

(Rev. 188, 04-26-19)

Home Health Agencies (HHAs)

2180 - HHA – Citations and Description

(Rev. 1, 05-21-04)

2180A - Citations

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 (§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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 §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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 §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 §484.55 for those patients receiving personal care services only regardless of payer 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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 located at such a distance from the parent agency that it is incapable of sharing administration, supervision, and services on a daily basis. Serves patients in a geographic area different from that of the parent. A subunit may have a branch.

Compliance with CoPs

Branch - Does not have to independently meet the CoPs as an HHA.

Subunit - Independently meets all CoPs as an HHA.

Organizational Structure (See §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 §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 §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 §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 §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 §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 §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 §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 §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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 424.540(a)(2) requires a provider or supplier to update its enrollment information, and recertify its accuracy when any changes are made. Additionally, §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 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)**

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 §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 § 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 §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 §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 §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 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 provides 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 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)**

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 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 (§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 §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 Cross State Lines

(Rev 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 146, Issued: 09-04-15, Effective: 09-04-15, Implementation: 09-04-15)

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 90 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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 §484.18(a) and (b) and §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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

The home health regulations at §484.55 require that each patient receive from the HHA a patient-specific, comprehensive assessment. As part 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 §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 §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 §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 §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 §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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 within 30 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) – The day that care resumes after an inpatient stay. The 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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 §484.55(e))

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 440.70(d). As such, HHAs servicing only Medicaid patients (Medicaid-only HHAs) must meet Medicare CoPs, including the comprehensive assessment and OASIS reporting requirements.

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

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

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

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

2202.3B - OASIS and the Medicare Home Health Benefit (Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 §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 §484.1 would

have to comply.

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

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

2. Medicaid Home Health Programs/Medicaid Waiver Programs

The comprehensive assessment regulations apply to HHAs that are required to meet the Medicare home health CoPs. An HHA that currently must meet the Medicare CoPs under Federal and/or State law must meet the Medicare CoPs related to OASIS and comprehensive assessment and reporting. If an HHA provides skilled services to individuals under Medicaid, then OASIS applies. If the patient is not receiving skilled nursing, physical therapy, occupational therapy, or speech language pathology services, then OASIS does not apply. The requirement to collect OASIS on patients receiving only personal care services has been delayed until further notice.

3. Medicare Hospice Benefit

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

4. Outpatient Therapy Benefit

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

5. SNF or Inpatient Hospital Benefit

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

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

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

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

2202.3C - Non-Medicare/Non-Medicaid Patients

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 Nonskilled Care (Rev. 1, 05-21-04)

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

- **Skilled Services for Medicare Patients** - The provision of skilled service is a pre-condition for Medicare payment for home health care. Therefore, all patients receiving Medicare (traditional) home health services are, by definition, receiving skilled care.
- **Skilled Services for Non-Medicare Patients** - For comprehensive assessment purposes, skilled services are services which can only be provided by a registered nurse (RN) (or a licensed practical nurse under the supervision of an RN), a physical therapist (PT), occupational therapist (OT), or a speech language pathologist (SLP), licensed by the State. Most States define the kind of care that is allowed by these practitioners under State practice acts.

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

2202.3E - Agencies Serving Medicaid Waiver and State Plan Patients (Rev. 1, 05-21-04)

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

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

2202.3F - Patients Turning 18

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 1/5/2013 a patient under the care of the agency turns 18 and is transferred to an inpatient facility on or after 1/5/2013, 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 §484.20 and §484.55)

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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

PATIENT CLASSIFICATION	COLLECT	ENCODE	TRANSMIT
SKILLED Medicare (traditional fee-for service) Medicare (HMO/Managed Care) Medicaid (traditional fee-for-service) Medicaid (HMO/Managed Care)	Yes	Yes	Yes
SKILLED Non-Medicare/Non-Medicaid:	No	No	No

PATIENT CLASSIFICATION	COLLECT	ENCODE	TRANSMIT
Workers' Compensation Title Programs Other Government Private insurance Private pay patients under a HMO/ PPO/Managed Care plan Self-pay; other; unknown	Temporarily Suspended		
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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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
1/15/20xx	1/15/20xx - 3/14/20xx	3/10/20xx - 3/14/20xx
1/15/20xx	3/15/20xx - 5/13/20xx	5/09/20xx - 5/13/20xx
1/15/20xx	5/14/20xx - 7/12/20xx	7/08/20xx - 7/12/20xx

4. Transfer to an Inpatient Facility

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

5. Discharge

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

2202.4B - OASIS Encoding and Locking

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 §484.20)

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)**

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)**

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 (§484.16, Group of Professional Personnel and §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>

2202.5A - Using Outcome Based Quality Monitoring (OBQM) and Risk Adjusted OBQI Reports in the Survey Process (Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 (§484.16, Group of Professional Personnel and §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](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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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

2202.6 - OASIS Instructions

(Rev. 1, 05-21-04)

2202.6A - OASIS Guidance Manual

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 Home Health Prospective Payment System (PPS)

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 M2200 (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 §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 M2200 = 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 M2200 = 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 §484.55)

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 payer 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 §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, 2014, the patient would be reassessed between August 18 and August 22, 2014.

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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		

RFA Type	RFA Description	Assessment Completed	Locked Date	Submission Timing
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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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

2202.9A - Informing Patients of OASIS Collection and Reporting **(Rev. 1, 05-21-04)**

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

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

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

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

(Rev. 188, Issued: 04-26-19, Effective: 04-26-19, Implementation: 04-26-19)

The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.

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, *Medicare beneficiary identifier*, 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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 (<https://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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 Deemed Status (Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 CMSnet for the applicable user identification numbers and passwords.

2202.10D - Compliance Dates and PPS

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 484. If maintained electronically, the HHA must be capable of retrieving and reproducing a hard copy of these assessments upon request. It is acceptable to have multiple corrected assessments for an OASIS assessment, as long as the OASIS and the clinical record are documented in accordance with the clinical record requirements at 42 CFR 484.

2202.11E - Clinical Implications of Corrected Assessment Records (Rev. 1, 05-21-04)

When corrections are made to an assessment already submitted to the OASIS State System, the HHA must determine if there is an impact on the patient's current care plan. If there is an impact, in addition to the correction made to the assessment, the HHA must make corresponding changes to the current care plan. If there are any other records where the correction has an impact, for example, the Home Health Resource Group, the Plan of Treatment (CMS Form-485), or the Request for Anticipated Payment, the agency should make corresponding changes to that record, as applicable. The agency should establish a procedure to review the impact of any corrections made to assessment records and make corresponding changes to other records that are affected.

2202.11F - Regarding Corrections in Lieu of Required Assessments (Rev. 1, 05-21-04)

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

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

2202.11G - Timeliness of Corrections (Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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, re-locking and re-submitting the assessment, as previously described above. "CORRECTION_NUM" (the counter field) is implemented in non-key field changes. For more specific information concerning the process of correction and inactivation, refer to the OASIS data specification notes on the OASIS web site.

See below for a flow chart depicting the most common situations necessitating corrections

2202.12 - OASIS State System

(Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 §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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 §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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 §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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 §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, Merger, and Termination Procedures Affecting HHAs and OASIS Requirements (Rev. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 §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 §489.18 and §3210, when there is a permissible change in ownership under §424.550(b)(2), as described below and the new owner does not reject automatic assignment of the existing provider agreement under §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 §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 §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 §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 §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 §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 §424.550(b)(2). Specifically, the provisions of §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: §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 §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 §489.53. Revocation of billing privileges in the Medicare program may be initiated by the MAC at §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 §498, where a final decision applies to both the billing privileges and the provider agreement. See §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 §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. 125, Issued: 10-31-14, Effective: 10-31-14, Implementation: 10-31-14)

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 <http://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> (<http://www.wocn.org>) and the

NPUAP website is located at <http://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.