

State Operations Manual

Appendix B - Guidance to Surveyors: Home Health Agencies

(Rev. 11, 08-12-05)

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The Interpretive Guidelines serve to interpret and clarify the Conditions of Participation for home health agencies (HHAs). The Interpretive Guidelines merely define or explain the relevant statute and regulations and do not impose any requirements that are not otherwise set forth in statute or regulation.

Conduct the HHA survey in accordance with the appropriate protocols and look to the substantive requirements in the statute and regulations to determine whether a citation of non-compliance is appropriate. Base any deficiency on a violation of the statute or regulations, which, in turn, is to be based on observations of the HHA's performance or practices. (See §2712.)

42 CFR PART 484

INTERPRETIVE GUIDELINES: HOME HEALTH AGENCIES

Subpart A - General Provisions

§484.1 Basis and Scope

This part implements the requirements of [§§1861\(o\) and 1891\(a\)](#) of the Social Security Act (the Act) for HHA services and also sets forth the additional requirements considered necessary to ensure the health and safety of patients.

§484.2 Definitions

As used in this part, unless the context indicates otherwise--

Bylaws or equivalent means a set of rules adopted by an HHA for governing the agency's operation

Branch office means a location or site from which a home health agency provides services within a portion of the total geographic area served by the parent agency. The branch office is part of the home health agency and is located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the branch independently to meet the conditions of participation as a home health agency.

Clinical note means a notation of a contact with a patient that is written and dated by a member of the health team, and that describes signs and symptoms, treatment and drugs administered and the patient's reaction, and any changes in physical or emotional condition.

HHA stands for home health agency. Nonprofit agency means an agency exempt from Federal income taxation under section 501 of the Internal Revenue Code of 1954.

Parent home health agency means the agency that develops and maintains administrative controls of subunits and/or branch offices. Primary home health agency means the agency that is responsible for the services furnished to patients and for implementation of the plan of care.

Progress note means a written notation, dated and signed by a member of the health team, that summarizes facts about care furnished and the patient's response during a given period of time.

Proprietary agency means a private profit-making agency licensed by the State.

Subdivision means a component of a multi-function health agency, such as the home care department of a hospital or the nursing division of a health department, which independently meets the conditions of participation for HHAs. A subdivision that has subunits or branch offices is considered a parent agency.

Subunit means a semi-autonomous organization that--

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

Summary report means the compilation of the pertinent factors of a patient's clinical notes and progress notes that is submitted to the patient's physician.

Supervision means authoritative procedural guidance by a qualified person for the accomplishment of a function or activity. Unless otherwise specified in this part, the supervisor must be on the premises to supervise an individual who does not meet the qualifications specified in §484.4

§484.4 Personnel Qualifications

Staff required to meet the conditions set forth in this part are staff who meet the qualifications specified in this section.

Administrator, home health agency. A person who:

- (a) Is a licensed physician; or**
- (b) Is a registered nurse; or**
- (c) Has training and experience in health service administration and at least 1 year of supervisory or administrative experience in home health care or related health programs.**

Audiologist. A person who:

- (a) Meets the education and experience requirements for a Certificate of Clinical Competence in audiology granted by the American Speech-Language-Hearing Association; or**
- (b) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.**

Home health aide. Effective for services furnished after August 14, 1990, a person who has successfully completed a State-established or other training program that meets the requirements of §484.36(a) and a competency evaluation program or State licensure program that meets the requirements of §484.36(b) or (e), or a competency evaluation program or State licensure program that meets the requirements of §484.36(b) or (e). An individual is not considered to have completed a training and competency evaluation program, or a competency evaluation program if, since the individual's most recent completion of this program(s), there has been a continuous period of 24 consecutive months during none of which the individual furnished services described in §409.45 of this chapter for compensation.

Occupational therapist. A person who:

- (a) Is a graduate of an occupational therapy curriculum accredited jointly by the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or**
- (b) Is eligible for the National Registration Examination of the American Occupational Therapy Association; or**

- (c) Has 2 years of appropriate experience as an occupational therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapist after December 31, 1977.**

Occupational Therapy Assistant. A person who:

- (a) Meets the requirements for certification as an occupational therapy assistant established by the American Occupational Therapy Association; or**
- (b) Has 2 years of appropriate experience as an occupational therapy assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapy assistant after December 31, 1977.**

Physical therapist. A person who is licensed as a physical therapist by the State in which practicing, and

- (a) Has graduated from a physical therapy curriculum approved by:
 - (1) The American Physical Therapy Association; or**
 - (2) The Committee on Allied Health Education and Accreditation of the American Medical Association; or**
 - (3) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association; or****
- (b) Prior to January 1, 1966:
 - (1) Was admitted to membership by the American Physical Therapy Association; or**
 - (2) Was admitted to registration by the American Registry of Physical Therapist; or**
 - (3) Has graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education; or****
- (c) Has 2 years of appropriate experience as a physical therapist and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service except that such**

determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking qualification as a physical therapist after December 31, 1977; or

(d) Was licensed or registered prior to January 1, 1966, and prior to January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy; or

(e) If trained outside the United States:

(1) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy;

(2) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.

Physical therapy assistant. A person who is licensed as a physical therapy assistant, if applicable, by the State in which practicing, and

(1) Has graduated from a 2-year college-level program approved by the American Physical Therapy Association; or

(2) Has 2 years of appropriate experience as a physical therapy assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a physical therapy assistant after December 31, 1977.

Physician. A doctor of medicine, osteopathy or podiatry legally authorized to practice medicine and surgery by the State in which such function or action is performed.

Practical (vocational) nurse. A person who is licensed as a practical (vocational) nurse by the State in which practicing.

Public health nurse. A registered nurse who has completed a baccalaureate degree program approved by the National League for Nursing for public health nursing preparation or postregistered nurse study that includes content approved by the National League for Nursing for public health nursing.

Registered nurse (RN). A graduate of an approved school of professional nursing, who is licensed as a registered nurse by the State in which practicing.

Social work assistant. A person who:

- (1) Has a baccalaureate degree in social work, psychology, sociology, or other field related to social work, and has had at least 1 year of social work experience in a health care setting; or**
- (2) Has 2 years of appropriate experience as a social work assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S.**

Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a social work assistant after December 31, 1977.

Social Worker. A person who has a master's degree from a school of social work accredited by the Council on Social Work Education, and has 1 year of social work experience in a health care setting.

Speech-language pathologist - A person who:

- (1) Meets the education and experience requirements for a Certificate of Clinical Competence (in speech pathology or audiology) granted by the American Speech-Language-Hearing Association; or**
- (2) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.**

Subpart B - Administration

The Conditions of Participation for HHAs apply to each individual under its care unless a requirement is specifically limited to Medicare beneficiaries. Section [1861\(o\)](#) of the Social Security Act (the Act) describes an HHA for purposes of participation in the Medicare program in broadly descriptive terms. All the requirements are stated generally as applicable to the HHA's overall activity, and not specifically to the Medicare patient. This provision, which was reaffirmed by Congress in the OBRA 1987 amendments to [§1891\(a\)](#) of the Act has been in the law since the inception of the Medicare program, and CMS' interpretation of it has remained the same. Do not attempt to resolve or enforce matters relating to Medicare/Medicaid coverage of services. If you observe what you believe are noncovered services, report this information to the Regional Office Medicare or Medicaid Divisions, as appropriate.

Section [1891\(c\)\(2\)\(C\)\(i\)\(II\)](#) of the Act requires that the standard survey shall include a survey of the quality of care and services furnished by the agency as measured by indicators of medical, nursing, and rehabilitative care.

G100

§484.10 Condition of Participation: Patient Rights

G101

The patient has the right to be informed of his or her rights. The HHA must protect and promote the exercise of these rights.

Interpretive Guidelines §484.10

The HHA has a responsibility to inform the patient of his or her rights. Patient rights should be explained to **ALL** patients admitted to the HHA. However, HHAs treat patients whose physical, mental, and emotional status varies widely. Overall, there should be evidence that the HHA has conscientiously tried, within the constraints of the individual situation, to inform the patient in writing, and orally ([§484.10\(e\)](#)), of his/her rights. If in a particular situation the HHA determines that the patient, despite the HHA's best efforts, is unable to understand these rights, a notation describing the circumstances should be placed in the patient's clinical record. The notation should be consistent with the patient's diagnosis, general state of physical or mental health, and/or other recorded clinical information, environmental information, or observations. Question clear patterns of seemingly routine notations that patients could not understand their rights.

During home visits, ask patients if the HHA informed them of their rights, and, if so, how. They should be able to give, in their own words, examples of how the rights apply

to the HHA care being received and any concerns they have about financial implications of the items or services being received. They should also be able to explain how to access information, services, and the HHA hotline.

If the patient is vague in answering questions, ask for written information about his or her rights that the HHA may have given him or her as resource material. Reviewing the written statement with the patient during the home visit may help the patient remember the HHA's patient rights instructions.

§484.10(a) Standard: Notice of Rights

G102

- (1) The HHA must provide the patient with a written notice of the patient's rights in advance of furnishing care to the patient or during the initial evaluation visit before the initiation of treatment.**
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Interpretive Guidelines §484.10(a)(1)

In the stratified sample of clinical records selected for review, look for notations that a statement of the patient's rights, including the statement concerning the collection and reporting of OASIS information, has been given to the patient by the HHA staff **prior to care being initiated**. This written statement must have been provided during admission, the patient's initial evaluation visit, or the patient's first professional visit.

The OASIS database is subject to the requirements of the Federal Privacy Act of 1974. The Privacy Act allows the disclosure of information from a system of records without an individual's consent if the information is to be used for a purpose that is compatible with the purposes for which the information was collected. However, under existing patient's rights regulations, the HHA **must** provide the patient with a written notice of this collection of information, i.e., OASIS in advance of furnishing care to the patient.

Before comprehensive assessments (that include collection of OASIS data items) are conducted, the HHA must tell patients about OASIS and explain their rights with respect to the collection and reporting of OASIS information. These rights include:

1. The right to be informed that OASIS information will be collected and for what purpose;
2. The right to have the information kept confidential and secure;
3. The right to be informed that OASIS information will not be disclosed except for legitimate purposes allowed by the Privacy Act;
4. The right to refuse to answer a specific question; and

5. The right to see, review, and request changes on their assessment.

A standard notice to patients that explains these rights in plain language was published in the “Federal Register” on June 18, 1999, (64 FR 32984) and is available in English and Spanish on the OASIS website (<http://www.cms.hhs.gov/oasis/>). HHAs must present and explain this required notice to beneficiaries before their initial OASIS assessment.

Review HHA admission information to determine if the OASIS Statement of Patient Privacy Rights (for Medicare/Medicaid patients) is included concerning OASIS data collection and transmission.

If the HHA chooses to continue to collect OASIS information from non-Medicare/non-Medicaid patients the patient should be provided with the Notice about Privacy (for non-Medicare/non-Medicaid patients). If a home visit is made, the verification could also include a conversation with the patient and any material on patient rights that the patient has received from the HHA. A notation in the clinical record might also include a statement regarding any limitations the patient had in being able to understand the information.

Probes §484.10(a)(1)

How do HHA employees, and staff used by the HHA under an arrangement or contract, implement HHA procedures for informing patients of their rights?

What are the HHA’s admission policies concerning the OASIS Privacy Act Statement?

How does the HHA assure that the patient understands the OASIS Privacy Act Statement? Is the patient given a copy of the OASIS Privacy Act Statement?

What is the HHA’s policy and procedure for requests to see, copy, review, or change assessment information?

Does the patient receive a written copy of the HHA’s response when a change request is not granted?

G103

(2) The HHA must maintain documentation showing that it has complied with the requirements of this section.

The documentation maintained by an HHA to show that the patient was informed of the patient’s rights might include a patient rights statement, signed and dated by the patient or some other documentation consistent with the HHA’s policies and procedures.

G104**§484.10(b) Standard: Exercise of Rights and Respect for Property and Person**

- (1) The patient has the right to exercise his or her rights as a patient of the HHA.
- (2) The patient's family or guardian may exercise the patient's rights when the patient has been judged incompetent.

G105

- (3) The patient has the right to have his or her property treated with respect.

G106

- (4) The patient has the right to voice grievances regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for property by anyone who is furnishing services on behalf of the HHA and must not be subjected to discrimination or reprisal for doing so.

G107

- (5) The HHA must investigate complaints made by a patient or the patient's family or guardian regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for the patient's property by anyone furnishing services on behalf of the HHA, and must document both the existence of the complaint and the resolution of the complaint.

Interpretive Guidelines §484.10(b)(4) and (5)

During home visits, ask the patient, the patient's family, guardian or other legal representative under state law, if they have any comments or concerns, or have registered any grievances or complaints about the HHA or its services. Also, note any patient-described problems recorded in the clinical records during your stratified sample clinical record review.

Review the agency's compliance with its stated procedures for grievance/complaint investigations and resolution. If resolution of the problem was not possible, the actions that were attempted and the outcomes should be documented by the HHA.

Probes §484.10(b)(4) and (5)

1. How does the HHA receive, record, investigate, and resolve patient grievances and complaints?
2. Who in the HHA is ultimately accountable for receiving and resolving any patient concerns or problems that cannot be resolved at the staff level?
3. During home visits, ask patients how they would express a grievance or problem should one occur. If one had already occurred, ask how it was handled and what were the results or outcomes.

§484.10(c) Standard: Right to be Informed and to Participate in Planning Care and Treatment

G108

- (1) **The patient has the right to be informed, in advance, about the care to be furnished, and of any changes in the care to be furnished.**
 - (i) **The HHA must advise the patient in advance of the disciplines that will furnish care, and the frequency of proposed visits.**
 - (ii) **The HHA must advise the patient in advance of any change in the plan of care before the change is made.**

G109

- (2) **The patient has the right to participate in the planning of the care.**
 - (i) **The HHA must advise the patient in advance of the right to participate in planning the care or**

G110

- (ii) **The HHA complies with the requirements of Subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. The HHA must inform and distribute written information to the patient, in advance, concerning its policies on advance directives, including a description of applicable State law. The HHA may furnish advanced directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided**

Interpretive Guidelines §484.10(c)

During home visits, discuss the services that the patient is receiving specific to the medical plan of care. Determine if the patient response shows that the HHA has offered specific instructions in areas mentioned in the standard. For example, if the patient is recovering from a fractured hip and has been receiving physical therapy services for several weeks, ask the patient to show or explain to you what exercises he or she has been doing, how often they are to be done, and what results are anticipated. Also, ask how often the physical therapist comes, when the therapist is expected next, and how plans for therapy have changed as the patient's condition has changed. If the patient responds that he/she has written instructions telling him or her what to do, request to see them.

Ask the patient how he or she participated in developing the plan of care to be furnished by the HHA and when he/she was told about changes in the plan of care. The HHA may discuss changes with the patient by telephone prior to the HHA visit or at the time of the visit, but the patient should feel that he or she has time to consider the implications of the change(s) and concur or object to them prior to implementation.

Advance directives generally refer to written statements, completed in advance of a serious illness, about how an individual wants medical decisions made. The two most common forms of advance directives are a living will and a durable medical power of attorney for health care.

Section [1866\(a\)\(1\)\(Q\)](#), as implemented by 42 CFR 484.10(c)(2)(ii), requires HHAs to maintain written policies and procedures regarding advance directives. The specific requirements HHAs must meet with respect to advance directives are set forth at [42 CFR 489, Subpart I](#). Under these provisions, the HHA must:

1. Provide all adult individuals with written information about their rights under State law to:
 - a. Make decisions about their medical care;
 - b. Accept or refuse medical or surgical treatment; and
 - c. Formulate, at the individual's option, an advance directive;
2. Inform patients about the HHA's written policies on implementing advance directives;
3. Document in the patient's medical record whether he or she has executed an advance directive;
4. Not condition the provision of care or otherwise discriminate against an individual based on whether he or she has executed an advance directive;

5. Ensure compliance with the related State requirements on advance directives; and
6. Provide staff and community education on issues concerning advance directives.

This information must be furnished in advance of the individual coming under the care of the HHA and may be provided during admission, the patient's initial evaluation, or the patient's first professional visit.

Probes §484.10(c)

1. What documentation in the clinical records indicates that the HHA advised the patient, in advance, of his or her right to participate in planning the care or treatment to be provided? What documentation indicates that the HHA informed the patient about the types of services to be provided, the disciplines involved, the frequency of the services, and the anticipated outcomes?
2. How does the HHA inform the patient about changes in the plan of care and solicit the patient's participation prior to the change being implemented?
3. How does the agency advise patients of the need for the physician to agree with the plan of treatment and with any changes to that plan?
4. During home visits, ask the patients how they would seek advice or care from their physician, the HHA or its representatives if problems, concerns, or emergencies that are part of the medical problems for which they are being treated by the HHA occur.
5. How do HHA employees implement advance directives requirements?

§484.10(d) Standard: Confidentiality of Medical Records

G111

The patient has the right to confidentiality of the clinical records maintained by the HHA.

G112

The HHA must advise the patient of the agency's policies and procedures regarding disclosure of clinical records

Interpretive Guidelines §484.10(d)

For specific requirements concerning the confidentiality of OASIS data, see the guidelines at §484.11.

Probes §484.10(d)

1. How does the HHA ensure the confidentiality of the patient's clinical record?
2. If the HHA leaves a portion of the clinical record in the home (such as in some high technology situations when frequent clinical entries are important), how does the HHA instruct the patient or caretaker about protecting the confidentiality of the record?
3. What documentation in the clinical record indicates that the HHA informed the patient of the HHA's policies and procedures concerning clinical record disclosure?

§484.10(e) Standard: Patient Liability for Payment

G113

(1) The patient has the right to be advised, before care is initiated, of the extent to which payment for the HHA services may be expected from Medicare or other sources, and the extent to which payment may be required from the patient.

G114

Before the care is initiated, the HHA must inform the patient, orally and in writing, of--

- (i) The extent to which payment may be expected from Medicare, Medicaid, or any other Federally funded or aided program known to the HHA;**
- (ii) The charges for services that will not be covered by Medicare; and**
- (iii) The charges that the individual may have to pay.**

Interpretive Guidelines §484.10(e)

During home visits, ask the patient whether the HHA has notified him or her of covered and noncovered services. Also, discuss whether the HHA has described any services for which the patient might have to pay and how payment sources might change (or have changed) during the course of care. Again, consider the patient's ability to understand and retain payment information. The subject of payment for home care services is often complex and confusing, particularly early in the course of treatment when the patient's illness or limitations appears to be the more pressing problem.

Look for a written statement in the home that might serve as a resource or reminder to the patient about the information the HHA has presented. Also, note whether there are subsequent written statements about payments for items or services of which the HHA has become aware.

In your evaluation of compliance with this standard, consider whether the HHA is making a reasonable attempt to help the patient understand how the charges for HHA services will be covered or not covered over the course of treatment. Based on the information provided by the HHA, do you believe that the patient has a reasonable understanding of how payment for home care services will likely occur and can make reasonable, informed decisions about financial matters related to the HHA's care and treatment of him or her.

Do **NOT** try to advise the patient about financial, coverage, or payment issues.

Probes §484.10(e)

1. What process is followed by the HHA to inform the patient of home care charges and probable payment sources, patient's payment liability (if any), and of changes in payment sources and patient liabilities?
2. What documentation in the clinical record indicates that the HHA informed the patient of Federally-funded or aided covered and noncovered services?

G115

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(2) The patient has the right to be advised orally and in writing of any changes in the information provided in accordance with paragraph (e)(1) of this section when they occur. The HHA must advise the patient of these changes orally and in writing as soon as possible, but no later than 30 calendar days from the date that the HHA becomes aware of a change.

Interpretive Guidelines §484.10(e)

During home visits, ask the patient whether the HHA has notified him or her of covered and non-covered services. Also, discuss whether the HHA has described any services for which the patient might have to pay and how payment sources might change (or have changed) during the course of care. Again, consider the patient's ability to understand and retain payment information. The subject of payment for home care services is often complex and confusing, particularly early in the course of treatment when the patient's illness or limitations appears to be the more pressing problem.

Look for a written statement in the home that might serve as a resource or reminder to the patient about the information the HHA has presented. Also, note whether there are subsequent written statements about payments for items or services of which the HHA has become aware.

In your evaluation of compliance with this standard, consider whether the HHA is making a reasonable attempt to help the patient understand how the charges for HHA services will be covered or not covered over the course of treatment. Based on the information provided by the HHA, do you believe that the patient has a reasonable understanding of how payment for home care services will likely occur and can make reasonable, informed decisions about financial matters related to the HHA's care and treatment of him or her.

Do NOT try to advise the patient about financial, coverage, or payment issues.

Probes §484.10(e)

- 1. What process is followed by the HHA to inform the patient of home care charges and probable payment sources, patient's payment liability (if any), and of changes in payment sources and patient liabilities?*
 - 2. What documentation in the clinical record indicates that the HHA informed the patient of Federally-funded or aided covered and non-covered services?*
-

G116

§484.10(f) Standard: Home Health Hotline

The patient has the right to be advised of the availability of the toll-free HHA hotline in the State. When the agency accepts the patient for treatment or care, the HHA must advise the patient in writing of the telephone number of the home health hotline established by the State, the hours of operation, and that the purpose of the hotline is to receive complaints or questions about local HHAs. The patient also has the right to use this hotline to lodge complaints concerning the implementation of the advanced directive requirements.

Interpretive Guidelines §484.10(f)

During home visits, ask the patient about the HHA State hotline, when he/she would use it, and what he/she would expect as a result of its use. If the patient has difficulty answering questions about the hotline, ask the patient for a copy of the written information that the HHA has provided.

Federal facilities are not required to participate in the HHA State hotline.

G310

§484.11 Condition of Participation: Release of Patient Identifiable OASIS Information

The HHA and agent acting on behalf of the HHA in accordance with a written contract must ensure the confidentiality of all patient identifiable information contained in the clinical record including OASIS data, and may not release patient identifiable information to the public.

Interpretive Guidelines §484.11

Protection of confidentiality of OASIS information is two-fold; the HHA has a responsibility to keep OASIS information confidential and CMS has a responsibility to keep it confidential, once it has been transmitted to the OASIS State system.

Under this condition of participation, the HHA is required to maintain the confidentiality of OASIS data while it is being used for patient care and may not release it without the consent of the patient for any reason other than for what it is intended, which is to appropriately deliver patient care. HHAs must have policies and procedures for limiting access to OASIS information to only those persons the HHA designates.

If the HHA contracts with a vendor for transmission of its OASIS data, a written agreement that addresses the confidentiality of that data must be in place. Violations of data confidentiality by an entity contracted by the HHA are still the responsibility of the HHA and would constitute condition-level non-compliance; therefore the HHA is ultimately responsible for compliance with the confidentiality requirements and is the responsible party if the contractor does not meet the requirements.

For privacy and security reasons, communication of OASIS information (from branch to branch, branch to parent, parent to vendor, etc.) must be done in accordance with CMS policies on the communication of patient-identifiable information. HHAs must have processes in place to assure that access to and transfer and delivery of OASIS information is limited to only authorized personnel.

HHAs that contract with accrediting organizations (AO), such as the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) and the [Community Health Accreditation Program](#) (CHAP), for determining compliance with the Medicare Conditions of Participation may share Outcome –based Quality Improvement /Monitoring (OBQI/M) reports with representatives of the appropriate AO on survey. The AO has a responsibility to review the OBQI/M reports and the HHA must provide the reports in the course of normal HHA business. State Agencies and Regional Offices may not share OBQI/M reports with the AO because no data use agreement exists with the SA/RO and the AO.

The other step in assuring confidentiality of the OASIS data is at the Federal level and involves the Federal Privacy Act of 1974. Coverage under the Federal Privacy Act begins when the data reaches the State agency. The Privacy Act requires that policies and procedures related to the collection of information be made available to the public describing the reasons for collecting OASIS data, what will be done with it, and who will have access to it in an identifiable format. The Privacy Act puts into place certain processes that protect patient identifiable data from unauthorized use and disclosure. Provisions of the Privacy Act as they relate to the collection of OASIS data are described in detail on the OASIS Statement of Patient Privacy Rights (See [§484.10\(a\)](#)).

Onsite Activity - Verify that the HHA has established a mechanism to ensure confidentiality of OASIS data. Interview the administrator and staff regarding:

- Protecting confidentiality of OASIS data (written and/or electronic).
- Assignment and maintenance of secure passwords for data encoding and transmission.
- Determine how OASIS data, whether in hard copy or electronic format is kept confidential before and after transmission to the State agency.

Interview the HHA administrator or system administrator for:

- Knowledge and application of rights to add, edit, or otherwise modify encoded OASIS data;
- Assignment of passwords;
- Assurance that only specified staff have contact with assessment information; and
- Actions taken when an employee with access to the system leaves the HHA's employment.

If possible, observe security of the OASIS data-entry location. Observe if the computer screen is logged off or password protected when not attended.

If applicable, review vendor contracts for provisions protecting confidentiality of OASIS data and determine what systems are in place to assure confidentiality throughout the transmission process. Vendors must be aware of the requirements and security policies of the HHA.

If questions are raised through interview or record review, review HHA's policies regarding confidentiality of patient information.

Probes §484.11

1. How does the HHA assure that only specified personnel have access to OASIS assessment information?
2. How is the security of passwords maintained?
3. What policies and procedures address password assignment and use?
4. How does the HHA assure that the computer is “logged off” or password protected when the data entry operator is away from the computer, i.e., at lunch or break times?
5. Who in the HHA has the password information needed to electronically report OASIS data to the State agency? At least two staff persons should have the password.
6. If the HHA has branches, how is OASIS data protected and kept secure during transfer from the branch to the parent agency?
7. If the HHA contracts out OASIS encoding and reporting, what systems are in place to assure that the contracted vendor maintains confidentiality of OASIS data?

G117

§484.12 Condition of Participation: Compliance With Federal, State and Local Laws, Disclosure and Ownership Information, and Accepted Professional Standards and Principles

G118

§484.12(a) Standard: Compliance With Federal, State, and Local Laws and Regulations

The HHA and its staff must operate and furnish services in compliance with all applicable Federal, State, and local laws and regulations. If State or applicable local law provides for the licensure of HHAs, an agency not subject to licensure is approved by the licensing authority as meeting the standards established for licensure.

Interpretive Guidelines §484.12(a)

Failure of the HHA to meet a Federal, State or local law may only be cited under the following circumstances:

1. When the Federal, State or local authority having jurisdiction has both made a determination of non-compliance and has taken a final adverse action as a result;

or

2. When the language of the Federal regulation requires compliance with explicit Federal, State or local laws and codes as a criterion for compliance.

If State law provides for the licensure of HHAs, request to see a copy of the current license. Publicly operated HHAs, such as public health agencies, or HHAs based in a public hospital, are examples of agencies that a State may exempt from State licensure.

Notify the RO if you suspect that you have observed noncompliance with an applicable Federal law related to the provider's HHA program. The RO will notify the appropriate Federal agency of your observations.

Probes §484.12(a)

How does the HHA ensure that **all** professional employees and personnel used under arrangement and by contract have current licenses and/or registrations if they are required?

§484.12(b) Standard: Disclosure of Ownership and Management Information

G119

The HHA must comply with the requirements of Part 420, Subpart C of this chapter.

G120

(Rev. 11, Issued: 08-12-05; Effective/Implementation: 08-12-05)

The HHA also must disclose the following information to the State survey agency at the time of the HHA's initial request for certification, for each survey, and at the time of any change in ownership or management:

- (1) The name and address of all persons with an ownership or control interest in the HHA as defined in [§§420.201](#), [420.202](#), and [420.206](#) of this chapter.

- (2) The name and address of each person who is an officer, a director, an agent or a managing employee of the HHA as defined in §§420.201, 420.202, and 420.206 of this chapter.
- (3) The name and address of the corporation, association, or other company that is responsible for the management of the HHA, and the name and address of the chief executive officer and the chairman of the board of directors of that corporation, association, or other company responsible for the management of the HHA.

Interpretive Guidelines §484.12(b)

Review the HHA's disclosure of ownership information carefully for completeness and compliance with this standard. This information can be found on the Form CMS-855 or CMS-1513 for HHAs Medicare approved prior to June 2003. Information required to be disclosed in this standard, but not required on the form, such as whether any person with an ownership interest in an HHA is related to another such individual, should be disclosed to the State Survey Agency by the HHA in writing and attached.

A “**managing employee**” is a general manager, business manager, administrator, director or other individual who exercises operational or managerial control over, or who directly or indirectly conducts the day-to-day operations of the HHA. The HHA administrator ([§484.14\(b\)](#)) and the supervisory physician or supervisory registered nurse ([§484.14\(d\)](#)) would meet the definition of a managing employee.

Probes §484.12(b)

1. Is the information on the Form CMS-855 or CMS-1513 (*for agencies Medicare approved prior to June 2003*), and in the disclosure letter previously submitted to the State, consistent with information you find in the agency's organizational structure (i.e., organizational charts and lines of authority, management contracts, bylaws, minutes of board meetings)?
2. How does the HHA implement its policy or procedure for reporting changes in ownership and management information to the State?

§484.12(c) Standard: Compliance With Accepted Professional Standards and Principles

G121

The HHA and its staff must comply with accepted professional standards and principles that apply to professionals furnishing services in an HHA.

Interpretive Guidelines §484.12(c)

The accepted professional standards and principles that the HHA and its staff must comply with include, but are not limited to, the HHA Federal regulations, State practice acts, commonly accepted health standards established by national organizations, boards, and councils (i.e., the American Nurses' Association standards) and the HHA's own policies and procedures.

An HHA may be surveyed for compliance with State practice acts for each relevant discipline. Any deficiency cited as a violation of a State practice act must reference the applicable section of the State practice act which is allegedly violated and a copy of that section of the act must be provided to the HHA along with the statement of deficiencies.

Any deficiency cited as a violation of accepted standards and principles must have a copy of the applicable standard provided to the HHA along with the statement of deficiencies.

If an HHA has developed professional practice standards and principles for its program staff, there should be information available, which demonstrates that the HHA monitors its staff for compliance and takes corrective action, as needed.

Probes §484.12(c)

1. How does the HHA monitor its employees and personnel serving the HHA under arrangement or contract to ensure that services provided to patients are within acceptable professional practice standards for each discipline?
2. How does the HHA monitor the professional skills of its staff to determine if skills are appropriate for the care required by the patients the HHA admits?

G122

§484.14 Condition of Participation: Organization, Services, and Administration

G123

Organization, services furnished, administrative control, and lines of authority for the delegation of responsibility down to the patient care level are clearly set forth in writing and are readily identifiable.

G124

Administrative and supervisory functions are not delegated to another agency or organization and

G125

All services not furnished directly, including services provided through subunits are monitored and controlled by the parent agency.

G126

If an agency has subunits, appropriate administrative records are maintained for each subunit

Interpretive Guidelines §484.14

The HHA's policies and procedures, disclosure information required for [§484.12](#), or other forms of documentation (e.g., organizational charts) should be used to determine compliance with this condition.

A local (city or county) health department may specify that the entire department or subdivision of the department is the HHA. If the entire department is identified as the HHA, the organizational structure, as documented, should specify:

- Where primary supervisory responsibility rests;
- How various divisions and bureaus are involved;
- Who has responsibility for the division or the bureau; and
- Where the focal point is for HHA relationships with the State agency and intermediary.

Similarly, a hospital-based HHA that reports through the hospital's organizational structure to several administrators and/or departments should specify the same points previously mentioned. (Refer to §2186 of the SOM.)

The same points of clarification would be necessary for any HHA, which has entered into agreements, contracts or mergers with one or more corporate entities.

Regardless of the formal organizational structure, the overall responsibility for all services provided, whether directly, through arrangements or contracts, rests with the HHA that has assumed responsibility for admitting patients and implementing plans of care.

Examples:

1. An HHA may, in arranging or contracting for a service such as physical therapy, require the other party to do the day-by-day professional evaluation of the therapy

service. However, the HHA may not delegate its overall administrative and supervisory responsibilities. The contract should specify how HHA supervision will occur.

2. An HHA may not use a full-time employee of another legal entity to fulfill its supervisory or administrative functions concurrently. For example: A freestanding HHA locates at a hospital and names a full-time hospital employee as the HHA supervisor. The HHA does not pay the nursing supervisor a salary for the HHA-related services. Because the hospital continues the nursing supervisor in its employ, this arrangement clearly delegates HHA supervisory functions to another legal entity, i.e., the hospital. The HHA would not meet the supervisory requirement of [§484.12](#).

Use §2182, Certification Process, State Operations Manual, to help make determinations regarding branches and/or subunits. Remember that these determinations **must** be made on a case-by-case basis using the definitions contained in [§484.2](#) and the additional criteria described in §2182. Request information that helps you decide if the organizational entity is “sufficiently” close to the parent agency that it is not impractical for it to share administration, supervision, and services from the parent agency on a day-to-day basis. If so, the organizational entity may be classified as a branch. Because circumstances may vary widely among regions and among States within regions, **it is inappropriate to set criteria such as mileage or time** for purposes of determining branch or subunit status. If there is doubt as to the appropriateness of branch and subunit delineation, a visit to the branch for further evaluation is encouraged.

A branch office, as an extension of the parent HHA, **may not** offer services that are different than those offered by the parent HHA.

The subunit may provide services other than those provided by the parent because it is semi-autonomous, serves patients in a different geographical area, and must meet the Conditions of Participation separately from the parent HHA. The subunit may have branches.

Probes §484.14

1. How does the HHA monitor and exercise control over services provided by personnel under arrangements or contracts? In a branch? In a subunit?
2. Can HHA administrative and clinical supervisory personnel describe clearly the lines of authority and responsibility for the administration, delivery, and supervision of services:
 - Between parent, branch, and/or subunits?
 - If the HHA is part of a larger organizational entity such as a State or local health department, hospital, skilled nursing facility or health maintenance organization?

- If the HHA offers services such as homemaker, personal care aides, private duty nursing, or hospice?
3. Who has responsibility for maintaining employee assignments, plans of care, and minutes of interdisciplinary and administrative meetings integral to the organization and supervision of the HHA's services?
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G127

§484.14(a) Standard: Services Furnished

Part-time or intermittent skilled nursing services and at least one other therapeutic service (physical, speech or occupational therapy; medical social services; or home health aide services) are made available on a visiting basis, in a place of residence used as a patient's home. An HHA must provide at least one of the qualifying services directly through agency employees, but may provide the second qualifying service and additional services under arrangements with another agency or organization.

Interpretive Guidelines §484.14(a)

An HHA is considered to provide a service "directly" when the person providing the service for the HHA is an HHA employee. For purposes of meeting 42 CFR 484.14(a), an individual who works for the HHA on an hourly or per-visit basis may be considered an agency employee if the HHA is required to issue a form W-2 on his/her behalf. An HHA is considered to provide a service "under arrangements" when the HHA provides the service through contractual or affiliation arrangements with other agencies or organizations, or with an individual(s) who is not an HHA employee.

Probes §484.14(a)

How do the terms of the HHA agreements/contracts ensure that the HHA has the requisite control over its provision of services?

§484.14(b) Standard: Governing Body

G128

A governing body (or designated persons so functioning) assumes full legal authority and responsibility for the operation of the agency.

G129

The governing body appoints a qualified administrator,

G130

arranges for professional advice as required under [§484.16](#).

G131

adopts and periodically reviews written bylaws or an acceptable equivalent, and

G132

oversees the management and fiscal affairs of the agency.

Interpretive Guidelines §484.14(b)

An HHA may use the services of a management company to strengthen its own administrative services. An HHA's documented agreement with a management company or employee leasing company must specify that the legal authority and full control of the HHA's operation remain with the HHA and that the HHA's governing body retains the responsibilities specified in §484.14(b). This means that the HHA, through the governing body (or designated persons so functioning), must assume the full legal authority and responsibility for the operations of the agency, including its policies, procedures, services, organization, and budget preparation. These responsibilities must be clearly defined in the written agreement with the management or employee leasing company.

Probes §484.14(b)

How does the governing body exercise its responsibility for the overall operation of the HHA, including the HHA's budget and capital expenditure plan, and the overall management, supervision, and evaluation of the HHA and its patients' outcomes? (Review documents which outline these responsibilities.)

§484.14(c) Standard: Administrator

G133

The administrator, who may also be the supervising physician or registered nurse required under paragraph (d) of this section, organizes and directs the agency's ongoing functions; maintains ongoing liaison among the governing body, the group of professional personnel, and the staff;

G134

employs qualified personnel and ensures adequate staff education and evaluations;

G135

ensures the accuracy of public information materials and activities; and

G136

implements an effective budgeting and accounting system.

G137

A qualified person is authorized in writing to act in the absence of the administrator.

Probes §484.14(c)

1. How do the specific administrative activities identified in the standard impact on the services of the HHA?
2. What individual is authorized to act in the absence of the administrator?

§484.14(d) Standard: Supervising Physician or Registered Nurse

G138

The skilled nursing and other therapeutic services furnished are under the supervision and direction of a physician or a registered nurse (who preferably has at least 1 year of nursing experience and is a public health nurse).

G139

This person, or similarly qualified alternate, is available at all times during operating hours and

G140

participates in all activities relevant to the professional services furnished, including the development of qualifications and the assignment of personnel.

Interpretive Guidelines §484.14(d)

“Available at all times during operating hours” means being readily available on the premises or by telecommunications. How the supervising physician or supervising registered nurse structures his or her availability is a management decision for the HHA.

“Operating hours” means all hours that staff from the agency are providing services to patients.

§484.14(e) Standard: Personnel Policies

G141

Personnel practices and patient care are supported by appropriate, written personnel policies.

Personnel records include qualifications and licensure that are kept current.

Interpretive Guidelines 484.14(e)

The numbers and qualifications of personnel available to provide services must be sufficient to implement the plans of care and the medical, nursing, and rehabilitative needs of the patients admitted by the HHA.

Probes §484.14(e)

1. What does the HHA include in the personnel records about the qualifications and licensure of its employees?
2. If the HHA does not keep duplicate personnel records of staff hired under arrangement, how does it ensure that records are kept current?

§484.14(f) Standard: Personnel Under Hourly or Per Visit Contracts

G142

If personnel under hourly or per visit contracts are used by the HHA, there is a written contract between those personnel and the agency that specifies the following:

- (1) Patients are accepted for care only by the primary HHA.**
- (2) The services to be furnished.**
- (3) The necessity to conform to all applicable agency policies, including personnel qualifications.**
- (4) The responsibility for participating in developing plans of care.**
- (5) The manner in which services will be controlled, coordinated, and evaluated by the primary HHA.**

(6) The procedures for submitting clinical and progress notes, scheduling of visits, periodic patient evaluation.

(7) The procedures for payment for services furnished under the contract.

Interpretive Guidelines §484.14(f)

If an HHA, which has been established as hospital-based for Medicare payment purposes, has arranged with the hospital to provide the second qualifying service or other HHA services (see [§484.14\(a\)](#)) through hospital employees, the HHA would not be required to have an hourly or per visit contract with these hospital employees. The HHA should identify in its records the names of these employees and the amount of time they spend at the HHA. However, if these hospital employees provide services to the HHA outside of their own usual working hours or shifts (i.e., “moonlight” as HHA employees, as opposed to working overtime for the hospital), a contract as specified in standard (f) applies.

Probes §484.14(f)

1. How does the HHA orient contractual personnel to HHA objectives, policies, procedures, and programs?
2. How does the HHA evaluate whether contractual personnel inform the patient of his/her rights prior to the beginning of care or when there are changes in care?
3. How are contractual personnel monitored by the HHA to confirm that the care provided is consistent with the plans of care and that their services meet the terms of the contract?
4. Who reviews the recertification requests to determine if continuing patient care is indicated as a probable medical necessity?

§484.14(g) Standard: Coordination of Patient Services

G143

All personnel furnishing services maintain liaison to ensure that their efforts are coordinated effectively and support the objectives outlined in the plan of care.

G144

The clinical record or minutes of case conferences establish that effective interchange, reporting, and coordination of patient care does occur.

G145

A written summary report for each patient is sent to the attending physician at least every 60 days.

Probes §484.14(g)

1. What is the HHA's policy related to facilitating exchange of information among staff?
2. How does coordination of care among staff and/or contract personnel providing services to individual patients occur?
3. How does the HHA ensure that patients' written summary reports sent to attending physicians every 60 days meet the regulatory requirements of [§482.2](#)?

Refer to [§484.48](#) regarding guidelines for the attending physician's written summary report.

§484.14(h) Standard: Services Under Arrangement

G146

Services furnished under arrangements are subject to a written contract conforming with the requirements specified in paragraph (f) of this section and with the requirements of [§1861\(w\)](#) of the Act (42 U.S.C. 1494x(w)).

Interpretive Guidelines §484.14(h)

Section [1861\(w\)](#) of the Act states that an HHA may have others furnish covered items or services through arrangements under which receipt of payment by the HHA for the services discharges the liability of the beneficiary or any other person to pay for the services. This holds true whether the services and items are furnished by the HHA itself or by another agency under arrangements. Both must agree not to charge the patient for covered services and items and to return money incorrectly collected.

§484.14(i) Standard: Institutional Planning

G147

The HHA, under the direction of the governing body, prepares an overall plan and a budget that includes an annual operating budget and capital expenditure plan.

§484.14(i)(1) Standard: Annual Operating Budget

There is an annual operating budget that includes all anticipated income and expenses related to items that would, under generally accepted accounting principles, be considered income and expense items. However, it is not required that there be prepared, in connection with any budget, an item by item identification of the components of each type of anticipated income or expense.

§484.14(i)(2) Standard: Capital Expenditure Plan

(i) There is a capital expenditure plan for at least a 3-year period, including the operating budget year. The plan includes and identifies in detail the anticipated sources of financing for, and the objectives of, each anticipated expenditure of more than \$600,000 for items that would, under generally accepted accounting principles, be considered capital items. In determining if a single capital expenditure exceeds \$600,000, the cost of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition, improvement, modernization, expansion, or replacement of land, plant, building, and equipment are included. Expenditures directly or indirectly related to capital expenditures, such as grading, paving, broker commissions, taxes assessed during the construction period, and costs involved in demolishing or razing structures on land are also included.

Transactions that are separated in time, but are components of an overall plan or patient care objective, are viewed in their entirety without regard to their timing. Other costs related to capital expenditures include title fees, permit and license fees, broker commissions, architect, legal, accounting, and appraisal fees; interest, finance, or carrying charges on bonds, notes and other costs incurred for borrowing funds.

(ii) If the anticipated source of financing is, in any part, the anticipated payment from title V (Maternal and Child Health and Crippled Children's Services) or title XVIII (Medicare) or title XIX (Medicaid) of the Social Security Act, the plan specifies the following:

(A) Whether the proposed capital expenditure is required to conform, or is likely to be required to conform, to current standards, criteria, or plans developed in accordance with the Public Health Service Act or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963.

(B) Whether a capital expenditure proposal has been submitted to the designated planning agency for approval in accordance with [section 1122](#) of the Act (42 U.S.C. 1320a-1) and implementing regulations.

(C) Whether the designated planning agency has approved or disapproved the proposed capital expenditure if it was presented to that agency.

G148

§484.14(i)(3) Standard: Preparation of Plan and Budget

The overall plan and budget is prepared under the direction of the governing body of the HHA by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff (if any) of the HHA.

G149

§484.14(i)(4) Standard: Annual Review of Plan and Budget

The overall plan and budget is reviewed and updated at least annually by the committee referred to in paragraph (i)(3) of this section under the direction of the governing body of the HHA.

Interpretive Guidelines §484.14(i)

An HHA with branches and/or subunits requires only one overall plan and one budget which should include the resources and expenditures of all branches and subunits.

§484.14(j) Standard: Laboratory Services

G150

(1) If the HHA engages in laboratory testing outside of the context of assisting an individual in self-administering a test with an appliance that has been cleared for that purpose by the FDA, such testing must be in compliance with all applicable requirements of part 493 of this chapter.

Interpretive Guidelines §484.14(j)(1)

Determine if the HHA is providing laboratory testing as set forth at [42 CFR 493](#). If the HHA is performing testing, request to see the CLIA certificate for the level of testing being performed, i.e., a certificate of waiver, certificate for provider-performed microscopy procedures, certificate of accreditation, certificate of registration, or certificate of compliance (issued upon the determination of compliance after an on-site survey.)

HHAs holding a certificate of waiver are limited to performing only those tests determined to be in the waived category. Some tests that an HHA may perform that fall into the waived category include:

- Dipstick/tablet reagent urinalysis;
- Blood glucose by glucose monitoring devices cleared by the Food and Drug Administration (FDA) specifically for home use;
- Some prothrombin time tests; and
- Some glycosolated hemoglobin tests.

For a complete listing of waived tests, refer to CMS' website at <http://www.cms.hhs.gov/>.

HHAs holding a certificate for provider-performed microscopy procedures are limited to performing only those tests determined to be in the provider-performed microscopy procedure category **or in combination with waived tests**:

The tests in the provider-performed microscopy procedures category (e.g., wet mounts, urine sediment examinations, and nasal smears for granulocytes) are not typical of those performed in an HHA; however, if they are conducted by HHA staff under a certificate for provider-performed microscopy procedures, they must be performed by a practitioner as specified at [§493.19](#) (i.e., a physician, nurse midwife, nurse practitioner, physician assistant, or dentist). If not performed by these personnel, the HHA would require a registration certificate (which allows the performance of such testing until a determination of compliance is made), certificate of accreditation, or certificate of compliance.

For a complete listing of provider-performed microscopy procedures, refer to CMS' website at <http://www.cms.hhs.gov/>.

If the HHA performs any other testing procedures, (i.e., moderate or high complexity testing), it would require a registration certificate, a certificate of accreditation, or a certificate of compliance. While some prothrombin testing is in the waived category, as mentioned above, other prothrombin testing is considered moderate complexity testing depending on the skill level required to operate the instrument.

For a complete listing of moderate and high complexity tests, refer to CMS' website at <http://www.cms.hhs.gov/>.

Assisting individuals in administering their own tests, such as fingerstick blood glucose or prothrombin testing, is not considered testing subject to the CLIA regulations. However, if the HHA staff is actually responsible for measuring the blood glucose level or prothrombin times of patients with an FDA approved blood glucose or prothrombin time monitor, and no other tests are being performed, request to see the facility's certificate of waiver, since glucose testing with a blood glucose meter (approved by the FDA specifically for home use) and some prothrombin time tests are waived tests under the provisions at [42 CFR 493.15](#).

If the facility does not possess the appropriate CLIA certificate, inform the facility that it is in violation of CLIA law and that it must apply immediately to the State agency for the appropriate certificate. The facility is out of compliance with [42 CFR 484.14\(j\)](#). Also, refer this facility's noncompliance to the department within the State agency responsible for CLIA surveys.

(2) If the HHA chooses to refer specimens for laboratory testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of [Part 493](#) of this chapter.

Interpretive Guidelines §484.14(j)(2)

If the HHA refers specimens for laboratory testing to an outside laboratory, the referral laboratory must be CLIA-certified. The HHA should have a copy of the referral laboratory's CLIA certificate in its administrative records.

G151

§484.16 Condition of Participation: Group of Professional Personnel

G152

A group of professional personnel, which includes at least one physician and one registered nurse (preferably a public health nurse), and with appropriate representation from other professional disciplines,

G153

establishes and annually reviews the agency's policies governing scope of services offered, admission and discharge policies, medical supervision and plans of care, emergency care, clinical records, personnel qualifications, and program evaluation. At least one member of the group is neither an owner nor an employee of the agency.

Interpretive Guidelines §484.16

If an HHA has a branch(es), the annual review includes services delivered through the branch(es).

The parent agency's group of professional personnel or a subcommittee of the group may also serve as the subunit's group of professional personnel or the subunit may establish its own group.

If the HHA is part of a larger organization (e.g., a State, county, hospital) and the parent organization's policies are mostly applicable to the HHA, the HHA does not have to develop new policies. Rather, the HHA should review and revise patient policies to accommodate the conditions of participation, the patient care needs of the HHA and the quality of services to be provided.

§484.16(a) Standard: Advisory and Evaluation Function

G154

The group of professional personnel meets frequently to advise the agency on professional issues, to participate in the evaluation of the agency's program, and to assist the agency in maintaining liaison with other health care providers in the community and in the agency's community information program.

G155

The meetings are documented by dated minutes.

Probes §484.16(a)

What documentation is there of advice concerning professional issues, evaluation of the professional service program, or assistance in maintaining liaison with other community groups by the professional group?

G156**§484.18 Condition of Participation: Acceptance of Patients, Plan of Care, and Medical Supervision**

G157

Patients are accepted for treatment on the basis of a reasonable expectation that the patient's medical, nursing, and social needs can be met adequately by the agency in the patient's place of residence.

G158

Care follows a written plan of care established and periodically reviewed by a doctor of medicine, osteopathy, or podiatric medicine.

Interpretive Guidelines §484.18

It is CMS' policy to require that the HHA must have a plan of care for each patient, regardless of the patient's Medicare status or that nurse practice acts do not specifically

require a physician's order. The CoPs do not require a physician's order for services furnished by the HHA that are not related to the patient's illness, injury, or treatment of the patient's medical, nursing, or social needs.

Medical orders may authorize a specific range in the frequency of visits for each service (i.e., 2-4 visits per week) to ensure that the most appropriate level of service is provided to the patient. However, ranges that include "0" as a frequency are not allowed, because "0" is not a frequency. The regulation requires the HHA to alert the physician to any changes that suggest a need to alter the plan of care. If the HHA provides fewer visits than the physician orders, it has altered the plan of care and the physician must be notified. The HHA must maintain documentation in the clinical record indicating that the physician was notified and is aware of the missed visit.

Probes §484.18

What evidence (if any) demonstrates that patients are admitted or denied services for reasons contrary to the intent of this standard?

§484.18(a) Standard: Plan of Care

G159

The plan of care developed in consultation with the agency staff covers all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items.

G160

If a physician refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician is consulted to approve additions or modification to the original plan.

G161

Orders for therapy services include the specific procedures and modalities to be used and the amount, frequency, and duration.

G162

(Rev. 11, Issued: 08-12-05; Effective/Implementation: 08-12-05)

The therapist and other agency personnel participate in developing the plan of care.

Interpretive Guidelines §484.18(a)

A statutory change renamed the “plan of treatment” to “the plan of care.” These terms are synonymous. Neither is to be confused with a nursing care plan.

The conditions do not require an HHA to either develop or maintain a nursing care plan as opposed to a medical plan of care. This does not preclude an HHA from using nursing care plans if it believes that such plans strengthen patient care management, the organization and delivery of services, and the ability to evaluate patient outcomes.

Review a case-mix, stratified sample of clinical records (see §2200B) to determine if the requirements of this standard are met.

Written HHA policies and procedures should specify that all clinical services are implemented only in accordance with a plan of care established by a physician’s written orders. Policies should also specify if the HHA:

- Accepts physician’s orders on referral communicated verbally by an institution’s discharge planner, nurse practitioner, physician’s assistant, or other authorized staff member followed by written, signed and dated physician’s orders, in order to begin HHA services as soon as possible.
- Accepts signed physician certification and recertification of plans of care, as well as signed orders changing the plan of care, by telecommunication systems (“fax”), which are filed in the clinical record.

The plan of care must be established and authorized in writing by the physician based on an evaluation of the patient’s immediate and long term needs. The HHA staff, and if appropriate, other professional personnel, shall have a substantial role in assessing patient needs, consulting with the physician, and helping to develop the overall plan of care.

The patient has the right, and should be encouraged, to participate in the development of the plan of care before care is started and when changes in the established plan of care are implemented. (See [§484.10\(c\)\(2\)](#).)

Section [1861\(r\)](#) of the Act defines the term “physician” to permit a podiatrist to establish and recertify an HHA patient’s plan of care. The podiatrist’s functions must be consistent with the HHA’s policies and procedures that pertain to therapeutic activities he/she is legally authorized by the State to perform.

The regulation requires at G161 that orders for therapy services include the specific procedures and modalities to be used and the amount, frequency, and duration of the therapy ordered.

“**Modalities**” are defined as any physical agent applied to produce therapeutic changes to biologic tissue and include, but are not limited to, thermal, acoustic, light, mechanical, or

electric energy. **“Procedures”** are defined as a manner of effecting change through the application of clinical skills and/or services that attempt to improve function. This can be achieved through exercise or training and must include active interventions between the therapist and patient.

Modalities that are supervised but do not require constant patient contact (by the provider) include hot or cold packs, traction, mechanical or electrical stimulation (unattended), acupuncture with electrical stimulation, vasopneumatic devices, paraffin bath, microwave, whirlpool, diathermy, infrared and ultraviolet. Modalities requiring constant attendance include electrical stimulation (manual), iontophoresis, contrast baths, ultrasound and Hubbard tank. Items such as Theraband, free weights and stationary bikes are not considered modalities. They are considered equipment or items used in support of a procedure such as therapeutic exercise or neuromuscular reeducation.

Probes §484.18(a)

1. How does an HHA evaluate whether the plan of care, and the coordination of services, help the patient attain and maintain his or her highest practicable functional capacity based on medical, nursing, and rehabilitative needs?
2. How does the HHA monitor the delivery of services, including those provided under arrangement or contract, to ensure compliance with the specificity and frequency of services ordered in the plan of care?
3. If a range of visits is ordered, how does the HHA ensure that the frequency of visits meets the clinical needs of the patient?

§484.18(b) Standard: Periodic Review of Plan of Care

G163

The total plan of care is reviewed by the attending physician and HHA personnel as often as the severity of the patient’s condition requires, but at least once every 60 days or more frequently when there is a beneficiary elected transfer; a significant change in condition resulting in a change in the case-mix assignment; or a discharge and return to the same HHA during the 60-day episode.

(Rev. 11, Issued: 08-12-05; Effective/Implementation: 08-12-05)

Agency professional staff promptly alert the physician to any changes that suggest a need to alter the plan of care.

Interpretive Guidelines §484.18(b)

Changes in the patient’s condition that require a change in the plan of care should be documented in the patient’s clinical record.

HHAs are required by the regulations at 42CFR 484.18(b) to promptly alert the physician to any changes that suggest a need to alter the plan of care, and to include instructions for timely discharge or referral in the plan of care.

In the situation where the patient progresses to the point where it is no longer reasonable and necessary to continue services, because the patient's medical, nursing, and rehabilitative needs have been met adequately by the HHA, the HHA may notify the physician and discharge the patient, even though the certification period has not ended. The clinical record should maintain documentation that the physician was notified of the discharge, but it does not need to contain a physician's order for discharge. If, however, an HHA has a policy or is required by state law to obtain a physician's order before discharging a patient, the agency would be expected to abide by their policy and/or state law.

When a Medicare beneficiary elects to transfer to a different HHA or is discharged and returns to the same HHA, it warrants a new clock for purposes of payment, OASIS assessment, and physician certification of the new plan of care. When a new 60-day episode begins, the original 60-day episode payment is proportionally adjusted to reflect the length of time the beneficiary remained under the HHA's care before the intervening event. The proportional payment is the Partial Episode Payment (PEP) adjustment.

A Significant Change In Condition (SCIC) adjustment occurs when a Medicare beneficiary experiences a significant change in condition during a 60-day episode that was not envisioned in the original plan of care. In order to receive a new case-mix assignment for purposes of SCIC payment during the 60-day episode, the HHA must complete an OASIS assessment and obtain the necessary physician change orders reflecting the significant change in treatment approach in the patient's plan of care. Refer to current policy for the use of the OASIS assessment for SCIC adjustments.

§484.18(c) Standard: Conformance With Physician Orders

G165

(Rev. 11, Issued: 08-12-05; Effective/Implementation: 08-12-05)

Drugs and treatments are administered by agency staff only as ordered by the physician with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per agency policy developed in consultation with a physician, and after an assessment of considerations.

G166

(Rev. 11, Issued: 08-12-05; Effective/Implementation: 08-12-05)

Verbal orders are put in writing and signed and dated with the date of receipt by the registered nurse or qualified therapist (as defined in [§484.4](#) of this chapter) responsible for furnishing or supervising the ordered services.

Interpretive Guidelines §484.18(c)

Review HHA policies and procedures in regard to obtaining physician orders, changes in orders, and verbal orders. All physician orders must be included in the patient's clinical record. Plans of care must be signed and dated by the physician.

Verbal orders must be countersigned by the physician as soon as possible. Ask HHA's, whose pattern of obtaining signed physicians' orders exceeds the HHA's policy or State law, to clarify or explain what circumstances created the time lapse, and how they are approaching a resolution to the problem.

Other designated HHA personnel who accept verbal orders must do so in accordance with State and Federal law and regulations and HHA policy. Verbal orders must be signed and dated by the registered nurse or qualified therapist who is furnishing or supervising the ordered service. It is the RN's or therapist's responsibility to make any necessary revisions to the plan of care based on that order.

Probes §484.18(c)

How does the HHA secure the physician's signature on verbal, change, or renewal orders?

How does the HHA ensure that verbal orders are accepted, co-signed by the nurse or therapist, and countersigned by the physician appropriately?

G167

See [484.55\(c\)](#)

Tag 167 expired on 6/1/99. A new tag concerning drug review is found at [G337](#) and is applicable to all patients serviced by the HHA.

G300

Verbal orders are only accepted by personnel authorized to do so by applicable State and Federal laws and regulations, as well as by the HHA's internal policies.

§484.20 Condition of Participation: Reporting OASIS Information

G320

(Rev. 11, Issued: 08-12-05; Effective/Implementation: 08-12-05)

HHA's must electronically report all OASIS data collected in accordance with [§484.55](#).

Interpretive Guidelines §484.20

HHA's must, at least monthly, electronically report OASIS data on all applicable patients in a format that meets CMS electronic data and edit specifications. For purposes of this requirement, the term "reporting" means electronic reporting.

Effective December 8, 2003, the collection of OASIS data on the non-Medicare/non-Medicaid patients of an HHA was temporarily suspended. HHAs must continue to comply with the aspects of the regulation at 42 CFR 484.55 regarding the comprehensive assessment of patients.

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

Private pay patients are defined to include any patient for whom (M0150) the Current Payment Source for Home Care does not include any of the following responses:

- 1- Medicare (Traditional fee-for-service)
- 2- Medicare (HMO/ managed care)
- 3- Medicaid (Traditional fee-for-service)
- 4- Medicaid(HMO/managed care).

If a patient has a private pay insurance **and** M0150 response 1, 2, 3, or 4 as an insurance to which the agency is billing the services, the comprehensive assessment including OASIS must be collected and transmitted. Medicare (HMO/managed care) does include Medicare Advantage (MA), formerly known as Medicare+Choice (M+C) plans and Medicare PPO plans.

HHAs or contracted entities acting on behalf of the HHA can report OASIS data to the State agency using the HAVEN software CMS provides free of charge or by using HAVEN-like software that conforms to the same specifications used to develop HAVEN. Reported OASIS data will be analyzed and findings made available to HHA's by way of reports that will help HHA's identify their performance level in the provision of care to

the patient population they serve as compared with other HHA's on either a national, State or local level.

As part of the ongoing survey process, State agencies may establish policies in keeping with unannounced surveys that include the ongoing request, at specified intervals, for the submission of a current census (number) of patients being serviced by the HHA. Census information should include only a count of non-Medicare/non-Medicaid patients. Since OASIS data on non-Medicare/non-Medicaid patients will be received by the OASIS State system in an unidentifiable format, names of non-Medicare/non-Medicaid patients on the census are not appropriate.

With this information, surveyors can conduct a gross comparison of patient counts to data from the OASIS State system and monitor, offsite, if required OASIS data are being transmitted to the State.

G321

§484.20(a) Standard: Encoding OASIS Data

The HHA must encode and be capable of transmitting OASIS data for each agency patient within 7 days of completing an OASIS data set.

Interpretive Guidelines §484.20(a)

After OASIS data are collected and completed by the qualified clinician as part of the comprehensive assessment at the required time points (i.e., start of care, resumption of care, follow-up, transfer to inpatient facility with or without discharge, discharge to community, and death at home), HHAs may take up to seven calendar days after the date of completion of the comprehensive assessment to enter (encode) the OASIS data into their computers using HAVEN or HAVEN-like software. The day the clinician completes the assessment is day zero for purposes of calculating the 7-day window. Encoding of **all** OASIS data items must be complete, i.e., locked, in order to accurately compute the information (health insurance prospective payment system or HIPPS code) necessary for billing Medicare patients under the prospective payment system.

Pre-Survey Activity - Check with the State OASIS Education or Automation Coordinator and/or review OASIS data management reports to determine if OASIS items are encoded, checked for errors and locked within 7 days of collection using Haven or Haven-like software, i.e., made transmission ready.

Onsite Activity - Check to see if the HHA is transmitting its own data or has an arrangement with an outside entity acting on behalf of the HHA to electronically submit OASIS data to the State agency. If so, make sure a written contract exists that describes the arrangement the HHA has with the outside entity to enter and transmit OASIS data on behalf of the HHA.

Determine the process for encoding and locking OASIS data being readied for transmission to the State.

If questions are raised through interview or record review, review the HHA's policies regarding encoding time frames.

Initial Survey - New HHA's seeking initial certification must apply for appropriate State and Federal HHA identification and passwords and be able to demonstrate compliance with collecting, completing, encoding and reporting OASIS data for all applicable patients in an electronic format that meets CMS specifications prior to the initial survey. Check with the OASIS Automation Coordinator for information on assignment of test identification numbers and passwords.

G322

§484.20(b) Standard: Accuracy of Encoded OASIS Data

The encoded OASIS data must accurately reflect the patient's status at the time of assessment.

Interpretive Guidelines §484.20(b)

Check to see how the HHA monitors the accuracy of their data to ensure the data collected, encoded, and reported accurately reflects the patient's status at the time of the assessment. Some tips for establishing a program to monitor the quality and accuracy of OASIS data are found in Chapter 12 of the OASIS Implementation Manual – Data Quality Audits.

Onsite Activity - When reviewing the clinical records, determine that a visit was made to conduct the assessment, as applicable. Also, determine that other clinical information in the patient record does not contradict OASIS data collected during the assessment, encoded or reported.

New patient admission: If possible, include a home visit for a newly admitted patient who is scheduled to have a comprehensive assessment done. Determine that the OASIS data collected accurately reflects the patient's status at the time of the assessment.

Patient currently on service: If a home visit is made on a patient for whom an assessment has already been conducted and is not now scheduled to have one conducted, review the most current assessment and compare it with your observation of patient status, keeping in mind the patient's progress/decline and the normal progression of the clinical condition.

Determine that other clinical information in the patient record does not contradict OASIS data.

Probes 484.20(b)

1. How does the HHA conduct clinical and data entry audits to verify that collected OASIS data is consistent with reported OASIS data?
2. How does the HHA assure consistency?
3. How does the HHA review the final validation reports for accuracy purposes?
4. Has the HHA identified any discrepancies in data collected and reported? If so, how were discrepancies addressed?
5. How does the HHA handle the correction of errors?

G323

§484.20(c) Standard: Transmittal of OASIS Data

The HHA must-

(1) Electronically transmit accurate, completed, encoded and locked OASIS data for each patient to the State agency or CMS OASIS contractor at least monthly;

Interpretive Guidelines §484.20(c)(1)

By the last day of the current month, HHA's must electronically transmit all OASIS data collected, encoded, and locked in the previous month for each patient (as applicable), to the State agency or CMS OASIS contractor. At a minimum, HHA's must transmit OASIS data at least monthly; HHA's may transmit OASIS data more frequently, if desired, and are free to develop schedules for transmitting data to best suit their needs.

Rejected data that requires correcting and re-transmitting must be received by the OASIS State system within the same required time frame. Submission of data with identified fatal errors does not justify extending the required time frame. While overdue assessments will be accepted, HHA's (or their contracted vendors) may not wait until the end of the month to transmit their OASIS data in case errors are identified that require re-transmittal or system problems develop that prevent transmission.

Entities submitting OASIS data to the State agency or CMS OASIS contractor on behalf of the HHA, i.e., corporate offices or vendors under contract, must share the feedback reports with the HHA in order for them to monitor their encoding and transmission process.

Pre-Survey Activity - Check with the State OASIS Education or Automation Coordinator and/or review OASIS data management reports to determine if OASIS data

are being transmitted as required. Determine whether the HHA is: 1) submitting data less often than monthly; and/or 2) has greater than 20 percent of records rejected in accordance with pre-survey preparation guidelines (SOM Section 2200).

Onsite Activity – If either probe noted above is triggered, investigate compliance with OASIS transmission requirements of this section, during the survey through the partial extended survey process. Ask the HHA to demonstrate how it creates, saves and transmits OASIS data to the State agency. Randomly select patient assessments and ask the HHA for the final validation report to demonstrate that they were received by the State.

Probes §484.20(c)(1)

1. Is the HHA successfully transmitting OASIS data at least once a month?
2. Review the HHA's OASIS validation reports. If the HHA's corporate office or contracted vendor submits OASIS data on its behalf, are feedback reports being shared with the HHA?
3. What is the HHA's back-up plan if it is unable to submit OASIS data to the State agency?

If questions arise, review HHA policies and procedures regarding OASIS data transmission.

G324

(2) For all assessments completed in the previous month, transmit OASIS data in a format that meets the requirements of paragraph (d) of this section:

Interpretive Guidelines §484.20(c)(2)

Determine that all required OASIS assessments are being transmitted.

Certain missing information or inconsistencies will cause a record to be completely rejected requiring correction by the HHA and retransmission. These are called fatal errors. For example, a fatal error will occur when a record is submitted without the HHA's State-assigned identification number, without the patient's last name, when the record is a duplicate of one previously received or the record is missing or has an incorrect branch identification number in M0016. A complete listing of current record rejection criteria is available in the HHA Error Message Guide on the OASIS website (<http://www.cms.hhs.gov/oasis/usermanu.asp>).

HHA's have the ability to electronically correct nearly all errors found in their production OASIS submissions that have been transmitted to the SA or CMS OASIS contractor. There is no current time limit to correcting errors in previously submitted records. SA

should not be accepting requests for manual key field changes. Instead, HHA's should use the inactivation procedures to correct assessments containing key field errors. HAVEN 5.0 or above will give HHA's the ability to electronically correct nearly any kind of assessment errors. (See SOM Section 2202.11.) A description of key fields vs. non-key fields is available on the OASIS website (<http://www.cms.hhs.gov/oasis/>).

Probes §484.20(c)(2)

1. What kind of errors is the HHA finding and correcting?
2. How is the HHA responding to identified fatal errors?
3. How does the HHA verify that assessment data is consistent with the required format?
4. What are the established times of OASIS data transmission to the State? (They must be at least monthly.)
5. Are all required OASIS assessments that are locked in the previous month, transmitted during the next month?
6. Who is assigned to transmit OASIS data?

If questions arise during interview and record review, review the HHA policies on OASIS data transmission.

G325

(3) Successfully transmit test data to the State agency or CMS OASIS contractor beginning 3/26/99 and no later than 4/26/99.

Interpretive Guidelines §484.20(c)(3)

The purpose of making a test transmission to the State agency or CMS OASIS contractor is to establish connectivity. Once the test has been successfully completed, HHA's must not routinely use the test function to prepare their submission of production (required) OASIS data.

Initial Survey - New HHA's seeking initial certification must apply for State and Federal HHA identification numbers and passwords in order to demonstrate compliance with the OASIS submission requirements prior to Medicare approval.

Prior to the initial survey, HHA's must demonstrate connectivity to the OASIS State system by--

1. Making a test transmission of any start of care or resumption of care OASIS data that passes CMS edit checks; and

2. Receiving validation reports back from the State confirming transmission of data.

NOTE: The OASIS system is not authorized to maintain unmasked OASIS information on non-Medicare/non-Medicaid patients receiving skilled services. If the HHA has indicated at M0150 that the patient is a non-Medicare/non-Medicaid patient, the data should be masked when the requirement to mask non-Medicare/non-Medicaid data is effective. Unmasked data on non-Medicare/non-Medicaid patients receiving skilled services are rejected by the State system.

G326

(4) Transmit data using electronic communications software that provides a direct telephone connection from the HHA to the State agency or CMS OASIS contractor.

Interpretive Guidelines §484.20(c)(4)

HHA's must have a computer system that supports dial-up communications for the transmission of OASIS data to the State agency or CMS OASIS contractor, transmits the export files, and receives validation information. Corporate offices or contracted vendors submitting OASIS data on behalf of the HHA must provide the HHA with either an electronic copy of the validation information received from the State agency or CMS OASIS contractor, or a summary of that information.

All HHA's must use of the Medicare Data Communication Network (MDCN) to connect to the State agency for submission of OASIS data. When incorporation is complete, OASIS data from branch locations may be submitted directly by the branch as long as the appropriate user identification and passwords have been obtained.

G327

§484.20(d) Standard: Data Format

The HHA must encode and transmit data using the software available from CMS or software that conforms to CMS standard electronic record layout, edit specification, and data dictionary, and that includes the required OASIS data set.

Interpretive Guidelines §484.20(d)

Reasons for non-submission include lack of compliance with the requirement to electronically transmit OASIS data by the HHA, or transmission using an improper format. HHA's must encode and transmit data using the HAVEN software available from CMS or HAVEN-like software that conforms to **all** CMS data transmission specifications available on the OASIS website. The software must also include the most current version of the OASIS data items which are available on the OASIS website at all times.

Pre-Survey Activity - Review any OASIS State system data management reports to determine if there are indications of problems with OASIS data transmission. Check with the State OASIS Education or Automation coordinator to see if he/she has identified a problem with OASIS data transmission.

Onsite Activity - If problems with OASIS data transmission were determined during pre-survey activity, on survey, interview the appropriate staff to assess the extent of the problem, and to identify steps the HHA is taking to correct any transmission problems.

Probes §484.20(d)

What steps did the HHA take to correct transmission problems, i.e., change in software vendor, notifying the State, or using HAVEN as a backup software program?

Does the HHA use the correct identifier in OASIS item M0016 Branch ID to identify if the assessment record is submitted by the parent agency, the branch, or an agency without branches?

Subpart C - Furnishing of Services

G168

§484.30 Condition of Participation: Skilled Nursing Services

G169

The HHA furnishes skilled nursing services by or under the supervision of a registered nurse; and

G170

in accordance with the plan of care.

§484.30(a) Standard: Duties of the Registered Nurse

G171

The registered nurse makes the initial evaluation visit,

G172

regularly re-evaluates the patient's nursing needs,

G173

initiates the plan of care and necessary revisions,

G174

furnishes those services requiring substantial and specialized nursing skill,

G175

initiates appropriate preventive and rehabilitative nursing procedures,

G176

prepares clinical and progress notes, coordinates services, informs the physician and other personnel of changes in the patient's condition and needs,

G177

counsels the patient and family in meeting nursing and related needs,

G178

participates in in-service programs, and supervises and teaches other nursing personnel.

Interpretive Guidelines 484.30(a)

An RN is required to make the initial evaluation visit except in those circumstances where the physician has ordered only therapy services. If the physician orders only therapy services, it would be acceptable for the appropriate therapist (physical therapist or speech-language pathologist) to perform the initial evaluation visit. This does **not** mean that an HHA is precluded from having the RN perform all initial evaluation visits if the HHA believes that this promotes coordinated patient care, and/or if this is part of the HHA's own policies, procedures, and particular approach to patient care services.

Review a case-mix, stratified sample of clinical records according to the HHA survey and certification process, and make home visits to determine if RNs perform their responsibilities within the State's nurse practice act and in compliance with the plan of care. (See [§§484.12\(c\)](#) and [484.18.](#)) See §§2200 and 2202 of the SOM.

Probes §484.30(a)

How does the HHA confirm that services requiring specialized nursing skills are furnished by individuals with the appropriate qualifications?

§484.30(b) Standard: Duties of the Licensed Practical Nurse

G179

The licensed practical nurse furnishes services in accordance with agency policies,

G180

prepares clinical and progress notes,

G181

assists the physician and registered nurse in performing specialized procedures,

G182

prepares equipment and materials for treatments observing aseptic technique as required; and

G183

assists the patient in learning appropriate self-care techniques.

Interpretive Guidelines §484.30(b)

Determine if services are provided in accordance with the HHA's professional practice standards and with guidance and supervision from RNs. Make the same comparisons set forth in the §484.30(a) probe when reviewing duties of the LPN.

G184**§484.32 Condition of Participation: Therapy Services**

G185

Any therapy services offered by the HHA directly or under arrangement are given by a qualified therapist or by a qualified therapy assistant under the supervision of a qualified therapist and in accordance with the plan of care.

G186

The qualified therapist assists the physician in evaluating level of function, helps develop the plan of care (revising it as necessary),

G187

prepares clinical and progress notes,

G188

advises and consults with the family and other agency personnel; and

G189

participates in in-service programs.

Probes §484.32

1. How does the HHA ensure that therapy services furnished by staff under arrangement or contract meet the requirements of this condition?
2. Does the clinical record documentation describe the patient responses to therapy?
3. How does the HHA coordinate therapy services with other skilled services to complete the plan of care and promote positive therapeutic outcomes?

§484.32(a) Standard: Supervision of Physical Therapy Assistant and Occupational Therapy Assistant

G190

Services furnished by a qualified physical therapy assistant or qualified occupational therapy assistant may be furnished under the supervision of a qualified physical or occupational therapist. A physical therapy assistant or occupational therapy assistant performs services planned, delegated, and supervised by the therapist;

G191

assists in preparing clinical notes and progress reports; and

G192

participates in educating the patient and family, and in in-service programs.

Interpretive Guidelines §484.32(a)

Specific instructions for assistants must be based on treatments prescribed in the plan of care, patient evaluations by the therapist, and accepted standards of professional practice. The therapist evaluates the effectiveness of the services furnished by the assistant.

Documentation in the clinical record should show that communication and supervision exist between the assistant and therapist about the patient's condition, the patient's response to services furnished by the assistant, and the need to change the plan of care.

Probes §484.32(a)

1. How does the therapist evaluate the patient's needs and responses to services furnished by the assistant to measure the patient's progress in achieving the anticipated outcomes?

2. How does the HHA ensure that the assistant initiates plans of care only with appropriate supervision by the therapist when therapy services are provided under arrangement or contract?
3. What kinds of in-service programs have the therapist and assistant participated in during the past year? Who provides them?
4. Were comprehensive assessments completed by the OTA, or PTA? Only qualified clinicians (RN, PT, SLP/ST, or OT) may assess and complete the comprehensive assessment.

§484.32(b) Standard: Supervision of Speech Therapy Services

G193

Speech therapy services are furnished only by or under the supervision of a qualified speech-language pathologist or audiologist.

Probes §484.32(b)

How does the HHA confirm that speech therapy services provided under arrangement or contract meet the requirements of this condition?

G194**§484.34 Condition of Participation: Medical Social Services**

G195

If the agency furnishes medical social services, those services are given by a qualified social worker or by a qualified social work assistant under the supervision of a qualified social worker, and in accordance with the plan of care. The social worker assists the physician and other team members in understanding the significant social and emotional factors related to the health problems,

G196

participates in the development of the plan of care,

G197

prepares clinical and progress notes,

G198

works with the family,

G199

uses appropriate community resources,

G200

participates in discharge planning and in-service programs,

G201

and acts as a consultant to other agency personnel.

Interpretive Guidelines §484.34

Medical social services, when required by the plan of care, must be available on a visiting, not consultative, basis in a patient's place of residence.

Either the social worker or a social work assistant may make the initial visit to the HHA patient. Information gathered during the home visit is reviewed by the social worker who makes suggestions to the physician for additions to the plan of care.

The social worker may provide the patient with approved professional services or assign the care to the assistant, providing supervision as required. (See [§484.2.](#))

Probes §484.34

How does the HHA confirm that patients' social service needs are adequately met, including those services provided under arrangement or contract?

G202**§484.36 Condition of Participation: Home Health Aide Services**

G203

Home health aides are selected on the basis of such factors as a sympathetic attitude toward the care of the sick, ability to read, write, and carry out directions, and maturity and ability to deal effectively with the demands of the job. They are closely supervised to ensure their competence in providing care. For home health services furnished (either directly or through arrangements with other

organizations) after August 14, 1990, the HHA must use individuals who meet the personnel qualifications specified in [§484.4](#) for “home health aide.”

Interpretive Guidelines §484.36

CMS has identified the requirements that a home health aide training program and competency evaluation program or competency evaluation program must have for individuals to qualify as home health aides in a Medicare participating HHA. CMS does not intend to provide any additional procedures or further elaboration concerning skills in which aides must become proficient beyond the subject areas identified. It is the responsibility of the HHA to ensure that aides are proficient to carry out the patient care they are assigned, in a safe, effective, and efficient manner.

The HHA is responsible for ensuring that home health aides used by the HHA meet the provisions of [§484.4](#) and §484.36. This includes home health aides trained and evaluated by other HHA's or other organizations, and those hired by the HHA under an arrangement as well as those who are employed by the HHA. While CMS will not establish a national program to approve each home health aide training and competency evaluation program, a sample of home health aides used by a particular HHA will have their files reviewed for documentation of compliance with the training and competency evaluation or competency evaluation requirements during a standard and/or partial extended or extended survey of the HHA.

If the HHA has been out of compliance with a Condition of Participation, it may not provide its own 75 hour training program, its initial training and competency evaluation, or the competency evaluation for its aides to meet the requirements of §484.36(a) and (b).

With the exception of licensed health professionals and volunteers, home health aide training and competency evaluation or competency evaluation requirements apply to all individuals who are employed by or work under contract with a Medicare-certified HHA and who provide “hands-on” patient care services regardless of the title of the individual. It is the FUNCTION of the aide that determines the need for training and competency evaluation or competency evaluation.

As discussed in general guidelines, all Conditions of Participation apply to a Medicare certified HHA as an entity and to all individuals or patients under the HHA's care. (See [§1861\(m\)](#), [1861\(o\)\(3\)](#) and [1891\(a\)\(1\)](#) of the Social Security Act.)

§484.36(a) Standard: Home Health Aide Training

G204**§484.36(a)(1) Standard: Content and Duration of Training**

The aide training program must address each of the following subject areas through classroom and supervised practical training totaling at least 75 hours, with at least 16 hours devoted to supervised practical training.

G205

The individual being trained must complete at least 16 hours of classroom training before beginning the supervised practical training.

G206

- (i) Communications skills.
- (ii) Observation, reporting and documentation of patient status and the care or service furnished.
- (iii) Reading and recording temperature, pulse, and respiration.
- (iv) Basic infection control procedures.
- (v) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor.
- (vi) Maintenance of a clean, safe, and healthy environment.
- (vii) Recognizing emergencies and knowledge of emergency procedures.
- (viii) The physical, emotional, and developmental needs of and ways to work with the populations served by the HHA, including the need for respect for the patient, his or her privacy and his or her property.
- (ix) Appropriate and safe techniques in personal hygiene and grooming that include--
 - (A) Bed bath.
 - (B) Sponge, tub, or shower bath.
 - (C) Shampoo, sink, tub, or bed.

(D) Nail and skin care.

(E) Oral hygiene.

(F) Toileting and elimination.

(x) Safe transfer techniques and ambulation.

(xi) Normal range of motion and positioning.

(xii) Adequate nutrition and fluid intake.

(xiii) Any other task that the HHA may choose to have the home health aide perform.

“Supervised practical training” means training in a laboratory or other setting in which the trainee demonstrates knowledge while performing tasks on an individual under the direct supervision of a registered nurse or licensed practical nurse.

Interpretive Guidelines §484.36(a)

Classroom and supervised practical training should be based on an instruction plan that includes learning objectives, clinical content, and minimum, acceptable performance standards that meet the requirements of the regulation.

A mannequin may be used for training purposes only.

G207

§484.36(a)(2) Standard: Conduct of Training

(i) Organizations. A home health aide training program may be offered by any organization except an HHA that, within the previous two years, has been found--

(A) Out of compliance with requirements of this paragraph (a) or paragraph (b) of this section;

(B) To permit an individual that does not meet the definition of “home health aide” as specified in [§484.4](#) to furnish home health aide services (with the exception of licensed health professionals and volunteers);

(C) Has been subject to an extended (or partial extended) survey as a result of having been found to have furnished substandard care (or for other reasons at the discretion of CMS or the State);

(D) Has been assessed a civil monetary penalty of not less than \$5,000 as an intermediate sanction;

(E) Has been found to have compliance deficiencies that endanger the health and safety of the HHA's patients and has had a temporary management appointed to oversee the management of the HHA;

(F) Has had all or part of its Medicare payments suspended; or

(G) Under any Federal or State law within the 2-year period beginning on October 1, 1988--

(1) Has had its participation in the Medicare program terminated;

(2) Has been assessed a penalty of not less than \$5,000 for deficiencies in Federal or State standards for HHAs;

(3) Was subject to a suspension of Medicare payments to which it otherwise would have been entitled;

(4) Had operated under a temporary management that was appointed to oversee the operation of the HHA and to ensure the health and safety of the HHA's patients; or

(5) Was closed or had its residents transferred by the State.

Interpretive Guidelines §484.36(a)(2)(i)

“Requirement” means compliance with a condition level deficiency.

Effective February 14, 1990, an HHA must not have had any Condition of Participation out of compliance within 24 months before it begins a training and competency evaluation or competency evaluation program.

Correction of a condition level deficiency does not relieve the 2-year restriction identified in this standard.

Nothing in this standard precludes an HHA that has a condition out of compliance from hiring or contracting for aides who have already completed a training and competency evaluation or competency evaluation program, or arranging for aides to attend a training and competency evaluation or competency evaluation program provided by another entity.

If a partial extended or extended survey is conducted, but substandard care (a condition out of compliance) is not found, the HHA would not be precluded from offering its own aide training and/or competency evaluation program.

If an HHA, while conducting its own training and competency evaluation program or competency evaluation program, has either a standard, partial extended or extended survey in which it is found to be out of compliance with a Condition of Participation, it may complete that training and competency evaluation program or competency evaluation program for aides currently enrolled, but it may not accept new candidates into the program or begin a new program, for 2 years after receiving written notice from the RO that the HHA was out of compliance with one or more Conditions of Participation.

G208

(ii) Qualifications for instructors.

The training of home health aides and the supervision of home health aides during the supervised practical portion of the training must be performed by or under the general supervision of a registered nurse who possesses a minimum of 2 years of nursing experience, at least 1 year of which must be in the provision of home health care.

G209

Other individuals may be used to provide instruction under the supervision of a qualified registered nurse.

Interpretive Guidelines §484.36(a)(2)(ii)

The required 2 years of nursing experience for the instructor should be “hands on” clinical experience such as providing care and/or supervising nursing services or teaching nursing skills in an organized curriculum or in-service program.

“Other individuals” who may help with aide training would include health care professionals such as physical therapists, occupational therapists, medical social workers, and speech-language pathologists. Experienced aides, nutritionists, pharmacists, lawyers and consumers might also be teaching resources.

G210

§484.36(a)(3) Standard: Documentation of Training

The HHA must maintain sufficient documentation to demonstrate that the requirements of this standard are met.

Interpretive Guidelines §484.36(a)(3)

It is the responsibility of the HHA to maintain adequate documentation of compliance with the regulation for home health aides employed by or under contract with the HHA.

A home health aide may receive training from different organizations if the amount of training totals 75 hours, the content of training addresses all subjects listed at [§484.36\(a\)](#) and the organization, training, instructors, and documentation meet the requirements of the regulation.

Documentation of training should include:

- A description of the training/competency evaluation program, including the qualifications of the instructors;
- A record that distinguishes between skills taught at a patient's bedside, with supervision, and those taught in a laboratory using a volunteer or "pseudo-patient," (not a mannequin) and indicators of which skills each aide was judged to be competent; and
- How additional skills (beyond the basic skills listed in the regulation) are taught and tested if the admission policies and case-mix of HHA patients require aides to perform more complex procedures.

§484.36(b) Standard: Competency Evaluation In-Service Training

G211

§484.36(b)(1) Standard: Applicability

An individual may furnish home health aide services on behalf of an HHA only after that individual has successfully completed a competency evaluation program as described in this paragraph.

G212

The HHA is responsible for ensuring that the individuals who furnish home health aide services on its behalf meet the competency evaluation requirements of this section.

Interpretive Guidelines §484.36(b)(1)

The HHA must ensure that skills learned or tested elsewhere can be transferred successfully to the care of the patient in his/her place of residence. The HHA should give careful attention to evaluating both employees and aides who provide services under arrangement or contract. This review of skills could be done when the nurse installs an aide into a new patient care situation, during a supervisory visit, or as part of the annual performance review. A mannequin may not be used for this evaluation.

If the HHA's admission policies and the case-mix of HHA patients demand that the aide care for individuals whose personal care and basic nursing or therapy needs require more complex training than the minimum required in the regulation, the HHA must document how these additional skills are taught and tested.

G213

(Rev. 11, Issued: 08-12-05; Effective/Implementation: 08-12-05)

§484.36(b)(2) Content and Frequency of Evaluations and Amount of In-Service Training

(i) The competency evaluation must address each of the subjects listed in paragraphs (a)(1)(ii) through (xiii) of *this section*.

G214

(Rev. 11, Issued: 08-12-05; Effective/Implementation: 08-12-05)

(ii) The HHA must complete a performance review of each home *health aide no less frequently than every 12 months*.

G215

(iii) The home health aide must receive at least 12 hours of in-service training during each 12-month period. The in-service training may be furnished while the aide is furnishing care to the patient.

Interpretive Guidelines §484.36(b)(2)

HHAs are not required to conduct a yearly competency evaluation of its aides, but are required to do a performance review of each aide at least every 12 months.

HHAs that are precluded from conducting their own training and/or competency evaluation programs must still complete their aides' annual performance reviews and in-service training as part of their administrative, personnel and patient care responsibilities.

An annual performance review may be completed and documented over a period of time during an aide's two-week supervisory visits in a patient's home or during the installation of an aide in a new patient care situation. Any reasonable performance review method that is logical and consistent with the HHA's policies and procedures would meet the intent of this standard.

Home health aide in-service training, that occurs with a patient in a place of residence, supervised by an RN, can occur as part of the two-week supervisory visit, but must be documented as to the exact new skill or theory taught. In-service training taught in the patient's environment should not be a repetition of a basic skill or part of the annual performance review of the aide's competency in basic skills.

HHA's may fulfill the annual 12-hour in-service training requirement on either a calendar year basis or an employment anniversary basis.

Probes §§484.36(b)(1) & (2)

If aide services are provided under arrangement or contract, how does the HHA ensure that aides providing patient care have the appropriate competency skills?

G216**§484.36(b)(3) Standard: Conduct of Evaluation and Training**

(i) Organizations. A home health aide competency evaluation program may be offered by an organization except as specified in paragraph (a)(2)(i) of this section. The in-service training may be offered by any organization.

G217

(ii) Evaluators and instructors. The competency evaluation must be performed by a registered nurse.

The in-service training generally must be supervised by a registered nurse who possesses a minimum of 2 years of nursing experience, at least 1 year of which must be in the provision of home health care.

G218

(iii) Subject areas. The subject areas listed at paragraphs (a)(1)(iii), (ix), (x) and (xi) of this section must be evaluated after observation of the aide's performance of the tasks with a patient. The other subject areas in paragraph (a)(1) of this section may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient.

Interpretive Guidelines §484.36(b)(3)

Subject areas (a)(1)(iii), (ix), (x) and (xi) may be evaluated with the tasks being performed on a pseudo-patient such as another aide or volunteer in a laboratory setting. The tasks must not be simulated in any manner and the use of a mannequin is not an acceptable substitute.

Probes §484.36(b)(3)

1. How does the HHA ensure that aides perform only tasks for which they received satisfactory ratings in the competency evaluation?
2. If the aide performs skills which exceed the basic skills included in this standard, how does the HHA train and test aides for competency?
3. How does the HHA plan for extended training if it is unable to train its own aides?
4. How does the HHA monitor the assignment of aides to match the skills needed for individual patients?

G219

§484.36(b)(4) Standard: Competency Determination

(i) A home health aide is not considered competent in any task for which he or she is evaluated as unsatisfactory. The aide must not perform that task without direct supervision by a licensed nurse until after he or she receives training in the task for which he or she was evaluated as unsatisfactory and passes a subsequent evaluation with satisfactory.

G220

(ii) A home health aide is not considered to have successfully passed a competency evaluation if the aide has an unsatisfactory rating in more than one of the required areas.

Interpretive Guidelines §§484.36(b)(4)

A home health aide who is evaluated as satisfactory in all subject areas except one would be considered competent. However, this aide would not be allowed to perform the task in which he or she was evaluated as unsatisfactory except under direct supervision. If a home health aide receives an unsatisfactory evaluation in more than one subject area, the aide would not be considered to have successfully passed a competency evaluation program and would be precluded from performing as a home health aide in any subject area. The regulations place no restrictions on the number of times or the period of time an aide can be tested in a deficient area.

A home health aide may have different skills evaluated by different organizations as long as the organizations, the training and competency evaluation program(s), the evaluators, and the documentation meet the requirements of the regulation. The aide must have had **ALL** of the required skills evaluated. Aides that have undergone a sampling methodology for the evaluation of aide skills must have the additional required skills evaluated before the aide is determined to be competent.

Aides required to provide items or services which exceed the basic skills must demonstrate competency before they are assigned to care for patients who require these skills.

It is not intended that all home health aides be required to deliver all types of home health services. However, each individual aide should be qualified to perform each individual task for which he or she is responsible.

Probes §484.36(b)(4)

1. How does the HHA confirm aide skills on an ongoing basis for its employees including new hires and personnel under arrangement or contract?
2. If aides are performing tasks that are an extension of home health services other than nursing, how does the HHA document that these aides have proven competency in these tasks to the appropriate health professional?

G221

§484.36(b)(5) Standard: Documentation of Competency Evaluation

The HHA must maintain documentation which demonstrates that the requirements of this standard are met.

G222

§484.36(b)(6) Standard: Effective Date

The HHA must implement a competency evaluation program that meets the requirements of this paragraph before February 14, 1990. The HHA must provide the preparation necessary for the individual to successfully complete the competency evaluation program. After August 14, 1990, the HHA may use only those aides that have been found to be competent in accordance with §484.36(b).

§484.36(c) Standard: Assignment and Duties of the Home Health Aide

G223

§484.36(c)(1) Standard: Assignment

The Home Health Aide Is Assigned to A Specific Patient By The Registered Nurse

G224

Written patient care instructions for the home health aide must be prepared by the registered nurse or other appropriate professional who is responsible for the supervision of the home health aide under paragraph (d) of this section.

Interpretive Guidelines §484.36(c)

The aide assignments must consider the skills of the aide, the amount and kind of supervision needed, specific nursing or therapy needs of the patient, and the capabilities of the patient's family.

During the standard survey, when possible, schedule at least one home health visit when a home health aide is present. Informal questions to the aide(s) or a review of the aide's assignment sheets will offer information about HHA compliance with this standard.

To evaluate coordination of home health aide services according to the requirements of [§484.14\(g\)](#), look for documentation by the aide in the clinical records that describes significant information or changes in his or her patients' conditions and to whom he or she reported the information. Notes should be dated and signed by the aide.

If the aide is performing simple procedures as an extension of therapy services, review documentation of how the aide was evaluated for competency to perform these tasks. Also, review the plan of care and therapy notes to ensure that the services performed by the aide are not services ordered by the physician to be performed by a qualified therapist or therapy assistant.

G225

§484.36(c)(2) Standard: Duties

The home health aide provides services that are ordered by the physician in the plan of care and that the aide is permitted to perform under State law.

G226

The duties of a home health aide include the provision of hands-on personal care, performance of simple procedures as an extension of therapy or nursing services, assistance in ambulation or exercises, and assistance in administering medications that are ordinarily self-administered.

G227

Any home health aide services offered by an HHA must be provided by a qualified home health aide.

Interpretive Guidelines §484.36(c)(2)

See [§484.4](#) for the definition of a home health aide.

§484.36(d) Standard: Supervision

G228

§484.36(d)(1)

If the patient receives skilled nursing care, the registered nurse must perform the supervisory visit required by paragraph (d)(2) of this section. If the patient is not receiving skilled nursing care, but is receiving another skilled service (that is, physical therapy, occupational therapy, or speech-language pathology services), supervision may be provided by the appropriate therapist.

G229

§484.36(d)(2)

The registered nurse (or another professional described in paragraph (d)(1) of this section) must make an on-site visit to the patient's home no less frequently than every 2 weeks.

G230

(Rev. 11, Issued: 08-12-05; Effective/Implementation: 08-12-05)

§484.36(d)(3)

If home health aide services are provided to a patient who is not receiving skilled nursing care, physical or occupational therapy or speech-language pathology services, the registered nurse must make a supervisory visit to the patient's home no less frequently than every 60 days.

In these cases, to ensure that the aide is properly caring for the patient, each supervisory visit must occur while the home health aide is providing patient care.

Interpretive Guidelines §484.36(d)

Supervision visits may be made in conjunction with a professional visit to provide services.

In any patient care situation where an HHA is providing care for an individual who has a condition which requires non-skilled, supportive home health aide services to help the patient with personal care or activities of daily living, the 2 week supervisory visit is not applicable. The RN must make a supervisory visit at least every *60 days*. The visit must be made while the aide is furnishing patient care.

Probes §484.36(d)

How does the HHA schedule supervisory visits so that aide skills can be evaluated?

G231

§484.36(d)(4)

If home health aide services are provided by an individual who is not employed directly by the HHA (or hospice), the services of the home health aide must be provided under arrangements, as defined in section 1861(w)(1) of the Act.

G232

If the HHA (or hospice) chooses to provide home health aide services under arrangements with another organization, the HHA's (or hospice's) responsibilities include, but are not limited to--

§484.36(d)(4)(i)

Ensuring the overall quality of the care provided by the aide;

G301

§484.36(d)(4)(ii)

Supervision of the aide's services as described in paragraphs (d)(1) and (d)(2) of this section; and

G302

§484.36(d)(4)(iii)

Ensuring that home health aides providing services under arrangements have met the training requirements of paragraph (a) and/or (b) of this section.

Interpretive Guidelines §484.36(d)(4)

An individual providing services under an arrangement can qualify as a home health aide by completing a training and competency evaluation program or a competency evaluation program.

Probes §484.36(d)(4)

How does the HHA ensure that home health aides providing services under arrangements are supervised according to the requirements of §484.36(d)(1) and (d)(2) and meet the training and/or competency evaluation requirements of §484.36(a) or (b)?

§484.36(e) Personal Care Attendant (PCA): Evaluation Requirements

G233

(1) Applicability. This paragraph applies to individuals who are employed by HHAs exclusively to furnish personal care attendant services under a Medicaid personal care benefit.

(2) Rule. An individual may furnish personal care services, as defined in [§410.170](#) of this chapter, on behalf of an HHA after the individual has been found competent by the State to furnish those services for which a competency evaluation is required by paragraph (b) of this section and which the individual is required to perform. The individual need not be determined competent in those services listed in paragraph (a) of this section that the individual is not required to furnish.

Interpretive Guidelines §484.36(e)

Personal care services also include those services defined at [§440.180](#).

PCAs who are employed by HHA's to furnish services under a Medicaid personal care benefit must abide by all other requirements for home health aides listed at 42 CFR 484.36 with the explicit exception of 42 CFR 484.36(e).

G234

§484.38 Condition of Participation: Qualifying to Furnish Outpatient Physical Therapy or Speech Pathology Services

An HHA that wishes to furnish outpatient physical therapy or speech pathology services must meet all the pertinent conditions of this part and also meet the additional health and safety requirements set forth in [§§485.711 through §485.715](#), [485.719](#), [485.723](#), and [485.727](#) of this chapter to implement section [1861\(p\)](#) of the Act.

Interpretive Guidelines §484.38

An HHA that furnishes outpatient therapy services on its own premises, including its branches, must comply with the listed citations as well as meet all other Conditions of Participation. [§485.723](#) and [§485.727](#) are not applicable when the patients are served in their **own** homes. [§485.723](#) and [§485.727](#) are applicable, and may be surveyed at the

SA's or RO's discretion, when specialized rehabilitation space and equipment is owned, leased, operated, contracted for, or arranged for at sites under the HHA's control and when the HHA bills the Medicare/Medicaid programs for services rendered at these sites. Complete the corresponding section of the Outpatient Physical Therapy or Speech Pathology Survey Report, Form [CMS-1893](#), and attach it to the Home Health Agency Survey and Deficiencies Report, Form CMS-1572, when surveying these sites. Indicate the agency's certification to provide outpatient therapy services via special remarks on the Certification and Transmittal, Form CMS-1539. (See §§2764, Item 16.)

The individual therapist may develop the plan of care for outpatient physical and speech pathology therapy services. For Medicare patients receiving outpatient physical and/or speech pathology therapy services, the plan of care and results of treatment must be reviewed by a physician. Non-Medicare patients are not required to be under the care of a physician, and therefore do not need a plan of care established by and reviewed by a physician. For non-Medicare patients, the plan of care may be reviewed by the therapist who established it or by a physician.

(See Appendix E, Interpretive Guidelines, Outpatient Physical or Speech Pathology Service – Physicians' Directions and Plan of Care.)

G235

§484.48 Condition of Participation: Clinical Records

G236

(Rev. 11, Issued: 08-12-05; Effective/Implementation: 08-12-05)

A clinical record containing pertinent past and current findings in accordance with accepted professional standards is maintained for every patient receiving home health services.

In addition to the plan of care, the record contains appropriate identifying information; name of physician; drug, dietary, treatment, and activity orders; signed and dated clinical and progress notes; copies of summary reports sent to the attending physician; and a discharge summary.

Interpretive Guidelines §484.48

The clinical record must provide a current, organized, and clearly written synopsis of the patient's course of treatment, including services provided for the HHA by arrangement or contract. The clinical record should facilitate effective, efficient, and coordinated care.

Questionable patterns, rather than isolated instances, in clinical records are an indicator that the quality of care provided by the HHA needs to be carefully assessed for compliance with the plan of care, coordination of service, concurrence with the HHA's stated policies and procedures, and evaluations of patient outcomes. However, isolated

instances, depending on their nature and severity, can serve as the basis of a deficiency and enforcement action (e.g., immediate and serious threat as outlined in Appendix Q).

Electronic Signatures

While the regulations specify that documents must be signed, they do not prohibit the use of electronic signatures. HHA's that have created the option for an individual's record to be maintained by computer, rather than hard copy, may use electronic signatures as long as there is a process for reconstruction of the information, and there are safeguards to prevent unauthorized access to the records. If necessary, review written policies maintained by the HHA describing the clinical record and authentication policy(ies) in force. Clinical, progress notes, and summary reports as defined at [§484.2](#) must be maintained on all patients.

Physician's Rubber Stamp Signatures

Home health agencies may accept a physician's rubber stamp signature for their clinical record documentation if this is permitted by Federal, state and local law and authorized by the HHA's policy. The individual whose signature the stamp represents must place in the Administrative office of the agency a signed statement attesting that he/she is the only one who has the stamp and uses it. All state licensure and state practice regulations continue to apply to Medicare approved HHA's. Where state law is more restrictive than Medicare, the provider needs to apply the state law standard. Note that this does not supersede any current policy related to Medicare coverage and eligibility rules or instructions from the Regional Home Health Intermediaries.

Correction of Clinical Records

The HHA is encouraged to create policies and procedures that govern correction of clinical records. It is prudent for the HHA to include latitude for correction of records in the event of staff turnover or staff schedules. For example, a clinical supervisor may be permitted by agency policy to make corrections when the original clinician is no longer available due to staff turnover.

When a comprehensive assessment is corrected, the HHA must maintain the original assessment record as well as all subsequent corrected assessments in the patient's clinical record for five years, or longer, in accordance with the clinical record requirements at [42 CFR 484.48](#). If maintained electronically, the HHA must be capable of retrieving and reproducing a hard copy of these assessments upon request. It is acceptable to have multiple corrected assessments for an OASIS assessment, as long as the OASIS and the clinical record are documented in accordance with the requirements at [42 CFR 484.48](#), Clinical records.

Clinical Implications of Corrected Assessment Records

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

Some agencies use a manual corrections form for one or more OASIS items that can be acceptable after confirming the correction with the original clinician or as described in the agency's policies and procedures. As long as the correction form clearly identifies the item or items of the specific assessment and remain with the original assessment as part of the permanent record in order to have a complete picture of the entire assessment; these suggestions are consistent with CMS's overall guidelines for maintaining clinical records in accordance with accepted professional standards.

(Rev. 11, Issued: 08-12-05; Effective/Implementation: 08-12-05)

The HHA must inform the attending physician of the availability of a discharge summary. The discharge summary must be sent to the attending physician upon request and must include the patient's medical and health status at discharge.

Interpretive Guidelines §484.48

The regulations do not dictate the form to be used as a progress note and/or a summary report. Notations should be appropriately labeled and should provide an overall, comprehensive view of the patient's total progress and/or current summary report including social, emotional, or behavioral adjustments relative to the diagnosis, treatment, rehabilitation potential, and anticipated outcomes toward recovery or further debilitation.

The regulation does not dictate the frequency with which progress notes must be written. If necessary, review the HHA's policies and procedures concerning the frequency of preparing progress notes.

The discharge summary need not be a separate piece of paper and may be incorporated into the routine summary reports already furnished to the physician.

Probes §484.48

1. Are there patterns in the clinical records that are of concern?

2. Do clinical records document patient progress and outcomes of care based on changes in the patient's condition?
3. How does the HHA inform the attending physician of the availability of a discharge summary?
4. How does the HHA ensure that the discharge summary is sent to the attending physician upon his/her request?
5. If you have concerns about any part of the clinical record or correction policy ask the HHA to explain its process.

§484.48(a) Standard: Retention of Records

G237

Clinical records are retained for 5 years after the month the cost report to which the records apply is filed with the intermediary, unless State law stipulates a longer period of time. Policies provide for retention even if the HHA discontinues operations.

G238

If a patient is transferred to another health facility, a copy of the record or abstract is sent with the patient.

Interpretive Guidelines §484.48(a)

An HHA may store clinical and health insurance records electronically (i.e., on disk, on microfilm, or on optical disk imaging systems.) This includes the storage of OASIS information. All material must be available for review by CMS, the intermediary, Department of Health and Human Services, or other specially designated components for bill review, audit, or other examination during the retention period.

With respect to a State agency or Federal survey to ensure compliance with the Conditions of Participation, clinical records requested by the surveyor, along with the equipment necessary to read them, must be made available during the course of the unannounced survey.

The final validation reports from submission of OASIS records and OBQI/M reports are not part of the clinical record and as such need not be retained for five years. It is recommended that final validation reports be retained for a period of 12 months until the new expected annual OBQI/M reports are received.

§484.48(b) Standard: Protection of Records

G239

Clinical record information is safeguarded against loss or unauthorized use.

G240

Written procedures govern use and removal of records and the conditions for release of information.

G241

Patient's written consent is required for release of information not authorized by law.

Probes §484.48(b)

1. How are clinical records stored to protect them from physical destruction and unauthorized use?
 2. What written policies and procedures govern the use, removal, and release of clinical records?
 3. How does the HHA make the records available for all personnel furnishing services on behalf of the HHA?
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G242**§484.52 Condition of Participation: Evaluation of the Agency's Program**

G243

The HHA has written policies requiring an overall evaluation of the agency's total program at least once a year by the group of professional personnel (or a committee of this group), HHA staff, and consumers, or by professional people outside the agency working in conjunction with consumers.

G244

The evaluation consists of an overall policy and administrative review and a clinical record review.

G245

The evaluation assesses the extent to which the agency's program is appropriate, adequate, effective, and efficient.

G246

Results of the evaluation are reported to and acted upon by those responsible for the operation of the agency and

G247

are maintained separately as administrative records.

Interpretive Guidelines §484.52

All aspects of the HHA's evaluation are not required to have been done at the same time or by the same evaluators. For example, fiscal, patient care, and administrative policies may be evaluated by different members or committees of the group responsible for performing the evaluation at different times of the year. Patient care services should have been evaluated by providers and consumers.

A consumer may be any individual in the community outside the agency, regardless of whether he or she has been a recipient of, or is eligible to receive, home health services.

The evaluation should address the total program, including services furnished directly to patients, and the administration and management of the HHA, including, but not limited to, policies and procedures, contract management, personnel management, clinical record review, patient care, and the extent to which the goals and objectives of the HHA are met. Results of the HHA's overall annual evaluation must be available for surveyor review, upon request.

§484.52(a) Standard: Policy and Administrative review.

G248

As part of the evaluation process, the policies and administrative practices of the agency are reviewed to determine the extent to which they promote patient care that is appropriate, adequate, effective, and efficient.

G249

Mechanisms are established in writing for the collection of pertinent data to assist in evaluation.

Interpretive Guidelines §484.52(a)

In evaluating each aspect of its total program, the HHA should have considered four main criteria:

Appropriateness - Assurance that the area being evaluated addresses existing or potential problems.

Adequacy - A determination as to whether the HHA has the capacity to overcome or minimize existing or potential problems.

Effectiveness - The services offered accomplish the objectives of the HHA and anticipated patient outcomes.

Efficiency - Whether there is a minimal expenditure of resources by the HHA to achieve desired goals and anticipated patient outcomes.

Probes §484.52(a)

1. How is consumer involvement in the evaluation process ensured?
2. How has the HHA responded to the recommendations made by the professional group in relation to the most recent annual evaluation?
3. What areas does the HHA view as requiring change based on the most recent annual evaluation?
4. How does the program evaluation highlight the agency's efforts to resolve patients' grievances and complaints, if any?

§484.52(b) Standard: Clinical Record Review

G250

At least quarterly, appropriate health professionals, representing at least the scope of the program, review a sample of both active and closed clinical records to determine whether established policies are followed in furnishing services directly or under arrangement.

G251

There is a continuing review of clinical records for each 60-day period that a patient receives home health services to determine adequacy of the plan of care and appropriateness of continuation of care.

Interpretive Guidelines §484.52(b)

Quarterly reviews need not be performed at a joint, sit-down meeting of the professionals performing the review. Each professional may review the records separately, at different times.

The HHA should evaluate all services provided for consistency with professional practice standards for HHA's and the HHA's policies and procedures, compliance with the plan of care, the appropriateness, adequacy, and effectiveness of the services offered, and evaluations of anticipated patient outcomes. Evaluations should be based on specific record review criteria that are consistent with the HHAs admission policies and other HHA specific patient care policies and procedures.

The review by appropriate health professionals should include those professionals representing the scope of services provided in that quarter. Therefore, for example, if no speech therapy services were performed, the speech therapist need not be a part of that quarterly review.

If the survey reveals that one (or more) approved services are never, or rarely, provided either for Medicare/Medicaid patients or non-Medicare/Medicaid patients, undertake the following actions to determine whether the HHA is complying with the patients' plans of care ([§484.18](#)):

- Review the HHA's policies relevant to the evaluation of patient care needs.
- Review HHA contracts for unserved or underserved services, if they are provided under contract or arrangement.
- Review plans of care to determine if the services were ordered by a physician but not delivered.
- Ask the HHA under what circumstances it would contact the patient's physician to request modification of a patient's plan of care.

Probes §484.52(b)

1. What patterns or problems does the summary report of the clinical record reviews identify?
2. What is the HHA's plan of correction? Are time frames for implementation and another evaluation review planned?
3. How does the HHA select the clinical records to be reviewed?
4. How do the procedures for review ensure that the review will ascertain whether:

HHA policies and procedures are followed?

Patients are being helped to attain and maintain their highest practicable functional capacity?

Goals or anticipated patient outcomes are appropriate to the diagnosis(es), plan of care, services provided, and patient potential?

§484.55 Condition of Participation: Comprehensive Assessment of Patients

G330

(Rev. 11, Issued: 08-12-05; Effective/Implementation: 08-12-05)

Each patient must receive, and an HHA must provide, a patient specific, comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward achievement of desired outcomes. The comprehensive assessment must identify the patient's continuing need for home care and meet the patient's medical, nursing, rehabilitative, social, and discharge planning needs. For Medicare beneficiaries, the HHA must verify the patient's eligibility for the Medicare home health benefit including homebound status, both at the time of the initial assessment visit and at the time of the comprehensive assessment. The comprehensive assessment must also incorporate the use of the current version of the Outcome and Assessment Information Set (OASIS) items, using the language and groupings of the OASIS items, as specified by the Secretary.

Interpretive Guidelines §484.55

The comprehensive assessment includes the collection of OASIS data items for most patients, as described below, by a qualified clinician, i.e., an RN, physical therapist, occupational therapist, or speech language pathologist. For Medicare patients, there are some additional requirements. HHAs are expected to conduct a comprehensive assessment of each patient that accurately reflects the patient's current health status and includes information to establish and monitor a plan of care. The plan of care must be reviewed and updated at least every 60 days or as often as the severity of the patient's condition requires, per the requirements at [42 CFR 484.18 \(a\) and \(b\)](#).

The requirement to conduct a drug regimen review at §484.55(c) as part of the comprehensive assessment applies to **all** patients serviced by the HHA.

Patients to whom OASIS applies: The regulations require a comprehensive assessment, with OASIS data items integrated, for all patients who receive skilled services from an HHA meeting Medicare's home health conditions of participation, except for those patients who are--

- Under age 18;

- Receiving maternity services;
- Receiving housekeeping or chore services only; or
- Receiving only personal care services until further notice.
- Patients for whom Medicare or Medicaid insurance is not billed

This includes Medicare, Medicaid, and Medicare Advantage (MA), formerly known as Medicare+Choice patients accepted by the HHA. It also includes Medicaid patients receiving services under a waiver program or demonstration to the extent they do not fall into one of the exception categories listed above, who are receiving services subject to the Medicare conditions of participation.

On December 8, 2003, Section 704 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MPDIMA), temporarily suspended the collection of OASIS data on non-Medicare/non-Medicaid patients of an HHA. However, Section 704 of the MMA does not effect or suspend any other provision of §484.55.

During this temporary suspension, CMS will conduct a study on how OASIS information on non-Medicare/non-Medicaid patients is and can be used by large HHAs. The study will also examine whether there are unique benefits for the analysis of this information that cannot be derived from other information available to, or conducted by, these HHAs. In addition, the study will address the value of collecting such information by small HHAs compared to the administrative burden of doing so. CMS will obtain recommendations from quality assessment experts in the use of the OASIS data and examine the necessity of small as well as large HHAs collecting this information. CMS is committed to thoroughly examining how all OASIS data may be used in future refinements of the Home Health Quality Initiative and oversight activities. At the conclusion of this study, CMS will submit a report to Congress. The results of the study will determine future CMS requirements regarding the collection of OASIS data as part of each patient's comprehensive assessment.

Until that time, SA and Regional Office (RO) surveyors should adhere to the following guidance when conducting HHA surveys:

- *HHAs must continue to comply with the aspects of the regulation at 42 CFR 484.55 regarding the comprehensive assessment of patients. HHAs must provide each agency patient, regardless of payment source, with a patient-specific comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward the achievement of desired outcomes. The comprehensive assessment must also identify the patient's continuing need for home care, medical, nursing, rehabilitative, social, and discharge planning needs.*
- *HHAs may continue to collect OASIS data on their non-Medicare/non-Medicaid patients for their own use.*

- *Surveyors must continue to examine the completeness of the comprehensive assessment for all patients during a survey. However, surveyors must not investigate whether the HHA included the specific OASIS items in its patient-specific comprehensive assessments of non-Medicare/non-Medicaid patients, nor cite deficiencies based solely on this finding.*
- *HHAs must continue to collect, encode, and transmit OASIS data for their non-maternity Medicare and Medicaid patients that are age 18 and over and receiving skilled services.*

Under this condition, in addition to an initial assessment visit, the HHA must also conduct a start of care comprehensive assessment with OASIS data items integrated on patients to whom the requirements are applicable. Subsequent comprehensive assessments (updates and recertification) must be conducted at certain time points during the admission. These updates must include certain data items, i.e., those in the current OASIS data set. The recertification, transfer to an inpatient facility, resumption of care, significant change in condition (SCIC), and discharge comprehensive assessment apply to **all** patients, but it does not have to include OASIS for private pay patients. The recertification comprehensive assessment can be completed before the 5 day window as long as it continues to be done “not less frequently than the last five days of every 60 day episode beginning with the start-of-care date.”

The phrase “not less frequently than the last five days of every 60 days beginning with the start of care date” does not mean that HHAs must wait until the 55th – 60th day to perform another comprehensive assessment on non-Medicare/non-Medicaid patients or for pediatric patients, maternity patients or those receiving personal care services even when Medicare is the payor source. The assessment may be performed any time up to and including the 60th day. The timetable for the subsequent 60-day period would then be measured from the completion date of the most recently completed assessment. Clinicians may perform the comprehensive assessment for these patients more frequently than the last 5 days of the 60-day episode without conducting another comprehensive assessment on day 55-60, and remain in compliance with §484.55(d). The agency may develop its own comprehensive assessment for each time point.

OASIS data items are not meant to be the only items included in an HHA’s assessment process. They are standardized health assessment items that must be incorporated into an HHA’s own existing assessment policies and process. An example of a comprehensive assessment showing an integration of the OASIS data items with other agency assessment items can be found in “Appendix C: Sample Clinical Records Incorporating OASIS B-1 Data Set,” in the OASIS User’s Manual. For therapy-only cases, the comprehensive assessment should incorporate OASIS data items as well as other assessment data items the HHA currently collects for therapy patients, as opposed to simply adding them at the beginning or end.

Medicare patients: For Medicare patients, the HHA must include a determination of the patient’s eligibility for the home health benefit, including homebound status.

Eligibility for the Medicare home health benefit is defined in the Medicare Benefit Policy Manual, CMS Pub.100-2 (see http://www.cms.hhs.gov/manuals/102_policy/bp102index.asp) and includes conditions patients must meet to qualify for coverage, such as:

- Patient is confined to the home;
- Services are provided under a plan of care established and approved by a physician;
- Patient is under the care of a physician; and
- Patient needs skilled nursing care on an intermittent basis or physical therapy or speech therapy services or has continued need for occupational therapy.

Incorporating OASIS items: HHA's must incorporate the OASIS data items into their own assessment instrument using the exact language of the items, replacing similar items/questions on their current assessment tool as opposed to simply adding the OASIS items at the beginning or end of the existing assessment tool.

§484.55(a) Standard: Initial Assessment Visit

G331

§484.55(a)(1)

A registered nurse must conduct an initial assessment visit to determine the immediate care and support needs of the patient; and, for Medicare patients, to determine eligibility for the Medicare home health benefit, including homebound status.

Interpretive Guidelines §484.55(a)(1)

The initial assessment visit is conducted to determine the immediate care and support needs of the patient.

For Medicare patients, the initial assessment visit must include a determination of the patient's eligibility for the home health benefit, including homebound status. Verification of a patient's eligibility for the Medicare home health benefit including homebound status does not apply to Medicaid patients, beneficiaries receiving Medicare outpatient services, or private pay patients. The required initial assessment visit at §484.55(a)(1) and the "initial evaluation visit" at [§484.30\(a\)](#) may be completed during the same visit.

See the guidelines at [§484.55](#) above for Medicare eligibility requirements.

For patients receiving only nursing services or both nursing and therapy services, a registered nurse must conduct the initial assessment visit.

Review a case-mix, stratified sample of clinical records and make home visits according to the survey process (see §§2200 and 2202) to determine compliance with this requirement.

Probes §484.55(a)(1)

What are the HHA's policies for conducting the initial assessment?

How is Medicare eligibility and homebound status determined?

G332

The initial assessment visit must be held either within 48 hours of referral, or within 48 hours of the patient's return home, or on the physician-ordered start of care date.

Interpretive Guidelines §484.55(a)(1)

In the absence of a physician-specified start of care date, the initial assessment visit is conducted within 48 hours of the referral. If the physician specified a start of care date, this supersedes the 48-hour time frame. Check the intake or clinical record for documentation of a specified start of care date.

For Medicare patients, if the initial assessment indicates that the patient is not eligible for the Medicare home health care benefit, i.e., the patient is not homebound, has no skilled need, etc., and the HHA does not admit the patient, then there is no indication for the HHA to conduct a comprehensive assessment or to collect, encode, or transmit OASIS data to the State.

Probes §484.55(a)(1)

How does the HHA assure that initial visits are conducted within the required time frames?

Compare the date of the physician referral and the date of the initial assessment visit. If the initial visit is later than 48 hours or later than the physician-ordered start of care date, check the individual patient's clinical record. Sometimes a patient requests that a visit not be made until a more convenient time. That request must be documented in the clinical record as well as a notation that the physician was notified of and approves the patient's request for a delayed start of care.

If the physician orders start of care to begin after the 48-hour time frame specified in the regulations, is there an order in the patient's chart specifying this start of care date?

G333

§484.55(a)(2)

When rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate rehabilitation skilled professional.

Interpretive Guidelines §484.55(a)(2)

For non-Medicare patients, if the need for a single therapy service establishes initial home health eligibility, the corresponding practitioner, (including a physical therapist, speech-language pathologist, or occupational therapist) can conduct the initial assessment visit.

For the Medicare home health benefit, occupational therapy services provided at the start of care alone do not establish eligibility; therefore, occupational therapists may not conduct the initial assessment visit under Medicare. Patients needing only occupational therapy services on admission to the agency may qualify for eligibility under programs other than Medicare.

These instructions are consistent with the guidance at [§484.30\(a\)](#), which states, “If the physician orders only therapy services, it would be acceptable for the appropriate therapist (physical therapist or speech-language pathologist) to perform the initial evaluation visit.”

When physical therapy (PT), speech language pathology (SLP), or occupational therapy (OT) is the only service ordered by the physician, a PT, SLP, or OT may complete the initial assessment visit if the need for that service establishes program eligibility. See 42 CFR [§484.55\(a\)\(2\)](#).

Review a case-mix, stratified sample of clinical records and make home visits according to the survey process (see §§2200 and 2202) to determine compliance with this requirement. For a sample of patients, determine who conducted the initial assessments, if the homebound status for Medicare was identified, and the dates of the referral and initial assessments.

NOTE: A patient who requires short term nursing determined at the start of care in addition to ongoing therapy is not considered a therapy-only case, i.e., a one-time visit by a nurse scheduled to remove sutures. Therefore, the RN must do the initial assessment.

Probes §484.55(a)(2)

How does the HHA assure that initial visits are conducted within the required time frames?

Compare the date of the physician referral and the date of the initial assessment visit. If the difference is greater than 48 hours or later than the physician ordered start of care date, check the individual patient's clinical record. If a patient requests that a visit not be made until a more convenient time, the request should be reported to the physician and documented in the clinical record.

Review patient records in which therapy (occupational therapy, physical therapy, or speech language pathology) was the only skilled service provided. Determine if the appropriate discipline completed the initial assessment. According to State law, some HHA's may use RNs for initial assessments in therapy-only cases.

Interview staff to determine how therapy-only initial assessment visits are conducted.

How does the HHA ensure that the skilled disciplines completing the initial assessment are performing this task accurately?

If questions are raised through interview and record review, review the HHA's policies regarding conducting and completing an initial assessment visit.

G334

§484.55(b) Standard: Completion of the comprehensive assessment.

(1) The comprehensive assessment must be completed in a timely manner, consistent with the patient's immediate needs, but no later than 5 calendar days after the start of care.

Interpretive Guidelines §484.55(b)(1)

For patients to whom OASIS applies, when a patient is admitted to the HHA, a start of care comprehensive assessment that includes certain required OASIS data items, must be completed no later than 5 calendar days after the start of care date.

Pre-Survey Activity - Review OASIS data management reports, as available, to determine if start of care comprehensive assessments are completed within the required time frame.

Onsite Activity - Identify the start of care date. For all practical purposes, the start of care date is the first billable home visit. For payers other than Medicare, the first billable visit might be a visit made by a home health aide.

Review any reasons presented for not completing the start of care comprehensive assessments within the required time frame (i.e., the HHA planned to complete the assessment within the required time frame but the patient refused the visit.). Document explanations for start of care comprehensive assessments completed outside of the required time frame.

M0090 on the OASIS data set reflects the final date the qualified clinician completed the actual patient assessment. This is usually the date of the last home visit made to complete the comprehensive assessment but may reflect a date subsequent to the onsite visit when the qualified clinician needs to follow up, offsite, with the patient's family or physician in order to complete an OASIS clinical data item. Compare the start of care date at M0030 with the date the assessment was completed (M0090). M0090 should be no more than 5 days later than M0030. The HHA has 7 additional days from the date the patient assessment is completed (M0090) to encode (data-enter), edit, and ensure the accuracy of the OASIS data and to consult with the qualified clinician who conducted and completed the comprehensive assessment for purposes of clarification or to complete missing OASIS data items such as diagnosis codes, etc., and to lock (export) the data for future submission to the State agency. (See [§484.20\(a\)](#)).

Probes §484.55(b)(1)

Was the start of care comprehensive assessment completed within 5 calendar days after the start of care date?

Did the HHA provide acceptable explanations and documentation for start of care comprehensive assessments completed outside of the required time frame?

G335

(2) Except as provided in paragraph (b)(3) of this section, a registered nurse must complete the comprehensive assessment and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status.

Interpretive Guidelines §484.55(b)(2)

For Medicare and Medicaid patients receiving skilled nursing services, an RN must conduct and complete the comprehensive assessment, and for Medicare patients confirm eligibility, including homebound verification, for the Medicare home health benefit. See the guidelines at [§484.55](#) for Medicare eligibility requirements.

When nursing and therapy are both ordered at the start of care, the registered nurse performs the start of care comprehensive assessment. Either discipline may perform subsequent assessments if the discipline is still actively providing skilled services to the patient.

Probes §484.55(b)(2)

Is the appropriate clinician conducting the comprehensive assessments, i.e., RN, physical therapist, occupational therapist, or speech-language pathologist? Check the signature of the clinician who completed the start of care assessment, and verify that it is a qualified clinician.

G336

(3) When physical therapy, speech-language pathology, or occupational therapy is the only service ordered by the physician, a physical therapist, speech-language pathologist or occupational therapist may complete the comprehensive assessment, and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status. The occupational therapist may complete the comprehensive assessment if the need for occupational therapy establishes program eligibility.

Interpretive Guidelines §484.55(b)(3)

For a therapy-only case, it is acceptable for a physical therapist or speech language pathologist to conduct and complete the comprehensive assessment at admission to the HHA. Occupational therapists may conduct and complete the assessment when the need for occupational therapy establishes program eligibility.

NOTE: Occupational therapy alone does not establish eligibility for the Medicare home health benefit at the start of care; however, occupational therapy services only may qualify for eligibility under other programs, such as Medicaid. Therefore, occupational therapists may not conduct the start of care comprehensive assessment under Medicare. In contrast, the Medicare home health patient receiving services of multiple disciplines, i.e., skilled nursing, physical therapy, and occupational therapy, during the episode of care, can retain eligibility if, over time, occupational therapy is the only remaining skilled discipline providing care. At that time, an occupational therapist can conduct OASIS assessments, i.e., resumption of care, follow-up, transfer, and discharge assessments.

For Medicare patients, at start of care, after the eligibility of the patient has been confirmed and the need for the qualifying service is established then the sequence of therapy services provided is irrelevant. Therefore, if physical, occupational and/or speech therapies are ordered, the order in which services are delivered is at the HHA's discretion based on the patient's plan of care. Since the need for occupational therapy alone does not constitute eligibility under Medicare, the HHA must provide the qualifying service, i.e., physical or speech therapy, prior to transfer or discharge.

A qualified therapist may conduct and complete the comprehensive assessment, and for Medicare patients confirm eligibility, including homebound verification, for the Medicare home health benefit. See the guidelines at [§484.55](#) for Medicare eligibility requirements.

For patients receiving services from multiple skilled disciplines, the comprehensive assessment, including OASIS items, may be completed by different disciplines such as a registered nurse, physical therapist or speech language pathologist at subsequent time points. The same discipline is not required to complete the comprehensive assessment at every required time point.

If an RN's entry into the case is known at start of care (i.e., nursing is scheduled, even if only for one skilled nurse visit), then the case is NOT considered to be therapy-only, and the RN must conduct the start of care comprehensive assessment. If the order for nursing is not known at start of care and originates from a verbal order after start of care, then the case is considered therapy-only at start of care, and the therapist can perform the start of care comprehensive assessment. Either discipline may perform subsequent comprehensive assessments.

In cases where state law and/or HHA policies require RNs to perform comprehensive assessments, even though therapy is the only service ordered, CMS does not require a physician's order for an RN to perform a comprehensive assessment within the RN's nursing scope of practice and licensing laws.

If local HHA policies and/or state regulations require an RN to perform the comprehensive assessments whenever they occur or are necessary, then the RN would need to perform all assessments for the home health patient, not just the start of care assessment. This would, of course, require close communication between the therapist and the RN to assure that the patient's condition and needs are assessed "as frequently as the patient's condition warrants" as required by [42 CFR 484.55\(d\)](#) Update of the comprehensive assessment. CMS does not consider this to be a multidiscipline case.

If it is the HHA's policy for the RN to perform a comprehensive assessment before the therapist's start of care visit, the nurse could perform a comprehensive assessment on or after the therapist's start of care date or the therapist could perform the start of care comprehensive assessment if this is a therapy only case. A comprehensive assessment performed BEFORE the start of care date (identified generally as being the first billable visit) cannot be entered into HAVEN (or HAVEN-like software).

Probes §484.55(b)(3)

Are the appropriate clinicians conducting the comprehensive assessments, i.e., RN, physical therapist, occupational therapist, speech-language pathologist? Check the signature of the clinician who completed the start of care assessment (only one clinician takes responsibility for an assessment, although more than one may collaborate.)

§484.55(c) Standard: Drug Regimen Review

The comprehensive assessment must include a review of all medications the patient is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy.

Interpretive Guidelines §484.55(c)

This requirement applies to **all** patients being serviced by the HHA, regardless of whether the specific requirements of OASIS apply. For patients to whom OASIS does not apply, the drug regimen review must be conducted in conjunction with the requirements at [42 CFR §484.18](#), Condition of Participation: Acceptance of patients, plan of care, and medical supervision.

The drug regimen review must include documentation of ALL medications the patient is taking. Review medications on the current physician plan of care and in clinical record notes to determine the accuracy of the medication regimen. This may be included as part of the case-mix, stratified sample of clinical records.

Determine if clinical record documentation includes medication review, etc. In therapy-only cases, determine the HHA's policy for medication review.

Drugs and treatments ordered by the patient's physician and not documented on the care plan should be recorded in the clinical record. This includes over-the-counter drugs. If the qualified clinician (RN or therapist) determines that the patient is experiencing problems with his/her medications or identifies any potential adverse effects and/or reactions, the physician must be alerted.

The label on the bottle of a prescription medication constitutes the pharmacist's transcription or documentation of the order. Such medications are noted in the patient's clinical record and listed on the physician plan of care. This is consistent with acceptable standards of practice. Federal regulations do not have additional requirements.

If questions are raised through interview or record review, examine the HHA's policies on drug review and actions.

Onsite Activity - Interview clinical staff, asking them to describe their process of drug regimen review including:

- How are potential adverse effects and drug reactions identified?

- What steps does the HHA require its personnel to take?
- What process is followed when a patient is found to be noncompliant?
- How is the drug regimen review completed if the patient is receiving only therapy services?
- How are drugs reviewed when medication orders are modified or changed after the start of care comprehensive assessment in multi-discipline cases and in therapy-only cases?

Probes §484.55(c)

What is the HHA's policy for drug regimen/medication review?

How does the HHA respond to medication discrepancies and prescriptions from physicians other than the physician responsible for the patient's home health care?

If HHA personnel identify patient sensitivity or other medication problems, what actions does the HHA require its personnel to take?

§484.55(d) Standard: Update of the comprehensive assessment.

G338

The comprehensive assessment must be updated and revised (including the administration of the OASIS) as frequently as the patient's condition warrants due to a major decline or improvement in the patient's health status, but not less frequently than:

Interpretive Guidelines §484.55(d)

The term "major decline or improvement in the patient's health status" is the impetus for collecting and reporting OASIS data in the following situations:

- As defined by the HHA (reason for assessment 5, other follow-up);
- To assess a patient on return from an inpatient facility, other than a hospital, if the patient was not discharged upon transfer (resumption of care); and
- As determined by CMS.

In the event an HHA determines that a patient's condition has improved or deteriorated beyond the HHA's expectations, the HHA may choose to collect and report additional assessment information. HHAs must code this as 'Other follow-up'. The start of care date does not change when an HHA conducts this optional assessment. The transfer

assessment should include required OASIS items as well as a clinical note describing the status of the patient on transfer to an inpatient facility.

The comprehensive assessment updates must include the appropriate OASIS data items as indicated on the current OASIS data set. The current OASIS data set is available on the CMS OASIS website at: <http://www.cms.hhs.gov/oasis/>

Probes §484.55(d)

When the HHA uses the “Other Follow-up” comprehensive assessment, how does it define a major decline or improvement that would require a new comprehensive assessment? Within the sample records reviewed, look for patients who have had a major decline or improvement in health status, as defined by the HHA. Determine if an OASIS assessment (reason for assessment 5, other follow-up) was completed.

G339

(1) The last 5 days of every 60 days beginning with the start-of-care date, unless there is a:

- (i) Beneficiary elected transfer;**
- (ii) Significant change in condition resulting in a new case-mix assignment; or**
- (iii) Discharge and return to the same HHA during the 60-day episode.**

Interpretive Guidelines §484.55(d)(1)

The follow-up comprehensive assessment is conducted by the qualified clinician to identify the patient’s current health status and continued need(s) for home health services. The follow-up comprehensive assessment must be performed within the last 5 days of the current 60-day certification period, i.e., between and including days 56-60.

In HHA’s that do not transmit any OASIS data for a month, verify that the HHA understands the transmission process and required comprehensive assessment time points. Review any validation reports the HHA has received from previous OASIS submissions to their respective State agency, i.e., OASIS initial feedback and final validation reports.

As part of the case-mix, stratified sample of clinical records, review patient records to determine that follow-up comprehensive assessments with OASIS data are conducted, collected, and completed within the required time frames.

When a Medicare beneficiary elects to transfer to a different HHA or is discharged and returns to the same HHA, it warrants a new clock for purposes of payment, OASIS assessment, and physician certification of the new plan of care.

A Significant Change In Condition (SCIC) adjustment occurs when a Medicare beneficiary experiences a significant change in condition during a 60-day episode that was not envisioned in the original plan of care. In order to receive a new case-mix assignment for purposes of SCIC payment during the 60-day episode, the HHA must complete an OASIS assessment and obtain the physician change orders reflecting the significant change in treatment approach in the patient's plan of care. Refer to current policy for use of the OASIS assessment for SCIC adjustments.

Probes §484.55(d)(1)

How does the HHA determine when the follow-up comprehensive assessment is due?
Ask clinical staff to describe their process.

Does the M0090 item (date assessment completed) fall within the time frame required for the follow-up comprehensive assessment?

How are follow-up comprehensive assessments completed if a skilled service is not projected at the time when the follow-up assessment is due? Are they incorporated into an aide supervisory visit, for example?

G340

(2) Within 48 hours of the patient's return to the home from a hospital admission of 24 hours or more for any reason other than diagnostic tests; or

Interpretive Guidelines §484.55(d)(2)

As part of the case-mix, stratified sample of clinical records, review patient records to determine if comprehensive assessments with OASIS data items integrated are collected at required time points. Evaluate the validity of any reasons why an assessment was not completed within the required time frame.

Updated comprehensive assessments are required:

- Within 48 hours of (or knowledge of) the patient's return home from a hospital stay of 24 hours or more for any reason except diagnostic tests (resumption of care OASIS data set); and
- Within 48 hours of (or knowledge of) the patient's return home from an inpatient stay (resumption of care OASIS data set).

Probes §484.55(d)(2)

Does the M0090 item (date assessment completed) fall within the time frame required for the resumption of care comprehensive assessment?

G341

(3) At discharge.

Interpretive Guidelines §484.55(d)(3)

Updated comprehensive assessments are required:

- Within 48 hours of (or knowledge of) transfer to any inpatient facility (transfer to an inpatient facility comprehensive assessment with OASIS data items integrated, with or without agency discharge); and
- Within 48 hours of (or knowledge of) discharge to the community or death at home (discharge OASIS assessment with OASIS data items integrated).

Review patient clinical records to determine if OASIS data are collected at the required time points for discharge. Discharge assessments are required.

Probes §484.55(d)(3)

How does the HHA readmit patients after transfer (“on hold” or “discharge”) and determine next assessment dates?

Interview HHA staff and review the HHA’s policy for inpatient facility admission. Does the HHA place the patient on hold or does the HHA discharge the patient for any inpatient facility admission?

Does the M0090 item (date assessment completed) fall within the time frame required for the transfer (with or without agency discharge, discharge to the community or death at home comprehensive assessment?)

What does the HHA do for unanticipated patient discharges?

§484.55(e) Standard: Incorporation of OASIS Data Items

G342

The OASIS data items determined by the Secretary must be incorporated into the HHA’s own assessment and must include: clinical record items, demographics and patient history, living arrangements, supportive assistance, sensory status, integumentary status, respiratory status, elimination status, neuro/emotional/behavioral status, activities of daily living, medications, equipment management, emergent care, and data items collected at inpatient facility admission or discharge only.

Interpretive Guidelines §484.55(e)

HHA's must incorporate the OASIS data items into their own assessment instrument using the exact language of the items, replacing similar items/questions on their existing assessment tool as opposed to simply adding the OASIS items at the beginning or end.

Review the HHA's comprehensive assessments to determine that required OASIS data items have been integrated into its comprehensive assessment tool. The comprehensive assessment forms (nursing or therapy) must include all required OASIS data items for each time point indicated. All comprehensive assessment forms, including those provided by vendors must be reviewed to ensure compliance with this standard. Appendix D of the OASIS Implementation Manual contains a checklist to assist HHA's in incorporating the appropriate OASIS items for each required assessment time point. Appending the OASIS data set to an HHA's existing assessment form is not appropriate. For private pay patients, OASIS items are not required to be collected; although all elements of the agency comprehensive assessment apply at all time points.

Initial Surveys and Recertification Surveys after an OASIS Modification - For new HHAs seeking initial certification, or the first HHA survey after the July 19, 1999, effective date, or the first HHA survey after a required change to the OASIS data set, randomly select approximately 8 OASIS items and compare them to the HHA's comprehensive assessment. Include items that have skip patterns and multiple responses. During recertification surveys after an OASIS modification, review data items that have been modified.

Probes §484.55(e)

Does the HHA have the required OASIS data items integrated into its comprehensive assessments, i.e., start of care, resumption of care, follow-up, transfer, discharge and death at home?

Is the OASIS data set appended at the beginning or end of the HHA's assessment form, rather than integrated into the HHA's own comprehensive assessment tool?