c) Standard: Right to be Informed and to Participate in Planning Care and Treatment

(1) The patient has the right to be informed, in advance, about the care to be furnished, and of any changes in the care to be furnished.

(i) The HHA must advise the patient in advance of the disciplines that will furnish care, and the frequency of proposed visits.

(ii) The HHA must advise the patient in advance of any change in the plan of care before the change is made.

G109

(Rev.)

§484.10(c)(2) - The patient has the right to participate in the planning of the care.

(i) The HHA must advise the patient in advance of the right to participate in planning the care or treatment and in planning changes in the care or treatment.

Interpretive Guidelines §484.10(c)(2)(i)

The expected outcome for this Level 1 standard is that patients are involved in developing their plan of care.

Probes §484.10(c)(2)(i)

- *Ask HHA staff how they facilitate patient/caregivers' participation in planning care.*

- *Ask patients/caregivers if they feel they were able to participate in planning their care or treatment.*
- *Is there evidence that the patient/caregiver was informed about and contributed to planning his/her care?*
- *Is there evidence that patient's plan of care addresses the patient's needs and goals?*

G110

§484.10(c)(2)(ii) - The HHA complies with the requirements of Subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. The HHA must inform and distribute written information to the patient, in advance, concerning its policies on advance directives, including a description of applicable State law. The HHA may furnish advanced directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided.

Interpretive Guidelines §484.10(c)

During home visits, discuss the services that the patient is receiving specific to the medical plan of care. Determine if the patient response shows that the HHA has offered specific instructions in areas mentioned in the standard. For example, if the patient is recovering from a fractured hip and has been receiving physical therapy services for several weeks, ask the patient to show or explain to you what exercises he or she has been doing, how often they are to be done, and what results are anticipated. Also, ask how often the physical therapist comes, when the therapist is expected next, and how plans for therapy have changed as the patient's condition has changed. If the patient responds that he/she has written instructions telling him or her what to do, request to see them.

Ask the patient how he or she participated in developing the plan of care to be furnished by the HHA and when he/she was told about changes in the plan of care. The HHA may discuss changes with the patient by telephone prior to the HHA visit or at the time of the visit, but the patient should feel that he or she has time to consider the implications of the change(s) and concur or object to them prior to implementation.

Advance directives generally refer to written statements, completed in advance of a serious illness, about how an individual wants medical decisions made. The two most common forms of advance directives are a living will and a durable medical power of attorney for health care.

Section 1866(a)(1)(Q), as implemented by § 484.10(c)(2)(ii), requires HHAs to maintain written policies and procedures regarding advance directives. The specific requirements HHAs must meet with respect to advance directives are set forth at § 489, Subpart I. Under these provisions, the HHA must:

1. Provide all adult individuals with written information about their rights under State law to:
    a. Make decisions about their medical care;
    b. Accept or refuse medical or surgical treatment; and
    c. Formulate, at the individual's option, an advance directive;

2. Inform patients about the HHA's written policies on implementing advance directives;
3. Document in the patient's medical record whether he or she has executed an advance directive;
4. Not condition the provision of care or otherwise discriminate against an individual based on whether he or she has executed an advance directive;
5. Ensure compliance with the related State requirements on advance directives; and
6. Provide staff and community education on issues concerning advance directives.

This information must be furnished in advance of the individual coming under the care of the HHA and may be provided during admission, the patient's initial evaluation, or the patient's first professional visit.

Probes §484.10(c)

- What documentation in the clinical records indicates that the HHA advised the patient, in advance, of his or her right to participate in planning the care or treatment to be provided? What documentation indicates that the HHA informed the patient about the types of services to be provided, the disciplines involved, the frequency of the services, and the anticipated outcomes?
- How does the HHA inform the patient about changes in the plan of care and solicit the patient's participation prior to the change being implemented?
- How does the agency advise patients of the need for the physician to agree with the plan of treatment and with any changes to that plan?
- During home visits, ask the patients how they would seek advice or care from their physician, the HHA or its representatives if problems, concerns, or emergencies that are part of the medical problems for which they are being treated by the HHA occur.
- How do HHA employees implement advance directives requirements?

G111

§484.10(d) Standard: Confidentiality of Medical Records

The patient has the right to confidentiality of the clinical records maintained by the HHA.

G112

§484.10(d) - The HHA must advise the patient of the agency's policies and procedures regarding disclosure of clinical records

Interpretive Guidelines §484.10(d)

For specific requirements concerning the confidentiality of OASIS data, see the guidelines at §484.11.

Probes §484.10(d)

- How does the HHA ensure the confidentiality of the patient's clinical record?
- If the HHA leaves a portion of the clinical record in the home (such as in some high technology situations when frequent clinical entries are important), how does the HHA instruct the patient or caretaker about protecting the confidentiality of the record?
- What documentation in the clinical record indicates that the HHA informed the patient of the HHA's policies and procedures concerning clinical record disclosure?

G113

§484.10(e) Standard: Patient Liability for Payment

(1) The patient has the right to be advised, before care is initiated, of the extent to which payment for the HHA services may be expected from Medicare or other sources, and the extent to which payment may be required from the patient.

G114

§484.10(e)(1) - Before the care is initiated, the HHA must inform the patient, orally and in writing, of--

(i) The extent to which payment may be expected from Medicare, Medicaid, or any other Federally funded or aided program known to the HHA;

(ii) The charges for services that will not be covered by Medicare; and

(iii) The charges that the individual may have to pay.

Interpretive Guidelines §484.10(e)(1)

During home visits, ask the patient whether the HHA has notified him or her of covered and noncovered services. Also, discuss whether the HHA has described any services for which the patient might have to pay and how payment sources might change (or have changed) during the course of care. Again, consider the patient's ability to understand and retain payment information. The subject of payment for home care services is often complex and confusing, particularly early in the course of treatment when the patient's illness or limitations appears to be the more pressing problem.

Look for a written statement in the home that might serve as a resource or reminder to the patient about the information the HHA has presented. Also, note whether there are subsequent written statements about payments for items or services of which the HHA has become aware.

In your evaluation of compliance with this standard, consider whether the HHA is making a reasonable attempt to help the patient understand how the charges for HHA services will be covered or not covered over the course of treatment. Based on the information provided by the HHA, do you believe that the patient has a reasonable understanding of how payment for home care services will likely occur and can make reasonable, informed decisions about financial matters related to the HHA's care and treatment of him or her.

Do **NOT** try to advise the patient about financial, coverage, or payment issues.

G115

(2) The patient has the right to be advised orally and in writing of any changes in the information provided in accordance with paragraph (e)(1) of this section when they occur. The HHA must advise the patient of these changes orally and in writing as soon as possible, but no later than 30 calendar days from the date that the HHA becomes aware of a change.

Interpretive Guidelines §484.10(e)

During home visits, ask the patient whether the HHA has notified him or her of covered and non-covered services. Also, discuss whether the HHA has described any services for which the patient might have to pay and how payment sources might change (or have changed) during the course of care. Again, consider the patient's ability to understand and retain payment information. The subject of payment for home care services is often complex and confusing, particularly early in the course of treatment when the patient's illness or limitations appears to be the more pressing problem.

Look for a written statement in the home that might serve as a resource or reminder to the patient about the information the HHA has presented. Also, note whether there are

subsequent written statements about payments for items or services of which the HHA has become aware.

Probes §484.10(e)

- What process is followed by the HHA to inform the patient of home care charges and probable payment sources, patient's payment liability (if any), and of changes in payment sources and patient liabilities?
- What documentation in the clinical record indicates that the HHA informed the patient of Federally-funded or aided covered and non-covered services?

G116

§484.10(f) Standard: Home Health Hotline

The patient has the right to be advised of the availability of the toll-free HHA hotline in the State. When the agency accepts the patient for treatment or care, the HHA must advise the patient in writing of the telephone number of the home health hotline established by the State, the hours of operation, and that the purpose of the hotline is to receive complaints or questions about local HHAs. The patient also has the right to use this hotline to lodge complaints concerning the implementation of the advanced directive requirements.

Interpretive Guidelines §484.10(f)

During home visits, ask the patient about the HHA State hotline, when he/she would use it, and what he/she would expect as a result of its use. If the patient has difficulty answering questions about the hotline, ask the patient for a copy of the written information that the HHA has provided.

Federal facilities are not required to participate in the HHA State hotline.

G310

§484.11 Condition of Participation: Release of Patient Identifiable OASIS Information

The HHA and agent acting on behalf of the HHA in accordance with a written contract must ensure the confidentiality of all patient identifiable information contained in the clinical record including OASIS data, and may not release patient identifiable information to the public.

Interpretive Guidelines §484.11

Protection of confidentiality of OASIS information is two-fold; the HHA has a responsibility to keep OASIS information confidential and CMS has a responsibility to keep it confidential, once it has been transmitted to the OASIS State system.

Under this condition of participation, the HHA is required to maintain the confidentiality of OASIS data while it is being used for patient care and may not release it without the consent of the patient for any reason other than for what it is intended, which is to appropriately deliver patient care. HHAs must have policies and procedures for limiting access to OASIS information to only those persons the HHA designates.

If the HHA contracts with a vendor for transmission of its OASIS data, a written agreement that addresses the confidentiality of that data must be in place. Violations of data confidentiality by an entity contracted by the HHA are still the responsibility of the HHA and would constitute condition-level non-compliance; therefore the HHA is ultimately responsible for compliance with the confidentiality requirements and is the responsible party if the contractor does not meet the requirements.

For privacy and security reasons, communication of OASIS information (from branch to branch, branch to parent, parent to vendor, etc.) must be done in accordance with CMS policies on the communication of patient-identifiable information. HHAs must have processes in place to assure that access to and transfer and delivery of OASIS information is limited to only authorized personnel.

HHAs that contract with accrediting organizations (AO), such as the Joint Commission (TJC), the Community Health Accreditation Program (CHAP), or the Accreditation Commission for Health Care, Inc., (ACHC) for determining compliance with the Medicare Conditions of Participation may share Outcome –based Quality Improvement /Monitoring (OBQI/M) reports with representatives of the appropriate AO on survey. The AO has a responsibility to review the OBQI/M reports and the HHA must provide the reports in the course of normal HHA business. State Agencies and Regional Offices may not share OBQI/M reports with the AO because no data use agreement exists with the SA/RO and the AO.

The other step in assuring confidentiality of the OASIS data is at the Federal level and involves the Federal Privacy Act of 1974. Coverage under the Federal Privacy Act begins when the data reaches the State agency. The Privacy Act requires that policies and procedures related to the collection of information be made available to the public describing the reasons for collecting OASIS data, what will be done with it, and who will have access to it in an identifiable format. The Privacy Act puts into place certain processes that protect patient identifiable data from unauthorized use and disclosure. Provisions of the Privacy Act as they relate to the collection of OASIS data are described in detail on the OASIS Statement of Patient Privacy Rights (See §484.10(a)).

Onsite Activity - Verify that the HHA has established a mechanism to ensure confidentiality of OASIS data. Interview the administrator and staff regarding:

- Protecting confidentiality of OASIS data (written and/or electronic).

- Assignment and maintenance of secure passwords for data encoding and transmission.
- Determine how OASIS data, whether in hard copy or electronic format is kept confidential before and after transmission to the State agency.

Interview the HHA administrator or system administrator for:

- Knowledge and application of rights to add, edit, or otherwise modify encoded OASIS data;
- Assignment of passwords;
- Assurance that only specified staff have contact with assessment information; and
- Actions taken when an employee with access to the system leaves the HHA's employment.

If possible, observe security of the OASIS data-entry location. Observe if the computer screen is logged off or password protected when not attended.

If applicable, review vendor contracts for provisions protecting confidentiality of OASIS data and determine what systems are in place to assure confidentiality throughout the transmission process. Vendors must be aware of the requirements and security policies of the HHA.

If questions are raised through interview or record review, review HHA's policies regarding confidentiality of patient information.

Probes §484.11

- How does the HHA assure that only specified personnel have access to OASIS assessment information?
- How is the security of passwords maintained?
- What policies and procedures address password assignment and use?
- How does the HHA assure that the computer is "logged off" or password protected when the data entry operator is away from the computer, i.e., at lunch or break times?
- Who in the HHA has the password information needed to electronically report OASIS data to the State agency? At least two staff persons should have the password.
- If the HHA has branches, how is OASIS data protected and kept secure during transfer from the branch to the parent agency?

- If the HHA contracts out OASIS encoding and reporting, what systems are in place to assure that the contracted vendor maintains confidentiality of OASIS data?

G117

§484.12 Condition of Participation: Compliance With Federal, State and Local Laws, Disclosure and Ownership Information, and Accepted Professional Standards and Principles

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G118

§484.12(a) Standard: Compliance with Federal, State, and Local Laws and Regulations

The HHA and its staff must operate and furnish services in compliance with all applicable Federal, State, and local laws and regulations. If State or applicable local law provides for the licensure of HHAs, an agency not subject to licensure is approved by the licensing authority as meeting the standards established for licensure.

Interpretive Guidelines §484.12(a)

Failure of the HHA to meet a Federal, State or local law may only be cited under the following circumstances:

1. When the Federal, State or local authority having jurisdiction has both made a determination of non-compliance and has taken a final adverse action as a result;

   or

2. When the language of the Federal regulation requires compliance with explicit Federal, State or local laws and codes as a criterion for compliance.

If State law provides for the licensure of HHAs, request to see a copy of the current license. Publicly operated HHAs, such as public health agencies, or HHAs based in a public hospital, are examples of agencies that a State may exempt from State licensure.

Notify the RO if you suspect that you have observed noncompliance with an applicable Federal law related to the provider's HHA program. The RO will notify the appropriate Federal agency of your observations.

Probes §484.12(a)

- How does the HHA ensure that **all** professional employees and personnel used under arrangement and by contract have current licenses and/or registrations if they are required?

G119

§484.12(b) Standard: Disclosure of Ownership and Management Information

The HHA must comply with the requirements of Part 420, Subpart C of this chapter.

G120

§484.12(b) - The HHA also must disclose the following information to the State survey agency at the time of the HHA's initial request for certification, for each survey, and at the time of any change in ownership or management:

(1) The name and address of all persons with an ownership or control interest in the HHA as defined in §§420.201, 420.202, and 420.206 of this chapter.

(2) The name and address of each person who is an officer, a director, an agent or a managing employee of the HHA as defined in §§420.201, 420.202, and 420.206 of this chapter.

(3) The name and address of the corporation, association, or other company that is responsible for the management of the HHA, and the name and address of the chief executive officer and the chairman of the board of directors of that corporation, association, or other company responsible for the management of the HHA.

Interpretive Guidelines §484.12(b)

Review the HHA's disclosure of ownership information carefully for completeness and compliance with this standard. This information can be found on the Form CMS-855. Information required to be disclosed in this standard, but not required on the form, such as whether any person with an ownership interest in an HHA is related to another such individual, should be disclosed to the State Survey Agency by the HHA in writing and attached.

A "**managing employee**" is a general manager, business manager, administrator, director or other individual who exercises operational or managerial control over, or who directly

or indirectly conducts the day-to-day operations of the HHA. The HHA administrator (§484.14(b)) and the supervisory physician or supervisory registered nurse (§484.14(d)) would meet the definition of a managing employee.

Probes §484.12(b)

- Is the information on the Form CMS-855, consistent with information you find in the agency's organizational structure (i.e., organizational charts and lines of authority, management contracts, bylaws, minutes of board meetings)?
- How does the HHA implement its policy or procedure for reporting changes in ownership and management information to the State?

G121

(Rev.)

§484.12(c) Standard: Compliance with Accepted Professional Standards and Principles

The HHA and its staff must comply with accepted professional standards and principles that apply to professionals furnishing services in an HHA.

Interpretive Guidelines §484.12(c)

The expected outcome for this Level 1 standard is that all care providers follow parameters defined by State practice acts, Federal and State laws and regulations, HHA policies and other professionally accepted guidelines (e.g., CDC guidelines for infection control).

The accepted professional standards and principles that the HHA and its staff must comply with include, but are not limited to, the HHA Federal regulations, State practice acts, commonly accepted health standards established by national organizations, boards, and councils (i.e., the American Nurses' Association standards) and the HHA's own policies and procedures.

An HHA may be surveyed for compliance with State practice acts for each relevant discipline. Any deficiency cited as a violation of a State practice act must reference the applicable section of the State practice act which is allegedly violated and a copy of that section of the act must be provided to the HHA along with the statement of deficiencies.

Any deficiency cited as a violation of accepted standards and principles must have a copy of the applicable standard provided to the HHA along with the statement of deficiencies.

If an HHA has developed professional practice standards and principles for its program staff, there should be information available which demonstrates that the HHA monitors its staff for compliance and takes corrective action, as needed.

If questions arise during interviews, home visits or record reviews, consider:

- *Reviewing the HHA policies and procedures for the area of concern.*
- *Identifying and reviewing materials that the HHA provides to staff as clinical/procedural resources.*

Probes §484.12(c)

- How does the HHA monitor its employees and personnel serving the HHA under arrangement or contract to ensure that services provided to patients are within acceptable professional practice standards for each discipline?
- How does the HHA monitor the professional skills of its staff to determine if skills are appropriate for the care required by the patients the HHA admits?
- Are there examples of care provision not in compliance with laws, regulations, accepted professional standards and/or HHA policies and procedures (e.g., documentation of wound care, wound assessment, or physical assessment)?

G122

§484.14 Condition of Participation: Organization, Services, and Administration

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G123

(Rev.)

§484.14 - Organization, services furnished, administrative control, and lines of authority for the delegation of responsibility down to the patient care level are clearly set forth in writing and are readily identifiable.

Interpretive Guidelines §484.14

The expected outcome for this Level 1 standard is that the lines of authority within the HHA are clearly defined for delegation of responsibility to the patient care level.

Probes §484.14

Review the organizational chart in relation to descriptions provided by administrative and clinical staff.

G124

§484.14 - Administrative and supervisory functions are not delegated to another agency or organization and

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G125

§484.14 - All services not furnished directly, including services provided through subunits are monitored and controlled by the parent agency.

G126

§484.14 - If an agency has subunits, appropriate administrative records are maintained for each subunit.

Interpretive Guidelines §484.14

The HHA's policies and procedures, disclosure information required for §484.12, or other forms of documentation (e.g., organizational charts) should be used to determine compliance with this condition.

A local (city or county) health department may specify that the entire department or subdivision of the department is the HHA. If the entire department is identified as the HHA, the organizational structure, as documented, should specify:

- Where primary supervisory responsibility rests;
- How various divisions and bureaus are involved;
- Who has responsibility for the division or the bureau; and
- Where the focal point is for HHA relationships with the State agency and intermediary.

Similarly, a hospital-based HHA that reports through the hospital's organizational structure to several administrators and/or departments should specify the same points previously mentioned. (Refer to §2186 of the SOM.)

The same points of clarification would be necessary for any HHA, which has entered into agreements, contracts or mergers with one or more corporate entities.

Regardless of the formal organizational structure, the overall responsibility for all services provided, whether directly, through arrangements or contracts, rests with the HHA that has assumed responsibility for admitting patients and implementing plans of care.

Examples:

1. An HHA may, in arranging or contracting for a service such as physical therapy, require the other party to do the day-by-day professional evaluation of the therapy service. However, the HHA may not delegate its overall administrative and supervisory responsibilities. The contract should specify how HHA supervision will occur.

2. An HHA may not use a full-time employee of another legal entity to fulfill its supervisory or administrative functions concurrently. For example: A freestanding HHA locates at a hospital and names a full-time hospital employee as the HHA supervisor. The HHA does not pay the nursing supervisor a salary for the HHA-related services. Because the hospital continues to employ the nursing supervisor, this arrangement clearly delegates HHA supervisory functions to another legal entity, i.e., the hospital.

Use §2182, Certification Process, State Operations Manual, to help make determinations regarding branches and/or subunits. Remember that these determinations **must** be made on a case-by-case basis using the definitions contained in §484.2 and the additional criteria described in §2182. Request information that helps you decide if the organizational entity is "sufficiently" close to the parent agency that it is not impractical for it to share administration, supervision, and services from the parent agency on a day-to-day basis. If so, the organizational entity may be classified as a branch. Because circumstances may vary widely among regions and among States within regions, **it is inappropriate to set criteria such as mileage or time** for purposes of determining branch or subunit status. If there is doubt as to the appropriateness of branch and subunit delineation, a visit to the branch for further evaluation is encouraged.

A branch office, as an extension of the parent HHA, **may not** offer services that are different than those offered by the parent HHA.

The subunit may provide services other than those provided by the parent because it is semi-autonomous, serves patients in a different geographical area, and must meet the Conditions of Participation separately from the parent HHA. The subunit may have branches.

Probes §484.14

- How does the HHA monitor and exercise control over services provided by personnel under arrangements or contracts? In a branch? In a subunit?
- Can HHA administrative and clinical supervisory personnel describe clearly the lines of authority and responsibility for the administration, delivery, and supervision of services:
    - Between parent, branch, and/or subunits?

    - If the HHA is part of a larger organizational entity such as a State or local health department, hospital, skilled nursing facility or health maintenance organization?
    - If the HHA offers services such as homemaker, personal care aides, private duty nursing, or hospice?
- Who has responsibility for maintaining employee assignments, plans of care, and minutes of interdisciplinary and administrative meetings integral to the organization and supervision of the HHA's services?

G127

§484.14(a) Standard: Services Furnished.

Part-time or intermittent skilled nursing services and at least one other therapeutic service (physical, speech or occupational therapy; medical social services; or home health aide services) are made available on a visiting basis, in a place of residence used as a patient's home. An HHA must provide at least one of the qualifying services directly through agency employees, but may provide the second qualifying service and additional services under arrangements with another agency or organization.

Interpretive Guidelines §484.14(a)

An HHA is considered to provide a service "directly" when the person providing the service for the HHA is an HHA employee. For purposes of meeting § 484.14(a), an individual who works for the HHA on an hourly or per-visit basis may be considered an agency employee if the HHA is required to issue a form W-2 on his/her behalf. An HHA is considered to provide a service "under arrangements" when the HHA provides the service through contractual or affiliation arrangements with other agencies or organizations, or with an individual(s) who is not an HHA employee.

Probes §484.14(a)

How do the terms of the HHA agreements/contracts ensure that the HHA has the requisite control over its provision of services?

G128

§484.14(b) Standard: Governing Body.

A governing body (or designated persons so functioning) assumes full legal authority and responsibility for the operation of the agency.

G129

§484.14(b) - The governing body appoints a qualified administrator,

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G130

§484.14(b) - arranges for professional advice as required under §484.16,

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G131

§484.14(b) - adopts and periodically reviews written bylaws or an acceptable equivalent, and

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G132

§484.14(b) - oversees the management and fiscal affairs of the agency.

Interpretive Guidelines §484.14(b)

An HHA may use the services of a management company to strengthen its own administrative services. An HHA's documented agreement with a management company or employee leasing company must specify that the legal authority and full control of the HHA's operation remain with the HHA and that the HHA's governing body retains the responsibilities specified in §484.14(b). This means that the HHA, through the governing body (or designated persons so functioning), must assume the full legal authority and responsibility for the operations of the agency, including its policies, procedures, services, organization, and budget preparation. These responsibilities must be clearly defined in the written agreement with the management or employee leasing company.

Probes §484.14(b)

- How does the governing body exercise its responsibility for the overall operation of the HHA, including the HHA's budget and capital expenditure plan, and the overall management, supervision, and evaluation of the HHA and its patients' outcomes? (Review documents which outline these responsibilities.)

G133

(Rev.)

§484.14(c) Standard: Administrator

The administrator, who may also be the supervising physician or registered nurse required under paragraph (d) of this section, organizes and directs the agency's ongoing functions; maintains ongoing liaison among the governing body, the group of professional personnel, and the staff;

Interpretive Guidelines §484.14(c)

The expected outcome for this Level 1 standard is that the HHA has a qualified administrator appointed by the governing body who directs day-to-day agency functions according to regulations, policies and procedures and maintains ongoing liaison among the governing body, the group of professional personnel, and the staff.

G134

§484.14(c) - employs qualified personnel and ensures adequate staff education and evaluations;

G135

§484.14(c) - ensures the accuracy of public information materials and activities; and

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G136

§484.14(c) - implements an effective budgeting and accounting system.

G137

§484.14(c) - A qualified person is authorized in writing to act in the absence of the administrator.

Probes §484.14(c)

- How do the specific administrative activities identified in the standard impact on the services of the HHA?
- What individual is authorized to act in the absence of the administrator?

G138

§484.14(d) Standard: Supervising Physician or Registered Nurse

The skilled nursing and other therapeutic services furnished are under the supervision and direction of a physician or a registered nurse (who preferably has at least 1 year of nursing experience and is a public health nurse).

G139

§484.14(d) - This person, or similarly qualified alternate, is available at all times during operating hours and

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G140

§484.14(d) - participates in all activities relevant to the professional services furnished, including the development of qualifications and the assignment of personnel.

Interpretive Guidelines §484.14(d)

"**Available at all times during operating hours**" means being readily available on the premises or by telecommunications. How the supervising physician or supervising registered nurse structures his or her availability is a management decision for the HHA. "Operating hours" means all hours that staff from the agency are providing services to patients.

G141

§484.14(e) Standard: Personnel Policies

Personnel practices and patient care are supported by appropriate, written personnel policies.

Personnel records include qualifications and licensure that are kept current.

Interpretive Guidelines 484.14(e)

The numbers and qualifications of personnel available to provide services must be sufficient to implement the plans of care and the medical, nursing, and rehabilitative needs of the patients admitted by the HHA.

Probes §484.14(e)

- What does the HHA include in the personnel records about the qualifications and licensure of its employees?
- If the HHA does not keep duplicate personnel records of staff hired under arrangement, how does it ensure that records are kept current?

G142

§484.14(f) Standard: Personnel Under Hourly or Per Visit Contracts

If personnel under hourly or per visit contracts are used by the HHA, there is a written contract between those personnel and the agency that specifies the following:

(1) Patients are accepted for care only by the primary HHA.

(2) The services to be furnished.

(3)The necessity to conform to all applicable agency policies, including personnel qualifications.

(4) The responsibility for participating in developing plans of care.

(5) The manner in which services will be controlled, coordinated, and evaluated by the primary HHA.

(6) The procedures for submitting clinical and progress notes, scheduling of visits, periodic patient evaluation.

(7) The procedures for payment for services furnished under the contract.

Interpretive Guidelines §484.14(f)

If an HHA, which has been established as hospital-based for Medicare payment purposes, has arranged with the hospital to provide the second qualifying service or other HHA services (see §484.14(a)) through hospital employees, the HHA would not be required to have an hourly or per visit contract with these hospital employees. The HHA should identify in its records the names of these employees and the amount of time they spend at the HHA. However, if these hospital employees provide services to the HHA outside of their own usual working hours or shifts (i.e., “moonlight” as HHA employees, as opposed to working overtime for the hospital), a contract as specified in standard (f) applies.

Probes §484.14(f)

- How does the HHA orient contractual personnel to HHA objectives, policies, procedures, and programs?
- How does the HHA evaluate whether contractual personnel inform the patient of his/her rights prior to the beginning of care or when there are changes in care?
- How are contractual personnel monitored by the HHA to confirm that the care provided is consistent with the plans of care and that their services meet the terms of the contract?
- Who reviews the recertification requests to determine if continuing patient care is indicated as a probable medical necessity?

G143

(Rev.)

§484.14(g) Standard: Coordination of Patient Services

All personnel furnishing services maintain liaison to ensure that their efforts are coordinated effectively and support the objectives outlined in the plan of care. . . . .

Interpretive Guidelines §484.14(g)

The expected outcome for this Level 1 standard is that information regarding each patient's health status and plan of care is communicated among all relevant care providers, including, but not limited to, the home health aide and the physician.

Probes §484.14(g)

- *Ask clinical managers and HHA staff about specific patients, including how information about patient condition, response to interventions and teaching, changes in the plan of care, and discharge planning are communicated among the appropriate care providers and where those communications are documented.*
- *How does coordination of care among staff and/or contract personnel providing services to individual patients occur?*
- *When pertinent clinical findings are noted during a visit (e.g., changes in patient condition, new medication, lab values, updates to the plan of care, etc.), how does the HHA follow up or share the information with the appropriate care providers? Is there evidence that the communication plan was implemented?*
- *Is information about patient condition, response to interventions (e.g., medication side effects, responses to wound therapy, laboratory values, etc.) and teaching, changes in the plan of care, and discharge planning discussed with or forwarded to the appropriate care providers, including but not limited to the home health aide and physician?*
- *Are case conferences, informal conferences and phone calls documented?*

If questions arise during interviews, home visits or record reviews, consider reviewing the following documents:

- *HHA policies regarding coordination of care, communication with team members, etc.*
- *Contracts of services provided under arrangement.*
- *The clinical records or minutes of case conferences.*

G144

(Rev.)

§484.14(g) - …The clinical record or minutes of case conferences establish that effective interchange, reporting, and coordination of patient care does occur.

Interpretive Guidelines §484.14(g)

The expected outcome for this Level 1 standard is that communication among care providers is documented (e.g., case conferences, phone calls, etc.).

G145

§484.14(g) - A written summary report for each patient is sent to the attending physician at least every 60 days.

Probes §484.14(g)

- What is the HHA's policy related to facilitating exchange of information among staff?
- How does the HHA ensure that patients' written summary reports sent to attending physicians every 60 days meet the regulatory requirements of §482.2?

Refer to §484.48 regarding guidelines for the attending physician's written summary report.

G146

§484.14(h) Standard: Services Under Arrangement.

Services furnished under arrangements are subject to a written contract conforming with the requirements specified in paragraph (f) of this section and with the requirements of §1861(w) of the Act (42 U.S.C. 1494x(w)).

Interpretive Guidelines §484.14(h)

Section 1861(w) of the Act states that an HHA may have others furnish covered items or services through arrangements under which receipt of payment by the HHA for the services discharges the liability of the beneficiary or any other person to pay for the services. This holds true whether the services and items are furnished by the HHA itself or by another agency under arrangements. Both must agree not to charge the patient for covered services and items and to return money incorrectly collected.

G147

§484.14(i) Standard: Institutional Planning.

The HHA, under the direction of the governing body, prepares an overall plan and a budget that includes an annual operating budget and capital expenditure plan.

§484.14(i)(1) Standard: Annual Operating Budget.

There is an annual operating budget that includes all anticipated income and expenses related to items that would, under generally accepted accounting principles, be considered income and expense items. However, it is not required that there be prepared, in connection with any budget, an item by item identification of the components of each type of anticipated income or expense.

§484.14(i)(2) Standard: Capital Expenditure Plan.

(i) There is a capital expenditure plan for at least a 3-year period, including the operating budget year. The plan includes and identifies in detail the anticipated sources of financing for, and the objectives of, each anticipated expenditure of more than $600,000 for items that would, under generally accepted accounting principles, be considered capital items. In determining if a single capital expenditure exceeds $600,000, the cost of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition, improvement, modernization, expansion, or replacement of land, plant, building, and equipment are included. Expenditures directly or indirectly related to capital expenditures, such as grading, paving, broker commissions, taxes assessed during the construction period, and costs involved in demolishing or razing structures on land are also included.

Transactions that are separated in time, but are components of an overall plan or patient care objective, are viewed in their entirety without regard to their timing. Other costs related to capital expenditures include title fees, permit and license fees, broker commissions, architect, legal, accounting, and appraisal fees; interest, finance, or carrying charges on bonds, notes and other costs incurred for borrowing funds.

(ii) If the anticipated source of financing is, in any part, the anticipated payment from title V (Maternal and Child Health and Crippled Children's Services) or title XVIII (Medicare) or title XIX (Medicaid) of the Social Security Act, the plan specifies the following:

(A) Whether the proposed capital expenditure is required to conform, or is likely to be required to conform, to current standards, criteria, or plans developed in accordance with the Public Health Service Act or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963.

(B) Whether a capital expenditure proposal has been submitted to the designated planning agency for approval in accordance with section 1122 of the Act (42 U.S.C. 1320a-1) and implementing regulations.

(C) Whether the designated planning agency has approved or disapproved the proposed capital expenditure if it was presented to that agency.

G148

§484.14(i)(3) - Standard: Preparation of Plan and Budget.

The overall plan and budget is prepared under the direction of the governing body of the HHA by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff (if any) of the HHA.

G149

§484.14(i)(4) - Standard: Annual Review of Plan and Budget

The overall plan and budget is reviewed and updated at least annually by the committee referred to in paragraph (i)(3) of this section under the direction of the governing body of the HHA.

Interpretive Guidelines §484.14(i)

An HHA with branches and/or subunits requires only one overall plan and one budget which should include the resources and expenditures of all branches and subunits.

G150

(Rev.)

§484.14(j) Standard: Laboratory Services.

(1) If the HHA engages in laboratory testing outside of the context of assisting an individual in self-administering a test with an appliance that has been cleared for that purpose by the FDA, such testing must be in compliance with all applicable requirements of part 493 of this chapter.

Interpretive Guidelines §484.14(j)(1)

Determine if the HHA is providing laboratory testing as set forth at § 493. If the HHA is performing testing, request to see the CLIA certificate for the level of testing being performed, i.e., a certificate of waiver, certificate for provider-performed microscopy procedures, certificate of accreditation, certificate of registration, or certificate of compliance (issued upon the determination of compliance after an on-site survey.)

HHAs holding a certificate of waiver are limited to performing only those tests determined to be in the waived category. Some tests that an HHA may perform that fall into the waived category include:

- Dipstick/tablet reagent urinalysis;
- Blood glucose by glucose monitoring devices cleared by the Food and Drug Administration (FDA) specifically for home use;
- Some prothrombin time tests; and
- Some glycosolated hemoglobin tests.

For a complete listing of waived tests, refer to CMS' website at *http://www.cms.hhs.gov/CLIA/10_Categorization_of_Tests.asp#TopOfPage*

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**:

The tests in the provider-performed microscopy procedures category (e.g., wet mounts, urine sediment examinations, and nasal smears for granulocytes) are not typical of those performed in an HHA; however, if they are conducted by HHA staff under a certificate for provider-performed microscopy procedures, they must be performed by a practitioner as specified at §493.19 (i.e., a physician, nurse midwife, nurse practitioner, physician assistant, or dentist). If not performed by these personnel, the HHA would require a registration certificate (which allows the performance of such testing until a determination of compliance is made), certificate of accreditation, or certificate of compliance.

For a complete listing of provider-performed microscopy procedures, refer to CMS' website at *http://www.cms.hhs.gov/CLIA/10_Categorization_of_Tests.asp#TopOfPage.*

If the HHA performs any other testing procedures, (i.e., moderate or high complexity testing), it would require a registration certificate, a certificate of accreditation, or a certificate of compliance. While some prothrombin testing is in the waived category, as mentioned above, other prothrombin testing is considered moderate complexity testing depending on the skill level required to operate the instrument.

For a complete listing of moderate and high complexity tests, refer to CMS' website at *http://www.cms.hhs.gov/CLIA/10_Categorization_of_Tests.asp#TopOfPage.*

Assisting individuals in administering their own tests, such as fingerstick blood glucose or prothrombin testing, is not considered testing subject to the CLIA regulations. However, if the HHA staff is actually responsible for measuring the blood glucose level or prothrombin times of patients with an FDA approved blood glucose or prothrombin time monitor, and no other tests are being performed, request to see the facility's certificate of waiver, since glucose testing with a blood glucose meter (approved by the FDA specifically for home use) and some prothrombin time tests are waived tests under the provisions at § 493.15.

If the facility does not possess the appropriate CLIA certificate, inform the facility that it is in violation of CLIA law and that it must apply immediately to the State agency for the appropriate certificate. The facility is out of compliance with § 484.14(j). Also, refer this facility's noncompliance to the department within the State agency responsible for CLIA surveys.

(2) If the HHA chooses to refer specimens for laboratory testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of Part 493 of this chapter.

Interpretive Guidelines §484.14(j)(2)

If the HHA refers specimens for laboratory testing to an outside laboratory, the referral laboratory must be CLIA-certified. The HHA should have a copy of the referral laboratory's CLIA certificate in its administrative records.

G151

§484.16 Condition of Participation: Group of Professional Personnel

G152

§484.16 - A group of professional personnel, which includes at least one physician and one registered nurse (preferably a public health nurse), and with appropriate representation from other professional disciplines,

G153

§484.16 - establishes and annually reviews the agency's policies governing scope of services offered, admission and discharge policies, medical supervision and plans of care, emergency care, clinical records, personnel qualifications, and program evaluation. At least one member of the group is neither an owner nor an employee of the agency.

Interpretive Guidelines §484.16

If an HHA has a branch(es), the annual review includes services delivered through the branch(es).

The parent agency's group of professional personnel or a subcommittee of the group may also serve as the subunit's group of professional personnel or the subunit may establish its own group.

If the HHA is part of a larger organization (e.g., a State, county, hospital) and the parent organization's policies are mostly applicable to the HHA, the HHA does not have to develop new policies. Rather, the HHA should review and revise patient policies to accommodate the conditions of participation, the patient care needs of the HHA and the quality of services to be provided.

G154

§484.16(a) Standard: Advisory and Evaluation Function

The group of professional personnel meets frequently to advise the agency on professional issues, to participate in the evaluation of the agency's program, and to assist the agency in maintaining liaison with other health care providers in the community and in the agency's community information program.

G155

§484.16(a) - The meetings are documented by dated minutes.

Probes §484.16(a)

- What documentation is there of advice concerning professional issues, evaluation of the professional service program, or assistance in maintaining liaison with other community groups by the professional group?

G156

§484.18 Condition of Participation: Acceptance of Patients, Plan of Care, and Medical Supervision.

G157

(Rev.)

§484.18 - Patients are accepted for treatment on the basis of a reasonable expectation that the patient's medical, nursing, and social needs can be met adequately by the agency in the patient's place of residence. . . .

Interpretive Guidelines §484.18

The expected outcome for this Level 1 standard is that the HHA will only accept patients for care if the HHA can adequately meet the patient's medical, nursing and social needs in the patient's place of residence.

G158

(Rev.)

§484.18 - . . . Care follows a written plan of care established and periodically reviewed by a doctor of medicine, osteopathy, or podiatric medicine.

Interpretive Guidelines §484.18

The expected outcome for this Level 1 standard is that every HHA patient will have a written plan of care established and periodically reviewed by a doctor of medicine, osteopathy, or podiatric medicine.

It is CMS' policy to require that the HHA must have a plan of care for each patient, regardless of the patient's Medicare status or that nurse practice acts do not specifically require a physician's order. The CoPs do not require a physician's order for services furnished by the HHA that are not related to the patient's illness, injury, or treatment of the patient's medical, nursing, or social needs.

Medical orders may authorize a specific range in the frequency of visits for each service (i.e., 2-4 visits per week) to ensure that the most appropriate level of service is provided to the patient. However, ranges *that* include "0" as a frequency are not allowed, because "0" is not a frequency. The regulation requires the HHA to alert the physician to any changes that suggest a need to alter the plan of care. If the HHA provides fewer visits than the physician orders, it has altered the plan of care and the physician must be notified. The HHA must maintain documentation in the clinical record indicating that the physician was notified and is aware of the missed visit.

Orders for services to be furnished "as needed" or "PRN" must be accompanied by a description of the patient's medical signs and symptoms that would occasion a visit and a specific limit on the number of those visits to be made under the order before an additional physician order would have to be obtained.

Probes §484.18

- What evidence (if any) demonstrates that patients are admitted or denied services for reasons contrary to the intent of this standard?

G159

(Rev.)

§484.18(a) Standard: Plan of Care

The plan of care developed in consultation with the agency staff covers all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items.

Interpretive Guidelines §484.18(a)

The expected outcomes for this Level 1standard are:

- *Patients receive appropriate services and care based on an assessment of their needs and physician orders.*
- *HHA develops a plan of care specific to each patient's needs and containing all required elements.*

G160

§484.18(a) - If a physician refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician is consulted to approve additions or modification to the original plan.

G161

§484.18(a) - Orders for therapy services include the specific procedures and modalities to be used and the amount, frequency, and duration.

G162

§484.18(a) - The therapist and other agency personnel participate in developing the plan of care.

Interpretive Guidelines §484.18(a)

A statutory change renamed the "plan of treatment" to "the plan of care." These terms are synonymous. Neither is to be confused with a nursing care plan.

The conditions do not require an HHA to either develop or maintain a nursing care plan as opposed to a medical plan of care. This does not preclude an HHA from using nursing care plans if it believes that such plans strengthen patient care management, the organization and delivery of services, and the ability to evaluate patient outcomes.

Review a case-mix, stratified sample of clinical records (see §2200B) to determine if the requirements of this standard are met.

Written HHA policies and procedures should specify that all clinical services are implemented only in accordance with a plan of care established by a physician's written orders. Policies should also specify if the HHA:

- Accepts physician's orders on referral communicated verbally by an institution's discharge planner, nurse practitioner, physician's assistant, or other authorized staff member followed by written, signed and dated physician's orders, in order to begin HHA services as soon as possible.

- Accepts signed physician certification and recertification of plans of care, as well as signed orders changing the plan of care, by telecommunication systems ("fax"), which are filed in the clinical record.

The plan of care must be established and authorized in writing by the physician based on an evaluation of the patient's immediate and long term needs. The HHA staff, and if appropriate, other professional personnel, shall have a substantial role in assessing patient needs, consulting with the physician, and helping to develop the overall plan of care.

The patient has the right, and should be encouraged, to participate in the development of the plan of care before care is started and when changes in the established plan of care are implemented. (See §484.10(c)(2).)

Section 1861(r) of the Act defines the term "physician" to permit a podiatrist to establish and recertify an HHA patient's plan of care. The podiatrist's functions must be consistent with the HHA's policies and procedures that pertain to therapeutic activities he/she is legally authorized by the State to perform.

The regulation requires at G161 that orders for therapy services include the specific procedures and modalities to be used and the amount, frequency, and duration of the therapy ordered.

"**Modalities**" are defined as any physical agent applied to produce therapeutic changes to biologic tissue and include, but are not limited to, thermal, acoustic, light, mechanical, or electric energy. **"Procedures**" are defined as a manner of effecting change through the application of clinical skills and/or services that attempt to improve function. This can be achieved through exercise or training and must include active interventions between the therapist and patient.

Modalities that are supervised but do not require constant patient contact (by the provider) include hot or cold packs, traction, mechanical or electrical stimulation (unattended), acupuncture with electrical stimulation, vasopneumatic devices, paraffin bath, microwave, whirlpool, diathermy, infrared and ultraviolet. Modalities requiring constant attendance include electrical stimulation (manual), iontophoresis, contrast baths, ultrasound and Hubbard tank. Items such as Theraband, free weights and stationary bikes are not considered modalities. They are considered equipment or items used in support of a procedure such as therapeutic exercise or neuromuscular reeducation.

Probes §484.18(a)

- How does an HHA evaluate whether the plan of care, and the coordination of services, help the patient attain and maintain his or her highest practicable functional capacity based on medical, nursing, and rehabilitative needs?
- How does the HHA monitor the delivery of services, including those provided under arrangement or contract, to ensure compliance with the specificity and frequency of services ordered in the plan of care?

- If a range of visits is ordered, how does the HHA ensure that the frequency of visits meets the clinical needs of the patient?

G163

§484.18(b) Standard: Periodic Review of Plan of Care

The total plan of care is reviewed by the attending physician and HHA personnel as often as the severity of the patient's condition requires, but at least once every 60 days or more frequently when there is a beneficiary elected transfer; a significant change in condition resulting in a change in the case-mix assignment; or a discharge and return to the same HHA during the 60-day episode. . . .

G164

(Rev.)

§484.18(b) - . . . Agency professional staff promptly alert the physician to any changes that suggest a need to alter the plan of care.

Interpretive Guidelines §484.18(b)

The expected outcome for this Level 1 standard is that changes in patient status, including measurements outside of stated parameters or any changes that suggest a need to alter the plan of care, are reported promptly to the physician. This includes notifying the physician of discharge when the patient's needs have been met.

Changes in the patient's condition that require a change in the plan of care should be documented in the patient's clinical record.

In the situation where the patient progresses to the point where it is no longer reasonable and necessary to continue services, because the patient's medical, nursing, and rehabilitative needs have been met adequately by the HHA, the HHA may notify the physician and discharge the patient, even though the certification period has not ended. The clinical record should maintain documentation that the physician was notified of the discharge, but it does not need to contain a physician's order for discharge. If, however, an HHA has a policy or is required by state law to obtain a physician's order before discharging a patient, the agency would be expected to abide by their policy and/or state law.

When a Medicare beneficiary elects to transfer to a different HHA or is discharged and returns to the same HHA, it warrants a new clock for purposes of payment, OASIS assessment, and physician certification of the new plan of care. When a new 60-day episode begins, the original 60-day episode payment is proportionally adjusted to reflect the length of time the beneficiary remained under the HHA's care before the intervening event. The proportional payment is the Partial Episode Payment (PEP) adjustment.

A Significant Change In Condition (SCIC) adjustment occurs when a Medicare beneficiary experiences a significant change in condition during a 60-day episode that was not envisioned in the original plan of care. In order to receive a new case-mix assignment for purposes of SCIC payment during the 60-day episode, the HHA must complete an OASIS assessment and obtain the necessary physician change orders reflecting the significant change in treatment approach in the patient's plan of care. Refer to current policy for the use of the OASIS assessment for SCIC adjustments.

G165

(Rev.)

§484.18(c) Standard: Conformance With Physician Orders.

Drugs and treatments are administered by agency staff only as ordered by the physician with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per agency policy developed in consultation with a physician, and after an assessment of contraindications . . . .

Interpretive Guidelines §484.18(c)

The expected outcome for this Level 1 standard is that HHA staff administer only medications and treatments as ordered by the physician (except influenza and pneumonia vaccines, which may be administered per agency policy developed in consultation with a physician, and after an assessment of contraindications.

G166

(Rev.)

§484.18(c) - . . . Verbal orders are put in writing and signed and dated with the date of receipt by the registered nurse or qualified therapist (as defined in §484.4 of this chapter) responsible for furnishing or supervising the ordered services. . . .

Interpretive Guidelines §484.18(c)

The expected outcome for this Level 1 standard is that all verbal orders are written, signed and dated by the appropriate RN or qualified skilled therapist.

Ask HHA's, whose pattern of obtaining signed physicians' orders exceeds the HHA's policy or State law, to clarify or explain what circumstances created the time lapse, and how they are approaching a resolution to the problem.

Other designated HHA personnel who accept verbal orders must do so in accordance with State and Federal law and regulations and HHA policy. Verbal orders must be

signed and dated by the registered nurse or qualified therapist who is furnishing or supervising the ordered service. It is the RN's or therapist's responsibility to make any necessary revisions to the plan of care based on that order.

Review HHA policies and procedures in regard to obtaining physician orders, changes in orders, and verbal orders. All physician orders must be included in the patient's clinical record. Plans of care must be signed and dated by the physician.

Probes §484.18(c)

- How does the HHA secure the physician's signature on verbal, change, or renewal orders?
- How does the HHA ensure that verbal orders are accepted, co-signed by the nurse or therapist, and countersigned by the physician appropriately?

G167

See 484.55(c)

Tag 167 expired on 6/1/99. A new tag concerning drug review is found at G337 and is applicable to all patients serviced by the HHA.

G300

Verbal orders are only accepted by personnel authorized to do so by applicable State and Federal laws and regulations, as well as by the HHA's internal policies.

G320

§484.20 Condition of Participation: Reporting OASIS Information

HHA's must electronically report all OASIS data collected in accordance with §484.55.

Interpretive Guidelines §484.20

(Rev.)

HHA's must electronically report OASIS data on all applicable patients in a format that meets CMS electronic data and edit specifications. For purposes of this requirement, the term "reporting" means electronic reporting.

Effective December 8, 2003, the collection of OASIS data on the non-Medicare/non-Medicaid patients of an HHA was temporarily suspended. HHAs must continue to

comply with the aspects of the regulation at § 484.55 regarding the comprehensive assessment of patients.

HHAs may continue to collect OASIS data on their non-Medicare/non-Medicaid patients for their own use. HHAs must continue to collect, encode, and transmit OASIS data for their non-maternity Medicare and Medicaid patients that are age 18 and over and receiving skilled services.

Private pay patients are defined to include any patient for whom (M0150) the Current Payment Source for Home Care does not include any of the following responses:

1- Medicare (Traditional fee-for-service)
2- Medicare (HMO/ managed care)
3- Medicaid (Traditional fee-for-service)
4- Medicaid(HMO/managed care).

If a patient has a private pay insurance **and** M0150 response 1, 2, 3, or 4 as an insurance to which the agency is billing the services, the comprehensive assessment including OASIS must be collected and transmitted. Medicare (HMO/managed care) does include Medicare Advantage (MA), formerly known as Medicare+Choice (M+C) plans and Medicare PPO plans.

HHAs or contracted entities acting on behalf of the HHA can report OASIS data to the State agency using the HAVEN software CMS provides free of charge or by using HAVEN-like software that conforms to the same specifications used to develop HAVEN. Reported OASIS data will be analyzed and findings made available to HHA's by way of reports that will help HHA's identify their performance level in the provision of care to the patient population they serve as compared with other HHA's on either a national, State or local level.

As part of the ongoing survey process, State agencies may establish policies in keeping with unannounced surveys that include the ongoing request, at specified intervals, for the submission of a current census (number) of patients being serviced by the HHA. Census information should include only a count of non-Medicare/non-Medicaid patients. Since OASIS data on non-Medicare/non-Medicaid patients will be received by the OASIS State system in an unidentifiable format, names of non-Medicare/non-Medicaid patients on the census are not appropriate.

With this information, surveyors can conduct a gross comparison of patient counts to data from the OASIS State system and monitor, offsite, if required OASIS data are being transmitted to the State.

G321

(Rev.)

§484.20(a) Standard: Encoding and transmitting OASIS Data

An HHA must encode and electronically transmit each completed OASIS assessment to the State agency or the CMS OASIS contractor, regarding each beneficiary with respect to which such information is required to be transmitted (as determined by the Secretary), within 30 days of completing the assessment of the beneficiary.

Interpretive Guidelines §484.20(a)

After OASIS data are collected and completed by the qualified clinician as part of the comprehensive assessment at the required time points (i.e., start of care, resumption of care, follow-up, transfer to inpatient facility with or without discharge, discharge to community, and death at home), HHAs may take up to 30 calendar days after the date of completion of the comprehensive assessment to transmit the OASIS data into their computers using HAVEN or HAVEN-like software and transmit to the State. Encoding of **all** OASIS data items must be complete, i.e., export ready, in order to accurately compute the information (health insurance prospective payment system or HIPPS code) necessary for billing Medicare patients under the prospective payment system.

Pre-Survey Activity - Check with the State OASIS Education or Automation Coordinator and/or review OASIS data management reports to determine if OASIS items are encoded, checked for errors and transmitted to the State within 30 days of completion of the assessment using Haven or Haven-like software, i.e., made transmission ready.

Onsite Activity - Check to see if the HHA is transmitting its own data or has an arrangement with an outside entity acting on behalf of the HHA to electronically submit OASIS data to the State agency. If so, make sure a written contract exists that describes the arrangement the HHA has with the outside entity to enter and transmit OASIS data on behalf of the HHA.

Determine the process for encoding and transmitting OASIS data.

If questions are raised through interview or record review, review the HHA's policies regarding encoding time frames.

Initial Survey - New HHA's seeking initial certification must apply for appropriate State and Federal HHA identification and passwords and be able to demonstrate compliance with collecting, completing, encoding and reporting OASIS data for all applicable patients in an electronic format that meets CMS specifications prior to the initial survey. Check with the OASIS Automation Coordinator for information on assignment of test identification numbers and passwords.

G322

§484.20(b) Standard: Accuracy of Encoded OASIS Data.

The encoded OASIS data must accurately reflect the patient's status at the time of assessment.

Interpretive Guidelines §484.20(b)

Check to see how the HHA monitors the accuracy of their data to ensure the data collected, encoded, and reported accurately reflects the patient's status at the time of the assessment. Some tips for establishing a program to monitor the quality and accuracy of OASIS data are found in Chapter 12 of the OASIS Implementation Manual – Data Quality Audits.

Onsite Activity - When reviewing the clinical records, determine that a visit was made to conduct the assessment, as applicable. Also, determine that other clinical information in the patient record does not contradict OASIS data collected during the assessment, encoded or reported.

New patient admission: If possible, include a home visit for a newly admitted patient who is scheduled to have a comprehensive assessment done. Determine that the OASIS data collected accurately reflects the patient's status at the time of the assessment.

Patient currently on service: If a home visit is made on a patient for whom an assessment has already been conducted and is not now scheduled to have one conducted, review the most current assessment and compare it with your observation of patient status, keeping in mind the patient's progress/decline and the normal progression of the clinical condition.

Determine that other clinical information in the patient record does not contradict OASIS data.

Probes 484.20(b)

- How does the HHA conduct clinical and data entry audits to verify that collected OASIS data is consistent with reported OASIS data?
- How does the HHA assure consistency?
- How does the HHA review the final validation reports for accuracy purposes?
- Has the HHA identified any discrepancies in data collected and reported? If so, how were discrepancies addressed?
- How does the HHA handle the correction of errors?

G324

(Rev.)

§484.20(c) Standard: Transmittal of OASIS Data

An HHA must—
(1) For all completed assessments, transmit OASIS data in a format that meets the requirements of paragraph (d) of this section.

Interpretive Guidelines §484.20(c)(1)

HHAs must electronically transmit all OASIS data collected and encoded, by the 30th day following any required Oasis assessment for each patient (as applicable), to the State agency or CMS OASIS contractor. HHAs may transmit OASIS data more frequently than required and are free to develop schedules for transmitting data to best suit their needs.

Rejected data that requires correcting and re-transmitting must be received by the OASIS State system within the same required time frame. Submission of data with identified fatal errors does not justify extending the required time frame. While overdue assessments will be accepted, HHAs (or their contracted vendors) should not wait until the 30th day deadline to transmit their OASIS data in case errors are identified that require re-transmittal or system problems develop that prevent transmission.

Entities submitting OASIS data to the State agency or CMS OASIS contractor on behalf of the HHA, i.e., corporate offices or vendors under contract, must share the feedback reports with the HHA in order for them to monitor their encoding and transmission process.

Pre-Survey Activity - Check with the State OASIS Education or Automation Coordinator and/or review OASIS data management reports to determine if OASIS data are being transmitted as required. Determine whether the HHA is: 1) submitting data less frequently than required; and/or 2) has greater than 20 percent of records rejected in accordance with pre-survey preparation guidelines (SOM Section 2200).

Onsite Activity – If either probe noted above is triggered, investigate compliance with OASIS transmission requirements of this section, during the survey through the partial extended survey process. Ask the HHA to demonstrate how it creates, saves and transmits OASIS data to the State agency. Randomly select patient assessments and ask the HHA for the final validation report to demonstrate that they were received by the State.

Determine that all required OASIS assessments are being transmitted.

Certain missing information or inconsistencies will cause a record to be completely rejected requiring correction by the HHA and retransmission. These are called fatal errors. For example, a fatal error will occur when a record is submitted without the

HHA's State-assigned identification number, without the patient's last name, when the record is a duplicate of one previously received or the record is missing or has an incorrect branch identification number in M0016. A complete listing of current record rejection criteria is available in the HHA Error Message Guide on the OASIS website (http://www.cms.hhs.gov/oasis/usermanu.asp).

HHA's have the ability to electronically correct nearly all errors found in their production OASIS submissions that have been transmitted to the SA or CMS OASIS contractor. There is no current time limit to correcting errors in previously submitted records. SA should not be accepting requests for manual key field changes. Instead, HHA's should use the inactivation procedures to correct assessments containing key field errors. HAVEN 5.0 or above will give HHA's the ability to electronically correct nearly any kind of assessment errors. (See SOM Section 2202.11.) A description of key fields vs. non-key fields is available on the OASIS website (http://www.cms.hhs.gov/oasis/).

Probes §484.20(c)(1)

- Is the HHA successfully transmitting OASIS data 30 days after each assessment?
- Review the HHA's OASIS validation reports. If the HHA's corporate office or contracted vendor submits OASIS data on its behalf, are feedback reports being shared with the HHA?
- What is the HHA's back-up plan if it is unable to submit OASIS data to the State agency?
- What kind of errors is the HHA finding and correcting?
- How is the HHA responding to identified fatal errors?
- How does the HHA verify that assessment data is consistent with the required format?
- What are the established times of OASIS data transmission to the State? (They must be at least monthly.)
- Who is assigned to transmit OASIS data?

If questions arise, review HHA policies and procedures regarding OASIS data transmission.

G325

(Rev.)

§484.20(c)(2) - ***(An HHA must --) Successfully transmit test data to the State agency or CMS OASIS contractor.***

Interpretive Guidelines §484.20(c)(2)

The purpose of making a test transmission to the State agency or CMS OASIS contractor is to establish connectivity. Once the test has been successfully completed, HHA's must

not routinely use the test function to prepare their submission of production (required) OASIS data.

Initial Survey - New HHA's seeking initial certification must apply for State and Federal HHA identification numbers and passwords in order to demonstrate compliance with the OASIS submission requirements prior to Medicare approval.

Prior to the initial survey, HHA's must demonstrate connectivity to the OASIS State system by--

1. Making a test transmission of any start of care or resumption of care OASIS data that passes CMS edit checks; and

2. Receiving validation reports back from the State confirming transmission of data.

NOTE: **The OASIS system is not authorized to maintain unmasked OASIS information on non-Medicare/non-Medicaid patients receiving skilled services. Effective January 1, 2010, non-Medicare and Non-Medicaid data will be rejected.**

G326

(Rev.)

§484.20(c)(3)- (An HHA must --) Transmit data using electronics communications software that provides a direct telephone connection from the HHA to the State agency or CMS OASIS contractor.

Interpretive Guidelines §484.20(c)(3)

HHA's must have a computer system that *complies with current CMS policy* and requirements for the transmission of OASIS data to the State agency or CMS OASIS contractor, *transmits* the export files, and *receives* validation information. Corporate offices or contracted vendors submitting OASIS data on behalf of the HHA must provide the HHA with either an electronic copy of the validation information received from the State agency or CMS OASIS contractor, or a summary of that information.

All HHA's must use the *CMSnet* to connect to the State agency for submission of OASIS data. When incorporation is complete, OASIS data from branch locations may be submitted directly by the branch as long as the appropriate user identification and passwords have been obtained.

G328

(Rev.)

§484.20(c)(4) – *(The HHA must --)* *Transmit data that includes the CMS-assigned branch identification number, as applicable.*

G327

§484.20(d) Standard: Data Format

The HHA must encode and transmit data using the software available from CMS or software that conforms to CMS standard electronic record layout, edit specifications, and data dictionary, and that includes the required OASIS data set.

Interpretive Guidelines §484.20(d)

Reasons for non-submission include lack of compliance with the requirement to electronically transmit OASIS data by the HHA, or transmission using an improper format. HHA's must encode and transmit data using the HAVEN software available from CMS or HAVEN-like software that conforms to **all** CMS data transmission specifications available on the OASIS website. The software must also include the most current version of the OASIS data items which are available on the OASIS website at all times.

Pre-Survey Activity - Review any OASIS State system data management reports to determine if there are indications of problems with OASIS data transmission. Check with the State OASIS Education or Automation coordinator to see if he/she has identified a problem with OASIS data transmission.

Onsite Activity - If problems with OASIS data transmission were determined during pre-survey activity, on survey, interview the appropriate staff to assess the extent of the problem, and to identify steps the HHA is taking to correct any transmission problems.

Probes §484.20(d)

- What steps did the HHA take to correct transmission problems, i.e., change in software vendor, notifying the State, or using HAVEN as a backup software program?

- Does the HHA use the correct identifier in OASIS item M0016 Branch ID to identify if the assessment record is submitted by the parent agency, the branch, or an agency without branches?

G168

§484.30 Condition of Participation: Skilled Nursing Services

G169

§484.30 - The HHA furnishes skilled nursing services by or under the supervision of a registered nurse; and . . .

G170

(Rev.)

§484.30 - . . . in accordance with the plan of care.

Interpretive Guidelines §484.30

The expected outcome for this Level 1 standard is that each patient receives nursing care as ordered on his/her plan of care.

G171

§484.30(a) Standard: Duties of the Registered Nurse.

The registered nurse makes the initial evaluation visit, . . .

G172

(Rev.)

§484.30(a) - . . . regularly re-evaluates the patient's nursing needs, . . .

Interpretive Guidelines §484.30(a)

The expected outcome for this Level 1 standard is that the patient's status and nursing needs are re-evaluated by the RN at least every 60 days (or more often if the patient's condition or needs change).

Probes §484.30(a)

- *For patients with co-morbidities, is there evidence that pertinent inter-related factors are addressed in managing patient's care (e.g., addressing nutrition and skin care in a patient with diabetes that has a wound)?*

G173

(Rev.)

§484.30(a) - … initiates the plan of care and necessary revisions, . . .

Interpretive Guidelines §484.30(a)

The expected outcome for this Level 1 standard is that the RN initiates the plan of care and any revisions to plan of care when appropriate.

Probes §484.30(a)

- *Is there evidence of patient's medical, nursing and rehabilitative needs that are not addressed in the plan of care or communicated to the physician?*
- *Are newly identified patient's medical, nursing and rehabilitative needs addressed in updates to plan of care?*

G174

(Rev.)

§484.30(a) - . . . furnishes those services requiring substantial and specialized nursing skill, . . .

Interpretive Guidelines §484.30(a)

The expected outcome for this Level 1standard is that patients who have specialized nursing needs receive care from qualified nurses who are capable and competent to provide care as ordered and needed (e.g., IV care, ostomy care, wound assessment and care).

G175

(Rev.)

§484.30(a) - . . . initiates appropriate preventive and rehabilitative nursing procedures, . . .

Interpretive Guidelines §484.30(a)

The expected outcome for this Level 1 standard is that patients receive appropriate preventive and rehabilitative nursing care as ordered on the plan of care.

G176

(Rev.)

§484.30(a) - . . . prepares clinical and progress notes, coordinates services, informs the physician and other personnel of changes in the patient's condition and needs, . . .

Interpretive Guidelines §484.30(a)

The expected outcomes for this Level 1 standard are:

- *The RN's clinical and progress nursing notes are complete and provide consistent (i.e., non-conflicting) data regarding patient status and treatments/services provided.*
- *The RN regularly coordinates and communicates with other staff members and the physician about the patient's condition and needs.*

G177

(Rev.)

§484.30(a) - . . . counsels the patient and family in meeting nursing and related needs, . . .

Interpretive Guidelines §484.30(a)

The expected outcome for this Level 1 standard is that the RN counsels the patient and family in meeting nursing and related needs.

G178

§484.30(a) - . . . participates in in-service programs, and supervises and teaches other nursing personnel.

Interpretive Guidelines §484.30(a)

An RN is required to make the initial evaluation visit except in those circumstances where the physician has ordered only therapy services. If the physician orders only therapy services, it would be acceptable for the appropriate therapist (physical therapist or speech-language pathologist) to perform the initial evaluation visit. This does **not** mean that an HHA is precluded from having the RN perform all initial evaluation visits if the HHA believes that this promotes coordinated patient care, and/or if this is part of the HHA's own policies, procedures, and particular approach to patient care services.

Review a case-mix, stratified sample of clinical records according to the HHA survey and certification process, and make home visits to determine if RNs perform their responsibilities within the State's nurse practice act and in compliance with the plan of care. (See §§484.12(c) and 484.18.) See §§2200 and 2202 of the SOM.

Probes §484.30(a)

- How does the HHA confirm that services requiring specialized nursing skills are furnished by individuals with the appropriate qualifications?

G179

§484.30(b) Standard: Duties of the Licensed Practical Nurse

The licensed practical nurse furnishes services in accordance with agency policies,

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G180

§484.30(b) - prepares clinical and progress notes,

G181

§484.30(b) - assists the physician and registered nurse in performing specialized procedures,

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G182

§484.30(b) - prepares equipment and materials for treatments observing aseptic technique as required; and

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G183

§484.30(b) - assists the patient in learning appropriate self-care techniques.

Interpretive Guidelines §484.30(b)

Determine if services are provided in accordance with the HHA's professional practice standards and with guidance and supervision from RNs. Make the same comparisons set forth in the §484.30(a) probe when reviewing duties of the LPN.

G184

§484.32 Condition of Participation: Therapy Services

G185

§484.32 - Any therapy services offered by the HHA directly or under arrangement are given by a qualified therapist or by a qualified therapy assistant under the supervision of a qualified therapist and in accordance with the plan of care. . . .

G186

(Rev.)

§484.32 - . . .The qualified therapist assists the physician in evaluating level of function, helps develop the plan of care (revising it as necessary), . . .

Interpretive Guidelines §484.32

The expected outcome for this Level 1 standard is that the qualified therapist assists the physician in evaluating the patient's level of function (e.g., evaluates the patient when ordered), and assists the physician in developing and revising a plan of care that addresses the patient's needs.

G187

(Rev.)

§484.32 - . . . prepares clinical and progress notes, . . .

Interpretive Guidelines §484.32

The expected outcome for this Level 1 standard is that the qualified therapist documents the patient's progress towards goals and outcomes appropriately.

G188

(Rev.)

§484.32 - . . . advises and consults with the family and other agency personnel; and…

Interpretive Guidelines §484.32

The expected outcome for this Level 1 standard is that the qualified therapist communicates with patient/family and other agency personnel such as the physician and other disciplines regarding patient's progress towards goals and outcomes.

G189

(Rev.)

§484.32 - . . . participates in in-service programs.

Probes for the entire condition §484.32, G184-189

- How does the HHA ensure that therapy services furnished by staff under arrangement or contract meet the requirements of this condition?
- Does the clinical record documentation describe the patient responses to therapy?
- How does the HHA coordinate therapy services with other skilled services to complete the plan of care and promote positive therapeutic outcomes?
- *Is therapy provided to each patient as ordered?*
- *Is there evidence of patient therapy or equipment needs that are not addressed in the plan of care or communicated to the physician?*
- *Are therapy visits made at the frequency ordered?*
- *Are assessments and communication with other care providers documented?*

G190

§484.32(a) Standard: Supervision of Physical Therapy Assistant and Occupational Therapy Assistant

Services furnished by a qualified physical therapy assistant or qualified occupational therapy assistant may be furnished under the supervision of a qualified physical or occupational therapist. A physical therapy assistant or occupational therapy assistant performs services planned, delegated, and supervised by the therapist;

G191

§484.32(a) - assists in preparing clinical notes and progress reports; and

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G192

§484.32(a) - participates in educating the patient and family, and in in-service programs.

Interpretive Guidelines §484.32(a)

Specific instructions for assistants must be based on treatments prescribed in the plan of care, patient evaluations by the therapist, and accepted standards of professional practice. The therapist evaluates the effectiveness of the services furnished by the assistant.

Documentation in the clinical record should show that communication and supervision exist between the assistant and therapist about the patient's condition, the patient's response to services furnished by the assistant, and the need to change the plan of care.

Probes §484.32(a)

- How does the therapist evaluate the patient's needs and responses to services furnished by the assistant to measure the patient's progress in achieving the anticipated outcomes?
- How does the HHA ensure that the assistant initiates plans of care only with appropriate supervision by the therapist when therapy services are provided under arrangement or contract?
- What kinds of in-service programs have the therapist and assistant participated in during the past year? Who provides them?
- Were comprehensive assessments completed by the OTA, or PTA? Only qualified clinicians (RN, PT, SLP/ST, or OT) may assess and complete the comprehensive assessment.

G193

§484.32(b) Standard: Supervision of Speech Therapy Services

Speech therapy services are furnished only by or under the supervision of a qualified speech-language pathologist or audiologist.

Probes §484.32(b)

- How does the HHA confirm that speech therapy services provided under arrangement or contract meet the requirements of this condition?

G194

§484.34 Condition of Participation: Medical Social Services

G195

§484.34 - If the agency furnishes medical social services, those services are given by a qualified social worker or by a qualified social work assistant under the supervision of a qualified social worker, and in accordance with the plan of care. The social worker assists the physician and other team members in understanding the significant social and emotional factors related to the health problems,

G196

§484.34 - participates in the development of the plan of care,

G197

§484.34 - prepares clinical and progress notes,

G198

§484.34 - works with the family,

G199

§484.34 - uses appropriate community resources,

G200

§484.34 - participates in discharge planning and in-service programs,

G201

§484.34 - and acts as a consultant to other agency personnel.

Interpretive Guidelines §484.34

Medical social services, when required by the plan of care, must be available on a visiting, not consultative, basis in a patient's place of residence.

Either the social worker or a social work assistant may make the initial visit to the HHA patient. Information gathered during the home visit is reviewed by the social worker who makes suggestions to the physician for additions to the plan of care.

The social worker may provide the patient with approved professional services or assign the care to the assistant, providing supervision as required. (See §484.2.)

Probes §484.34

How does the HHA confirm that patients' social service needs are adequately met, including those services provided under arrangement or contract?

G202

§484.36 Condition of Participation: Home Health Aide Services.

G203

§484.36 - Home health aides are selected on the basis of such factors as a sympathetic attitude toward the care of the sick, ability to read, write, and carry out directions, and maturity and ability to deal effectively with the demands of the job. They are closely supervised to ensure their competence in providing care. For home health services furnished (either directly or through arrangements with other organizations) after August 14, 1990, the HHA must use individuals who meet the personnel qualifications specified in §484.4 for "home health aide."

Interpretive Guidelines §484.36

CMS has identified the requirements that a home health aide training program and competency evaluation program or competency evaluation program must have for individuals to qualify as home health aides in a Medicare participating HHA. CMS does not intend to provide any additional procedures or further elaboration concerning skills in which aides must become proficient beyond the subject areas identified. It is the responsibility of the HHA to ensure that aides are proficient to carry out the patient care they are assigned, in a safe, effective, and efficient manner.

The HHA is responsible for ensuring that home health aides used by the HHA meet the provisions of §484.4 and §484.36. This includes home health aides trained and evaluated by other HHA's or other organizations, and those hired by the HHA under an arrangement as well as those who are employed by the HHA. While CMS will not establish a national program to approve each home health aide training and competency evaluation program, a sample of home health aides used by a particular HHA will have their files reviewed for documentation of compliance with the training and competency evaluation or competency evaluation requirements during a standard and/or partial extended or extended survey of the HHA.

If the HHA has been out of compliance with a Condition of Participation, it may not provide its own 75 hour training program, its initial training and competency evaluation, or the competency evaluation for its aides to meet the requirements of §484.36(a) and (b).

With the exception of licensed health professionals and volunteers, home health aide training and competency evaluation or competency evaluation requirements apply to all individuals who are employed by or work under contract with a Medicare-certified HHA and who provide "hands-on" patient care services regardless of the title of the individual. It is the FUNCTION of the aide that determines the need for training and competency evaluation or competency evaluation.

As discussed in general guidelines, all Conditions of Participation apply to a Medicare certified HHA as an entity and to all individuals or patients under the HHA's care. (See §1861(m), 1861(o)(3) and 1891(a)(1) of the Social Security Act.)

G204

§484.36(a) Standard: Home Health Aide Training

(1) Standard: Content and Duration of Training

The aide training program must address each of the following subject areas through classroom and supervised practical training totaling at least 75 hours, with at least 16 hours devoted to supervised practical training.

G205

§484.36(a)(1) - The individual being trained must complete at least 16 hours of classroom training before beginning the supervised practical training.

G206

§484.36(a)(1) -

(i) Communications skills.
(ii) Observation, reporting and documentation of patient status and the care or service furnished.
(iii) Reading and recording temperature, pulse, and respiration.

(iv) Basic infection control procedures.
(v) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor.
(vi) Maintenance of a clean, safe, and healthy environment.
(vii) Recognizing emergencies and knowledge of emergency procedures.
(viii) The physical, emotional, and developmental needs of and ways to work with the populations served by the HHA, including the need for respect for the patient, his or her privacy and his or her property.

(ix) Appropriate and safe techniques in personal hygiene and grooming that include--

(A) Bed bath.
(B) Sponge, tub, or shower bath.
(C) Shampoo, sink, tub, or bed.
(D) Nail and skin care.
(E) Oral hygiene.
(F) Toileting and elimination.

(x) Safe transfer techniques and ambulation.
(xi) Normal range of motion and positioning.
(xii) Adequate nutrition and fluid intake.
(xiii) Any other task that the HHA may choose to have the home health aide perform.

"Supervised practical training" means training in a laboratory or other setting in which the trainee demonstrates knowledge while performing tasks on an individual under the direct supervision of a registered nurse or licensed practical nurse.

Interpretive Guidelines §484.36(a)

Classroom and supervised practical training should be based on an instruction plan that includes learning objectives, clinical content, and minimum, acceptable performance standards that meet the requirements of the regulation.

A mannequin may be used for training purposes only.

G207

§484.36(a)(2) Standard: Conduct of Training

(i) Organizations. A home health aide training program may be offered by any organization except an HHA that, within the previous two years, has been found--

(A) Out of compliance with requirements of this paragraph (a) or paragraph (b) of this section;

(B) To permit an individual that does not meet the definition of "home health aide" as specified in §484.4 to furnish home health aide services (with the exception of licensed health professionals and volunteers);

(C) Has been subject to an extended (or partial extended) survey as a result of having been found to have furnished substandard care (or for other reasons at the discretion of CMS or the State);

(D) Has been assessed a civil monetary penalty of not less than $5,000 as an intermediate sanction;

(E) Has been found to have compliance deficiencies that endanger the health and safety of the HHA's patients and has had a temporary management appointed to oversee the management of the HHA;

(F) Has had all or part of its Medicare payments suspended; or

(G) Under any Federal or State law within the 2-year period beginning on October 1, 1988--

(1) Has had its participation in the Medicare program terminated;

(2) Has been assessed a penalty of not less than $5,000 for deficiencies in Federal or State standards for HHAs;

(3) Was subject to a suspension of Medicare payments to which it otherwise would have been entitled;

(4) Had operated under a temporary management that was appointed to oversee the operation of the HHA and to ensure the health and safety of the HHA's patients; or

(5) Was closed or had its residents transferred by the State.

Interpretive Guidelines §484.36(a)(2)(i)

"Requirement" means compliance with a condition level deficiency.

Effective February 14, 1990, an HHA must not have had any Condition of Participation out of compliance within 24 months before it begins a training and competency evaluation or competency evaluation program.

Correction of a condition level deficiency does not relieve the 2-year restriction identified in this standard.

Nothing in this standard precludes an HHA that has a condition out of compliance from hiring or contracting for aides who have already completed a training and competency evaluation or competency evaluation program, or arranging for aides to attend a training and competency evaluation or competency evaluation program provided by another entity.

If a partial extended or extended survey is conducted, but substandard care (a condition out of compliance) is not found, the HHA would not be precluded from offering its own aide training and/or competency evaluation program.

If an HHA, while conducting its own training and competency evaluation program or competency evaluation program, has either a standard, partial extended or extended survey in which it is found to be out of compliance with a Condition of Participation, it may complete that training and competency evaluation program or competency evaluation program for aides currently enrolled, but it may not accept new candidates into the program or begin a new program, for 2 years after receiving written notice from the RO that the HHA was out of compliance with one or more Conditions of Participation.

G208

§484.36(a)(2) –

(ii) Qualifications for instructors.

The training of home health aides and the supervision of home health aides during the supervised practical portion of the training must be performed by or under the general supervision of a registered nurse who possesses a minimum of 2 years of nursing experience, at least 1 year of which must be in the provision of home health care.

G209

Other individuals may be used to provide instruction under the supervision of a qualified registered nurse.

Interpretive Guidelines §484.36(a)(2)(ii)

The required 2 years of nursing experience for the instructor should be "hands on" clinical experience such as providing care and/or supervising nursing services or teaching nursing skills in an organized curriculum or in-service program.

"Other individuals" who may help with aide training would include health care professionals such as physical therapists, occupational therapists, medical social workers, and speech-language pathologists. Experienced aides, nutritionists, pharmacists, lawyers and consumers might also be teaching resources.

G210

§484.36(a)(3) Standard: Documentation of Training

The HHA must maintain sufficient documentation to demonstrate that the requirements of this standard are met.

Interpretive Guidelines §484.36(a)(3)

It is the responsibility of the HHA to maintain adequate documentation of compliance with the regulation for home health aides employed by or under contract with the HHA.

A home health aide may receive training from different organizations if the amount of training totals 75 hours, the content of training addresses all subjects listed at §484.36(a) and the organization, training, instructors, and documentation meet the requirements of the regulation.

Documentation of training should include:

- A description of the training/competency evaluation program, including the qualifications of the instructors;
- A record that distinguishes between skills taught at a patient's bedside, with supervision, and those taught in a laboratory using a volunteer or "pseudo-patient," (not a mannequin) and indicators of which skills each aide was judged to be competent; and
- How additional skills (beyond the basic skills listed in the regulation) are taught and tested if the admission policies and case-mix of HHA patients require aides to perform more complex procedures.

G211

§484.36(b) Standard: Competency Evaluation In-Service Training

(1) Standard: Applicability

An individual may furnish home health aide services on behalf of an HHA only after that individual has successfully completed a competency evaluation program as described in this paragraph.

G212

§484.36(b)(1) - The HHA is responsible for ensuring that the individuals who furnish home health aide services on its behalf meet the competency evaluation requirements of this section.

Interpretive Guidelines §484.36(b)(1)

The HHA must ensure that skills learned or tested elsewhere can be transferred successfully to the care of the patient in his/her place of residence. The HHA should give careful attention to evaluating both employees and aides who provide services under arrangement or contract. This review of skills could be done when the nurse installs an aide into a new patient care situation, during a supervisory visit, or as part of the annual performance review. A mannequin may not be used for this evaluation.

If the HHA's admission policies and the case-mix of HHA patients demand that the aide care for individuals whose personal care and basic nursing or therapy needs require more complex training than the minimum required in the regulation, the HHA must document how these additional skills are taught and tested.

G213

§484.36(b)(2) Content and Frequency of Evaluations and Amount of In-Service Training

> **(i) The competency evaluation must address each of the subjects listed in paragraphs (a)(1)(ii) through (xiii) of this section.**

G214

§484.36(b)(2)(ii) The HHA must complete a performance review of each home health aide no less frequently than every 12 months.

G215

> **§484.36(b)(2)(iii) The home health aide must receive at least 12 hours of in-service training during each 12-month period. The in-service training may be furnished while the aide is furnishing care to the patient.**

Interpretive Guidelines §484.36(b)(2)

HHAs are not required to conduct a yearly competency evaluation of its aides, but are required to do a performance review of each aide at least every 12 months.

HHAs that are precluded from conducting their own training and/or competency evaluation programs must still complete their aides' annual performance reviews and in-service training as part of their administrative, personnel and patient care responsibilities.

An annual performance review may be completed and documented over a period of time during an aide's two-week supervisory visits in a patient's home or during the installation of an aide in a new patient care situation. Any reasonable performance review method

that is logical and consistent with the HHA's policies and procedures would meet the intent of this standard.

Home health aide in-service training, that occurs with a patient in a place of residence, supervised by an RN, can occur as part of the two-week supervisory visit, but must be documented as to the exact new skill or theory taught. In-service training taught in the patient's environment should not be a repetition of a basic skill or part of the annual performance review of the aide's competency in basic skills.

HHA's may fulfill the annual 12-hour in-service training requirement on either a calendar year basis or an employment anniversary basis.

Probes §§484.36(b)(1) & (2)

If aide services are provided under arrangement or contract, how does the HHA ensure that aides providing patient care have the appropriate competency skills?

G216

§484.36(b)(3) Standard: Conduct of Evaluation and Training

(i) Organizations. A home health aide competency evaluation program may be offered by an organization except as specified in paragraph (a)(2)(i) of this section. The in-service training may be offered by any organization.

G217

§484.36(b)(3)(ii) Evaluators and instructors. The competency evaluation must be performed by a registered nurse.

The in-service training generally must be supervised by a registered nurse who possesses a minimum of 2 years of nursing experience, at least 1 year of which must be in the provision of home health care.

G218

§484.36(b)(3) (iii) Subject areas. The subject areas listed at paragraphs (a)(1)(iii), (ix), (x) and (xi) of this section must be evaluated after observation of the aide's performance of the tasks with a patient. The other subject areas in paragraph (a)(1) of this section may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient.

Interpretive Guidelines §484.36(b)(3)

Subject areas (a)(1)(iii), (ix), (x) and (xi) may be evaluated with the tasks being performed on a pseudo-patient such as another aide or volunteer in a laboratory setting.

The tasks must not be simulated in any manner and the use of a mannequin is not an acceptable substitute.

Probes §484.36(b)(3)

- How does the HHA ensure that aides perform only tasks for which they received satisfactory ratings in the competency evaluation?
- If the aide performs skills which exceed the basic skills included in this standard, how does the HHA train and test aides for competency?
- How does the HHA plan for extended training if it is unable to train its own aides?
- How does the HHA monitor the assignment of aides to match the skills needed for individual patients?

G219

§484.36(b)(4) Standard: Competency Determination

(i) A home health aide is not considered competent in any task for which he or she is evaluated as unsatisfactory. The aide must not perform that task without direct supervision by a licensed nurse until after he or she receives training in the task for which he or she was evaluated as unsatisfactory and passes a subsequent evaluation with satisfactory.

G220

§484.36(b)(4)(ii) - A home health aide is not considered to have successfully passed a competency evaluation if the aide has an unsatisfactory rating in more than one of the required areas.

Interpretive Guidelines §484.36(b)(4)

A home health aide who is evaluated as satisfactory in all subject areas except one would be considered competent. However, this aide would not be allowed to perform the task in which he or she was evaluated as unsatisfactory except under direct supervision. If a home health aide receives an unsatisfactory evaluation in more than one subject area, the aide would not be considered to have successfully passed a competency evaluation program and would be precluded from performing as a home health aide in any subject area. The regulations place no restrictions on the number of times or the period of time an aide can be tested in a deficient area.

A home health aide may have different skills evaluated by different organizations as long as the organizations, the training and competency evaluation program(s), the evaluators, and the documentation meet the requirements of the regulation. The aide must have had **ALL** of the required skills evaluated. Aides that have undergone a sampling

methodology for the evaluation of aide skills must have the additional required skills evaluated before the aide is determined to be competent.

Aides required to provide items or services which exceed the basic skills must demonstrate competency before they are assigned to care for patients who require these skills.

It is not intended that all home health aides be required to deliver all types of home health services. However, each individual aide should be qualified to perform each individual task for which he or she is responsible.

Probes §484.36(b)(4)

1. How does the HHA confirm aide skills on an ongoing basis for its employees including new hires and personnel under arrangement or contract?

2. If aides are performing tasks that are an extension of home health services other than nursing, how does the HHA document that these aides have proven competency in these tasks to the appropriate health professional?

G221

§484.36(b)(5) Standard: Documentation of Competency Evaluation

The HHA must maintain documentation which demonstrates that the requirements of this standard are met.

G222

§484.36(b)(6) Standard: Effective Date

The HHA must implement a competency evaluation program that meets the requirements of this paragraph before February 14, 1990. The HHA must provide the preparation necessary for the individual to successfully complete the competency evaluation program. After August 14, 1990, the HHA may use only those aides that have been found to be competent in accordance with §484.36(b).

G223

§484.36(c) Standard: Assignment and Duties of the Home Health Aide

(1) -The home health aide is assigned to a specific patient by the registered nurse…

G224

(Rev.)

§484.36(c)(1) - . . . Written patient care instructions for the home health aide must be prepared by the registered nurse or other appropriate professional who is responsible for the supervision of the home health aide under paragraph (d) of this section.

Interpretive Guidelines §484.36(c)(*1*)

The expected outcome for this Level 1 standard is that the home health aide receives written instructions by the RN or other appropriate professional responsible for supervising the aide for patient care that are clear and complete and address patients' current needs.

The aide assignments must consider the skills of the aide, the amount and kind of supervision needed, specific nursing or therapy needs of the patient, and the capabilities of the patient's family.

During the standard survey, when possible, schedule at least one home health visit when a home health aide is present. Informal questions to the aide(s) or a review of the aide's assignment sheets will offer information about HHA compliance with this standard.

To evaluate coordination of home health aide services according to the requirements of §484.14(g), look for documentation by the aide in the clinical records that describes significant information or changes in his or her patients' conditions and to whom he or she reported the information. Notes should be dated and signed by the aide.

If the aide is performing simple procedures as an extension of therapy services, review documentation of how the aide was evaluated for competency to perform these tasks. Also, review the plan of care and therapy notes to ensure that the services performed by the aide are not services ordered by the physician to be performed by a qualified therapist or therapy assistant.

G225

§484.36(c)(2) Standard: Duties

The home health aide provides services that are ordered by the physician in the plan of care and that the aide is permitted to perform under State law.

G226

§484.36(c)(2) - The duties of a home health aide include the provision of hands-on personal care, performance of simple procedures as an extension of therapy or nursing services, assistance in ambulation or exercises, and assistance in administering medications that are ordinarily self-administered.

G227

§484.36(c)(2) - Any home health aide services offered by an HHA must be provided by a qualified home health aide.

Interpretive Guidelines §484.36(c)(2)

See §484.4 for the definition of a home health aide.

G228

§484.36(d) Standard: Supervision

(1) - If the patient receives skilled nursing care, the registered nurse must perform the supervisory visit required by paragraph (d)(2) of this section. If the patient is not receiving skilled nursing care, but is receiving another skilled service (that is, physical therapy, occupational therapy, or speech-language pathology services), supervision may be provided by the appropriate therapist.

G229

(Rev.)

§484.36(d)(2) - The registered nurse (or another professional described in paragraph (d)(1) of this section) must make an on-site visit to the patient's home no less frequently than every 2 weeks.

Interpretive Guidelines §484.36(d)(2)

The determination as to whether the aide should be present and observed during the supervisory visit should be based on the level of experience, performance, and abilities of the aide and the complexity of the patient's needs.

The expected outcome for this Level 1 standard is that the aide supervisory visits occur no less frequently than every 14 days. Additional instruction is provided to the aide if needed based on the information obtained from the supervisory visits.

G230

§484.36(d)(3) - If home health aide services are provided to a patient who is not receiving skilled nursing care, physical or occupational therapy or speech-language pathology services, the registered nurse must make a supervisory visit to the patient's home no less frequently than every 60 days.

In these cases, to ensure that the aide is properly caring for the patient, each supervisory visit must occur while the home health aide is providing patient care.

Interpretive Guidelines §484.36(d)

Supervision visits may be made in conjunction with a professional visit to provide services.

In any patient care situation where an HHA is providing care for an individual who has a condition which requires non-skilled, supportive home health aide services to help the patient with personal care or activities of daily living, the 2 week supervisory visit is not applicable. The RN must make a supervisory visit at least every 60 days. The visit must be made while the aide is furnishing patient care.

Probes §484.36(d)

How does the HHA schedule supervisory visits so that aide skills can be evaluated?

G231

§484.36(d)(4) - If home health aide services are provided by an individual who is not employed directly by the HHA (or hospice), the services of the home health aide must be provided under arrangements, as defined in section 1861(w)(1) of the Act.

G232

§484.36(d)(4) - If the HHA (or hospice) chooses to provide home health aide services under arrangements with another organization, the HHA's (or hospice's) responsibilities include, but are not limited to--

(i) Ensuring the overall quality of the care provided by the aide;

G301

§484.36(d)(4)(ii) - Supervision of the aide's services as described in paragraphs (d)(1) and (d)(2) of this section; and

G302

§484.36(d)(4)(iii) - Ensuring that home health aides providing services under arrangements have met the training requirements of paragraph (a) and/or (b) of this section.

Interpretive Guidelines §484.36(d)(4)

An individual providing services under an arrangement can qualify as a home health aide by completing a training and competency evaluation program or a competency evaluation program.

Probes §484.36(d)(4)

How does the HHA ensure that home health aides providing services under arrangements are supervised according to the requirements of §484.36(d)(1) and (d)(2) and meet the training and/or competency evaluation requirements of §484.36(a) or (b)?

G233

§484.36(e) Personal Care Attendant (PCA): Evaluation Requirements

(1) Applicability. This paragraph applies to individuals who are employed by HHAs exclusively to furnish personal care attendant services under a Medicaid personal care benefit.

(2) Rule. An individual may furnish personal care services, as defined in §410.170 of this chapter, on behalf of an HHA after the individual has been found competent by the State to furnish those services for which a competency evaluation is required by paragraph (b) of this section and which the individual is required to perform. The individual need not be determined competent in those services listed in paragraph (a) of this section that the individual is not required to furnish.

Interpretive Guidelines §484.36(e)

Personal care services also include those services defined at §440.180.

PCAs who are employed by HHA's to furnish services under a Medicaid personal care benefit must abide by all other requirements for home health aides listed at § 484.36 with the explicit exception of § 484.36(e).

G234

§484.38 Condition of Participation: Qualifying to Furnish Outpatient Physical Therapy or Speech Pathology Services

An HHA that wishes to furnish outpatient physical therapy or speech pathology services must meet all the pertinent conditions of this part and also meet the additional health and safety requirements set forth in §§485.711 through §§485.715, 485.719, 485.723, and 485.727 of this chapter to implement section 1861(p) of the Act.

Interpretive Guidelines §484.38

An HHA that furnishes outpatient therapy services on its own premises, including its branches, must comply with the listed citations as well as meet all other Conditions of Participation. §485.723 and §485.727 are not applicable when the patients are served in their **own** homes. §485.723 and §485.727 are applicable, and may be surveyed at the SA's or RO's discretion, when specialized rehabilitation space and equipment is owned, leased, operated, contracted for, or arranged for at sites under the HHA's control and when the HHA bills the Medicare/Medicaid programs for services rendered at these sites. Complete the corresponding section of the Outpatient Physical Therapy or Speech Pathology Survey Report, Form CMS-1893 when surveying these sites. Indicate the

agency's certification to provide outpatient therapy services via special remarks on the Certification and Transmittal, Form CMS-1539. (See §§2764, Item 16.)

The individual therapist may develop the plan of care for outpatient physical and speech pathology therapy services. For Medicare patients receiving outpatient physical and/or speech pathology therapy services, the plan of care and results of treatment does not need to be reviewed by a physician. Non-Medicare patients are not required to be under the care of a physician, and therefore do not need a plan of care established by and reviewed by a physician. For non-Medicare patients, the plan of care may be reviewed by the therapist who established it or by a physician.

(See Appendix E, Interpretive Guidelines, Outpatient Physical or Speech Pathology Service – Physicians' Directions and Plan of Care.)

G235

§484.48 Condition of Participation: Clinical Records

G236

(Rev.)

§484.48 - A clinical record containing pertinent past and current findings in accordance with accepted professional standards is maintained for every patient receiving home health services.

In addition to the plan of care, the record contains appropriate identifying information; name of physician; drug, dietary, treatment, and activity orders; signed and dated clinical and progress notes; copies of summary reports sent to the attending physician; and a discharge summary. . . .

Interpretive Guidelines §484.48

The expected outcomes for this Level 1 standard are:

- *Every patient must have a clinical record. The clinical record for every patient contains all required elements and is current, organized, and provides a clear synopsis of the services provided to the patient.*
- *Filing of documents into the clinical record is current according to agency policy and any applicable State filing timelines.*
- *If electronic signatures are accepted, the HHA follows its policies governing their use.*
- *When comprehensive assessments are corrected, the HHA maintains the original assessment as well as all subsequent corrected assessments.*

The clinical record must provide a current, organized, and clearly written synopsis of the patient's course of treatment, including services provided for the HHA by arrangement or contract. The clinical record should facilitate effective, efficient, and coordinated care.

Questionable patterns, rather than isolated instances, in clinical records are an indicator that the quality of care provided by the HHA needs to be carefully assessed for compliance with the plan of care, coordination of service, concurrence with the HHA's stated policies and procedures, and evaluations of patient outcomes. However, isolated instances, depending on their nature and severity, can serve as the basis of a deficiency and enforcement action (e.g., immediate and serious threat as outlined in Appendix Q).

Electronic Health Records (EHR):

While the regulations specify that documents must be signed, they do not prohibit the use of electronic signatures. HHAs that have created the option for an individual's record to be maintained by computer, rather than hard copy, may use electronic signatures as long as there is a process for reconstruction of the information, and there are safeguards to prevent unauthorized access to the records. If necessary, review written policies maintained by the HHA describing the clinical record and authentication policy(ies) in force. Clinical, progress notes, and summary reports as defined at §484.2 must be maintained on all patients.

If the HHA uses an EHR, the HHA will (a) provide the surveyor with a tutorial on how to use its particular electronic system, and (b) designate an individual who will, when requested by the surveyor, access the system, respond to any questions, or assist the surveyor as needed in accessing electronic information in a timely fashion. Each surveyor will determine the EHR access method that best meets the need for that survey.

If the agency is unable to provide direct print capability to the surveyor, the agency must make available a printout of any record or part of a record upon request in a timeframe that does not impede the survey process. Undue delays in the production of records are unacceptable. Whenever possible, the agency must provide surveyors electronic access to records in a read-only format or other secure format to avoid any inadvertent changes to the record. The provider is solely responsible for ensuring that all necessary back up of data and security measures are in place.

NOTE: HHAs may not accept stamped physician signatures on orders, treatments, or other documents that are a part of the patient's clinical record.

Correction of Clinical Records

The HHA is encouraged to create policies and procedures that govern correction of clinical records. It is prudent for the HHA to include latitude for correction of records in the event of staff turnover or staff schedules. For example, a clinical supervisor may be permitted by agency policy to make corrections when the original clinician is no longer available due to staff turnover.

When a comprehensive assessment is corrected, the HHA must maintain the original assessment record as well as all subsequent corrected assessments in the patient's clinical record for five years, or longer, in accordance with the clinical record requirements at § 484.48. If maintained electronically, the HHA must be capable of retrieving and reproducing a hard copy of these assessments upon request. It is acceptable to have multiple corrected assessments for an OASIS assessment, as long as the OASIS and the clinical record are documented in accordance with the requirements at § 484.48, Clinical records.

Clinical Implications of Corrected Assessment Records

When corrections are made to an assessment already submitted to the state system, the HHA must determine if there is an impact on the patient's current plan of care. If there is an impact, in addition to the correction made to the assessment, the HHA must make corresponding changes to the current plan of care. If there are any other records where the correction has an impact, for example, the Home Health Resource Group, the Plan of Treatment, or the Request for Anticipated Payment, the agency should make corresponding changes to that record, as applicable. The agency should establish a procedure to review the impact of any corrections made to assessment records and make corresponding changes to other records that are affected."

Some agencies use a manual corrections form for one or more OASIS items that can be acceptable after confirming the correction with the original clinician or as described in the agency's policies and procedures. As long as the correction form clearly identifies the item or items of the specific assessment and remain with the original assessment as part of the permanent record in order to have a complete picture of the entire assessment; these suggestions are consistent with CMS's overall guidelines for maintaining clinical records in accordance with accepted professional standards.

G303

(Rev.)

§484.48 -… The HHA must inform the attending physician of the availability of a discharge summary. The discharge summary must be sent to the attending physician upon request and must include the patient's medical and health status at discharge.

Interpretive Guidelines §484.48

The regulations do not dictate the form to be used as a progress note and/or a summary report. Notations should be appropriately labeled and should provide an overall, comprehensive view of the patient's total progress and/or current summary report including social, emotional, or behavioral adjustments relative to the diagnosis, treatment, rehabilitation potential, and anticipated outcomes toward recovery or further debilitation.

The regulation does not dictate the frequency with which progress notes must be written. If necessary, review the HHA's policies and procedures concerning the frequency of preparing progress notes.

The discharge summary need not be a separate piece of paper and may be incorporated into the routine summary reports already furnished to the physician.

Probes §484.48

- Are there patterns in the clinical records that are of concern?
- Do clinical records document patient progress and outcomes of care based on changes in the patient's condition?
- How does the HHA inform the attending physician of the availability of a discharge summary?
- How does the HHA ensure that the discharge summary is sent to the attending physician upon his/her request?
- If you have concerns about any part of the clinical record or correction policy ask the HHA to explain its process.

G237

§484.48(a) Standard: Retention of Records.

Clinical records are retained for 5 years after the month the cost report to which the records apply is filed with the intermediary, unless State law stipulates a longer period of time. Policies provide for retention even if the HHA discontinues operations.

G238

§484.48(a) - If a patient is transferred to another health facility, a copy of the record or abstract is sent with the patient.

Interpretive Guidelines §484.48(a)

An HHA may store clinical and health insurance records electronically (i.e., on disk, on microfilm, or on optical disk imaging systems.) This includes the storage of OASIS information. All material must be available for review by CMS, the intermediary, Department of Health and Human Services, or other specially designated components for bill review, audit, or other examination during the retention period.

With respect to a State agency or Federal survey to ensure compliance with the Conditions of Participation, clinical records requested by the surveyor, along with the equipment necessary to read them, must be made available during the course of the unannounced survey.

The final validation reports from submission of OASIS records and OBQI/M reports are not part of the clinical record and as such need not be retained for five years. It is recommended that final validation reports be retained for a period of 12 months until the new expected annual OBQI/M reports are received.

G239

§484.48(b) Standard: Protection of Records

Clinical record information is safeguarded against loss or unauthorized use.

G240

§484.48(b) - Written procedures govern use and removal of records and the conditions for release of information.

G241

§484.48(b) - Patient's written consent is required for release of information not authorized by law.

Probes §484.48(b)

- How are clinical records stored to protect them from physical destruction and unauthorized use?
- What written policies and procedures govern the use, removal, and release of clinical records?
- How does the HHA make the records available for all personnel furnishing services on behalf of the HHA?

G242

§484.52 Condition of Participation: Evaluation of the Agency's Program

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G243

§484.52 - The HHA has written policies requiring an overall evaluation of the agency's total program at least once a year by the group of professional personnel (or a committee of this group), HHA staff, and consumers, or by professional people outside the agency working in conjunction with consumers.

G244

§484.52 - The evaluation consists of an overall policy and administrative review and a clinical record review.

G245

§484.52 - The evaluation assesses the extent to which the agency's program is appropriate, adequate, effective, and efficient.

G246

§484.52 - Results of the evaluation are reported to and acted upon by those responsible for the operation of the agency and

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G247

§484.52 - are maintained separately as administrative records.

Interpretive Guidelines §484.52

All aspects of the HHA's evaluation are not required to have been done at the same time or by the same evaluators. For example, fiscal, patient care, and administrative policies may be evaluated by different members or committees of the group responsible for performing the evaluation at different times of the year. Patient care services should have been evaluated by providers and consumers.

A consumer may be any individual in the community outside the agency, regardless of whether he or she has been a recipient of, or is eligible to receive, home health services.

The evaluation should address the total program, including services furnished directly to patients, and the administration and management of the HHA, including, but not limited to, policies and procedures, contract management, personnel management, clinical record review, patient care, and the extent to which the goals and objectives of the HHA are met. Results of the HHA's overall annual evaluation must be available for surveyor review, upon request.

G248

§484.52(a) Standard: Policy and Administrative review.

As part of the evaluation process, the policies and administrative practices of the agency are reviewed to determine the extent to which they promote patient care that is appropriate, adequate, effective, and efficient.

G249

§484.52(a) - Mechanisms are established in writing for the collection of pertinent data to assist in evaluation.

Interpretive Guidelines §484.52(a)

In evaluating each aspect of its total program, the HHA should have considered four main criteria:

- Appropriateness - Assurance that the area being evaluated addresses existing or potential problems.

- Adequacy - A determination as to whether the HHA has the capacity to overcome or minimize existing or potential problems.

- Effectiveness - The services offered accomplish the objectives of the HHA and anticipated patient outcomes.

- Efficiency - Whether there is a minimal expenditure of resources by the HHA to achieve desired goals and anticipated patient outcomes.

Probes §484.52(a)

- How is consumer involvement in the evaluation process ensured?
- How has the HHA responded to the recommendations made by the professional group in relation to the most recent annual evaluation?
- What areas does the HHA view as requiring change based on the most recent annual evaluation?
- How does the program evaluation highlight the agency's efforts to resolve patients' grievances and complaints, if any?

G250

§484.52(b) Standard: Clinical Record Review

At least quarterly, appropriate health professionals, representing at least the scope of the program, review a sample of both active and closed clinical records to determine whether established policies are followed in furnishing services directly or under arrangement.

G251

§484.52(b) - There is a continuing review of clinical records for each 60-day period that a patient receives home health services to determine adequacy of the plan of care and appropriateness of continuation of care.

Interpretive Guidelines §484.52(b)

Quarterly reviews need not be performed at a joint, sit-down meeting of the professionals performing the review. Each professional may review the records separately, at different times.

The HHA should evaluate all services provided for consistency with professional practice standards for HHA's and the HHA's policies and procedures, compliance with the plan of care, the appropriateness, adequacy, and effectiveness of the services offered, and evaluations of anticipated patient outcomes. Evaluations should be based on specific record review criteria that are consistent with the HHAs admission policies and other HHA specific patient care policies and procedures.

The review by appropriate health professionals should include those professionals representing the scope of services provided in that quarter. Therefore, for example, if no speech therapy services were performed, the speech therapist need not be a part of that quarterly review.

If the survey reveals that one (or more) approved services are never, or rarely, provided either for Medicare/Medicaid patients or non-Medicare/Medicaid patients, undertake the following actions to determine whether the HHA is complying with the patients' plans of care (§484.18):

- Review the HHA's policies relevant to the evaluation of patient care needs.

- Review HHA contracts for unserved or underserved services, if they are provided under contract or arrangement.

- Review plans of care to determine if the services were ordered by a physician but not delivered.

- Ask the HHA under what circumstances it would contact the patient's physician to request modification of a patient's plan of care.

Probes §484.52(b)

- What patterns or problems does the summary report of the clinical record reviews identify?
- What is the HHA's plan of correction? Are time frames for implementation and another evaluation review planned?
- How does the HHA select the clinical records to be reviewed?
- How do the procedures for review ensure that the review will ascertain whether:
    - HHA policies and procedures are followed?
    - Patients are being helped to attain and maintain their highest practicable functional capacity?

- Goals or anticipated patient outcomes are appropriate to the diagnosis(es), plan of care, services provided, and patient potential?

G330

(Rev.)

§484.55 Condition of Participation: Comprehensive Assessment of Patients

Each patient must receive, and an HHA must provide, a patient specific, comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward achievement of desired outcomes. The comprehensive assessment must identify the patient's continuing need for home care and meet the patient's medical, nursing, rehabilitative, social, and discharge planning needs. For Medicare beneficiaries, the HHA must verify the patient's eligibility for the Medicare home health benefit including homebound status, both at the time of the initial assessment visit and at the time of the comprehensive assessment. The comprehensive assessment must also incorporate the use of the current version of the Outcome and Assessment Information Set (OASIS) items, using the language and groupings of the OASIS items, as specified by the Secretary.

Interpretive Guidelines §484.55

The comprehensive assessment includes the collection of OASIS data items for most patients, as described below, by a qualified clinician, i.e., an RN, physical therapist, occupational therapist, or speech language pathologist. For Medicare patients, there are some additional requirements. HHAs are expected to conduct a comprehensive assessment of each patient that accurately reflects the patient's current health status and includes information to establish and monitor a plan of care. The plan of care must be reviewed and updated at least every 60 days or as often as the severity of the patient's condition requires, per the requirements at §484.18 (a) and (b).

The requirement to conduct a drug regimen review at §484.55(c) as part of the comprehensive assessment applies to **all** patients serviced by the HHA.

Patients to whom OASIS applies: The regulations require a comprehensive assessment, with OASIS data items integrated, for all patients who receive skilled services from an HHA meeting Medicare's home health conditions of participation, except for those patients who are--

- Under age 18;
- Receiving maternity services;
- Receiving housekeeping or chore services only;
- Receiving only personal care services until further notice*; or*
- Patients for whom Medicare or Medicaid insurance is not billed.

This includes Medicare, Medicaid, and any health plan options that are part of the Medicare program (e.g., Medicare Advantage (MA) plans. It also includes Medicaid patients receiving services under a waiver program or demonstration to the extent they do not fall into one of the exception categories listed above, who are receiving services subject to the Medicare conditions of participation.

On December 8, 2003, Section 704 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MPDIMA), temporarily suspended the collection of OASIS data on non-Medicare/non-Medicaid patients of an HHA. However, Section 704 of the MMA does not effect or suspend any other provision of §484.55.

During this temporary suspension, SA and Regional Office (RO) surveyors should adhere to the following guidance when conducting HHA surveys:

- HHAs must continue to comply with the aspects of the regulation at § 484.55 regarding the comprehensive assessment of patients. HHAs must provide each agency patient, regardless of payment source, with a patient-specific comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward the achievement of desired outcomes. The comprehensive assessment must also identify the patient's continuing need for home care, medical, nursing, rehabilitative, social, and discharge planning needs.
- HHAs may continue to collect OASIS data on their non-Medicare/non-Medicaid patients for their own use.
- Surveyors must continue to examine the completeness of the comprehensive assessment for all patients during a survey. However, surveyors must not investigate whether the HHA included the specific OASIS items in its patient-specific comprehensive assessments of non-Medicare/non-Medicaid patients, nor cite deficiencies based solely on this finding.
- HHAs must continue to collect, encode, and transmit OASIS data for their non-maternity Medicare and Medicaid patients that are age 18 and over and receiving skilled services.

Under this condition, in addition to an initial assessment visit, the HHA must also conduct a start of care comprehensive assessment with OASIS data items integrated on patients to whom the requirements are applicable. Subsequent comprehensive assessments (updates and recertification) must be conducted at certain time points during the admission. These updates must include certain data items, i.e., those in the current OASIS data set. The recertification, transfer to an inpatient facility, resumption of care, significant change in condition (SCIC), and discharge comprehensive assessment apply to **all** patients, but it does not have to include OASIS for private pay patients. The recertification comprehensive assessment can be completed before the 5 day window as long as it continues to be done "not less frequently than the last five days of every 60 day episode beginning with the start-of-care date."

The phrase "not less frequently than the last five days of every 60 days beginning with the start of care date" does not mean that HHAs must wait until the *56th* – 60th day to perform another comprehensive assessment on non-Medicare/non-Medicaid patients or for pediatric patients, maternity patients or those receiving personal care services even when Medicare is the payor source. The assessment may be performed any time up to and including the 60th day. The timetable for the subsequent 60-day period would then be measured from the completion date of the most recently completed assessment. Clinicians may perform the comprehensive assessment for these patients more frequently than the last 5 days of the 60-day episode without conducting another comprehensive assessment on day *56*-60, and remain in compliance with §484.55(d). The agency may develop its own comprehensive assessment for each time point.

OASIS data items are not meant to be the only items included in an HHA's assessment process. They are standardized health assessment items that must be incorporated into an HHA's own existing assessment policies and process. An example of a comprehensive assessment showing an integration of the OASIS data items with other agency assessment items can be found in "Appendix C: Sample Clinical Records Incorporating OASIS B-1 Data Set," in the OASIS User's Manual. For therapy-only cases, the comprehensive assessment should incorporate OASIS data items as well as other assessment data items the HHA currently collects for therapy patients, as opposed to simply adding them at the beginning or end.

Medicare patients: For Medicare patients, the HHA must include a determination of the patient's eligibility for the home health benefit, including homebound status.

Eligibility for the Medicare home health benefit is defined in the Medicare Benefit Policy Manual, CMS Pub.100-2 (see http://www.cms.hhs.gov/manuals/102_policy/bp102index.asp) and includes conditions patients must meet to qualify for coverage, such as:

- Patient is confined to the home;
- Services are provided under a plan of care established and approved by a physician;
- Patient is under the care of a physician; and
- Patient needs skilled nursing care on an intermittent basis or physical therapy or speech therapy services or has continued need for occupational therapy.

Incorporating OASIS items: HHA's must incorporate the OASIS data items into their own assessment instrument using the exact language of the items, replacing similar items/questions on their current assessment tool as opposed to simply adding the OASIS items at the beginning or end of the existing assessment tool.

G331

(Rev.)

§484.55(a) Standard: Initial Assessment Visit

(1) - A registered nurse must conduct an initial assessment visit to determine the immediate care and support needs of the patient; and, for Medicare patients, to determine eligibility for the Medicare home health benefit, including homebound status. . . .

Interpretive Guidelines §484.55(a)(1)

The expected outcome for this Level 1 standard is:

- *The RN completes the initial assessment and the comprehensive assessment when skilled nursing is ordered.*
- *The comprehensive assessment is consistently complete and findings are addressed in plan of care.*

The initial assessment visit is conducted to determine the immediate care and support needs of the patient.

For Medicare patients, the initial assessment visit must include a determination of the patient's eligibility for the home health benefit, including homebound status. Verification of a patient's eligibility for the Medicare home health benefit including homebound status does not apply to Medicaid patients, beneficiaries receiving Medicare outpatient services, or private pay patients. The required initial assessment visit at §484.55(a)(1) and the "initial evaluation visit" at §484.30(a) may be completed during the same visit.

See the guidelines at §484.55 above for Medicare eligibility requirements.

For patients receiving only nursing services or both nursing and therapy services, a registered nurse must conduct the initial assessment visit.

Review a case-mix, stratified sample of clinical records and make home visits according to the survey process (see §§2200 and 2202) to determine compliance with this requirement.

Probes §484.55(a)(1)

- What are the HHA's policies for conducting the initial assessment?
- How is Medicare eligibility and homebound status determined?

G332

(Rev.)

. . . The initial assessment visit must be held either within 48 hours of referral, or within 48 hours of the patient's return home, or on the physician-ordered start of care date.

Interpretive Guidelines §484.55(a)(1)

The expected outcome for this Level 1 standard is that the patient receives an initial assessment within the required time frames.

In the absence of a physician-specified start of care date, the initial assessment visit is conducted within 48 hours of the referral. If the physician specified a start of care date, this supersedes the 48-hour time frame. Check the intake or clinical record for documentation of a specified start of care date.

For Medicare patients, if the initial assessment indicates that the patient is not eligible for the Medicare home health care benefit, i.e., the patient is not homebound, has no skilled need, etc., and the HHA does not admit the patient, then there is no indication for the HHA to conduct a comprehensive assessment or to collect, encode, or transmit OASIS data to the State.

Probes §484.55(a)(1)

- How does the HHA assure that initial visits are conducted within the required time frames?
- Compare the date of the physician referral and the date of the initial assessment visit. If the initial visit is later than 48 hours or later than the physician-ordered start of care date, check the individual patient's clinical record. Sometimes a patient requests that a visit not be made until a more convenient time. That request must be documented in the clinical record as well as a notation that the physician was notified of and approves the patient's request for a delayed start of care.
- If the physician orders start of care to begin after the 48-hour time frame specified in the regulations, is there an order in the patient's chart specifying this start of care date?

G333

§484.55(a)(2) - When rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate rehabilitation skilled professional.

Interpretive Guidelines §484.55(a)(2)

For non-Medicare patients, if the need for a single therapy service establishes initial home health eligibility, the corresponding practitioner, (including a physical therapist, speech-language pathologist, or occupational therapist) can conduct the initial assessment visit.

For the Medicare home health benefit, occupational therapy services provided at the start of care alone do not establish eligibility; therefore, occupational therapists may not conduct the initial assessment visit under Medicare. Patients needing only occupational therapy services on admission to the agency may qualify for eligibility under programs other than Medicare.

These instructions are consistent with the guidance at §484.30(a), which states, "If the physician orders only therapy services, it would be acceptable for the appropriate therapist (physical therapist or speech-language pathologist) to perform the initial evaluation visit."

When physical therapy (PT), speech language pathology (SLP), or occupational therapy (OT) is the only service ordered by the physician, a PT, SLP, or OT may complete the initial assessment visit if the need for that service establishes program eligibility. See § §484.55(a)(2).

Review a case-mix, stratified sample of clinical records and make home visits according to the survey process (see §§2200 and 2202) to determine compliance with this requirement. For a sample of patients, determine who conducted the initial assessments, if the homebound status for Medicare was identified, and the dates of the referral and initial assessments.

NOTE: A patient who requires short term nursing determined at the start of care in addition to ongoing therapy is not considered a therapy-only case, i.e., a one-time visit by a nurse scheduled to remove sutures. Therefore, the RN must do the initial assessment.

Probes §484.55(a)(2)

- How does the HHA assure that initial visits are conducted within the required time frames?
- Compare the date of the physician referral and the date of the initial assessment visit. If the difference is greater than 48 hours or later than the physician ordered start of care date, check the individual patient's clinical record. If a patient requests that a visit not be made until a more convenient time, the request should be reported to the physician and documented in the clinical record.
- Review patient records in which therapy (occupational therapy, physical therapy, or speech language pathology) was the only skilled service provided. Determine

if the appropriate discipline completed the initial assessment. According to State law, some HHA's may use RNs for initial assessments in therapy-only cases.

- Interview staff to determine how therapy-only initial assessment visits are conducted.
- How does the HHA ensure that the skilled disciplines completing the initial assessment are performing this task accurately?

If questions are raised through interview and record review, review the HHA's policies regarding conducting and completing an initial assessment visit.

G334

(Rev.)

§484.55(b) Standard: Completion of the comprehensive assessment.

(1) The comprehensive assessment must be completed in a timely manner, consistent with the patient's immediate needs, but no later than 5 calendar days after the start of care.

Interpretive Guidelines §484.55(b)(1)

The expected outcome for this Level 1 standard is that the comprehensive assessment is completed within required time frames.

For patients to whom OASIS applies, when a patient is admitted to the HHA, a start of care comprehensive assessment that includes certain required OASIS data items, must be completed no later than 5 calendar days after the start of care date.

Pre-Survey Activity - Review OASIS data management reports, as available, to determine if start of care comprehensive assessments are completed within the required time frame.

Onsite Activity - Identify the start of care date. For all practical purposes, the start of care date is the first billable home visit. For payers other than Medicare, the first billable visit might be a visit made by a home health aide.

Review any reasons presented for not completing the start of care comprehensive assessments within the required time frame (i.e., the HHA planned to complete the assessment within the required time frame but the patient refused the visit.). Document explanations for start of care comprehensive assessments completed outside of the required time frame.

M0090 on the OASIS data set reflects the final date the qualified clinician completed the actual patient assessment. This is usually the date of the last home visit made to complete the comprehensive assessment but may reflect a date subsequent to the onsite

visit when the qualified clinician needs to follow up, offsite, with the patient's family or physician in order to complete an OASIS clinical data item. Compare the start of care date at M0030 with the date the assessment was completed (M0090). M0090 should be no more than 5 days later than M0030. The HHA has *30* additional days from the date the patient assessment is completed (M0090) to encode (data-enter), edit, and ensure the accuracy of the OASIS data and to consult with the qualified clinician who conducted and completed the comprehensive assessment for purposes of clarification or to complete missing OASIS data items such as diagnosis codes, etc., and to lock (export) the data for future submission to the State agency. (See §484.20(a)).

Probes §484.55(b)(1)

- Was the start of care comprehensive assessment completed within 5 calendar days after the start of care date?
- Did the HHA provide acceptable explanations and documentation for start of care comprehensive assessments completed outside of the required time frame?

G335

(Rev.)

§484.55(b)(2) - Except as provided in paragraph (b)(3) of this section, a registered nurse must complete the comprehensive assessment and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status.

Interpretive Guidelines §484.55(b)(2)

The expected outcome for this Level 1 standard is that for Medicare and Medicaid patients receiving skilled nursing services, an RN conducts and completes the comprehensive assessment, and confirms the eligibility of Medicare patients, including homebound verification, for the Medicare home health benefit. See the guidelines at §484.55 for Medicare eligibility requirements.

When nursing and therapy are both ordered at the start of care, the registered nurse performs the start of care comprehensive assessment. Either discipline may perform subsequent assessments if the discipline is still actively providing skilled services to the patient.

Probes §484.55(b)(2)

- Is the appropriate clinician conducting the comprehensive assessments, i.e., RN, physical therapist, occupational therapist, or speech-language pathologist? Check the signature of the clinician who completed the start of care assessment, and verify that it is a qualified clinician.

G336

(Rev.)

§484.55(b)(3) - When physical therapy, speech-language pathology, or occupational therapy is the only service ordered by the physician, a physical therapist, speech-language pathologist or occupational therapist may complete the comprehensive assessment, and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status. The occupational therapist may complete the comprehensive assessment if the need for occupational therapy establishes program eligibility.

Interpretive Guidelines §484.55(b)(3)

The expected outcome for this Level 1 standard is that for a therapy-only case, the RN (if required by agency policy or State law) or the physical therapist or speech language pathologist conducts and completes the comprehensive assessment at the patient's admission to the HHA. Occupational therapists may conduct and complete the assessment when the need for occupational therapy establishes program eligibility.

> **NOTE**: Occupational therapy alone does not establish eligibility for the Medicare home health benefit at the start of care; however, occupational therapy services only may qualify for eligibility under other programs, such as Medicaid. Therefore, occupational therapists may not conduct the start of care comprehensive assessment under Medicare. In contrast, the Medicare home health patient receiving services of multiple disciplines, i.e., skilled nursing, physical therapy, and occupational therapy, during the episode of care, can retain eligibility if, over time, occupational therapy is the only remaining skilled discipline providing care. At that time, an occupational therapist can conduct OASIS assessments, i.e., resumption of care, follow-up, transfer, and discharge assessments.

For Medicare patients, at start of care, after the eligibility of the patient has been confirmed and the need for the qualifying service is established then the sequence of therapy services provided is irrelevant. Therefore, if physical, occupational and/or speech therapies are ordered, the order in which services are delivered is at the HHA's discretion based on the patient's plan of care. Since the need for occupational therapy alone does not constitute eligibility under Medicare, the HHA must provide the qualifying service, i.e., physical or speech therapy, prior to transfer or discharge.

A qualified therapist may conduct and complete the comprehensive assessment, and for Medicare patients confirm eligibility, including homebound verification, for the Medicare home health benefit. See the guidelines at §484.55 for Medicare eligibility requirements.

For patients receiving services from multiple skilled disciplines, the comprehensive assessment, including OASIS items, may be completed by different disciplines such as a

registered nurse, physical therapist or speech language pathologist at subsequent time points. The same discipline is not required to complete the comprehensive assessment at every required time point.

If an RN's entry into the case is known at start of care (i.e., nursing is scheduled, even if only for one skilled nurse visit), then the case is NOT considered to be therapy-only, and the RN must conduct the start of care comprehensive assessment. If the order for nursing is not known at start of care and originates from a verbal order after start of care, then the case is considered therapy-only at start of care, and the therapist can perform the start of care comprehensive assessment. Either discipline may perform subsequent comprehensive assessments.

In cases where state law and/or HHA policies require RNs to perform comprehensive assessments, even though therapy is the only service ordered, CMS does not require a physician's order for an RN to perform a comprehensive assessment within the RN's nursing scope of practice and licensing laws.

If local HHA policies and/or state regulations require an RN to perform the comprehensive assessments whenever they occur or are necessary, then the RN would need to perform all assessments for the home health patient, not just the start of care assessment. This would, of course, require close communication between the therapist and the RN to assure that the patient's condition and needs are assessed "as frequently as the patient's condition warrants" as required by §484.55(d) Update of the comprehensive assessment. CMS does not consider this to be a multidiscipline case.

If it is the HHA's policy for the RN to perform a comprehensive assessment before the therapist's start of care visit, the nurse could perform a comprehensive assessment on or after the therapist's start of care date or the therapist could perform the start of care comprehensive assessment if this is a therapy only case. A comprehensive assessment performed BEFORE the start of care date (identified generally as being the first billable visit) cannot be entered into HAVEN (or HAVEN-like software).

Probes §484.55(b)(3)

- Are the appropriate clinicians conducting the comprehensive assessments, i.e., RN, physical therapist, occupational therapist, speech-language pathologist? Check the signature of the clinician who completed the start of care assessment (only one clinician takes responsibility for an assessment, although more than one may collaborate.)

G337

(Rev.)

§484.55(c) Standard: Drug Regimen Review

The comprehensive assessment must include a review of all medications the patient is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy.

Interpretive Guidelines §484.55(c)

The expected outcomes for this Level 1 standard are:

- *The comprehensive assessment consistently includes a thorough review of the patient's medications, including all prescribed and over-the-counter medications the patient is using, to identify any potential adverse effects and drug reactions;*
- *The patient's medication list or medications are reviewed and the medication profile/list is updated; and*
- *The physician is notified promptly regarding any medication discrepancies, side effects, problems or reactions. See also §484.30(a)*

This requirement applies to **all** patients being serviced by the HHA, regardless of whether the specific requirements of OASIS apply. For patients to whom OASIS does not apply, the drug regimen review must be conducted in conjunction with the requirements at §484.18, Condition of Participation: Acceptance of patients, plan of care, and medical supervision.

The drug regimen review must include documentation of ALL medications the patient is taking. Review medications on the current physician plan of care and in clinical record notes to determine the accuracy of the medication regimen. This may be included as part of the case-mix, stratified sample of clinical records.

Determine if clinical record documentation includes medication review, etc. In therapy-only cases, determine the HHA's policy for medication review.

Drugs and treatments ordered by the patient's physician and not documented on the care plan should be recorded in the clinical record. This includes over-the-counter drugs. If the qualified clinician (RN or therapist) determines that the patient is experiencing problems with his/her medications or identifies any potential adverse effects and/or reactions, the physician must be alerted.

The label on the bottle of a prescription medication constitutes the pharmacist's transcription or documentation of the order. Such medications are noted in the patient's clinical record and listed on the physician plan of care. This is consistent with

acceptable standards of practice. Federal regulations do not have additional requirements.

If questions are raised through interview or record review, examine the HHA's policies on drug review and actions.

Onsite Activity - Interview clinical staff, asking them to describe their process of drug regimen review including:

- How are potential adverse effects and drug reactions identified?
- What steps does the HHA require its personnel to take?
- What process is followed when a patient is found to be noncompliant?
- How is the drug regimen review completed if the patient is receiving only therapy services?
- How are drugs reviewed when medication orders are modified or changed after the start of care comprehensive assessment in multi-discipline cases and in therapy-only cases?

Probes §484.55(c)

- What is the HHA's policy for drug regimen/medication review?
- How does the HHA respond to medication discrepancies and prescriptions from physicians other than the physician responsible for the patient's home health care?
- If HHA personnel identify patient sensitivity or other medication problems, what actions does the HHA require its personnel to take?

G338

(Rev.)

§484.55(d) Standard: Update of the comprehensive assessment.

The comprehensive assessment must be updated and revised (including the administration of the OASIS) as frequently as the patient's condition warrants due to a major decline or improvement in the patient's health status, but not less frequently than . . .:

Interpretive Guidelines §484.55(d)

The expected outcomes for this Level 1 standard are:

- *The comprehensive assessment is updated and revised as required and updated patient information is included in care planning; and*
- *The comprehensive assessment data are consistent with other patient status data in the clinical record.*

The term "major decline or improvement in the patient's health status" is the impetus for collecting and reporting OASIS data in the following situations:

- As defined by the HHA (reason for assessment 5, other follow-up);
- To assess a patient on return from an inpatient facility, other than a hospital, if the patient was not discharged upon transfer (resumption of care); and
- As determined by CMS.

In the event an HHA determines that a patient's condition has improved or deteriorated beyond the HHA's expectations, the HHA may choose to collect and report additional assessment information. HHAs must code this as 'Other follow-up". The start of care date does not change when an HHA conducts this optional assessment. The transfer assessment should include required OASIS items as well as a clinical note describing the status of the patient on transfer to an inpatient facility.

The comprehensive assessment updates must include the appropriate OASIS data items as indicated on the current OASIS data set. The current OASIS data set is available on the CMS OASIS website at: http://www.cms.hhs.gov/oasis/

Probes §484.55(d)

- When the HHA uses the "Other Follow-up" comprehensive assessment, how does it define a major decline or improvement that would require a new comprehensive assessment? Within the sample records reviewed, look for patients who have had a major decline or improvement in health status, as defined by the HHA. Determine if an OASIS assessment (reason for assessment 5, other follow-up) was completed.

G339

(Rev.)

§484.55(d)(1) - … The last 5 days of every 60 days beginning with the start-of-care date, unless there is a:

(i) Beneficiary elected transfer;
(ii) Significant change in condition; or
(iii) Discharge and return to the same HHA during the 60-day episode.

Interpretive Guidelines §484.55(d)(1)

The follow-up comprehensive assessment is conducted by the qualified clinician to identify the patient's current health status and continued need(s) for home health services. The follow-up comprehensive assessment must be performed within the last 5 days of the current 60-day certification period, i.e., between and including days 56-60.

In HHA's that do not transmit any OASIS data for a month, verify that the HHA understands the transmission process and required comprehensive assessment time points. Review any validation reports the HHA has received from previous OASIS submissions to their respective State agency, i.e., OASIS initial feedback and final validation reports.

As part of the case-mix, stratified sample of clinical records, review patient records to determine that follow-up comprehensive assessments with OASIS data are conducted, collected, and completed within the required time frames.

When a Medicare beneficiary elects to transfer to a different HHA or is discharged and returns to the same HHA, it warrants a new clock for purposes of payment, OASIS assessment, and physician certification of the new plan of care.

A Significant Change In Condition (SCIC) occurs when a Medicare beneficiary experiences a significant change in condition (improvement or deterioration) during a 60-day episode that was not envisioned in the original plan of care. The HHA must complete an OASIS assessment and obtain the physician change orders reflecting the significant change in treatment approach in the patient's plan of care.

Probes §484.55(d)(1)

- How does the HHA determine when the follow-up comprehensive assessment is due? Ask clinical staff to describe their process.
- Does the M0090 item (date assessment completed) fall within the time frame required for the follow-up comprehensive assessment?
- How are follow-up comprehensive assessments completed if a skilled service is not projected at the time when the follow-up assessment is due? Are they incorporated into a *home health* aide supervisory visit, for example?
- Does the HHA have a policy defining a significant change in condition?

G340

(Rev.)

§484.55(d)(2) - . . . Within 48 hours of the patient's return to the home from a hospital admission of 24 hours or more for any reason other than diagnostic tests;

Interpretive Guidelines §484.55(d)(2)

The expected outcome for this Level 1 standard is that the patient's needs are assessed and incorporated into the plan of care upon his/her return home from a hospital stay (as described in this requirement).

As part of the case-mix, stratified sample of clinical records, review patient records to determine if comprehensive assessments with OASIS data items integrated are collected

at required time points. Evaluate the validity of any reasons why an assessment was not completed within the required time frame.

Updated comprehensive assessments are required:

- Within 48 hours of (or knowledge of) the patient's return home from a hospital stay of 24 hours or more for any reason except diagnostic tests (resumption of care OASIS data set); and
- Within 48 hours of (or knowledge of) the patient's return home from an inpatient stay (resumption of care OASIS data set).

Probes §484.55(d)(2)

- Does the M0090 item (date assessment completed) fall within the time frame required for the resumption of care comprehensive assessment?

G341

§484.55(d)(3) - At discharge.

Interpretive Guidelines §484.55(d)(3)

Updated comprehensive assessments are required:

- Within 48 hours of (or knowledge of) transfer to any inpatient facility (transfer to an inpatient facility comprehensive assessment with OASIS data items integrated, with or without agency discharge); and
- Within 48 hours of (or knowledge of) discharge to the community or death at home (discharge OASIS assessment with OASIS data items integrated).

Review patient clinical records to determine if OASIS data are collected at the required time points for discharge. Discharge assessments are required.

Probes §484.55(d)(3)

- How does the HHA readmit patients after transfer ("on hold" or "discharge") and determine next assessment dates?
- Interview HHA staff and review the HHA's policy for inpatient facility admission. Does the HHA place the patient on hold or does the HHA discharge the patient for any inpatient facility admission?
- Does the M0090 item (date assessment completed) fall within the time frame required for the transfer (with or without agency discharge, discharge to the community or death at home comprehensive assessment?)
- What does the HHA do for unanticipated patient discharges?

G342

§484.55(e) Standard: Incorporation of OASIS Data Items

The OASIS data items determined by the Secretary must be incorporated into the HHA's own assessment and must include: clinical record items, demographics and patient history, living arrangements, supportive assistance, sensory status, integumentary status, respiratory status, elimination status, neuro/emotional/behavioral status, activities of daily living, medications, equipment management, emergent care, and data items collected at inpatient facility admission or discharge only.

Interpretive Guidelines §484.55(e)

HHAs must incorporate the OASIS data items into their own assessment instrument using the exact language of the items, replacing similar items/questions on their existing assessment tool as opposed to simply adding the OASIS items at the beginning or end.

Review the HHA's comprehensive assessments to determine that required OASIS data items have been integrated into its comprehensive assessment tool. The comprehensive assessment forms (nursing or therapy) must include all required OASIS data items for each time point indicated. All comprehensive assessment forms, including those provided by vendors must be reviewed to ensure compliance with this standard. Appendix D of the OASIS Implementation Manual contains a checklist to assist HHA's in incorporating the appropriate OASIS items for each required assessment time point. Appending the OASIS data set to an HHA's existing assessment form is not appropriate. For private pay patients, OASIS items are not required to be collected; although all elements of the agency comprehensive assessment apply at all time points.

Initial Surveys and Recertification Surveys after an OASIS Modification - For new HHAs seeking initial certification, or the first HHA survey after a required change to the OASIS data set, randomly select approximately 8 OASIS items and compare them to the HHA's comprehensive assessment. Include items that have skip patterns and multiple responses. During recertification surveys after an OASIS modification, review data items that have been modified.

Probes §484.55(e)

- Does the HHA have the required OASIS data items integrated into its comprehensive assessments, i.e., start of care, resumption of care, follow-up, transfer, discharge and death at home?
- Is the OASIS data set appended at the beginning or end of the HHA's assessment form, rather than integrated into the HHA's own comprehensive assessment tool?