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INFORMATIONAL LETTER #2014-05

DATE: May 23, 2014

TO: ALL IDAHO HOME HEALTH AGENCIES

FROM: DEBBY RANSOM, R.N., R.H.I.T., Chief
Bureau of Facility Standards

SUBJECT: **CMS S&C: 14-14-HHA**

The CMS Survey & Certification Letter #14-14, SOM Chapter 2, and SOM Chapter 10 are being distributed to all Idaho Home Health Agencies.

If you have any questions, please contact our office at 208/334-6626, Option 4.

Debby Ransom

DEBBY RANSOM, R.N., R.H.I.T., Chief
Bureau of Facility Standards

DR/nm
Enclosures (3)
c: Idaho Association of Home Health Agencies

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 14-14-HHA
REVISED 05-20-2014

DATE: **March 14, 2014**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: REVISED - 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). Office of Strategic Operation and Regulatory Affairs (OSORA) has determined that the Chapter 9 designation is already in use. This chapter has been renumbered as Chapter 10.
- **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. An error in section 2202.10 has resulted in 2 corrections.

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. After publication of the original S&C letter, an error was identified in section 2202.10. This has been corrected to read:

> *To acquire an HHA personal login ID, agencies will be required to complete and submit the CMSNet Access Request form and the OASIS Individual User Account Request form. The forms are available on the QIES Technical Support Office website (*www.qtso.com*).* To meet the OASIS transmission requirements prior to the initial certification survey, new HHAs need two different sets of user identification numbers and passwords; one set to access the *CMSnet* and one set to access the OASIS System.

The following sentence has been deleted:

> ~~*Once Medicare approval has been determined the HHA must apply for permanent user identification numbers and passwords for access to the CMSNet by contacting the help desk at 1-800-905-2069*~~.

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

CMS State Operations Manual
Chapter 2 – The Certification Process

Home Health Agencies (HHAs)

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.)

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;
- Patients receiving personal care services only; and
- 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,	Inpatient services	No

Type of Medicare/*Medicaid* Service	Further Description	Application of OASIS
Hospital		

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			

PATIENT CLASSIFICATION	COLLECT	ENCODE	TRANSMIT
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*/ PPO*/Managed *Care plan* Self-pay; other; unknown	*No* Tempora*rily* Suspen*ded*	*No*	*No*
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 payer source (1) Medicare (traditional fee-for-service), (2) Medicare (HMO/Managed Care), (3) Medicaid (traditional fee-for-service), or (4) Medicaid (HMO/Managed Care) on OASIS item M0150, the HHA must collect, encode and transmit all required OASIS information to the SA. If Medicare/Medicaid is contributing to the payment of the patient's episode of care, the patient is considered a Medicare/Medicaid patient. The payer source for services provided as part of a Medicaid waiver or home and community-based waiver program by a Medicare-approved HHA are coded as (3) Medicaid (traditional fee-for-service) at item M0150.

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

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

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

1.) *The supported version of the dialer/CMS vendor is posted on the CMSNet page on https://www.qtso.com/mdcn.html. The helpdesk that supports the CMS vendor is the CMSnet Help Desk. Their phone number is: 1-800-905-2069 Opt 2.*
In the event that CMS changes telecommunication vendors, updates to requirements will be made known on the All State Technical Call and on the QTSO website.

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

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

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

4. Data Format

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

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

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

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

OASIS ASSESSMENT REFERENCE SHEET

RFA = Reason For Assessment

RFA Type	RFA Description	Assessment Completed	Locked Date	Submission Timing
01	SOC - further visits planned	Within 5 calendar days following the SOC Date (M0030)	*Effective 6/21/2006 No required lock date*	*Effective 6/21/2006 Transmission required within 30 calendar days of completing the assessment (M0090)*
02	SOC - no further visits planned	Within 5 calendar days following the SOC Date (M0030)		
03	ROC - after inpatient stay	Within 2 calendar days following the ROC Date (M0032)		
04	Recertification - Follow-up	Completed (M0090) every 60 days following SOC: no earlier than day 56 and no later than the day (day 60) on which the certification period ends		
05	Other Follow-up	Complete assessment (M0090) within 2 calendar days following identification of significant change of patient's condition		
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 CMSNet Access Request form and the OASIS Individual User Account Request form. The forms are 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 user identification numbers and passwords; one set to access the *CMSnet* and one set to access the OASIS System.

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

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

2202.10A **- Determining Compliance with the OASIS Transmission Requirements** ***(Rev.)***

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 10 – Survey and Enforcement Process for Home Health Agencies

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(Rev.)

Transmittals for Chapter 10

State Operations Manual

Chapter 10 – Survey and Enforcement Process for Home Health Agencies

(Rev.)

10000 - Introduction

(Rev.)

Chapter 10 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 18101(a) of the Act. The regulations implementing sections 1861(o) and 18101(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.

10000.1- Expectations of the Regulations

(Rev.)

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 18101(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.

10001 - Definitions and Acronyms

(Rev.)

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)*

10002 Home Health Agencies - Citations and Description

(Rev.)

10002.1 - Citations
(Rev.)

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.

10002.2 - Description
(Rev.)

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 18101(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.*

10002.3 - Home Health Services
(Rev.)

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

10003 - Emphasis, Components, and Applicability
(Rev.)

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.

10003.1 - Introduction
(Rev.)

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 11002(a)(10) 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.

10003.2 - Survey and Certification Responsibility
(Rev.)

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.)

10004 - Survey Team
(Rev.)

10004.1 - Survey Team Size
(Rev.)

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.*

10004.2 - Survey Team Composition
(Rev.)

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.

10004.3 - Length of Survey
(Rev.)

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.

10004.4 - Surveyor Qualifications
(Rev.)

Section 18101(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.

10005 - Conflicts of Interest for Federal and State Employees
(Rev.)

10005.1 - Introduction

(Rev.)

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.

10005.2 - Conflicts of Interest

(Rev.)

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.

10005.3 - Examples of Potential Conflicts of Interest

(Rev.)

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.*

10005.4 - Report and Investigation of Improper Acts
(Rev.)

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.

10006 - Survey Protocol
(Rev.)

10006.1 - Introduction
(Rev.)

Surveys conducted on a HHA must be based upon protocols developed, tested, and validated by the Secretary under section 18101(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.

10006.2 - Types of Surveys
(Rev.)

Sections 18101(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.

10006.3 - Standard Survey
(Rev.)

A standard survey is conducted not later than 36 months after the date of the previous standard survey, as is specified in section 18101(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 18101 (c)(2)(B)(i) and (ii). Section 18101(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.

10006.4 - Initial Certification Surveys
(Rev.)

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.

10006.5 - Recertification of Participating Facilities
(Rev.)

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.

10006.6 - Post Survey Revisit (Follow-Up)
(Rev.)

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.

10006.7 - Abbreviated Standard Survey
(Rev.)

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.

10006.7A - Complaint Investigations
(Rev.)

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-010-08 (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.*

10006.7B - Substantial Changes in an HHA's Organization and Management

(Rev.)

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.

10006.8 - Partial Extended Survey

(Rev.)

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.

10006.9 - Extended Survey

(Rev.)

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.

10007 - Survey Frequency

(Rev.)

10007.1 - Citations
(Rev.)

Section 18101(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.

10008 - Unannounced Surveys
(Rev.)

10008.1 – Citations
(Rev.)

Section 18101(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.

10008.2 - Scheduling Requirements
(Rev.)

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.

10008.3 - CMS Review of State Scheduling Procedures
(Rev.)

Section 18101(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.

10008.4 - Penalty for Announcing a Survey
(Rev.)

Section 18101(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.

10009 - Informal Dispute Resolution (IDR)
(Rev.)

10009.1 - Introduction
(Rev.)

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.*

10009.2 – Purpose
(Rev.)

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.

10009.3 - Mandatory Elements of IDR
(Rev.)

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; and*
   - *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 1310 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; and*
   - *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

10010 - Alternative Sanctions for Home Health Agencies
(Rev.)

10010.1 - Statutory Basis
(Rev.)

Sections 18101(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 100 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.

10010.2 - General Provisions
(Rev.)

Under section 18101(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 18101(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 18101(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.

10010.3 - Effect of Sanctions on HHAs that participate in Medicare via Deemed Status through an Accrediting Organization
(Rev.)

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).

10010.4 -Effect of Sanctions on HHA Branches
(Rev.)

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.

10010.5 - Available Sanctions
(Rev.)

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.*

10010.6 - Factors to be considered in selecting sanctions
(Rev.)

Consistent with section 18101(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.

10011 - Action when Deficiencies Pose Immediate Jeopardy.
(Rev.)

10011.1 - Statutory and Regulatory Basis
(Rev.)

Sections 18101(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.

10011.2 - Purpose
(Rev.)

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.

10012 - Enforcement Action When Immediate Jeopardy Exists
(Rev.)

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§4810.53 and §488.825. In addition to termination, one or more alternative sanctions may be imposed.

10013 - Action When Deficiencies are Condition-level But Do Not Pose Immediate Jeopardy.

(Rev.)

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 100 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.

10014 - Guidance for Individual Sanctions

(Rev.)

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.

10015 - Temporary Management

(Rev.)

10015.1- Introduction

(Rev.)

This sanction is established pursuant to §18101 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.

10015.2- Purpose

(Rev.)

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.

10015.3 - Authority of Temporary Manager

(Rev.)

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.

10015.4 - Selection of Temporary Manager
(Rev.)

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.

10015.5 - Conditions of Temporary Management
(Rev.)

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.

10015.6 - Orienting and Supervising Temporary Manager
(Rev.)

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.

10015.7 - Notice of Imposition of Temporary Management
(Rev.)

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.

10015.8 - Duration of Temporary Management
(Rev.)

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.

10016 - Suspension of Payment for All New Medicare Admissions
(Rev.)

10016.1 - Introduction
(Rev.)

Sections 18101(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.

10016.2 - Notice of Sanction
(Rev.)

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.

10016.3 - Effect of Sanction on Patients Admitted before the Effective Date of Sanction

(Rev.)

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.

10016.4 - Duration

(Rev.)

The suspension of payment would end when CMS terminates the provider agreement or when CMS finds, in accordance with section 18101(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.

10017 - Civil Money Penalties
(Rev.)

10017.1 - Basis for Imposing Civil Money Penalties
(Rev.)

Under sections 18101(e) and 18101(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 10020 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.

10017.2 - Determining Amount of Civil Money Penalty
(Rev.)

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; and*
- *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.

10017.3 - Adjustments to penalties
(Rev.)

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.

10018 - Range of Penalty Amounts
(Rev.)

10018.1- Upper range of penalty
(Rev.)

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 100th 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. *$10,000 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 $10,000 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.*

10018.2 - Middle range of penalty

(Rev.)

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.

10018.3 - Lower range of penalty
(Rev.)

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.

10018.4 - Per instance civil money penalty
(Rev.)

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.

10018.5 - Decreased penalty amounts
(Rev.)

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.

10018.6 - Increased penalty amounts
(Rev.)

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 .

10018.7 - Considerations in determining the penalty amount

(Rev.)

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.

10019- Suggested Penalty Amounts

(Rev.)

10019.1 - Upper Range Civil Money Penalties for Immediate Jeopardy Citations

(Rev.)

Immediate Jeopardy – results in harm	*$10,000*
Immediate Jeopardy – results in a potential for harm	*$10,000*
Immediate Jeopardy – isolated event of non-compliance in violation of an established HHA policy	*$8,500*

10019.2 - Middle Range Penalties for Non-Immediate Jeopardy Citations
(Rev.)

	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* ***§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*	*$5,000 - $6,000*	*$6,000 - $7,000*	*$8,500*
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 administration* ***§484.48*** *Clinical records*	*$1,500 - $2000*	*$2,000 - $3,000*	*$3,500*

10019.3 Lower Range Penalties for Structure and Process Citations Not Directly Related to Patient Care

(Rev.)

	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*

10020 – Procedures

(Rev.)

10020.1 - Notice of imposition of civil money penalty

(Rev.)

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; and*

IX. *Implications of waiving the right to a hearing and information about how to waive the right to a hearing (see §10021.4 below).*

10020.2 - Sending the Notice

(Rev.)

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.

10020.3 - Appeal of Noncompliance That Led to Imposition of Civil Money Penalty

(Rev.)

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. §4108.40 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.

10020.4 - HHA Waives Right to a hearing

(Rev.)

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 (G1510) 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.

10020.5 - Accrual and duration of per day penalty

(Rev.)

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.

10020.6 - Amount of per instance penalty

(Rev.)

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), $10,000with 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.*

10020.7 - Duration of Civil Money Penalty
(Rev.)

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 $10000.

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 G320 and a civil money penalty of $8,000 is imposed for Tag G330. 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.*

10020.8 - Duration of per day penalty when there is immediate jeopardy

(Rev.)

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.

10020.9 - Duration of penalty when there is no immediate jeopardy

(Rev.)

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.

10020.10 - When Penalty Is Due and Payable
(Rev.)

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.

10021 - Notice of Amount Due and Collectible

(Rev.)

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.

10021.1 - Computation and Notice of Total Penalty Amount
(Rev.)

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); and*
- *Instructions for submitting payment to CMS CO with the reference number on the check.*

10021.2 - When a penalty is due and payable
(Rev.)

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 §4108.40(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.

10021.3 - Method of Payment

(Rev.)

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 10022 below).

10021.4 - Settlement of Civil Money Penalty

(Rev.)

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.

10021.5 - Offsets

(Rev.)

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 110106 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.

10022 - Disbursement of Recovered CMP funds

(Rev.)

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 20010 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 2007-20010 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.

10023 - Directed Plan of Correction

(Rev.)

10023.1 – Introduction

(Rev.)

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.

10023.2 - Purpose

(Rev.)

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.

10023.3 - Imposition of a Directed Plan of Correction
(Rev.)

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.

10023.4 - Elements of a Directed Plan of Correction
(Rev.)

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.*

10023.5 - Achieving Compliance
(Rev.)

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.

10023.6 - Notice of Imposition of Directed Plan of Correction
(Rev.)

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.

10024 - Directed In-Service Training
(Rev.)

10024.1 - Introduction
(Rev.)
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.

10024.2 - Purpose
(Rev.)

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.

10024.3 - Appropriate Resources for Directed In-Service Training Programs
(Rev.)

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.

10024.4 - Further Responsibilities
(Rev.)

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.

10024.5 - Notice of Imposition of Directed In-Service Training

(Rev.)

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.

10025 - Effect of Termination on the HHA's patients

(Rev.)

Under the provisions of §§1866(b)(2)(A) and (B) of the Act (also 42 CFR 4810.53), 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 §4810.55(b).