State Operations Manual
Appendix B - Guidance to Surveyors: Home Health Agencies

(Rev. 12, PUB Date here)

Part I – Investigative Procedures

I – Introduction –

- *A. Survey Team*
- *B. Surveyor Qualifications*
- *C. Unannounced Surveys*
- *D. Frequency of Surveys*

II – Types of Home Health Agency Surveys

- *A. Standard Survey*
- *B. Abbreviated Standard Survey*
- *C. Complaint Survey*
- *D. Partial – extended survey*
- *E. Extended Survey*
- *F. Initial Certification Survey*
- *G. Recertification Survey*

III – The Survey Tasks

- *Task 1 Pre-Survey Preparation*
- *Task 2 Entrance Interview*
- *Task 3 Information Gathering*
- *Task 4 Information Analysis*
- *Task 5 Exit Conference*
- *Task 6 Formation of the Statement of Deficiencies*

Part II – Interpretive Guidelines

Subpart A - General Provisions

§484.1 Basis and Scope

§484.2 Definitions

§484.4 Personnel Qualifications

Subpart B - Administration

§484.10 Condition of Participation: Patient Rights

§484.10(a) Standard: Notice of Rights

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

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

§484.10(d) Standard: Confidentiality of Medical Records

§484.10(e) Standard: Patient Liability for Payment

§484.10(f) Standard: Home Health Hotline

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

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

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

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

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

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

§484.14(a) Standard: Services Furnished

§484.14(b) Standard: Governing Body

§484.14(c) Standard: Administrator

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

§484.14(e) Standard: Personnel Policies

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

§484.14(g) Standard: Coordination of Patient Services

§484.14(h) Standard: Services Under Arrangement

§484.14(i) Standard: Institutional Planning

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

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

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

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

§484.14(j) Standard: Laboratory Services

§484.16 Condition of Participation: Group of Professional Personnel

§484.16(a) Standard: Advisory and Evaluation Function

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

§484.18(a) Standard: Plan of Care

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

§484.18(c) Standard: Conformance With Physician Orders

§484.20 Condition of Participation: Reporting OASIS Information

§484.20(a) Standard: Encoding OASIS Data

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

§484.20(c) Standard: Transmittal of OASIS Data

§484.20(d) Standard: Data Format

Subpart C - Furnishing of Services

§484.30 Condition of Participation: Skilled Nursing Services

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

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

§484.32 Condition of Participation: Therapy Services

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

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

§484.34 Condition of Participation: Medical Social Services

§484.36 Condition of Participation: Home Health Aide Services

§484.36(a) Standard: Home Health Aide Training

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

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

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

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

§484.36(b)(1) Standard: Applicability

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

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

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

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

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

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

§484.36(c)(1) Standard: Assignment

§484.36(c)(2) Standard: Duties

§484.36(d) Standard: Supervision

§484.36(d)(1)

§484.36(d)(2)

§484.36(d)(3)

§484.36(d)(4)

§484.36(d)(4)(i)

§484.36(d)(4)(ii)

§484.36(d)(4)(iii)

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

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

§484.48 Condition of Participation: Clinical Records

§484.48(a) Standard: Retention of Records

§484.48(b) Standard: Protection of Records

§484.52 Condition of Participation: Evaluation of the Agency's Program

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

§484.52(b) Standard: Clinical Record Review

§484.55 Condition of Participation: Comprehensive Assessment of Patients

§484.55(a) Standard: Initial Assessment Visit

§484.55(a)(1)

§484.55(a)(2)

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

§484.55(c) Standard: Drug Regimen Review

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

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

Part I – Investigative Procedures

I – Introduction

Home health agencies (HHAs) are required to meet the definition of an HHA in section 1861(o) of the Social Security Act (the Act) as well as be in compliance with the Federal requirements set forth in the Medicare Conditions of Participation (CoPs) in order to receive Medicare/Medicaid payment. The goal of the HHA survey is to determine if the agency is in compliance with the CoPs set forth at 42 CFR Part 484.

The survey and certification process provides a method to evaluate HHA compliance with the CoPs, ensuring that patient services provided meet minimum health and safety standards and a basic level of quality. The HHA survey process incorporates an approach that is patient-focused, outcome-oriented, and data-driven, making it more effective and efficient in assessing, monitoring, and evaluating the quality of care delivered by an HHA. Through the survey process, the SA needs to determine if the HHA has the ability to deliver needed patient services and, most importantly, if the delivery of those services impacts the quality of care and results in positive patient outcomes.

The purpose of the survey protocols and interpretive guidelines is to direct the surveyor's attention to avenues of investigation in preparation for the survey, conducting the survey, and evaluating the survey findings.

Surveyors conduct the HHA survey in accordance with the appropriate protocols, which are intended to promote consistency in the survey process. Surveyors should base any deficiency on a violation of the statute or regulations, which, in turn, is to be based on clinical record reviews, interviews with the HHA's patients and staff, and observations of the HHA's performance and practices. (See §2712.)

Surveyors gather information during the entrance interview, HHA patient and staff interviews, home visit observations, and clinical record reviews. Since they gather information from staff interviews as a data source, and focus on those areas of HHA functioning that are most related to the delivery of high-quality patient care, surveyors are able to minimize the review of non-clinical record documentation. During their pre-survey preparation, surveyors also use information available from agency level reports derived from the Outcome and Assessment Information Set (OASIS) data to select HHA patients and records for survey and to increase focus on clinical outcomes in preparing for the survey. This is further outlined in Task One of the Survey Tasks.

Survey Team

The State survey agency (SA), or the CMS Regional Office (RO) for Federal teams, decides the size of the team. Each home health survey team should include at least one RN with home health survey experience. Other surveyors who have the expertise to determine whether the HHA is in compliance may be used as needed.

Surveyor Qualifications

HHA surveyors should have the necessary training and experience to conduct an HHA survey. Each individual on a survey team must meet certain minimum CMS qualifications. Surveyor minimum qualifications are found at §488.735. Before any surveyor can serve on an HHA survey team (except as a trainee), he/she must

successfully complete the relevant CMS-sponsored Basic HHA Surveyor Training Course and any associated course prerequisites. Individuals who have not completed the course but are currently in training may accompany the survey team in an observational role only, as part of their training prior to completing the CMS Basic HHA Surveyor Training Course.

Section 488.735(b) describes the circumstances that would disqualify a surveyor from surveying a particular HHA. A surveyor will be prohibited from surveying an HHA when:

(1) The surveyor currently works for, or, within the past two years, has worked with the HHA to be surveyed as:

(i) A direct employee;

(ii) An employment agency staff at the agency; or

(iii) An officer, consultant, or agent for the agency to be surveyed concerning compliance with conditions of participation specified in or pursuant to sections 1861(o) or 1891(a) of the Act.

(2) The surveyor has a financial interest or an ownership interest in the HHA to be surveyed.

(3) The surveyor has a family member who has a relationship with the HHA to be surveyed.

(4) The surveyor has an immediate family member who is a patient of the HHA to be surveyed.

Unannounced surveys

All HHA surveys must be unannounced and conducted with procedures and scheduling that render the onsite surveys as unpredictable in their timing as possible. SAs make every effort to lessen the predictability of a survey occurring at a specific time, day, or month. CMS reviews state scheduling and survey procedures to ensure that the agency has taken all reasonable steps to avoid giving advance notice to HHAs of impending surveys through these procedures. Any individual who notifies (or causes to be notified) an HHA of the time or date of the standard survey is subject to a civil money penalty not to exceed $2,000 under section 1891(c)(1) of the Act and §488.725.

Frequency of HHA Surveys

In addition to the standard survey conducted at the HHA's initial application for Medicare certification and at its periodic recertification, section 1891(c)(2)(B)(ii)of the Act provides that a standard survey, or abbreviated standard survey, must be conducted of an HHA within 2 months of when a significant number of complaints against the HHA are reported to CMS, the State, the State or local agency responsible for maintaining a toll-free hotline and investigative unit, or any other appropriate Federal, State, or local agency, or as otherwise required to determine compliance with the conditions of participation, such as the investigation of a complaint. See also §488.730.

Section 1891(c)(2)(B(i) provides that a standard survey or an abbreviated standard survey may be conducted at the discretion of CMS or the State within 2 months of a change, or knowledge of a change, of the ownership, administration, or management of

the HHA to determine whether the change has resulted in any decline in the quality of care furnished by the HHA.

Neither CMS nor the Medicare Administrative Contractor (MAC) requires a survey when a new service is added to a Medicare-certified HHA. Rather, the SA directs the HHA to notify the MAC about the added service. Review the new service at the next scheduled survey, unless a complaint is received about the HHA or there are concerns about the ability of the HHA to provide the new service(s).

An HHA may also be subject to a partial extended or extended survey at the discretion of CMS or the State. The specific types of HHA surveys are discussed below.

II - Types of Home Health Surveys

HHAs are subject to the following unannounced surveys:

A. Standard Survey

The standard survey is a survey in which the surveyor reviews the HHA's compliance with a select number of standards and/or conditions of participation in order to determine the quality of care and services furnished by an HHA as measured by indicators related to medical, nursing, and rehabilitative care. This survey is required of all HHAs under section 1891(c)(2)(C)(i)(II) of the Act and §488.710.

During the standard survey, the surveyor reviews, to the extent practicable, a case-mix stratified sample of individuals to whom the HHA furnishes services. The survey includes visits to the homes of sampled patients who have given their consent, either directly or through their guardian or legal representative. The purpose of the home visit is to evaluate the extent to which the quality and scope of services furnished by the HHA has attained and maintained the highest practicable functional capacity of each patient, as reflected in the patient's written plan of care and clinical records. Other forms of communication with patients, such as through telephone calls, could also be used to complete the survey, in addition to home visits, if determined necessary by the SA or CMS.

During the standard survey, the surveyor reviews the HHA's compliance with a select number of regulations (standards) most related to high-quality patient care. These highest priority standards are called Level 1 standards, and cover 9 of the 15 total CoPs for HHAs (see table below for the specific standards reviewed during the standard survey and partial extended survey). These standards include both process standards and administrative standards most closely related to the agency's ability to deliver high-quality patient care. Compliance with these Level 1 highest priority standards is highly likely to affect care delivery and patient outcomes.

When standard-level deficiencies are found during the standard survey and it is suspected that a more comprehensive review of the CoPs examined under the standard survey would determine condition-level rather than standard-level deficiencies or to

determine if standard or condition-level deficiencies are present in the CoPs not examined in the standard survey, the standard survey is expanded to a partial extended survey. The partial extended survey reviews Level 2 standards which are additional standards that are considered the next highest priority standards See Table below for a listing of the Level 1 (highest priority) standards which must be reviewed in the standard survey and the Level II (next highest) priority standards which are reviewed during the partial extended survey.

Level 1 and Level 2 Standards

Condition	***Level 1 (Highest Priority Standards)*** *(Standard Survey)*	***Level 2 (Next Highest Priority Standards)****(Partial Extended Survey)*
484.10 Patient Rights	*G107, G109*	*G101, G108, G111, G114*
484.12 Compliance with Federal, State and Local Laws	*G121*	*G118*
484.14 Organization, Services and Administration	*G123, G133, G143, G144*	*G124, G125, G137, G138, G139, G150*
484.18 Acceptance of Patients, Plan of Care, Medical Supervision	*G157, G158, G159, G164, G165, G166*	*G160, G162, G163*
484.30 Skilled Nursing Services	*G170, G172, G173, G174, G175, G176, G177*	*G169, G179*
484.32 Therapy Services	*G186, G187, G188*	*G190, G193*
484.36 Home Health Aide Services	*G224, G229*	*G212, G215, G225, G226, G230, G232*
484.48 Clinical Records	*G236*	*G239*
484.55 Comprehensive Assessment of Patients	*G331, G332, G334, G335, G336, G337, G338, G340*	*G339, G341*

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

The abbreviated standard survey focuses on particular tasks that relate, for example, to complaints received, or a change of ownership, or management. It does not cover all the aspects reviewed in the standard survey, but rather concentrates on a particular area or areas of concern. The surveyor may investigate any area of concern and make a compliance decision regarding any regulatory requirement, whether or not it is related to the original purpose of the survey or complaint. The abbreviated standard survey can be

expanded and changed to a standard, partial extended or extended survey when necessary.

C. Complaint survey

The complaint survey is a survey that is conducted to investigate specific allegations of noncompliance. The complaint survey is an example of an abbreviated standard survey.

D. Partial Extended Survey

The partial extended survey is a survey conducted to determine if deficiencies and/or deficient practice(s) exist that were not fully examined during the standard survey. It is conducted when standard-level noncompliance is identified in a Level 1 standard or if a surveyor believes that a deficient practice exists at a standard or condition-level that was not examined during the standard survey. The standard survey is then immediately expanded to become a partial extended survey.

During the partial extended survey, the surveyor reviews, at a minimum, the Level 2 Next Highest Priority standards under the same condition of participation for which the Level 1 standard(s) were determined to be out of compliance. The surveyors may review any additional standards under the same or related conditions which would assist them in making a compliance decision. See Table above for a listing of the Level 2 standards reviewed in the partial extended survey.

E. Extended Survey

Extended survey means a survey that reviews additional conditions of participation not examined during a standard survey. It may be conducted at any time but must be conducted when substandard care is identified. Substandard care means noncompliance with one or more conditions of participation(i.e, at the condition-level) that are identified on a standard survey, including deficiencies which could result in actual or potential harm to patients of an HHA.

The extended survey may review all conditions of participation or a focused number of conditions that were not examined in the standard survey. At a minimum, the surveyor should investigate the HHA's compliance with any other conditions of participation that are related to the condition(s) found to be out of compliance (regardless of the level of seriousness). See chart below for the related conditions that should be investigated, at a minimum, when a particular condition of participation is cited:

Condition Cited	***Related Conditions for Further Investigation***
484.10 Patient Rights	*CoP 484.12: Compliance with Federal, State & Local Laws* *CoP 484.14: Organization, Services & Administration* *CoP 484.18: Acceptance of Patients, Plan of Care, & Medical Supervision*
484.12 Compliance with Federal, State & Local Laws, Disclosure & Ownership Information, & Accepted Professional Standards & Principles	*CoP 484.14: Organization, Services & Administration* *CoP 484.18: Acceptance of Patients, Plan of Care, & Medical Supervision* *CoP 484.30: Skilled Nursing Services* *CoP 484.32: Therapy Services* *CoP 484.34: Medical Social Services* *CoP 484.36: Home Health Aide Services* *CoP 484.48: Clinical Records* *CoP 484.55: Comprehensive Assessment of Patients*
484.14 Organization, Services, & Administration	*CoP 484.12: Compliance with Federal, State & Local Laws* *CoP 484.18: Acceptance of Patients, Plan of Care, & Medical Supervision* *CoP 484.30: Skilled Nursing Services* *CoP 484.32: Therapy Services* *CoP 484.34: Medical Social Services* *CoP 484.36: Home Health Aide Services* *CoP 484.48: Clinical Records* *CoP 484.52: Evaluation of Agency's Program* *CoP 484.55: Comprehensive Assessment of Patients*
484.18 Acceptance of Patients, Plan of Care, & Medical Supervision	*CoP 484.12: Compliance with Federal, State & Local Laws* *CoP 484.14: Organization, Services and Administration* *CoP 484.30: Skilled Nursing Services* *CoP 484.32: Therapy Services* *CoP 484.34: Medical Social Services* *CoP 484.36: Home Health Aide Services* *CoP 484.48: Clinical Records* *CoP 484.52: Evaluation of Agency's Program* *CoP 484.55: Comprehensive Assessment of Patients*

Condition Cited	***Related Conditions for Further Investigation***
484.30 *Skilled Nursing Services*	*CoP 484.12: Compliance with Federal, State & Local Laws* *CoP 484.14: Organization, Services and Administration* *CoP 484.20: Reporting OASIS Information* *CoP 484.32: Therapy Services* *CoP 484.34: Medical Social Services* *CoP 484.36: Home Health Aide Services* *CoP 484.48: Clinical Records* *CoP 484.52: Evaluation of Agency's Program* *CoP 484.55: Comprehensive Assessment of Patients*
484.32 *Therapy Services*	*CoP 484.12: Compliance with Federal, State & Local Laws* *CoP 484.14: Organization, Services and Administration* *CoP 484.30: Skilled Nursing Services* *CoP 484.34: Medical Social Services* *CoP 484.36: Home Health Aide Services* *CoP 484.48: Clinical Records* *CoP 484.52: Evaluation of Agency's Program* *CoP 484.55: Comprehensive Assessment of Patients*
484.36 *Home Health Aide Services*	*CoP 484.12: Compliance with Federal, State & Local Laws* *CoP 484.14: Organization, Services and Administration* *CoP 484.30: Skilled Nursing Services* *CoP 484.32: Therapy services* *CoP 484.48: Clinical Records* *CoP 484.52: Evaluation of Agency's Program* *CoP 484.55: Comprehensive Assessment of Patients*
484.48 *Clinical Records*	*CoP 484.12: Compliance with Federal, State & Local Laws* *CoP 484.14: Organization, Services and Administration* *CoP 484.20: Reporting OASIS Information* *CoP 484.30: Skilled Nursing Services* *CoP 484.32: Therapy services* *CoP 484.34: Medical Social Services* *CoP 484.36: Home Health Aide* *CoP 484.52: Evaluation of Agency's Program* *CoP 484.55: Comprehensive Assessment of Patients*
484.55 *Comprehensive Assessment of Patients*	*Related Conditions for Further Investigation:* *CoP 484.12: Compliance with Federal, State & Local Laws* *CoP 484.14: Organization, Services and Administration* *CoP 484.20 Reporting OASIS Information* *CoP 484.30: Skilled Nursing Services* *CoP 484.32: Therapy services* *CoP 484.48: Clinical records* *CoP 484.52: Evaluation of Agency's Program*

Whether the extended survey examines all, or a focused number, of the conditions of participation not examined during the standard survey is determined on the basis of the nature and extent of serious risk to patients that is identified in the survey.

Under section 1891(c)(2)(D) of the Act, each home health agency that has been found during a standard survey to have provided substandard care shall be subject to an extended survey to review and identify the policies and procedures which produced this substandard care and to determine if the agency is in compliance with the conditions of participation. The extended survey must be conducted not later than 14 calendar days after completion of a standard survey which found the HHA out of compliance with a condition of participation.

F Initial Certification Survey of Prospective HHA Providers

The initial certification survey of a prospective HHA provider seeking to participate in the Medicare program begins (and may end) as a standard survey. As noted above, all standard surveys can be converted to partial extended and extended surveys as appropriate. See guidelines above for standard, partial extended and extended surveys. The SA conducts a standard survey during the initial Medicare certification of an HHA. (see SOM, section 2202.10B) The AO will conduct an extended survey during the initial Medicare certification of an HHA in accordance with the requirements oat 1865 of the Act. Before the initial certification survey, the SA must have received written documentation submitted by the prospective HHA requesting an initial certification survey and MAC initial approval of the 855A application for enrollment. At the time of the certification survey, the prospective HHA must:

1. *Be operational;*
2. *Meet the capitalization requirements;*
3. *Be providing nursing and at least one other therapeutic service (physical therapy, speech language pathology, occupational therapy, medical social services or home health aide) - See §484.14(a);*
4. *Be capable of demonstrating the operational capability of all facets of its operation;*
5. *Have successfully completed an OASIS transmission to the State repository;*
6. *Have provided care to a minimum of 10 patients requiring skilled care (not required to be Medicare patients) that is consistent with the conditions of participation. At least 7 of the 10 required patients should be receiving skilled care from the HHA at the time of the initial Medicare survey. If this is not the case, contact the CMS RO. If the HHA is located in a medically underserved area, as determined by the CMS RO, the CMS RO may reduce the minimum number of patients from 10 to 5. In such situations, at least 2 of the 5 required patients should be receiving skilled care from the HHA at the time of the initial Medicare survey; and*
7. *Have submitted a complete Form CMS-855A to the MAC.*

The MAC will verify the information on the Form CMS-855A enrollment application and provide the SA and RO with written notification, via a recommendation of approval, that the initial certification survey to determine compliance with the conditions of

participation may be conducted. The SA or AO completes the initial survey and makes a recommendation to the RO for certification if the survey has been successful.

The RO reviews the SA or AO recommendation for initial certification, and if it concurs, the RO notifies the MAC via e-mail that the initial survey has been completed, the HHA is in compliance with the conditions of participation and that the RO is awaiting notification from the MAC of the results of its re-review before the certification is processed.

The RO will hold the issuance of a CCN and provider agreement until the MAC has re-reviewed certain Medicare enrollment requirements (e.g., site visit verification, capitalization requirements and Medicare exclusion checks). Criteria for a successful site visit includes a determination that the facility is open and operational, staffed with personnel, and, if applicable, serving customers. If the provider/supplier does not pass the site visit, the contractor must deny its enrollment.

The MAC will conduct its re-review and notify the RO of the results via e-mail. If the re-review indicates that the prospective HHA remains in compliance with all enrollment criteria and the RO concurs, the RO will issue the CCN and the provider agreement and forward a Form CMS-2007 to the MAC with the effective date of participation being the date on which the HHA was determined to be in compliance with the conditions of participation.

If, however, the MAC re-review determines that the prospective HHA is no longer in compliance with the enrollment requirements, the MAC will deny enrollment and notify the prospective HHA of this by letter with a copy sent to the RO. Upon receipt of this recommendation of denial of enrollment, the RO will then issue an initial certification denial letter to the HHA explaining that certification has not been granted due to the HHA's failure to meet the enrollment requirements as described in the MAC letter. The basis for denial contained within the RO denial letter should be §424.530(a)(1). The associated appeal rights will be provided by the MAC through the provider enrollment process to the prospective HHA. The letter should include standard appeals language from the Program Integrity Manual, Chapter 15, Section 15.24.11.

G. Recertification

Once initially certified to participate as an HHA in the Medicare program, all HHAs are subject to periodic recertifications. Under section 1891(c)(2)(A) of the Act, an HHA is subject to an unannounced SA standard survey no later than 36 months from the previous standard survey. These recertification surveys begin (and may end) as a standard survey, but may be converted to a partial extended or extended surveys as appropriate. See guidelines above for standard, partial extended and extended surveys. Under 1865 of the Act, an HHA accredited by AO's approved program is subject to an unannounced AO survey no later than 36 months from the previous extended survey. Each State must follow CMS's instructions for survey frequency within this 36-month interval commensurate with the need to assure the delivery of quality home health services. HHA branch locations should be included in the unannounced standard survey of a parent

HHA. When the recertification standard survey is performed at a branch location of an HHA, or when deficiencies are found at a branch of an HHA, the survey findings apply to the entire HHA. Routinely conduct the recertification survey at a branch location when that location serves more patients than the parent. Include a sample of clinical records from all branches in the record review selection and make every attempt to visit all branch locations during the survey.

III – The Survey Tasks

The outcome-oriented survey process for HHAs involves the following six steps:

- *Task 1 - Pre-Survey Preparation*
- *Task 2 - Entrance Interview*
- *Task 3 - Information Gathering*
- *Task 4 - Information Analysis*
- *Task 5 - Exit Conference*
- *Task 6 - Formation of the Statement of Deficiencies*

Task 1 - Pre-Survey Preparation

Prior to each survey, review the HHA file (or application, in the case of an initial) in accordance with SOM Ch. 2, §2704. Follow §2710, Reviewing Forms at the Beginning of a Survey. In addition, review any disclosure of information statements (Form CMS-1513), complaint data, previous survey data, and reports generated from the OASIS data. These reports contain valuable information that may assist in identifying areas of concern during the survey and possibly identify individuals to be included in the sample selection. Ask the OASIS Educational Coordinator or the OASIS Automation Coordinator for pertinent information regarding compliance with the OASIS CoPs that can be monitored offsite. Available OASIS reports can be generated for specific time periods (e.g., case-mix, potentially avoidable event, risk adjusted Outcome-based Quality Improvement (OBQI) reports, or process measure reports).

Use the worksheet in Exhibit 285 *to conduct a review of the following five OASIS reports:*

- *Potentially Avoidable Events Report and Patient Listing Report*
- *OBQI Outcome Report (risk adjusted outcome report)*
- *Patient/Agency Characteristics report (case-mix report)*
- *Submission Statistics by Agency Report*
- *Error Summary Report by HHA*

Outcome-based Quality Monitoring (OBQM) Potentially Avoidable Events Report and Patient Listing

As part of the pre-survey process, review the most recent quarter (3 months) or whatever time period is necessary to reach at least 60 patients.

Tier 1 Potentially Avoidable Events

The threshold for each Tier 1 potentially avoidable event is one patient. Therefore, the surveyor must—

a. Identify if any agency patients experienced either of the 2 Tier 1 potentially avoidable events:

- *Emergent care for injury caused by a fall at home; or*
- *Emergent care for wound infections, deteriorating wound status.*

b. During the onsite survey, select patient records and home visits that focus on either (or both) potentially avoidable events identified on the report.

Tier 2 Potentially Avoidable Event Outcomes and Patient Listing

There are six Tier 2 Potentially Avoidable Event outcomes for consideration. The following thresholds must be met for a potentially avoidable event in Tier 2 to become a focus area:

a. *There must be patients who experienced the event; and*
b. *The HHA's current incidence rate must be equal to or greater than twice the reference rate.*

During the onsite survey, select patient records and home visits that focus on the outcomes identified on the report that met the investigation thresholds of equal to or greater than twice the reference value. In addition to providing areas for focus during the onsite survey, the Potentially Avoidable Event Patient Listing Report provides surveyors the opportunity of selecting closed records of specific patients under those outcomes meeting the investigation criteria.

If, after working through the Tier 2 Potentially Avoidable Event outcomes, none of the outcome rates are greater than or equal to twice the reference rate, surveyors may optionally focus on other potentially avoidable events (not listed on the Pre Survey Outcome Worksheet, exhibit 285) with incidence rates equal to or greater than twice the reference rate.

OBQI Outcome Report

As part of the pre-survey process, using the Pre-Survey Worksheet as a guide, review the HHA's most recent Risk-adjusted Outcome Report for those outcomes listed on the Worksheet and choose (if possible) two outcomes for focus during the onsite survey that have:

- *At least 30 eligible cases;*
- *A large and unfavorable magnitude of difference between the HHA's and the national reference rates (specific thresholds are described for each of the target outcomes on the Worksheet); and*
- *Statistical significance equal to or less than 0.10 (as depicted by one or two asterisks).*

To calculate the percentage point difference between the agency and the reference outcomes, compare the reference percentage point value (found at the end of the "reference" bar) and the agency percentage point value (found at the end of the "current" bar). When looking at "Acute Care Hospitalization," determine if the HHA's outcome is at least 10 percentage points higher than the reference value. When looking at the remaining nine outcomes on the worksheet, evaluate whether the agency's outcome is lower than the reference outcome by an amount equal to or greater than the listed threshold.

During the onsite survey, select patient records and home visits that focus on the outcomes identified on the OBQI report meeting the individual investigation thresholds.

If none of the 10 listed outcomes on the Worksheet trigger the selection criteria, another outcome should be selected from the OBQI report that is not on the Worksheet but meets the selection criteria. If there are no statistically significant outcomes that meet the selection criteria, the survey will not focus on an OBQI Outcome.

Patient/Agency Characteristics Report

The Patient/Agency Characteristics report identifies the HHA patient population trends to investigate during the onsite survey. As part of the pre-survey process:

- *Use the Patient/Agency Characteristics report for the same timeframe as the OBQI Outcome Report;*
- *Focus on acute conditions and home care diagnoses that are statistically significant and are equal to or greater than 15 percentage points higher than the reference rate;*
- *Choose up to three conditions or diagnoses that meet the criteria; and*
- *Select one or two records of patients with diagnoses that meet the criteria for review with or without home visits.*

If no conditions or diagnoses trigger the investigation criteria, this will not be an area of focus during the survey.

Submission Statistics by Agency Report

As part of the pre-survey process, determine whether the HHA:

- *Is submitting data less often than monthly; and/or*
- *Has greater than 20 percent of records rejected in accordance with Worksheet instructions.*

If either probe is triggered, investigate compliance with the OASIS transmission requirements (§ 484.20, Reporting OASIS Information) during the onsite survey through the partial extended survey process.

Error Summary Report by HHA

As part of the pre-survey process, focus on the errors listed on the ***Pre-Survey Process and Sample Selection Worksheet for OBQM & OBQI Reports -***

- *Error 262, Inconsistent M0090 date – M0090 is the date the assessment is completed. The recertification assessment must be done on an every 60-day cycle. Investigate if the HHA's percent of assessments with the error is at or above 20 percent.*
- *Error 1003, Inconsistent effective date sequence – This error warns the HHA that the effective date of the assessment it just submitted was earlier than the most current assessment received. Investigate further if the HHA's percent of assessments with this error is at or above 10 percent; and*
- *Error 1002, Inconsistent record sequence – This error warns the HHA that the assessment it just submitted does not logically follow the previous one submitted and may indicate the HHA has missed submitting a record. Investigate further if the HHA's percent of assessments with this error is at or above 10 percent.*

Note whether the error appears on the report ***and*** *meets or exceeds the identified thresholds by checking "Y" or "N" on the Worksheet.*

If any of the errors listed on this Worksheet meet the investigation thresholds, further investigate compliance with the applicable OASIS reporting requirements (§ 484.20, Reporting OASIS Information) during the onsite survey through the partial extended survey process.

SAs must not cite any deficiency for an HHA's failure to include the OASIS data set as part of the patient-specific, comprehensive assessment for non-Medicare non-Medicaid patients as required by §484.55.

Task 2 - Entrance Interview

The entrance interview, which sets the tone for the entire survey, is the critical first stage of the onsite survey process. The surveyor must establish rapport with the HHA staff and establish his or her authority as the leader of the survey. Be aware that the unannounced survey may be disruptive to the normal daily activities of the HHA.

Upon arrival at the HHA, complete the following activities.

- *Inform the HHA administrator, director, or supervisor of the purpose of the survey.*
- *Present identification and introduce the survey team members.*
- *Explain the survey process and estimate the number of days onsite.*
- *Discuss the extent to which the HHA staff may be involved during the survey.*
- *Request verbal explanation of organizational structure, lines of authority, delegation of responsibility, and services furnished (both directly and under arrangement) and the HHA's relationship to any corporate structure.*
- *Ask if the HHA is operating any additional locations, including branches.*
- *Request a meeting with appropriate staff based on the organizational characteristics of the HHA. Request a copy of the organization chart, if available.*

- *Ask for the number of unduplicated patients admitted receiving skilled services during a recent 12-month period.*
- *Ask for a list or access to names of patients scheduled for a home visit during the survey. Include all branch locations.*
- *Ask for a list of current (direct and contracted) employees (including name and title).*
- *Request the names of key staff (i.e., staff persons most knowledgeable about the home health aides, in-service training, clinical supervision) and the clinical staff person who will be the primary resource to respond to the surveyor's questions.*
- *Verify the process to follow in order to have unrestricted access to the clinical records.*
- *Request access to all active patient names (Medicare/Medicaid/private pay) receiving skilled services that identifies the start of care (SOC) date, primary diagnosis, and services provided. This will aid in selecting the sample for home visits with record review based on the review of the OBQM and OBQI reports.*
- *Request specific closed records for review from the agency's Potentially Avoidable Event Patient Listing report.*
- *Set up the schedules for any necessary interviews with staff.*
- *Request space to work after the completion of the entrance interview.*

During this entrance interview, begin to gather information from the HHA about its compliance with the Level 1 standards. For example:

- *Ask how complaints are investigated and how the existence, investigation and resolution are documented. Request and review a copy of the HHA documentation of complaint investigation and resolution.*
- *Review patient admission packet for instructions for making a complaint.*
- *Ask how the HHA ensures that all clinical staff members (direct and contractual) follow professional practice standards, laws, HHA policies and procedures.*
- *Ask how the HHA monitors the professional skills of its staff to determine if those skills are appropriate and adequate for the agency's patients (e.g., competency testing, supervisory visits, skills labs, etc.).*
- *Ask if there are any services that the agency sometimes has trouble staffing, and if so, what they do when a patient needing those services is referred.*
- *Ask administrative staff if the HHA has a policy regarding how quickly an order for therapy, medical social worker or an aide will be staffed.*
- *Ask how the HHA staffs RNs and LPNs. If HHA relies primarily on LPNs for most visits, how does HHA ensure that RNs supervise and manage each case?*
- *Ask how the HHA staffs therapists and therapy assistants.*
- *How does the HHA ensure that qualified therapists supervise and manage their patients?*
- *Ask if aides are direct employees of the HHA or provided by arrangement.*
- *Ask what the HHA's system is for tracking aide supervisory visits.*
- *Ask if the HHA accepts electronic signatures by either clinicians or physicians, and what the related policies allow.*

- *Ask how the clinical records are maintained (i.e., all electronic, all paper, or combination), stored, and accessed. How is confidentiality of records maintained out of the office?*
- *Ask what time frame is allowed for clinicians to turn in documentation following a visit. If there is a stated/published policy, is there a monitoring system present? What are results of internal monitoring?*
- *Ask what the HHA's time frame is for documents to be filed in patient record.*
- *Ask where clinicians document aide supervisory visits, case conferences, phone calls, medications, etc.*
- *Ask what the HHA's policy is for making corrections in the clinical record.*
- *Ask what the HHA's policies are for conducting the initial and comprehensive assessments (including whether therapists complete these assessments).*
- *Ask how the HHA ensures that initial assessments are conducted within the required time frame.*
- *If problems with OASIS data submission are evident in the reports reviewed pre-survey, ask the administrative staff to address those issues.*

Arrange a time with clinical managers to ask them the following questions:

- *Describe the HHA's process of drug regimen review, including how this is accomplished when a therapist completes the comprehensive assessment.*
- *How does the HHA address medication discrepancies (e.g., medications in the home differ from orders received) or patient non-compliance?*
- *How does the HHA respond to prescriptions from physicians other than the physician responsible for the patient's home health care?*
- *How does the HHA determine when there has been a "major decline or improvement in the patient's health status" that would warrant an update of the comprehensive assessment?*
- *How does the HHA track due dates for updating the comprehensive assessments?*

Task 3 - Information Gathering

The information-gathering task is an organized, systematic, and consistent process designed to enable surveyors to make decisions concerning the HHA's compliance with the CoPs. During the standard survey, activities focus on Level 1 standards unless problems are found. ***Surveyors gather critical information by focusing on home visits, observations, interviews, and clinical record reviews.*** *Non-clinical record materials are not reviewed unless problems are identified through HHA staff interviews, patient/caregiver interviews, home visits, and clinical record reviews. If problems are found with Level 1 standards, surveyors move to a partial extended survey and evaluate Level 2 standards as necessary. If concerns arise during interview, record reviews or home visits, it may be necessary to include a review of additional material as needed, such as personnel records, contracts, policies and procedures, clinical/procedural references, documentation of home health aide training and/or competency evaluation, documentation of complaint investigation and resolution, CLIA waiver, and/or other materials.*

During the standard survey and partial extended surveys, the surveyor's focus is on the Level 1 and Level 2 standards.

Probes for Interviewing Clinical Managers

- *How do clinical managers ensure that physician orders, agency policies, and regulations are being followed in delivering care to each patient (including obtaining interim orders and getting physician signatures)? How are prescriptions from other physicians seeing the patient handled?*
- *How are clinicians (all services) assigned to cases, including case managers?*
- *How are clinicians and aides instructed to maintain clinical record confidentiality outside the office? What is the time frame for submitting completed documentation? How are errors identified and corrected?*
- *How do clinicians ensure that initial assessments are conducted within the required time frame and that all assessments are comprehensive?*
- *Who completes the drug regimen review? How is it documented for therapy-only cases? At follow-up and discharge time points?*
- *How do clinicians determine when there has been a "major decline or improvement in the patient's health status" that would warrant an update of the comprehensive assessment? How does the HHA track due dates for updating the comprehensive assessments?*
- *Where in the clinical records should surveyors find documentation of aide supervisory visits, case conferences, phone calls, medications, wound care and wound measurements, etc?*
- *What resources are available to nurses and therapists for care problems and how do they access the resources when the need is identified?*
- *Who documents patient care instructions for aides and where are the instructions filed? Is a copy left in patient's home?*
- *Who determines whether an aide needs in-home demonstration or instruction in a care procedure? Who does the aide call with patient-specific questions?*

Probes for interviewing case managers and clinical staff members

- *How do clinicians involve patients and their caregivers in planning care?*
- *How do case managers and other clinicians communicate necessary information about patient condition, response to interventions and teaching, changes in the plan of care, and discharge planning to the patient/caregivers? How is this same information shared among the appropriate care providers (including physicians and aides)?*
- *Is the clinical staff member knowledgeable about where to turn for help with difficult clinical problems? Has he/she sought help regarding a specific issue noted on home visit or record review? What response was received?*
- *How do clinicians ensure the safety and confidentiality of patient records when transported for use during home visits?*

- *Is clinician knowledgeable about the correct way to make a correction in a clinical record?*
- *What actions are taken when the medication(s) in the home differs from orders received or when patients are non-compliant with medications, diet or treatments?*
- *How do you handle prescriptions from physicians other than the physician responsible for the patient's home health care?*

Clinical Records

The minimum number of clinical records of patients to be reviewed during the HHA survey will be the sum of the number of clinical records without home visits and the number of clinical records with home visits. More clinical records may be reviewed and more home visits may be made if necessary to assess compliance with the CoPs. See chart below.

Unduplicated Skilled Admissions in Recent 12 months.	*Min # of Record Reviews With No Home Visit*	*Min # of Record Reviews With Home Visit*	*Total Record Reviews*
< 150	*5*	*5*	*10*
150-750	*6*	*6*	*12*
751-1250	*8*	*8*	*16*
1251 or more	*10*	*10*	*20*

Clinical Record and Home Visit Selection for Standard Survey

The surveyor selects, to the extent practical, a case-mix, stratified sample of clinical records of patients who have received or who are currently receiving interventions and skilled therapeutic services by the HHA under a plan of care. "Stratified' means patients selected are grouped (stratified) based on the primary admitting diagnosis for which the patient is receiving care and treatment from the HHA. "Case-mix" means that the sample includes patients receiving different services from different HHA caregivers (nurse, therapist, social worker, home health aide).

For example, a patient who is admitted to the HHA for treatment of a surgical wound is considered in a different stratum from the patient recuperating from a cerebrovascular accident. Since HHAs treat patients with a wide range of medical conditions, the review is to encompass patients with varying needs and services. The surveyor may also select some patients for review based on OASIS reports reviewed during pre-survey preparation. The OASIS reports only represent Medicare and Medicaid skilled patients. The sample selected for record review with home visits and record review without home visits should include patients from all payment sources. The patients selected through the use of the OBQM and OBQI reports should not replace the entire stratified sample. Additional current patients should be selected for record review with home visits and record review without home visits.

Use the approximate number of unduplicated admissions from all payer sources for skilled services to the HHA (including branches) during the recent 12 months prior to the survey to determine both the number of clinical record reviews with home visits and the

number of clinical record reviews without home visits. Include records from branches in your selection of clinical records.

Use the HHA's current visit schedule (or plans for visits) during the survey week to select the sample for clinical record review with home visits. The sample for clinical record review without home visits may include closed records. The surveyor works with HHA staff to develop, as simply as possible and in the shortest period of time, a survey sample that meets, in its entirety, the following criteria:

- *The sample includes a range of primary admitting diagnoses (stratification); and*
- *The sample represents patients who are receiving various kinds of services (case-mix).*

Selecting a Sample of Patients for Clinical Record Review With Home Visits
Surveyors may conduct home visits to any patient receiving skilled services who grants permission. For clinical record reviews with home visits, the surveyor identifies and selects patients who will receive skilled services at their residence during the days of the survey. Whenever possible, include (at a minimum) at least one patient who is receiving a "high-tech" service, (e.g., infusion therapies such as artificial nutrition and hydration, or chemotherapy; mechanical ventilation; tracheostomy care, etc.) Also, include a patient from one or more of the HHA's branches when possible. An ideal selection might include (at a minimum) at least one home visit with a registered nurse (RN), one home visit with a therapist, and one home visit with a home health aide. Other home visits could replicate the ideal selection or add more visits of one service based on the HHA's current visit schedule. Include patients receiving only home health aide or personal care services to complete the survey sample size if the number of patients receiving skilled care is not available.

Surveyors continue completing the surveyor worksheet and:
Select one or two patients triggered to be "at risk" of Tier 1 potentially avoidable events.
Select one or two patients triggered to be "at risk" for Tier 2 potentially avoidable events of:

a. *Emergent Care for Improper Medication Administration and Side Effects; and*
b. *Emergent care for Hypo/hyperglycemia.*

Select one or two patients with a medical condition relevant to the OBQI outcomes triggered. (For example, if the outcome "Improvement in Urinary Incontinence" is a focus outcome, select one or two patients with or at risk for urinary incontinence.)

The number of records reviewed, based on the total number of unduplicated admissions requiring skilled services during a recent 12-month period, is as follows:

Number of Unduplicated Skilled Admissions During Recent 12 Months	*Minimum Number of Record Reviews With Home Visits*
Less than 150	*5*
150 – 750	*6*

Number of Unduplicated Skilled Admissions During Recent 12 Months	*Minimum Number of Record Reviews With Home Visits*
751 – 1250	*8*
1,251 or more	*10*

If the surveyor is unable to draw the required sample size for home visits, increase the clinical record reviews without home visits by one for each home visit not made. If the HHA patient census is still inadequate to provide the samples necessary, include a review all of the standard-level requirements under § 484.14 in addition to the level 1 and level 2 standards as part of the standard survey.

Selecting Sample of Clinical Records of Patients Who Will Not Receive a Home Visit
Select both closed and active clinical records for review based on the potentially avoidable events and OBQI outcome(s) triggered for focus and targeted case mix characteristics. If possible, review of closed clinical records identified on the Potentially Avoidable Event Patient Listing report under any triggered outcomes can begin while the HHA obtains the patient roster and home visit schedule.

- *Select one or two clinical records for review for each Tier 1 potentially avoidable event triggered.*
- *Select one or two clinical records for review for each Tier 2 potentially avoidable event outcome triggered.*

NOTE: Patients experiencing more than one Tier1/Tier2 potentially avoidable events are good candidates for clinical record reviews.

For clinical records without home visits, the surveyor uses the clinical records of any patients not selected for home visits, regardless of payer source. If additional records are needed to complete the sample size, include records of patients visited one to two weeks prior to the survey or patients discharged within the same 1 to 2 week period. The number of records reviewed, based on the number of unduplicated admissions of all patients receiving skilled services during a recent 12-month period, is as follows:

Number of Unduplicated Skilled Admissions During Recent 12 Months	*Minimum Number of Record Reviews With No Home Visits*
Less than 150	*5*
150 – 750	*6*
751 – 1250	*8*
1,251 or more	*10*

Clinical Record Review
Ask to see where the clinical records are stored in the agency and how access to records is controlled. The arrangement and format of clinical records vary among HHAs. To

minimize surveyor time spent in reviewing a clinical record and maximize the substantive information that can be obtained, ask the HHA staff person recommended by the administrator to guide you through the contents of a clinical record, whether electronic or paper. See how it is organized and where to find key elements.

Use the HHA Survey Investigation Worksheets to note any areas that you want to remember for a particular patient or survey. It is a helpful tool for documenting problems identified and findings from the survey – as well as to use as a review to see if the problems were related to more than one standard. If the survey becomes an extended survey, use the current interpretive guidelines to evaluate those conditions and standards not reviewed in the standard and partial extended surveys. Use additional sheets as necessary to record your findings in the "other" category.

Record Review Guidelines:

- *Review the most recent plan of care for the primary admitting diagnosis, and the goals to be accomplished by the care.*
- *Based on the initial assessment and current clinical notes, determine if the patient's medical situation, drug regimen and functional abilities have progressed in relation to the specific care that has been provided. If the patient's clinical and functional abilities have not progressed, have intervening events been recorded appropriately?*
- *If the initial assessment occurred greater than 48 hours after the referral was received, was the discrepancy explained (physician ordered, patient request, or approved by physician)?*
- *Are comprehensive assessments complete?*
- *Are comprehensive assessments completed on time and by the appropriate clinician during a home visit at start of care, within 48 hours of (or knowledge of) patient's return home from an inpatient stay (or referral or on the physician ordered start date), every 60 days (or more frequently), and at discharge?*
- *Are medications on plan of care, medication list (if applicable), and visit notes the same?*
- *If a record indicates that a patient had a "major decline or improvement," was the comprehensive assessment updated?*
- *Determine how the HHA ensures coordination of services among and between personnel providing services. What evidence do you find in the clinical record(s) that this is occurring?*
- *Determine if the patient's continuation of services or discharge seems appropriate at the time of record review.*
- *If information cannot be found or cannot be interpreted or integrated, ask the HHA staff to either find the information or help you understand its content.*
- *Is there evidence that patients verbalized complaints and how the complaints were addressed?*
- *Is there evidence that the patient/caregiver was informed about and contributed to planning the patient's care?*

- *Are there examples of care provision not in compliance with laws, regulations, accepted professional standards or HHA policies and procedures (e.g., documentation of wound care, wound assessment, or physical assessment)?*
- *Is information about patient condition, response to interventions (e.g., medication side effects, responses to wound therapy, laboratory values, etc.,) and teaching, changes in the plan of care, and discharge planning discussed with or forwarded to the appropriate care providers as applicable, including home health aide and physician?*
- *Are case conferences, informal conferences and phone calls documented?*
- *Did the HHA begin services as ordered within the ordered time frame, at the frequency ordered?*
- *Do plans of care contain all required elements and are they reviewed by the physician at least every 60 days?*
- *Are plans of care patient-specific (i.e., contain measurable goals and instructions for care that are specific to the individual patient) with stated parameters for measurements where appropriate?*
- *Is there evidence that physician orders obtained after the beginning of each 60-day episode of care are documented and implemented?*
- *Do clinicians promptly report patient status changes, including variance from any parameters stated in the plan of care?*
- *Is there evidence of patients denied or not offered needed services?*
- *Review records of patients that have been hospitalized or Medicare low utilization payment adjustment (LUPA) patients to determine if sufficient care is being provided.*
- *Is nursing care provided to each patient as ordered on the plan of care?*
- *For patients with co-morbidities, is there evidence that inter-related factors are addressed in managing the patient's care (e.g., addressing nutrition and skin care in a wound care patient who has diabetes)?*
- *Is there evidence of patient needs that are not addressed in the plan of care or communicated to the physician?*
- *Are therapy visits made at the frequency ordered?*
- *Are assessments & communication with other care providers documented?*
- *Is therapy provided to each patient as ordered?*
- *Is there evidence of patient therapy or equipment needs that are not addressed in the plan of care or communicated to the physician?*
- *Were physical therapy assistants, occupational therapy assistants, and licensed practical nurses appropriately supervised according to State practice acts and the HHA's policies and procedures?*
- *Were home health aide supervisory visits made every two weeks?*
- *Did the RN or therapist ever observe aide's provision of care?*
- *Was aide instructed in any clean dressing changes or other specialized procedures?*
- *Was aide's care provided according to the written instructions and the physician's orders?*
- *Were written instructions provided to the aide specific to the patient?*

- *If record seems incomplete, note the date of the latest filing in records and ask about any documentation waiting to be filed.*
- *Do clinicians consistently document vital signs; insulin injections; blood glucose values; wound appearance, location(s) and treatment; and pain location(s), frequency, severity, interventions, and response to interventions?*
- *How are corrections made in clinical record? Is there evidence of different handwriting in the record signed by the same clinician?*
- *Do records of discharged patients contain discharge summaries?*
- *Do records contain periodic summaries of patient care that were sent to physicians?*
- *Do records show consistency in assessment of patient's status and progress over many visits (e.g., wounds in consistent locations, patient weights seem logical, pain management, presence of Foley catheter, etc.)?*

Home Visits

Prior to Making Home Visits

The surveyor visits patient homes or other places of residence only when patients have given prior consent for the visit (or family/caretaker consent if the patient is unable to give consent as a result of his or her medical, psychosocial or emotional problems). Patient participation is strictly voluntary. It is important to contact the patient before you arrive at the home or place of residence, if possible, because the first onsite contact may be intimidating to the patient or may generate some fear that would interfere with access to the patient's home or the quality of the interview. In most situations, the HHA representative who provides care or services should contact the patient/family/caretaker to request permission and make the arrangements for the home visit. However, you may choose to contact the patient/family/caretaker directly.

If you believe that the HHA representative is not representing the purpose of the visit fairly or appears reluctant to contact the patient/families in the sample, or if you have suspicions or concerns about the care being provided, you may contact the patient/family/caretaker directly to request permission to make the home visit by yourself.

Be sure that the HHA representative (or the surveyor, if appropriate) explains clearly to the patient/family/caretaker that the permission for the RN surveyor home visit (or therapist surveyor home visit for a patient who is only receiving therapy) is voluntary and that refusal to consent to the home visit will not affect his or her Medicare/Medicaid status or coverage, or other health benefits. If a patient refuses to have the RN or therapist surveyor accompany the HHA representative, select an alternate patient care situation from the sample.

Home visits may be made before or after reviewing a patient's clinical record. It is preferable to review the comprehensive assessment and plan of care before meeting the patient since this may assist you in making appropriate observations and asking pertinent questions during the home visit.

A home visit is more effective in assessing the scope and quality of care being provided if the surveyor is able to observe how HHA personnel implement one or more parts of the patient's plan of care. There may be circumstances that should be reviewed during a home visit without the HHA representative being present (for example, concern that the presence of the HHA representative may prevent the patient from speaking freely).

Conducting Home Visits

When the surveyor arrives at the home or other place of residence, he/she explains that the purpose of the visit is to ensure that care being provided by the HHA meets the health and safety standards of the Medicare program and is done in accordance with the plan of care ordered by his or her physician. The surveyor asks the patient to sign a Consent for Home Visit Form (see Exhibit 104), and leaves a copy of the signed consent form with the patient and a copy of signed consent form is filed in the patient's clinical record. Also, the surveyor maintains a copy of the consent statement in the survey file. A Spanish version of the Consent for Home Visit Form is also available.

The surveyor must be continuously aware that as a guest in a patient's home or place of residence, courtesy, common sense, and sensitivity to the importance of an individual's own environment is absolutely essential regardless of the condition of the home.

The surveyor should observe, but not interfere with, the delivery of care or the interaction between the HHA representative and the individual patient/family/caretaker.

Prior to interviewing the patient/family/caretaker, the surveyor reassures them that any discussion is voluntary and refusal to participate will not affect his or her Medicare/Medicaid or other health benefits, they may be entitled to.

During the home visit, surveyors are in a key position to assess the HHA's compliance with requirements related to patient's rights, accepted professional standards of practice, coordination of care, comprehensive assessment of patients, plan of care, services provided, and clinical records. Use the following probes as you gather information during home visits.

Home Visit Probes

- *Are there instances of staff providing care that may not be in accordance with laws, regulations, state practice acts, accepted professional standards or HHA policies/procedures (e.g., wound care procedures, prevention of infection, physical assessment, and medication review)?*
- *How do providers communicate with patient/caregivers and identify the need to communicate with other providers?*
- *When pertinent clinical findings are noted during visit (e.g., changes in patient condition, new medication, lab values, updates to the plan of care, etc.,) how will the provider follow up or share the information with the appropriate care providers? Is there evidence that the communication plan was implemented?*
- *Did the care provider(s) deliver care as ordered and according to accepted professional standards of practice (e.g., CDC guidelines) and agency policy?*

- *Did the care provider report any untoward or unexpected patient changes immediately?*
- *Do clinicians follow CDC infection control guidelines, state practice acts, HHA policies and procedures and accepted clinical standards in providing care?*
- *How does the aide interact with patient/caregiver(s)?*
- *Did the aide provide care as described on written instructions?*
- *Are medications in the home the same as those listed on plan of care, interim orders and the clinical record notes?*
- *Ask the clinical staff about instances of patient care noted in home visits or record reviews that deviated from the physician's orders, accepted professional standards or agency policy.*

Interviewing the Patient/Caregiver

Ask the patient/caregiver(s) the following questions:

- *What care does the aide provide?*
- *Are your needs being met?*
- *Are you satisfied with the care?*
- *What medication are you currently taking? Compare this with the orders and medications in the clinical record.*
- *Have there been setbacks or problems during your episode of home care and how has the HHA has addressed them?*
- *Are you concerned about problems that have not been addressed by HHA staff to your satisfaction?*
- *Have you been able to participate in planning care?*
- *If you had a complaint, would you know who to contact and how?*
- *Is the care being provided as you were told it would be?*

Discontinue the interview if:

- *The patient shows signs of being uncomfortable or seems reluctant to talk, and if, after asking the patient, he or she says they would rather discontinue the discussion;*
- *The patient appears tired, overly concerned, agitated, etc., and would like to end the interview, or, if in your judgment, it appears to be in the patient's best interest to end the interview; or*
- *Conditions in the patient' home, such as safety factors, perceptions of intimidation, etc., are of concern to you or the HHA representative.*

Task 4 - Information Analysis

The information analysis process requires surveyors to review the information gathered during the survey process and to make judgments about the compliance of the HHA. When analyzing information and making determinations about the importance of the findings, the following guidance should be helpful:

Analyze findings relative to each requirement for:

- *The effect or potential effect on the patient care outcomes;*
- *The degree of severity;*
- *The frequency of occurrence; and*
- *The impact on the delivery of services.*

Review your findings from the clinical record reviews and home visits. Use the Home Health Agency Survey Investigation Worksheet to review your findings.

Standard and Condition Level Deficiencies

Deficiencies under the home health requirements are cited on the Form CMS-2567 at either the standard level or the condition level. To facilitate documentation of a deficiency citation, data tags are assigned to the HHA conditions and each standard under the condition in the interpretive guidelines. For example, G100 is the condition level tag for the Condition at 484.100, Patient rights; G101 is the tag for the standard to inform, promote and protect patient rights. A data tag assigned to a condition is considered a condition-level data tag. Any data tags that are not a condition level deficiency (e.g., those not placed at the condition) are standard level data tags. A condition level deficiency is identified by citing the condition level tag A standard level deficiency is cited at the standard level tag. If Immediate Jeopardy (IJ) is cited, IJ is cited at the condition level, with any associated standard level tags.

Guidelines for Citing Standard Level deficiencies:

Because the Level 1 highest priority standards are identified as those most related to the delivery of high-quality patient care, a single problematic finding with an actual (or potential) poor outcome(s) would support a determination of noncompliance with a standard tag (e.g., one clinical record finding and/or one home visit finding). Determine if a deficiency exists, and if it does, move to a partial extended survey.

NOTE: *This does not preclude a deficiency citation at a Level 2 standard or any other standard if findings are identified that affect actual or potential negative patient outcomes due to non-compliance with the standard.*

Guidelines for a Partial extended Survey:

The partial extended survey may be conducted at any time, at the discretion of CMS or the SA, but must be conducted when a Level 1 standard level deficiency is identified during a survey. When a Level 1 standard-level deficiency is identified, the survey is expanded to a partial extended survey and the surveyor examines, at a minimum, the Level 2 standards under the same condition and any other standards which the surveyor chooses to examine. This review may or may not result in additional standard level deficiencies. For example, if the surveyor identifies the existence of a problem for the standard G157 (Patients are accepted for treatment with the expectation that the patients' needs can be adequately met by the HHA in patient's residence), the standard survey is expanded to a partial extended survey. Therefore, in addition to evaluating HHA compliance with other Level 1 tags, the surveyors assess compliance with the following Level 2 tags under the same condition as G157 (CoP 484.18 Acceptance of Patients, Plan of Care, and Medical Supervision),G160 (Physician is consulted to

*approve additions or modifications to the plan of care), G162 (Therapist, other personnel participate in developing the plan of care), and G163 (Total plan of care is reviewed by the physician and HHA personnel at least every 60 days). A review of all Level 2 standards that relate to a deficiency of a Level 1 standard is the **minimum** requirement. Surveyors may also identify other standards for investigation as part of a partial extended survey. For example, if, during review of the data sources, additional problems with standards not designated as being Level 1 or Level 2 are found, the surveyor should investigate those problems further as part of a partial extended survey.*

Since the Level 2 next highest priority standards are identified as also being related to the delivery of high-quality patient care, a single problematic finding with an actual (or potential) poor outcome(s) would support a determination of noncompliance with a standard tag (e.g., one clinical record finding and/or one home visit finding).

Guidelines for an Extended Survey

The extended survey means a survey that reviews additional conditions of participation not examined during a standard survey. It may be conducted at any time, at the discretion of CMS or the SA, but will be conducted when substandard care is identified during a survey. Substandard care is defined in §488.705 as noncompliance with one or more conditions of participation at the condition-level. When substandard care is identified, the extended survey reviews and identifies the HHA's policies, procedures, and practices that produced the substandard care. It may also review additional conditions of participation depending on the nature and extent of serious risk to patients that is identified in the standard survey. Additionally, the survey will review any associated activities that might have contributed to the deficient practice.

The extended survey should be conducted immediately after a finding of substandard care (or, if not practical, not later than 2 weeks after the date of completion of the standard survey or partial extended survey). However, if the surveyor identifies or suspects an immediate jeopardy situation, he/she must immediately follow the guidelines in SOM §3010 and in Appendix Q. Immediate jeopardy is interpreted as a crisis situation in which the health and safety of patients is at risk and is defined in §489.3 as "a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident."

Guidelines for Citing Condition Level Deficiencies

According to §488.24, the SA will certify that a provider is not in compliance with the CoPs where the deficiencies are of such character as to substantially limit the provider's capacity to furnish adequate care or which adversely affect the health and safety or patients. A CoP may be considered out of compliance for one or more deficiencies and cited at the condition-level, if, in a surveyor's judgment, the deficiency constitutes a significant or a serious finding that adversely affects, or has the potential to adversely affect, patient outcomes. Surveyors are to use their professional judgment, in concert with the Federal forms, policies and interpretive guidelines in their assessment of an HHA's compliance with the CoPs.

§484.10 Condition of Participation: Patient Rights

Consider citing this condition (i.e., at the condition-level) when:

- *The HHA is found out of compliance with tags G107 or G109 and one additional tag within §484.10.*

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

Consider citing the condition when:

- *The HHA is out of compliance with G118 and G121; OR*
- *The HHA is out of compliance with G118* ***or*** *G121* ***and*** *two additional tags within §484.12.*

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

Consider citing the condition when:

- *Expected outcomes are not met for three of the four Level 1 tags listed (G123, G133, G143, G144); OR*
- *The agency is out of compliance with one of the Level 1 tags plus two additional tags within §484.14.*

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

Consider citing the condition when:

- *Expected outcomes are not met for three of the six Level 1tags listed (G157, G158, G159, G164, G165, G166); OR*
- *The HHA is out of compliance with one Level 1 tag plus two additional tags within 484.18.*

§484.30 Condition of Participation: Skilled Nursing Services

Consider citing the condition when:

- *Expected outcomes are not met for three of the seven Level 1 tags (G170, G172, G173, G174, G175, G176, G177); OR*
- *The HHA is out of compliance with one Level 1 tag plus two additional tags within §484.30.*

§484.32 Condition of Participation: Therapy Services

Consider citing the condition when:

- *Expected outcomes are not met for two of the Level 1 tags listed (G186, G187, G188); OR*
- *The HHA is out of compliance with one Level 1 tag plus one additional tag within §484.32.*

§484.36 Condition of Participation: Home Health Aide Services

Consider citing the condition when:

- *Expected outcomes are not met for the two Level 1 tags listed (G224, G229); OR*
- *The HHA is out of compliance with one Level 1 tag plus one additional tag within §484.36.*

§484.48 Condition of Participation: Clinical Records

Consider citing the condition when:

- *Expected outcomes are not met for G236; OR*
- *The HHA is out of compliance with G239 plus one additional tag within §484.48.*

§484.55 Condition of Participation: Comprehensive Assessment of Patients

Consider citing the condition when:

- *Expected outcomes are not met for three of the eight Level 1 tags listed (G331, G332, G334, G335, G336, G337, G338, G340); OR*
- *The HHA is out of compliance with one of the Level 1 plus two additional tags within §484.55.*

If the surveyor finds a condition level deficiency with one of the 9 conditions listed above, additional related conditions, including the following 6 conditions listed below, are examined under the extended survey:

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

Consider citing the condition when:

Expected outcomes are not met for G310.

§484.16 Condition of Participation: Group of Professional Personnel

Consider citing the condition when:

- *Expected outcomes are not met for G152, G153 and G154.*

§484.20 Condition of Participation: Reporting OASIS Information

Consider citing the condition when:

- *Expected outcomes are not met for G321 and 322.*

§484.34 Condition of Participation: Medical Social Services

Consider citing the condition when:

- *Expected outcomes are not met for G 195, 196 and one additional tag within §484.36.*

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

Consider citing the condition when:

- *Expected outcomes are not met for G234*

§484.52 Condition of Participation: Evaluation of the Agency's Program
Consider citing the condition when:

- *Expected outcomes are not met for G 245, 246, and one other tag within §484.52.*

Task 5 - Exit Conference

- *Following a standard, partial extended, and/or extended survey, the surveyor conducts an exit conference in accordance with §2724. The purpose of the exit conference is to inform the HHA staff of the observations and preliminary findings of the survey.*

Because of ongoing dialogue between the surveyor(s) and HHA staff during the survey, there should be few instances of findings where the HHA is not aware of the surveyor concerns prior to the exit conference. Implement the following guidelines during the conference:

- *Conduct the exit conference with the HHA administrator, clinical managers, and other staff invited by the HHA. Clarify and note the names and positions of all HHA personnel or other individuals attending the meeting.*
- *Summarize the facts of the onsite evaluation (e.g., team size, composition, days onsite, the sample size for record review and home visits).*
- *Describe the regulatory requirements that the HHA does not meet and the findings that substantiate these deficiencies. Avoid using data tag numbers when referring to findings.*
- *Present findings regarding citations of deficient practice(s) in a straight forward, understandable way, and in a clear logical sequence. Offer examples to support the findings as appropriate.*
- *Offer the HHA the opportunity to ask questions regarding the findings or provide further pertinent information for the surveyors to consider offsite prior to making formal citation recommendations to CMS on Form CMS-2567.*
- *Respond to any HHA procedural questions with timely and accurate survey process information (e.g., recertification status: the timeframe for receiving Form CMS-2567 and submitting a plan of correction to the SA in response to the written citations). Clarify any areas for which further possible deficiency citations may be made offsite after further analysis with team members or the SA supervisor.*
- *Present the Form CMS-2567 in accordance with the State agency's policy, but no later than 10 working days after the exit conference. A listing of patient identifiers should accompany the CMS-2567.*
- *Provide instructions and time frame for submitting a plan of correction. The plan of correction must be submitted to the SA within 10 calendar days after receipt of the Form CMS-2567.*
- *Refer to SOM §2724 and §2728 for additional information on the exit conference, presence of counsel, taping of the conference, and situations that would justify refusal to conduct or continue an exit conference.*

Task 6 - Formation of the Statement of Deficiencies

Use the guidance in Part I - Investigative Procedures and Part II - Interpretive Guidelines in Appendix B to conduct standard, partial extended and extended surveys to determine compliance with HHA requirements. Write the deficiency statement in terms specific enough to allow a reasonably knowledgeable person to understand how the aspects of each requirement are not met. Follow SOM §2728 for preparation of the Statement of Deficiencies and Plan of Correction. Refer to the document "Principles of Documentation for the Statement of Deficiencies" for detailed instructions on completing the Form CMS-2567.

Follow up on all deficiencies cited on the HHA's plan of correction according to the instructions in SOM §2732A and §2732B.

Part II – Interpretive Guidelines

Subpart A - General Provisions

§ 484.1 Basis and scope.

(a) Basis and scope. This part is based on the indicated provisions of the following sections of the Act:

(1) Sections 1861(o) and 1891 establish the conditions that an HHA must meet in order to participate in Medicare.

(2) Section 1861(z) specifies the Institutional planning standards that HHAs must meet.

(3) Section 1895 provides for the establishment of a prospective payment system for home health services covered under Medicare.

(b) This part also sets forth additional requirements that are considered necessary to ensure the health and safety of patients.

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§ 484.2 Definitions.

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

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

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

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

HHA stands for home health agency.

Nonprofit agency means an agency exempt from Federal income taxation under section 501 of the Internal Revenue Code of 1954.

Parent home health agency means the agency that develops and maintains administrative controls of subunits and/or branch offices.

Primary home health agency means the agency that is responsible for the services furnished to patients and for implementation of the plan of care.

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

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

Public agency means an agency operated by a State or local government.

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

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

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

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

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§ 484.4 Personnel qualifications.

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

Administrator, home health agency. A person who:

(a) Is a licensed physician; or

(b) Is a registered nurse; or

(c) Has training and experience in health service administration and at least 1 year of supervisory or administrative experience in home health care or related health programs.

Audiologist. A person who:

(a) Meets the education and experience requirements for a Certificate of Clinical Competence in audiology granted by the American Speech-Language-Hearing Association; or

(b) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

Home health aide. Effective for services furnished after August 14, 1990, a person who has successfully completed a State-established or other training program that meets the requirements of §484.36(a) and a competency evaluation program or State licensure program that meets the requirements of §484.36 (b) or (e), or a competency evaluation program or State licensure program that meets the requirements of §484.36 (b) or (e). An individual is not considered to have completed a training and competency evaluation program, or a competency evaluation program if, since the individual's most recent completion of this program(s), there has been a continuous period of 24 consecutive months during none of which the individual furnished services described in §409.40 of this chapter for compensation.

Occupational therapist. A person who—

(a)(1) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing, unless licensure does not apply;

(2) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA), or successor organizations of ACOTE; and

(3) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(b) On or before December 31, 2009—

(1) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing; or

(2) When licensure or other regulation does not apply—

(i) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or successor organizations of ACOTE; and

(ii) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc., (NBCOT).

(c) On or before January 1, 2008—

(1) Graduated after successful completion of an occupational therapy program accredited jointly by the committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or

(2) Is eligible for the National Registration Examination of the American Occupational Therapy Association or the National Board for Certification in Occupational Therapy.

(d) On or before December 31, 1977—

(1) Had 2 years of appropriate experience as an occupational therapist; and

(2) Had achieved a satisfactory grade on an occupational therapist proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(e) If educated outside the United States, must meet all of the following:

(1) Graduated after successful completion of an occupational therapist education program accredited as substantially equivalent to occupational therapist entry level education in the United States by one of the following:

(i) The Accreditation Council for Occupational Therapy Education (ACOTE).

(ii) Successor organizations of ACOTE.

(iii) The World Federation of Occupational Therapists.

(iv) A credentialing body approved by the American Occupational Therapy Association.

(2) Successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(3) On or before December 31, 2009, is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing.

Occupational therapy assistant. A person who—

(a) Meets all of the following:

(1) Is licensed, unless licensure does not apply, or otherwise regulated, if applicable, as an occupational therapy assistant by the State in which practicing.

(2) Graduated after successful completion of an occupational therapy assistant education program accredited by the Accreditation Council for Occupational Therapy Education, (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or its successor organizations.

(3) Is eligible to take or successfully completed the entry-level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(b) On or before December 31, 2009—

(1) Is licensed or otherwise regulated as an occupational therapy assistant, if applicable, by the State in which practicing; or any qualifications defined by the State in which practicing, unless licensure does not apply; or

(2) Must meet both of the following:

(i) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association.

(ii) After January 1, 2010, meets the requirements in paragraph (a) of this section.

(c) After December 31, 1977 and on or before December 31, 2007—

(1) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association; or

(2) Completed the requirements to practice as an occupational therapy assistant applicable in the State in which practicing.

(d) On or before December 31, 1977—

(1) Had 2 years of appropriate experience as an occupational therapy assistant; and

(2) Had achieved a satisfactory grade on an occupational therapy assistant proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(e) If educated outside the United States, on or after January 1, 2008—

(1) Graduated after successful completion of an occupational therapy assistant education program that is accredited as substantially equivalent to occupational therapist assistant entry level education in the United States by—

(i) The Accreditation Council for Occupational Therapy Education (ACOTE).

(ii) Its successor organizations.

(iii) The World Federation of Occupational Therapists.

(iv) By a credentialing body approved by the American Occupational Therapy Association; and

(2) Successfully completed the entry-level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

Physical therapist. A person who is licensed, if applicable, by the State in which practicing, unless licensure does not apply and meets one of the following requirements:

(a)(1) Graduated after successful completion of a physical therapist education program approved by one of the following:

(i) The Commission on Accreditation in Physical Therapy Education (CAPTE).

(ii) Successor organizations of CAPTE.

(iii) An education program outside the United States determined to be substantially equivalent to physical therapist entry-level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or an organization identified in 8 CFR 212.15(e) as it relates to physical therapists; and

(2) Passed an examination for physical therapists approved by the State in which physical therapy services are provided.

(b) On or before December 31, 2009—

(1) Graduated after successful completion of a physical therapy curriculum approved by the Commission on Accreditation in Physical Therapy Education (CAPTE); or

(2) Meets both of the following:

(i) Graduated after successful completion of an education program determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified in 8 CFR 212.15(e) as it relates to physical therapists.

(ii) Passed an examination for physical therapists approved by the State in which physical therapy services are provided.

(c) Before January 1, 2008—

(1) Graduated from a physical therapy curriculum approved by one of the following:

(i) The American Physical Therapy Association.

(ii) The Committee on Allied Health Education and Accreditation of the American Medical Association.

(iii) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association.

(d) On or before December 31, 1977 was licensed or qualified as a physical therapist and meets both of the following:

(1) Has 2 years of appropriate experience as a physical therapist.

(2) Has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(e) Before January 1, 1966—

(1) Was admitted to membership by the American Physical Therapy Association; or

(2) Was admitted to registration by the American Registry of Physical Therapists; or

(3) Has graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education.

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

(g) If trained outside the United States before January 1, 2008, meets the following requirements:

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

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

Physical therapist assistant. A person who is licensed, unless licensure does not apply, registered, or certified as a physical therapist assistant, if applicable, by the State in which practicing, and meets one of the following requirements:

(a)(1) Graduated from a physical therapist assistant curriculum approved by the Commission on Accreditation in Physical Therapy Education of the American Physical Therapy Association; or if educated outside the United States or trained in the United States military, graduated from an education program determined to be substantially equivalent to physical therapist assistant entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified at 8 CFR 212.15(e); and

(2) Passed a national examination for physical therapist assistants.

(b) On or before December 31, 2009, meets one of the following:

(1) Is licensed, or otherwise regulated in the State in which practicing.

(2) In States where licensure or other regulations do not apply, graduated on or before December 31, 2009, from a 2-year college-level program approved by the American Physical Therapy Association and, effective January 1, 2010 meets the requirements of paragraph (a) of this definition.

(c) Before January 1, 2008, where licensure or other regulation does not apply, graduated from a 2-year college-level program approved by the American Physical Therapy Association.

(d) On or before December 31, 1977, was licensed or qualified as a physical therapist assistant and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

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

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

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

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

Social work assistant. A person who:

(1) Has a baccalaureate degree in social work, psychology, sociology, or other field related to social work, and has had at least 1 year of social work experience in a health care setting; or

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

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

Speech-language pathologist. A person who meets either of the following requirements:

(a) The education and experience requirements for a Certificate of Clinical Competence in speech-language pathology granted by the American Speech-Language-Hearing Association.

(b) The educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

Subpart B - Administration

The Conditions of Participation for HHAs apply to each individual under its care unless a requirement is specifically limited to Medicare beneficiaries. Section 1861(o) of the Social Security Act (the Act) describes an HHA for purposes of participation in the Medicare program in broadly descriptive terms. All the requirements are stated generally

as applicable to the HHA's overall activity, and not specifically to the Medicare patient. This provision, which was reaffirmed by Congress in the OBRA 1987 amendments to §1891(a) of the Act has been in the law since the inception of the Medicare program, and CMS' interpretation of it has remained the same. Do not attempt to resolve or enforce matters relating to Medicare/Medicaid coverage of services. If you observe what you believe are noncovered services, report this information to the *CMS* Regional Office Medicare or Medicaid Divisions, as appropriate.

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

G100

§484.10 Condition of Participation: Patient Rights

G101

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

Interpretive Guidelines §484.10

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

During home visits, ask patients if the HHA informed them of their rights, and, if so, how. They should be able to give, in their own words, examples of how the rights apply to the HHA care being received and any concerns they have about financial implications of the items or services being received. They should also be able to explain how to access information, services, and the HHA hotline.

If the patient is vague in answering questions, ask for written information about his or her rights that the HHA may have given him or her as resource material. Reviewing the

written statement with the patient during the home visit may help the patient remember the HHA's patient rights instructions.

G102

§484.10(a) Standard: Notice of Rights

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

Interpretive Guidelines §484.10(a)(1)

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

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

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

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

A standard notice to patients that explains these rights in plain language is available in English and Spanish on the OASIS website (http://www.cms.hhs.gov/oasis/). HHAs must present and explain this required notice to beneficiaries before their initial OASIS assessment.

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

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

Probes §484.10(a)(1)

- How do HHA employees, and staff used by the HHA under an arrangement or contract, implement HHA procedures for informing patients of their rights?
- What are the HHA's admission policies concerning the OASIS Privacy Act Statement?
- How does the HHA assure that the patient understands the OASIS Privacy Act Statement? Is the patient given a copy of the OASIS Privacy Act Statement?
- What is the HHA's policy and procedure for requests to see, copy, review, or change assessment information?
- Does the patient receive a written copy of the HHA's response when a change request is not granted?

G103

§484.10(a)(1)(2) -- The HHA must maintain documentation showing that it has complied with the requirements of this section.

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

G104

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

(1) The patient has the right to exercise his or her rights as a patient of the HHA.

(2) The patient's family or guardian may exercise the patient's rights when the patient has been judged incompetent.

G105

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

G106

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

G107

(Rev.)

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

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

The expected outcome for this Level 1 standard is that all complaints are investigated, resolved and documented by the HHA.

During home visits, ask the patient, the patient's family, guardian or other legal representative under state law, if they have *or had* any comments or concerns *and how they pursued them*, or if they have registered any grievances or complaints about the HHA or its services. *Determine whether the patient/caregiver would know whom and how to contact if they had a complaint or grievance.* Also, note any patient-described problems recorded in the clinical records during your stratified sample clinical record review. *Is there evidence that the patients verbalized complaints and how the complaints were addressed and resolved?*

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

Probes §484.10(b)(4) and (5)

- *How does the HHA receive, record, investigate, and resolve patient grievances and complaints?*
- *Who in the HHA is ultimately accountable for receiving and resolving any patient concerns or problems that cannot be resolved at the staff level?*
- *How does the HHA document the existence, investigation and resolution of complaints?*
- *Follow-up on investigation and documentation of complaints noted in home visits or record reviews with administrator, clinical manager, and HHA staff.*

G108

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

(1) The patient has the right to be informed, in advance, about the care to be furnished, and of any changes in the care to be furnished.

(i) The HHA must advise the patient in advance of the disciplines that will furnish care, and the frequency of proposed visits.

(ii) The HHA must advise the patient in advance of any change in the plan of care before the change is made.

G109

(Rev.)

§484.10(c)(2) - The patient has the right to participate in the planning of the care.

(i) The HHA must advise the patient in advance of the right to participate in planning the care or treatment and in planning changes in the care or treatment.

Interpretive Guidelines §484.10(c)(2)(i)

The expected outcome for this Level 1 standard is that patients are involved in developing their plan of care.

Probes §484.10(c)(2)(i)

- *Ask HHA staff how they facilitate patient/caregivers' participation in planning care.*

- *Ask patients/caregivers if they feel they were able to participate in planning their care or treatment.*
- *Is there evidence that the patient/caregiver was informed about and contributed to planning his/her care?*
- *Is there evidence that patient's plan of care addresses the patient's needs and goals?*

G110

§484.10(c)(2)(ii) - The HHA complies with the requirements of Subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. The HHA must inform and distribute written information to the patient, in advance, concerning its policies on advance directives, including a description of applicable State law. The HHA may furnish advanced directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided.

Interpretive Guidelines §484.10(c)

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

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

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

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

1. Provide all adult individuals with written information about their rights under State law to:
    a. Make decisions about their medical care;
    b. Accept or refuse medical or surgical treatment; and
    c. Formulate, at the individual's option, an advance directive;

2. Inform patients about the HHA's written policies on implementing advance directives;
3. Document in the patient's medical record whether he or she has executed an advance directive;
4. Not condition the provision of care or otherwise discriminate against an individual based on whether he or she has executed an advance directive;
5. Ensure compliance with the related State requirements on advance directives; and
6. Provide staff and community education on issues concerning advance directives.

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

Probes §484.10(c)

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

G111

§484.10(d) Standard: Confidentiality of Medical Records

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

G112

§484.10(d) - The HHA must advise the patient of the agency's policies and procedures regarding disclosure of clinical records

Interpretive Guidelines §484.10(d)

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

Probes §484.10(d)

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

G113

§484.10(e) Standard: Patient Liability for Payment

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

G114

§484.10(e)(1) - Before the care is initiated, the HHA must inform the patient, orally and in writing, of--

(i) The extent to which payment may be expected from Medicare, Medicaid, or any other Federally funded or aided program known to the HHA;

(ii) The charges for services that will not be covered by Medicare; and

(iii) The charges that the individual may have to pay.

Interpretive Guidelines §484.10(e)(1)

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

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

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

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

G115

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

Interpretive Guidelines §484.10(e)

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

Look for a written statement in the home that might serve as a resource or reminder to the patient about the information the HHA has presented. Also, note whether there are

subsequent written statements about payments for items or services of which the HHA has become aware.

Probes §484.10(e)

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

G116

§484.10(f) Standard: Home Health Hotline

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

Interpretive Guidelines §484.10(f)

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

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

G310

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

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

Interpretive Guidelines §484.11

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

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

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

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

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

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

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

- Protecting confidentiality of OASIS data (written and/or electronic).

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

Interview the HHA administrator or system administrator for:

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

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

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

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

Probes §484.11

- How does the HHA assure that only specified personnel have access to OASIS assessment information?
- How is the security of passwords maintained?
- What policies and procedures address password assignment and use?
- How does the HHA assure that the computer is "logged off" or password protected when the data entry operator is away from the computer, i.e., at lunch or break times?
- Who in the HHA has the password information needed to electronically report OASIS data to the State agency? At least two staff persons should have the password.
- If the HHA has branches, how is OASIS data protected and kept secure during transfer from the branch to the parent agency?

- If the HHA contracts out OASIS encoding and reporting, what systems are in place to assure that the contracted vendor maintains confidentiality of OASIS data?

G117

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

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G118

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

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

Interpretive Guidelines §484.12(a)

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

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

   or

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

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

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

Probes §484.12(a)

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

G119

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

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

G120

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

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

(2) The name and address of each person who is an officer, a director, an agent or a managing employee of the HHA as defined in §§420.201, 420.202, and 420.206 of this chapter.

(3) The name and address of the corporation, association, or other company that is responsible for the management of the HHA, and the name and address of the chief executive officer and the chairman of the board of directors of that corporation, association, or other company responsible for the management of the HHA.

Interpretive Guidelines §484.12(b)

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

A "**managing employee**" is a general manager, business manager, administrator, director or other individual who exercises operational or managerial control over, or who directly

or indirectly conducts the day-to-day operations of the HHA. The HHA administrator (§484.14(b)) and the supervisory physician or supervisory registered nurse (§484.14(d)) would meet the definition of a managing employee.

Probes §484.12(b)

- Is the information on the Form CMS-855, consistent with information you find in the agency's organizational structure (i.e., organizational charts and lines of authority, management contracts, bylaws, minutes of board meetings)?
- How does the HHA implement its policy or procedure for reporting changes in ownership and management information to the State?

G121

(Rev.)

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

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

Interpretive Guidelines §484.12(c)

The expected outcome for this Level 1 standard is that all care providers follow parameters defined by State practice acts, Federal and State laws and regulations, HHA policies and other professionally accepted guidelines (e.g., CDC guidelines for infection control).

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

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

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

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

If questions arise during interviews, home visits or record reviews, consider:

- *Reviewing the HHA policies and procedures for the area of concern.*
- *Identifying and reviewing materials that the HHA provides to staff as clinical/procedural resources.*

Probes §484.12(c)

- How does the HHA monitor its employees and personnel serving the HHA under arrangement or contract to ensure that services provided to patients are within acceptable professional practice standards for each discipline?
- How does the HHA monitor the professional skills of its staff to determine if skills are appropriate for the care required by the patients the HHA admits?
- Are there examples of care provision not in compliance with laws, regulations, accepted professional standards and/or HHA policies and procedures (e.g., documentation of wound care, wound assessment, or physical assessment)?

G122

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

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G123

(Rev.)

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

Interpretive Guidelines §484.14

The expected outcome for this Level 1 standard is that the lines of authority within the HHA are clearly defined for delegation of responsibility to the patient care level.

Probes §484.14

Review the organizational chart in relation to descriptions provided by administrative and clinical staff.

G124

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

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G125

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

G126

§484.14 - If an agency has subunits, appropriate administrative records are maintained for each subunit.

Interpretive Guidelines §484.14

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

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

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

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

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

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

Examples:

1. An HHA may, in arranging or contracting for a service such as physical therapy, require the other party to do the day-by-day professional evaluation of the therapy service. However, the HHA may not delegate its overall administrative and supervisory responsibilities. The contract should specify how HHA supervision will occur.

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

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

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

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

Probes §484.14

- How does the HHA monitor and exercise control over services provided by personnel under arrangements or contracts? In a branch? In a subunit?
- Can HHA administrative and clinical supervisory personnel describe clearly the lines of authority and responsibility for the administration, delivery, and supervision of services:
    - Between parent, branch, and/or subunits?

    - If the HHA is part of a larger organizational entity such as a State or local health department, hospital, skilled nursing facility or health maintenance organization?
    - If the HHA offers services such as homemaker, personal care aides, private duty nursing, or hospice?
- Who has responsibility for maintaining employee assignments, plans of care, and minutes of interdisciplinary and administrative meetings integral to the organization and supervision of the HHA's services?

G127

§484.14(a) Standard: Services Furnished.

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

Interpretive Guidelines §484.14(a)

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

Probes §484.14(a)

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

G128

§484.14(b) Standard: Governing Body.

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

G129

§484.14(b) - The governing body appoints a qualified administrator,

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G130

§484.14(b) - arranges for professional advice as required under §484.16,

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G131

§484.14(b) - adopts and periodically reviews written bylaws or an acceptable equivalent, and

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G132

§484.14(b) - oversees the management and fiscal affairs of the agency.

Interpretive Guidelines §484.14(b)

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

Probes §484.14(b)

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

G133

(Rev.)

§484.14(c) Standard: Administrator

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

Interpretive Guidelines §484.14(c)

The expected outcome for this Level 1 standard is that the HHA has a qualified administrator appointed by the governing body who directs day-to-day agency functions according to regulations, policies and procedures and maintains ongoing liaison among the governing body, the group of professional personnel, and the staff.

G134

§484.14(c) - employs qualified personnel and ensures adequate staff education and evaluations;

G135

§484.14(c) - ensures the accuracy of public information materials and activities; and

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G136

§484.14(c) - implements an effective budgeting and accounting system.

G137

§484.14(c) - A qualified person is authorized in writing to act in the absence of the administrator.

Probes §484.14(c)

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

G138

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

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

G139

§484.14(d) - This person, or similarly qualified alternate, is available at all times during operating hours and

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G140

§484.14(d) - participates in all activities relevant to the professional services furnished, including the development of qualifications and the assignment of personnel.

Interpretive Guidelines §484.14(d)

"**Available at all times during operating hours**" means being readily available on the premises or by telecommunications. How the supervising physician or supervising registered nurse structures his or her availability is a management decision for the HHA. "Operating hours" means all hours that staff from the agency are providing services to patients.

G141

§484.14(e) Standard: Personnel Policies

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

Personnel records include qualifications and licensure that are kept current.

Interpretive Guidelines 484.14(e)

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

Probes §484.14(e)

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

G142

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

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

(1) Patients are accepted for care only by the primary HHA.

(2) The services to be furnished.

(3)The necessity to conform to all applicable agency policies, including personnel qualifications.

(4) The responsibility for participating in developing plans of care.

(5) The manner in which services will be controlled, coordinated, and evaluated by the primary HHA.

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

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

Interpretive Guidelines §484.14(f)

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

Probes §484.14(f)

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

G143

(Rev.)

§484.14(g) Standard: Coordination of Patient Services

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

Interpretive Guidelines §484.14(g)

The expected outcome for this Level 1 standard is that information regarding each patient's health status and plan of care is communicated among all relevant care providers, including, but not limited to, the home health aide and the physician.

Probes §484.14(g)

- *Ask clinical managers and HHA staff about specific patients, including how information about patient condition, response to interventions and teaching, changes in the plan of care, and discharge planning are communicated among the appropriate care providers and where those communications are documented.*
- *How does coordination of care among staff and/or contract personnel providing services to individual patients occur?*
- *When pertinent clinical findings are noted during a visit (e.g., changes in patient condition, new medication, lab values, updates to the plan of care, etc.), how does the HHA follow up or share the information with the appropriate care providers? Is there evidence that the communication plan was implemented?*
- *Is information about patient condition, response to interventions (e.g., medication side effects, responses to wound therapy, laboratory values, etc.) and teaching, changes in the plan of care, and discharge planning discussed with or forwarded to the appropriate care providers, including but not limited to the home health aide and physician?*
- *Are case conferences, informal conferences and phone calls documented?*

If questions arise during interviews, home visits or record reviews, consider reviewing the following documents:

- *HHA policies regarding coordination of care, communication with team members, etc.*
- *Contracts of services provided under arrangement.*
- *The clinical records or minutes of case conferences.*

G144

(Rev.)

§484.14(g) - …The clinical record or minutes of case conferences establish that effective interchange, reporting, and coordination of patient care does occur.

Interpretive Guidelines §484.14(g)

The expected outcome for this Level 1 standard is that communication among care providers is documented (e.g., case conferences, phone calls, etc.).

G145

§484.14(g) - A written summary report for each patient is sent to the attending physician at least every 60 days.

Probes §484.14(g)

- What is the HHA's policy related to facilitating exchange of information among staff?
- How does the HHA ensure that patients' written summary reports sent to attending physicians every 60 days meet the regulatory requirements of §482.2?

Refer to §484.48 regarding guidelines for the attending physician's written summary report.

G146

§484.14(h) Standard: Services Under Arrangement.

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

Interpretive Guidelines §484.14(h)

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

G147

§484.14(i) Standard: Institutional Planning.

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

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

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

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

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

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

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

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

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

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

G148

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

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

G149

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

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

Interpretive Guidelines §484.14(i)

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

G150

(Rev.)

§484.14(j) Standard: Laboratory Services.

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

Interpretive Guidelines §484.14(j)(1)

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

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

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

For a complete listing of waived tests, refer to CMS' website at *http://www.cms.hhs.gov/CLIA/10_Categorization_of_Tests.asp#TopOfPage*

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

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

For a complete listing of provider-performed microscopy procedures, refer to CMS' website at *http://www.cms.hhs.gov/CLIA/10_Categorization_of_Tests.asp#TopOfPage.*

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

For a complete listing of moderate and high complexity tests, refer to CMS' website at *http://www.cms.hhs.gov/CLIA/10_Categorization_of_Tests.asp#TopOfPage.*

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

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

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

Interpretive Guidelines §484.14(j)(2)

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

G151

§484.16 Condition of Participation: Group of Professional Personnel

G152

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

G153

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

Interpretive Guidelines §484.16

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

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

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

G154

§484.16(a) Standard: Advisory and Evaluation Function

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

G155

§484.16(a) - The meetings are documented by dated minutes.

Probes §484.16(a)

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

G156

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

G157

(Rev.)

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

Interpretive Guidelines §484.18

The expected outcome for this Level 1 standard is that the HHA will only accept patients for care if the HHA can adequately meet the patient's medical, nursing and social needs in the patient's place of residence.

G158

(Rev.)

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

Interpretive Guidelines §484.18

The expected outcome for this Level 1 standard is that every HHA patient will have a written plan of care established and periodically reviewed by a doctor of medicine, osteopathy, or podiatric medicine.

It is CMS' policy to require that the HHA must have a plan of care for each patient, regardless of the patient's Medicare status or that nurse practice acts do not specifically require a physician's order. The CoPs do not require a physician's order for services furnished by the HHA that are not related to the patient's illness, injury, or treatment of the patient's medical, nursing, or social needs.

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

Orders for services to be furnished "as needed" or "PRN" must be accompanied by a description of the patient's medical signs and symptoms that would occasion a visit and a specific limit on the number of those visits to be made under the order before an additional physician order would have to be obtained.

Probes §484.18

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

G159

(Rev.)

§484.18(a) Standard: Plan of Care

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

Interpretive Guidelines §484.18(a)

The expected outcomes for this Level 1standard are:

- *Patients receive appropriate services and care based on an assessment of their needs and physician orders.*
- *HHA develops a plan of care specific to each patient's needs and containing all required elements.*

G160

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

G161

§484.18(a) - Orders for therapy services include the specific procedures and modalities to be used and the amount, frequency, and duration.

G162

§484.18(a) - The therapist and other agency personnel participate in developing the plan of care.

Interpretive Guidelines §484.18(a)

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

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

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

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

- Accepts physician's orders on referral communicated verbally by an institution's discharge planner, nurse practitioner, physician's assistant, or other authorized staff member followed by written, signed and dated physician's orders, in order to begin HHA services as soon as possible.

- Accepts signed physician certification and recertification of plans of care, as well as signed orders changing the plan of care, by telecommunication systems ("fax"), which are filed in the clinical record.

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

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

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

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

"**Modalities**" are defined as any physical agent applied to produce therapeutic changes to biologic tissue and include, but are not limited to, thermal, acoustic, light, mechanical, or electric energy. **"Procedures**" are defined as a manner of effecting change through the application of clinical skills and/or services that attempt to improve function. This can be achieved through exercise or training and must include active interventions between the therapist and patient.

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

Probes §484.18(a)

- How does an HHA evaluate whether the plan of care, and the coordination of services, help the patient attain and maintain his or her highest practicable functional capacity based on medical, nursing, and rehabilitative needs?
- How does the HHA monitor the delivery of services, including those provided under arrangement or contract, to ensure compliance with the specificity and frequency of services ordered in the plan of care?

- If a range of visits is ordered, how does the HHA ensure that the frequency of visits meets the clinical needs of the patient?

G163

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

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

G164

(Rev.)

§484.18(b) - . . . Agency professional staff promptly alert the physician to any changes that suggest a need to alter the plan of care.

Interpretive Guidelines §484.18(b)

The expected outcome for this Level 1 standard is that changes in patient status, including measurements outside of stated parameters or any changes that suggest a need to alter the plan of care, are reported promptly to the physician. This includes notifying the physician of discharge when the patient's needs have been met.

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

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

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

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

G165

(Rev.)

§484.18(c) Standard: Conformance With Physician Orders.

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

Interpretive Guidelines §484.18(c)

The expected outcome for this Level 1 standard is that HHA staff administer only medications and treatments as ordered by the physician (except influenza and pneumonia vaccines, which may be administered per agency policy developed in consultation with a physician, and after an assessment of contraindications.

G166

(Rev.)

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

Interpretive Guidelines §484.18(c)

The expected outcome for this Level 1 standard is that all verbal orders are written, signed and dated by the appropriate RN or qualified skilled therapist.

Ask HHA's, whose pattern of obtaining signed physicians' orders exceeds the HHA's policy or State law, to clarify or explain what circumstances created the time lapse, and how they are approaching a resolution to the problem.

Other designated HHA personnel who accept verbal orders must do so in accordance with State and Federal law and regulations and HHA policy. Verbal orders must be

signed and dated by the registered nurse or qualified therapist who is furnishing or supervising the ordered service. It is the RN's or therapist's responsibility to make any necessary revisions to the plan of care based on that order.

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

Probes §484.18(c)

- How does the HHA secure the physician's signature on verbal, change, or renewal orders?
- How does the HHA ensure that verbal orders are accepted, co-signed by the nurse or therapist, and countersigned by the physician appropriately?

G167

See 484.55(c)

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

G300

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

G320

§484.20 Condition of Participation: Reporting OASIS Information

HHA's must electronically report all OASIS data collected in accordance with §484.55.

Interpretive Guidelines §484.20

(Rev.)

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

Effective December 8, 2003, the collection of OASIS data on the non-Medicare/non-Medicaid patients of an HHA was temporarily suspended. HHAs must continue to

comply with the aspects of the regulation at § 484.55 regarding the comprehensive assessment of patients.

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

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

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

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

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

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

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

G321

(Rev.)

§484.20(a) Standard: Encoding and transmitting OASIS Data

An HHA must encode and electronically transmit each completed OASIS assessment to the State agency or the CMS OASIS contractor, regarding each beneficiary with respect to which such information is required to be transmitted (as determined by the Secretary), within 30 days of completing the assessment of the beneficiary.

Interpretive Guidelines §484.20(a)

After OASIS data are collected and completed by the qualified clinician as part of the comprehensive assessment at the required time points (i.e., start of care, resumption of care, follow-up, transfer to inpatient facility with or without discharge, discharge to community, and death at home), HHAs may take up to 30 calendar days after the date of completion of the comprehensive assessment to transmit the OASIS data into their computers using HAVEN or HAVEN-like software and transmit to the State. Encoding of **all** OASIS data items must be complete, i.e., export ready, in order to accurately compute the information (health insurance prospective payment system or HIPPS code) necessary for billing Medicare patients under the prospective payment system.

Pre-Survey Activity - Check with the State OASIS Education or Automation Coordinator and/or review OASIS data management reports to determine if OASIS items are encoded, checked for errors and transmitted to the State within 30 days of completion of the assessment using Haven or Haven-like software, i.e., made transmission ready.

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

Determine the process for encoding and transmitting OASIS data.

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

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

G322

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

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

Interpretive Guidelines §484.20(b)

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

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

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

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

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

Probes 484.20(b)

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

G324

(Rev.)

§484.20(c) Standard: Transmittal of OASIS Data

An HHA must—
(1) For all completed assessments, transmit OASIS data in a format that meets the requirements of paragraph (d) of this section.

Interpretive Guidelines §484.20(c)(1)

HHAs must electronically transmit all OASIS data collected and encoded, by the 30th day following any required Oasis assessment for each patient (as applicable), to the State agency or CMS OASIS contractor. HHAs may transmit OASIS data more frequently than required and are free to develop schedules for transmitting data to best suit their needs.

Rejected data that requires correcting and re-transmitting must be received by the OASIS State system within the same required time frame. Submission of data with identified fatal errors does not justify extending the required time frame. While overdue assessments will be accepted, HHAs (or their contracted vendors) should not wait until the 30th day deadline to transmit their OASIS data in case errors are identified that require re-transmittal or system problems develop that prevent transmission.

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

Pre-Survey Activity - Check with the State OASIS Education or Automation Coordinator and/or review OASIS data management reports to determine if OASIS data are being transmitted as required. Determine whether the HHA is: 1) submitting data less frequently than required; and/or 2) has greater than 20 percent of records rejected in accordance with pre-survey preparation guidelines (SOM Section 2200).

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

Determine that all required OASIS assessments are being transmitted.

Certain missing information or inconsistencies will cause a record to be completely rejected requiring correction by the HHA and retransmission. These are called fatal errors. For example, a fatal error will occur when a record is submitted without the

HHA's State-assigned identification number, without the patient's last name, when the record is a duplicate of one previously received or the record is missing or has an incorrect branch identification number in M0016. A complete listing of current record rejection criteria is available in the HHA Error Message Guide on the OASIS website (http://www.cms.hhs.gov/oasis/usermanu.asp).

HHA's have the ability to electronically correct nearly all errors found in their production OASIS submissions that have been transmitted to the SA or CMS OASIS contractor. There is no current time limit to correcting errors in previously submitted records. SA should not be accepting requests for manual key field changes. Instead, HHA's should use the inactivation procedures to correct assessments containing key field errors. HAVEN 5.0 or above will give HHA's the ability to electronically correct nearly any kind of assessment errors. (See SOM Section 2202.11.) A description of key fields vs. non-key fields is available on the OASIS website (http://www.cms.hhs.gov/oasis/).

Probes §484.20(c)(1)

- Is the HHA successfully transmitting OASIS data 30 days after each assessment?
- Review the HHA's OASIS validation reports. If the HHA's corporate office or contracted vendor submits OASIS data on its behalf, are feedback reports being shared with the HHA?
- What is the HHA's back-up plan if it is unable to submit OASIS data to the State agency?
- What kind of errors is the HHA finding and correcting?
- How is the HHA responding to identified fatal errors?
- How does the HHA verify that assessment data is consistent with the required format?
- What are the established times of OASIS data transmission to the State? (They must be at least monthly.)
- Who is assigned to transmit OASIS data?

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

G325

(Rev.)

§484.20(c)(2) - ***(An HHA must --) Successfully transmit test data to the State agency or CMS OASIS contractor.***

Interpretive Guidelines §484.20(c)(2)

The purpose of making a test transmission to the State agency or CMS OASIS contractor is to establish connectivity. Once the test has been successfully completed, HHA's must

not routinely use the test function to prepare their submission of production (required) OASIS data.

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

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

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

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

NOTE: **The OASIS system is not authorized to maintain unmasked OASIS information on non-Medicare/non-Medicaid patients receiving skilled services. Effective January 1, 2010, non-Medicare and Non-Medicaid data will be rejected.**

G326

(Rev.)

§484.20(c)(3)- (An HHA must --) Transmit data using electronics communications software that provides a direct telephone connection from the HHA to the State agency or CMS OASIS contractor.

Interpretive Guidelines §484.20(c)(3)

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

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

G328

(Rev.)

§484.20(c)(4) – *(The HHA must --)* *Transmit data that includes the CMS-assigned branch identification number, as applicable.*

G327

§484.20(d) Standard: Data Format

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

Interpretive Guidelines §484.20(d)

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

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

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

Probes §484.20(d)

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

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

G168

§484.30 Condition of Participation: Skilled Nursing Services

G169

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

G170

(Rev.)

§484.30 - . . . in accordance with the plan of care.

Interpretive Guidelines §484.30

The expected outcome for this Level 1 standard is that each patient receives nursing care as ordered on his/her plan of care.

G171

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

The registered nurse makes the initial evaluation visit, . . .

G172

(Rev.)

§484.30(a) - . . . regularly re-evaluates the patient's nursing needs, . . .

Interpretive Guidelines §484.30(a)

The expected outcome for this Level 1 standard is that the patient's status and nursing needs are re-evaluated by the RN at least every 60 days (or more often if the patient's condition or needs change).

Probes §484.30(a)

- *For patients with co-morbidities, is there evidence that pertinent inter-related factors are addressed in managing patient's care (e.g., addressing nutrition and skin care in a patient with diabetes that has a wound)?*

G173

(Rev.)

§484.30(a) - … initiates the plan of care and necessary revisions, . . .

Interpretive Guidelines §484.30(a)

The expected outcome for this Level 1 standard is that the RN initiates the plan of care and any revisions to plan of care when appropriate.

Probes §484.30(a)

- *Is there evidence of patient's medical, nursing and rehabilitative needs that are not addressed in the plan of care or communicated to the physician?*
- *Are newly identified patient's medical, nursing and rehabilitative needs addressed in updates to plan of care?*

G174

(Rev.)

§484.30(a) - . . . furnishes those services requiring substantial and specialized nursing skill, . . .

Interpretive Guidelines §484.30(a)

The expected outcome for this Level 1standard is that patients who have specialized nursing needs receive care from qualified nurses who are capable and competent to provide care as ordered and needed (e.g., IV care, ostomy care, wound assessment and care).

G175

(Rev.)

§484.30(a) - . . . initiates appropriate preventive and rehabilitative nursing procedures, . . .

Interpretive Guidelines §484.30(a)

The expected outcome for this Level 1 standard is that patients receive appropriate preventive and rehabilitative nursing care as ordered on the plan of care.

G176

(Rev.)

§484.30(a) - . . . prepares clinical and progress notes, coordinates services, informs the physician and other personnel of changes in the patient's condition and needs, . . .

Interpretive Guidelines §484.30(a)

The expected outcomes for this Level 1 standard are:

- *The RN's clinical and progress nursing notes are complete and provide consistent (i.e., non-conflicting) data regarding patient status and treatments/services provided.*
- *The RN regularly coordinates and communicates with other staff members and the physician about the patient's condition and needs.*

G177

(Rev.)

§484.30(a) - . . . counsels the patient and family in meeting nursing and related needs, . . .

Interpretive Guidelines §484.30(a)

The expected outcome for this Level 1 standard is that the RN counsels the patient and family in meeting nursing and related needs.

G178

§484.30(a) - . . . participates in in-service programs, and supervises and teaches other nursing personnel.

Interpretive Guidelines §484.30(a)

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

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

Probes §484.30(a)

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

G179

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

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

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G180

§484.30(b) - prepares clinical and progress notes,

G181

§484.30(b) - assists the physician and registered nurse in performing specialized procedures,

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G182

§484.30(b) - prepares equipment and materials for treatments observing aseptic technique as required; and

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G183

§484.30(b) - assists the patient in learning appropriate self-care techniques.

Interpretive Guidelines §484.30(b)

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

G184

§484.32 Condition of Participation: Therapy Services

G185

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

G186

(Rev.)

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

Interpretive Guidelines §484.32

The expected outcome for this Level 1 standard is that the qualified therapist assists the physician in evaluating the patient's level of function (e.g., evaluates the patient when ordered), and assists the physician in developing and revising a plan of care that addresses the patient's needs.

G187

(Rev.)

§484.32 - . . . prepares clinical and progress notes, . . .

Interpretive Guidelines §484.32

The expected outcome for this Level 1 standard is that the qualified therapist documents the patient's progress towards goals and outcomes appropriately.

G188

(Rev.)

§484.32 - . . . advises and consults with the family and other agency personnel; and…

Interpretive Guidelines §484.32

The expected outcome for this Level 1 standard is that the qualified therapist communicates with patient/family and other agency personnel such as the physician and other disciplines regarding patient's progress towards goals and outcomes.

G189

(Rev.)

§484.32 - . . . participates in in-service programs.

Probes for the entire condition §484.32, G184-189

- How does the HHA ensure that therapy services furnished by staff under arrangement or contract meet the requirements of this condition?
- Does the clinical record documentation describe the patient responses to therapy?
- How does the HHA coordinate therapy services with other skilled services to complete the plan of care and promote positive therapeutic outcomes?
- *Is therapy provided to each patient as ordered?*
- *Is there evidence of patient therapy or equipment needs that are not addressed in the plan of care or communicated to the physician?*
- *Are therapy visits made at the frequency ordered?*
- *Are assessments and communication with other care providers documented?*

G190

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

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

G191

§484.32(a) - assists in preparing clinical notes and progress reports; and

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G192

§484.32(a) - participates in educating the patient and family, and in in-service programs.

Interpretive Guidelines §484.32(a)

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

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

Probes §484.32(a)

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

G193

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

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

Probes §484.32(b)

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

G194

§484.34 Condition of Participation: Medical Social Services

G195

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

G196

§484.34 - participates in the development of the plan of care,

G197

§484.34 - prepares clinical and progress notes,

G198

§484.34 - works with the family,

G199

§484.34 - uses appropriate community resources,

G200

§484.34 - participates in discharge planning and in-service programs,

G201

§484.34 - and acts as a consultant to other agency personnel.

Interpretive Guidelines §484.34

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

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

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

Probes §484.34

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

G202

§484.36 Condition of Participation: Home Health Aide Services.

G203

§484.36 - Home health aides are selected on the basis of such factors as a sympathetic attitude toward the care of the sick, ability to read, write, and carry out directions, and maturity and ability to deal effectively with the demands of the job. They are closely supervised to ensure their competence in providing care. For home health services furnished (either directly or through arrangements with other organizations) after August 14, 1990, the HHA must use individuals who meet the personnel qualifications specified in §484.4 for "home health aide."

Interpretive Guidelines §484.36

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

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

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

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

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

G204

§484.36(a) Standard: Home Health Aide Training

(1) Standard: Content and Duration of Training

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

G205

§484.36(a)(1) - The individual being trained must complete at least 16 hours of classroom training before beginning the supervised practical training.

G206

§484.36(a)(1) -

(i) Communications skills.
(ii) Observation, reporting and documentation of patient status and the care or service furnished.
(iii) Reading and recording temperature, pulse, and respiration.

(iv) Basic infection control procedures.
(v) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor.
(vi) Maintenance of a clean, safe, and healthy environment.
(vii) Recognizing emergencies and knowledge of emergency procedures.
(viii) The physical, emotional, and developmental needs of and ways to work with the populations served by the HHA, including the need for respect for the patient, his or her privacy and his or her property.

(ix) Appropriate and safe techniques in personal hygiene and grooming that include--

(A) Bed bath.
(B) Sponge, tub, or shower bath.
(C) Shampoo, sink, tub, or bed.
(D) Nail and skin care.
(E) Oral hygiene.
(F) Toileting and elimination.

(x) Safe transfer techniques and ambulation.
(xi) Normal range of motion and positioning.
(xii) Adequate nutrition and fluid intake.
(xiii) Any other task that the HHA may choose to have the home health aide perform.

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

Interpretive Guidelines §484.36(a)

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

A mannequin may be used for training purposes only.

G207

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Requirement" means compliance with a condition level deficiency.

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

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

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

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

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

G208

§484.36(a)(2) –

(ii) Qualifications for instructors.

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

G209

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

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

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

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

G210

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

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

Interpretive Guidelines §484.36(a)(3)

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

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

Documentation of training should include:

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

G211

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

(1) Standard: Applicability

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

G212

§484.36(b)(1) - The HHA is responsible for ensuring that the individuals who furnish home health aide services on its behalf meet the competency evaluation requirements of this section.

Interpretive Guidelines §484.36(b)(1)

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

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

G213

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

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

G214

§484.36(b)(2)(ii) The HHA must complete a performance review of each home health aide no less frequently than every 12 months.

G215

> **§484.36(b)(2)(iii) The home health aide must receive at least 12 hours of in-service training during each 12-month period. The in-service training may be furnished while the aide is furnishing care to the patient.**

Interpretive Guidelines §484.36(b)(2)

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

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

An annual performance review may be completed and documented over a period of time during an aide's two-week supervisory visits in a patient's home or during the installation of an aide in a new patient care situation. Any reasonable performance review method

that is logical and consistent with the HHA's policies and procedures would meet the intent of this standard.

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

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

Probes §§484.36(b)(1) & (2)

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

G216

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

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

G217

§484.36(b)(3)(ii) Evaluators and instructors. The competency evaluation must be performed by a registered nurse.

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

G218

§484.36(b)(3) (iii) Subject areas. The subject areas listed at paragraphs (a)(1)(iii), (ix), (x) and (xi) of this section must be evaluated after observation of the aide's performance of the tasks with a patient. The other subject areas in paragraph (a)(1) of this section may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient.

Interpretive Guidelines §484.36(b)(3)

Subject areas (a)(1)(iii), (ix), (x) and (xi) may be evaluated with the tasks being performed on a pseudo-patient such as another aide or volunteer in a laboratory setting.

The tasks must not be simulated in any manner and the use of a mannequin is not an acceptable substitute.

Probes §484.36(b)(3)

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

G219

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

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

G220

§484.36(b)(4)(ii) - A home health aide is not considered to have successfully passed a competency evaluation if the aide has an unsatisfactory rating in more than one of the required areas.

Interpretive Guidelines §484.36(b)(4)

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

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

methodology for the evaluation of aide skills must have the additional required skills evaluated before the aide is determined to be competent.

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

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

Probes §484.36(b)(4)

1. How does the HHA confirm aide skills on an ongoing basis for its employees including new hires and personnel under arrangement or contract?

2. If aides are performing tasks that are an extension of home health services other than nursing, how does the HHA document that these aides have proven competency in these tasks to the appropriate health professional?

G221

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

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

G222

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

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

G223

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

(1) -The home health aide is assigned to a specific patient by the registered nurse…

G224

(Rev.)

§484.36(c)(1) - . . . Written patient care instructions for the home health aide must be prepared by the registered nurse or other appropriate professional who is responsible for the supervision of the home health aide under paragraph (d) of this section.

Interpretive Guidelines §484.36(c)(*1)*

The expected outcome for this Level 1 standard is that the home health aide receives written instructions by the RN or other appropriate professional responsible for supervising the aide for patient care that are clear and complete and address patients' current needs.

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

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

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

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

G225

§484.36(c)(2) Standard: Duties

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

G226

§484.36(c)(2) - The duties of a home health aide include the provision of hands-on personal care, performance of simple procedures as an extension of therapy or nursing services, assistance in ambulation or exercises, and assistance in administering medications that are ordinarily self-administered.

G227

§484.36(c)(2) - Any home health aide services offered by an HHA must be provided by a qualified home health aide.

Interpretive Guidelines §484.36(c)(2)

See §484.4 for the definition of a home health aide.

G228

§484.36(d) Standard: Supervision

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

G229

(Rev.)

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

Interpretive Guidelines §484.36(d)(2)

The determination as to whether the aide should be present and observed during the supervisory visit should be based on the level of experience, performance, and abilities of the aide and the complexity of the patient's needs.

The expected outcome for this Level 1 standard is that the aide supervisory visits occur no less frequently than every 14 days. Additional instruction is provided to the aide if needed based on the information obtained from the supervisory visits.

G230

§484.36(d)(3) - If home health aide services are provided to a patient who is not receiving skilled nursing care, physical or occupational therapy or speech-language pathology services, the registered nurse must make a supervisory visit to the patient's home no less frequently than every 60 days.

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

Interpretive Guidelines §484.36(d)

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

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

Probes §484.36(d)

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

G231

§484.36(d)(4) - If home health aide services are provided by an individual who is not employed directly by the HHA (or hospice), the services of the home health aide must be provided under arrangements, as defined in section 1861(w)(1) of the Act.

G232

§484.36(d)(4) - If the HHA (or hospice) chooses to provide home health aide services under arrangements with another organization, the HHA's (or hospice's) responsibilities include, but are not limited to--

(i) Ensuring the overall quality of the care provided by the aide;

G301

§484.36(d)(4)(ii) - Supervision of the aide's services as described in paragraphs (d)(1) and (d)(2) of this section; and

G302

§484.36(d)(4)(iii) - Ensuring that home health aides providing services under arrangements have met the training requirements of paragraph (a) and/or (b) of this section.

Interpretive Guidelines §484.36(d)(4)

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

Probes §484.36(d)(4)

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

G233

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

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

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

Interpretive Guidelines §484.36(e)

Personal care services also include those services defined at §440.180.

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

G234

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

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

Interpretive Guidelines §484.38

An HHA that furnishes outpatient therapy services on its own premises, including its branches, must comply with the listed citations as well as meet all other Conditions of Participation. §485.723 and §485.727 are not applicable when the patients are served in their **own** homes. §485.723 and §485.727 are applicable, and may be surveyed at the SA's or RO's discretion, when specialized rehabilitation space and equipment is owned, leased, operated, contracted for, or arranged for at sites under the HHA's control and when the HHA bills the Medicare/Medicaid programs for services rendered at these sites. Complete the corresponding section of the Outpatient Physical Therapy or Speech Pathology Survey Report, Form CMS-1893 when surveying these sites. Indicate the

agency's certification to provide outpatient therapy services via special remarks on the Certification and Transmittal, Form CMS-1539. (See §§2764, Item 16.)

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

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

G235

§484.48 Condition of Participation: Clinical Records

G236

(Rev.)

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

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

Interpretive Guidelines §484.48

The expected outcomes for this Level 1 standard are:

- *Every patient must have a clinical record. The clinical record for every patient contains all required elements and is current, organized, and provides a clear synopsis of the services provided to the patient.*
- *Filing of documents into the clinical record is current according to agency policy and any applicable State filing timelines.*
- *If electronic signatures are accepted, the HHA follows its policies governing their use.*
- *When comprehensive assessments are corrected, the HHA maintains the original assessment as well as all subsequent corrected assessments.*

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

Questionable patterns, rather than isolated instances, in clinical records are an indicator that the quality of care provided by the HHA needs to be carefully assessed for compliance with the plan of care, coordination of service, concurrence with the HHA's stated policies and procedures, and evaluations of patient outcomes. However, isolated instances, depending on their nature and severity, can serve as the basis of a deficiency and enforcement action (e.g., immediate and serious threat as outlined in Appendix Q).

Electronic Health Records (EHR):

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

If the HHA uses an EHR, the HHA will (a) provide the surveyor with a tutorial on how to use its particular electronic system, and (b) designate an individual who will, when requested by the surveyor, access the system, respond to any questions, or assist the surveyor as needed in accessing electronic information in a timely fashion. Each surveyor will determine the EHR access method that best meets the need for that survey.

If the agency is unable to provide direct print capability to the surveyor, the agency must make available a printout of any record or part of a record upon request in a timeframe that does not impede the survey process. Undue delays in the production of records are unacceptable. Whenever possible, the agency must provide surveyors electronic access to records in a read-only format or other secure format to avoid any inadvertent changes to the record. The provider is solely responsible for ensuring that all necessary back up of data and security measures are in place.

NOTE: HHAs may not accept stamped physician signatures on orders, treatments, or other documents that are a part of the patient's clinical record.

Correction of Clinical Records

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

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

Clinical Implications of Corrected Assessment Records

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

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

G303

(Rev.)

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

Interpretive Guidelines §484.48

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

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

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

Probes §484.48

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

G237

§484.48(a) Standard: Retention of Records.

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

G238

§484.48(a) - If a patient is transferred to another health facility, a copy of the record or abstract is sent with the patient.

Interpretive Guidelines §484.48(a)

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

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

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

G239

§484.48(b) Standard: Protection of Records

Clinical record information is safeguarded against loss or unauthorized use.

G240

§484.48(b) - Written procedures govern use and removal of records and the conditions for release of information.

G241

§484.48(b) - Patient's written consent is required for release of information not authorized by law.

Probes §484.48(b)

- How are clinical records stored to protect them from physical destruction and unauthorized use?
- What written policies and procedures govern the use, removal, and release of clinical records?
- How does the HHA make the records available for all personnel furnishing services on behalf of the HHA?

G242

§484.52 Condition of Participation: Evaluation of the Agency's Program

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G243

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

G244

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

G245

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

G246

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

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G247

§484.52 - are maintained separately as administrative records.

Interpretive Guidelines §484.52

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

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

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

G248

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

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

G249

§484.52(a) - Mechanisms are established in writing for the collection of pertinent data to assist in evaluation.

Interpretive Guidelines §484.52(a)

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

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

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

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

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

Probes §484.52(a)

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

G250

§484.52(b) Standard: Clinical Record Review

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

G251

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

Interpretive Guidelines §484.52(b)

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

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

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

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

- Review the HHA's policies relevant to the evaluation of patient care needs.

- Review HHA contracts for unserved or underserved services, if they are provided under contract or arrangement.

- Review plans of care to determine if the services were ordered by a physician but not delivered.

- Ask the HHA under what circumstances it would contact the patient's physician to request modification of a patient's plan of care.

Probes §484.52(b)

- What patterns or problems does the summary report of the clinical record reviews identify?
- What is the HHA's plan of correction? Are time frames for implementation and another evaluation review planned?
- How does the HHA select the clinical records to be reviewed?
- How do the procedures for review ensure that the review will ascertain whether:
    - HHA policies and procedures are followed?
    - Patients are being helped to attain and maintain their highest practicable functional capacity?

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

G330

(Rev.)

§484.55 Condition of Participation: Comprehensive Assessment of Patients

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

Interpretive Guidelines §484.55

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

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

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

- Under age 18;
- Receiving maternity services;
- Receiving housekeeping or chore services only;
- Receiving only personal care services until further notice*; or*
- Patients for whom Medicare or Medicaid insurance is not billed.

This includes Medicare, Medicaid, and any health plan options that are part of the Medicare program (e.g., Medicare Advantage (MA) plans. It also includes Medicaid patients receiving services under a waiver program or demonstration to the extent they do not fall into one of the exception categories listed above, who are receiving services subject to the Medicare conditions of participation.

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

During this temporary suspension, SA and Regional Office (RO) surveyors should adhere to the following guidance when conducting HHA surveys:

- HHAs must continue to comply with the aspects of the regulation at § 484.55 regarding the comprehensive assessment of patients. HHAs must provide each agency patient, regardless of payment source, with a patient-specific comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward the achievement of desired outcomes. The comprehensive assessment must also identify the patient's continuing need for home care, medical, nursing, rehabilitative, social, and discharge planning needs.
- HHAs may continue to collect OASIS data on their non-Medicare/non-Medicaid patients for their own use.
- Surveyors must continue to examine the completeness of the comprehensive assessment for all patients during a survey. However, surveyors must not investigate whether the HHA included the specific OASIS items in its patient-specific comprehensive assessments of non-Medicare/non-Medicaid patients, nor cite deficiencies based solely on this finding.
- HHAs must continue to collect, encode, and transmit OASIS data for their non-maternity Medicare and Medicaid patients that are age 18 and over and receiving skilled services.

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

The phrase "not less frequently than the last five days of every 60 days beginning with the start of care date" does not mean that HHAs must wait until the *56th* – 60th day to perform another comprehensive assessment on non-Medicare/non-Medicaid patients or for pediatric patients, maternity patients or those receiving personal care services even when Medicare is the payor source. The assessment may be performed any time up to and including the 60th day. The timetable for the subsequent 60-day period would then be measured from the completion date of the most recently completed assessment. Clinicians may perform the comprehensive assessment for these patients more frequently than the last 5 days of the 60-day episode without conducting another comprehensive assessment on day *56*-60, and remain in compliance with §484.55(d). The agency may develop its own comprehensive assessment for each time point.

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

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

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

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

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

G331

(Rev.)

§484.55(a) Standard: Initial Assessment Visit

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

Interpretive Guidelines §484.55(a)(1)

The expected outcome for this Level 1 standard is:

- *The RN completes the initial assessment and the comprehensive assessment when skilled nursing is ordered.*
- *The comprehensive assessment is consistently complete and findings are addressed in plan of care.*

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

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

See the guidelines at §484.55 above for Medicare eligibility requirements.

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

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

Probes §484.55(a)(1)

- What are the HHA's policies for conducting the initial assessment?
- How is Medicare eligibility and homebound status determined?

G332

(Rev.)

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

Interpretive Guidelines §484.55(a)(1)

The expected outcome for this Level 1 standard is that the patient receives an initial assessment within the required time frames.

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

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

Probes §484.55(a)(1)

- How does the HHA assure that initial visits are conducted within the required time frames?
- Compare the date of the physician referral and the date of the initial assessment visit. If the initial visit is later than 48 hours or later than the physician-ordered start of care date, check the individual patient's clinical record. Sometimes a patient requests that a visit not be made until a more convenient time. That request must be documented in the clinical record as well as a notation that the physician was notified of and approves the patient's request for a delayed start of care.
- If the physician orders start of care to begin after the 48-hour time frame specified in the regulations, is there an order in the patient's chart specifying this start of care date?

G333

§484.55(a)(2) - When rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate rehabilitation skilled professional.

Interpretive Guidelines §484.55(a)(2)

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

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

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

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

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

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

Probes §484.55(a)(2)

- How does the HHA assure that initial visits are conducted within the required time frames?
- Compare the date of the physician referral and the date of the initial assessment visit. If the difference is greater than 48 hours or later than the physician ordered start of care date, check the individual patient's clinical record. If a patient requests that a visit not be made until a more convenient time, the request should be reported to the physician and documented in the clinical record.
- Review patient records in which therapy (occupational therapy, physical therapy, or speech language pathology) was the only skilled service provided. Determine

if the appropriate discipline completed the initial assessment. According to State law, some HHA's may use RNs for initial assessments in therapy-only cases.

- Interview staff to determine how therapy-only initial assessment visits are conducted.
- How does the HHA ensure that the skilled disciplines completing the initial assessment are performing this task accurately?

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

G334

(Rev.)

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

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

Interpretive Guidelines §484.55(b)(1)

The expected outcome for this Level 1 standard is that the comprehensive assessment is completed within required time frames.

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

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

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

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

M0090 on the OASIS data set reflects the final date the qualified clinician completed the actual patient assessment. This is usually the date of the last home visit made to complete the comprehensive assessment but may reflect a date subsequent to the onsite

visit when the qualified clinician needs to follow up, offsite, with the patient's family or physician in order to complete an OASIS clinical data item. Compare the start of care date at M0030 with the date the assessment was completed (M0090). M0090 should be no more than 5 days later than M0030. The HHA has *30* additional days from the date the patient assessment is completed (M0090) to encode (data-enter), edit, and ensure the accuracy of the OASIS data and to consult with the qualified clinician who conducted and completed the comprehensive assessment for purposes of clarification or to complete missing OASIS data items such as diagnosis codes, etc., and to lock (export) the data for future submission to the State agency. (See §484.20(a)).

Probes §484.55(b)(1)

- Was the start of care comprehensive assessment completed within 5 calendar days after the start of care date?
- Did the HHA provide acceptable explanations and documentation for start of care comprehensive assessments completed outside of the required time frame?

G335

(Rev.)

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

Interpretive Guidelines §484.55(b)(2)

The expected outcome for this Level 1 standard is that for Medicare and Medicaid patients receiving skilled nursing services, an RN conducts and completes the comprehensive assessment, and confirms the eligibility of Medicare patients, including homebound verification, for the Medicare home health benefit. See the guidelines at §484.55 for Medicare eligibility requirements.

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

Probes §484.55(b)(2)

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

G336

(Rev.)

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

Interpretive Guidelines §484.55(b)(3)

The expected outcome for this Level 1 standard is that for a therapy-only case, the RN (if required by agency policy or State law) or the physical therapist or speech language pathologist conducts and completes the comprehensive assessment at the patient's admission to the HHA. Occupational therapists may conduct and complete the assessment when the need for occupational therapy establishes program eligibility.

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

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

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

For patients receiving services from multiple skilled disciplines, the comprehensive assessment, including OASIS items, may be completed by different disciplines such as a

registered nurse, physical therapist or speech language pathologist at subsequent time points. The same discipline is not required to complete the comprehensive assessment at every required time point.

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

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

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

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

Probes §484.55(b)(3)

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

G337

(Rev.)

§484.55(c) Standard: Drug Regimen Review

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

Interpretive Guidelines §484.55(c)

The expected outcomes for this Level 1 standard are:

- *The comprehensive assessment consistently includes a thorough review of the patient's medications, including all prescribed and over-the-counter medications the patient is using, to identify any potential adverse effects and drug reactions;*
- *The patient's medication list or medications are reviewed and the medication profile/list is updated; and*
- *The physician is notified promptly regarding any medication discrepancies, side effects, problems or reactions. See also §484.30(a)*

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

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

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

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

The label on the bottle of a prescription medication constitutes the pharmacist's transcription or documentation of the order. Such medications are noted in the patient's clinical record and listed on the physician plan of care. This is consistent with

acceptable standards of practice. Federal regulations do not have additional requirements.

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

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

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

Probes §484.55(c)

- What is the HHA's policy for drug regimen/medication review?
- How does the HHA respond to medication discrepancies and prescriptions from physicians other than the physician responsible for the patient's home health care?
- If HHA personnel identify patient sensitivity or other medication problems, what actions does the HHA require its personnel to take?

G338

(Rev.)

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

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

Interpretive Guidelines §484.55(d)

The expected outcomes for this Level 1 standard are:

- *The comprehensive assessment is updated and revised as required and updated patient information is included in care planning; and*
- *The comprehensive assessment data are consistent with other patient status data in the clinical record.*

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

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

In the event an HHA determines that a patient's condition has improved or deteriorated beyond the HHA's expectations, the HHA may choose to collect and report additional assessment information. HHAs must code this as 'Other follow-up". The start of care date does not change when an HHA conducts this optional assessment. The transfer assessment should include required OASIS items as well as a clinical note describing the status of the patient on transfer to an inpatient facility.

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

Probes §484.55(d)

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

G339

(Rev.)

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

(i) Beneficiary elected transfer;
(ii) Significant change in condition; or
(iii) Discharge and return to the same HHA during the 60-day episode.

Interpretive Guidelines §484.55(d)(1)

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

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

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

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

A Significant Change In Condition (SCIC) occurs when a Medicare beneficiary experiences a significant change in condition (improvement or deterioration) during a 60-day episode that was not envisioned in the original plan of care. The HHA must complete an OASIS assessment and obtain the physician change orders reflecting the significant change in treatment approach in the patient's plan of care.

Probes §484.55(d)(1)

- How does the HHA determine when the follow-up comprehensive assessment is due? Ask clinical staff to describe their process.
- Does the M0090 item (date assessment completed) fall within the time frame required for the follow-up comprehensive assessment?
- How are follow-up comprehensive assessments completed if a skilled service is not projected at the time when the follow-up assessment is due? Are they incorporated into a *home health* aide supervisory visit, for example?
- Does the HHA have a policy defining a significant change in condition?

G340

(Rev.)

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

Interpretive Guidelines §484.55(d)(2)

The expected outcome for this Level 1 standard is that the patient's needs are assessed and incorporated into the plan of care upon his/her return home from a hospital stay (as described in this requirement).

As part of the case-mix, stratified sample of clinical records, review patient records to determine if comprehensive assessments with OASIS data items integrated are collected

at required time points. Evaluate the validity of any reasons why an assessment was not completed within the required time frame.

Updated comprehensive assessments are required:

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

Probes §484.55(d)(2)

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

G341

§484.55(d)(3) - At discharge.

Interpretive Guidelines §484.55(d)(3)

Updated comprehensive assessments are required:

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

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

Probes §484.55(d)(3)

- How does the HHA readmit patients after transfer ("on hold" or "discharge") and determine next assessment dates?
- Interview HHA staff and review the HHA's policy for inpatient facility admission. Does the HHA place the patient on hold or does the HHA discharge the patient for any inpatient facility admission?
- Does the M0090 item (date assessment completed) fall within the time frame required for the transfer (with or without agency discharge, discharge to the community or death at home comprehensive assessment?)
- What does the HHA do for unanticipated patient discharges?

G342

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

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

Interpretive Guidelines §484.55(e)

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

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

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

Probes §484.55(e)

- Does the HHA have the required OASIS data items integrated into its comprehensive assessments, i.e., start of care, resumption of care, follow-up, transfer, discharge and death at home?
- Is the OASIS data set appended at the beginning or end of the HHA's assessment form, rather than integrated into the HHA's own comprehensive assessment tool?