

CMS Manual System

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Provider Certification

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 11

Date: AUGUST 12, 2005

SUBJECT: Revised Chapter 2--"The Certification Process," Sections 2180E thru 2200F, and Appendix B--"Interpretive Guidelines: Home Health Agencies"

- I. SUMMARY OF CHANGES:** The purpose of these revisions is to include current CMS policy memorandum, delete material and reference forms that are obsolete, and make minor editorial changes within Chapter 2, §2180E thru §2200F.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: August 12, 2005

IMPLEMENTATION DATE: August 12, 2005

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

- II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)**
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	2/Table of Contents
N	2/2180E/Application of Home Health Agency Conditions of Participation to Patients Receiving Chore Services Exclusively
N	2/2182.4D/Drop Sites
R	2/2182.5/Branch Identification Numbers
R	2/2184/Operation of HHAs Across State Lines
R	2/2195.1/Tracking and Monitoring the Survey Cycles
R	2/2200E/Task 5 - Exit Conference
R	2/2200F/Task 6 - Formation of the Statement of Deficiencies
N	Appendix B/484.10(e)(2)/Standard: Patient Liability for Payment/ Tag G115
R	Appendix B/484.12(b)/Standard: Disclosure of Ownership and Management Information/Tag G120/ Interpretive Guidelines & Probes
R	Appendix B/484.18(a)/Standard: Plan of Care/Tag G162
R	Appendix B/484.18(b)/Standard: Periodic Review of Plan of Care/Tag G164
R	Appendix B/484.18(c)/Standard: Conformance with Physician Orders/Tags G165 – G166
R	Appendix B/484.20/Condition of Participation: Reporting OASIS Information/Tag G320
R	Appendix B/484.36(b)/Standard: Competency Evaluation In-Service Training /Tags G213 – G214

R	Appendix B/484.36(d)/Standard: Supervision/Tag G230
R	Appendix B/484.48/Condition of Participation: Clinical Records/Tags G236 & G303
R	Appendix B/484.55/Condition of Participation: Comprehensive Assessment of Patients/Tags G330

III. FUNDING: * No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2005 operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

State Operations Manual

Chapter 2 - The Certification Process

(Rev. 11, 08-12-05)

Table of Contents

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

2182.4D – Drop Sites

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

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

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

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

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

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

CMS considers as a medical service any hands-on service, personal care service, cueing, or activity that is in any way involved in monitoring the patient’s health condition. As soon as the HHA provides any Medicare service to an individual, or any standard service permitted by Federal law under the Medicaid State Plan (such as personal care), we will consider the individual to be receiving medical care. The CoPs will apply for all services rendered to such an individual. For example, the CoPs would apply in the case of an individual who received both chore services and personal

care (regardless of funding source), but would not apply in the case of an individual receiving only chore services from the HHA.

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

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

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

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

2182.4D - Drop Sites

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

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

2182.5 - Branch Identification Numbers

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

An identification number is assigned to every branch of a parent HHA and subunit, as applicable, effective January 1, 2004. The identification system uniquely identifies every branch of every HHA certified to participate in the Medicare home health program. It also links the parent or subunit to the branch. Having a system to identify branches gives CMS the capability of associating survey results with individual HHA branches. Also, submission of branch identification numbers on Outcome and Assessment Information Set (OASIS) assessments will provide the capability of developing outcome reports that will help HHAs differentiate and monitor the quality of care delivered by their agencies down to the branch level.

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

EXAMPLE

- ABC Home Health Agency in Alabama has three branches.

- ABC Home Health Agency in Alabama = Medicare Provider number 017001.
- ABC's branches would be assigned the branch identification numbers 01Q7001001, 01Q7001002, and 01Q7001003.
- As directed by the ROs, HHA branch identification numbers will be entered into the Automated Survey Processing Environment (ASPEN) system along with the branch demographic information.

Assignment of Branch Identification Numbers

The Form CMS-1572, which captures survey and deficiency information on every survey, requests branch information at field G17 that includes an HHA's total number of branches and name and address of each branch location. This information should be entered into ASPEN after every survey as part of the survey kit. As surveys are conducted, SAs should verify that the information they have on branch locations is current and accurate. As branch identification numbers are assigned, HHAs and their respective branches are informed of their assigned branch identification number(s). A sample letter is attached available at [*\(Exhibit 151\)*](#) for use by the RO or SA to notify HHAs of their branch identification number(s). HHAs will need this information to enter on OASIS item M0016 (Branch ID). HHAs and subunits that do not have branches will not be assigned any branch IDs.

Form CMS 1572 and Assignment of Branch Identification Numbers

ROs are responsible for assigning branch identification numbers according to the RO's existing policies for assignment of provider numbers. The Form CMS-1572, which captures survey and deficiency information on every survey, requests branch information at field G17 that includes an HHA's total number of branches and name and address of each branch location. This information should be entered into ASPEN after every survey as part of the survey kit. Current branch information is collected on every state agency home health survey.

When future HHA branches are approved, the ROs must assure that all branch locations nationwide are identified, enumerated, and entered into ASPEN prior to sending the approval letter to the HHA. As surveys are conducted, states should verify that the information they have on branch locations is current and accurate.

Branch Identification Numbers and OASIS

As branch identification numbers are assigned, the RO must ensure that HHAs and their respective branches are informed of their assigned branch identification number. At this time the fiscal intermediaries are not in need of branch identification information.

HHAs will need this information to complete OASIS item M0016 Branch ID. Detailed instructions for completion of M0016 by parent HHAs, subunits, branches, and HHAs

and subunits without branches are included in M0016 Branch ID in Chapter 8 of the OASIS Implementation Manual.

2184 - Operation of HHAs *Across State Lines*

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

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

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

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

The CMS RO will review the required reciprocal agreement between the States to assure that the SA in which the branch resides is assuming responsibility for any necessary surveys of the branch. If the SAs involved are unable to come to a reciprocal agreement on assuring the necessary surveys of the branch, the branch should not be approved. The provision of interstate service without a written reciprocal agreement could severely undermine a State's ability to fulfill its statutory responsibilities under §1864 of the Act to enforce Medicare's health and safety requirements. It is at the discretion of the States to decide whether entering into reciprocal agreements is in the best interest of their residents, provider markets, and quality assurance and oversight systems.

Exhibit 152 contains a model reciprocal agreement document that States may use to assist them in fulfilling their statutory responsibilities under §1864 of the Act to enforce Medicare's health and safety requirements when an HHA provides services across State lines. In those States that have a reciprocal agreement, providers are not required to be separately approved in each State; consequently they would not have to obtain a separate Medicare provider agreement/number in each state. Providers residing in a State that does not have a written reciprocal survey agreement with a contiguous State are precluded from providing services across State lines.

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

In the event that an HHA operates in two CMS ROs, the CMS RO responsible for the State in which the parent resides should take the lead in assuring that the required survey and certification activities are met.

A branch office may also be physically located in a neighboring State if it is near enough to the parent agency to share administration, supervision, and services on a daily basis, and if the SAs responsible for certification in each State approve the operation.

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

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

2195.1 - Tracking and Monitoring the Survey Cycles

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

The following codes should be entered into the ASPEN system to enable the SAs and ROs to track and monitor the survey cycles of HHAs *except that the coding is optional for 2006 as CMS tests an alternate system. States may, however, elect to continue the coding. If so, the code should be entered* when the survey is completed and the survey results are ready for upload to the national system. Surveyors or other appropriate staff should clearly mark the length of the survey cycle on the Application (Form CMS-1572A) tab in the designated field. The codes are outlined below:

- A = 36 months;
- B = 12-36 months;
- C = 12 months;
- D = 4-6 months; and
- E = 18 months (5% sample).

For 2006, a CMS-generated list will be used to target those HHAs that will be surveyed more frequently than once every 3 years. For all other years, the following will apply:

With the exception of code B, the codes will identify the survey interval for all HHAs, i.e., code A HHAs will be surveyed every 36 months, code C HHAs will be surveyed every 12 months, etc. Survey the majority of code B HHAs at least every 24 months; however, SAs may use their discretion in surveying more or less frequently. HHAs that meet the criteria for a code A as the result of their last survey may be selected for the 5% sample in 18 months and entered into the system as a code "E."

Once the survey frequency code has been entered and uploaded to the national system, the SA shall have the responsibility to enter any subsequent changes to the survey frequency code, providing the reason for the change. A history of survey frequency code changes, the reasons for each change, and other information as required by CMS will be maintained on the national system. The two most likely reasons to change the survey frequency code between surveys are a complaint investigation with deficiency citations or a change of ownership. The SA and RO should keep apprised of such events by generating reports that track HHA survey frequency code change details.

2200E - Task 5 - Exit Conference

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

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.

Information recorded on the component parts of the FAIs or other comments recorded on Form CMS-1572 serve as the surveyor's official worksheets. They are not to be given to or copied by HHA staff.

Follow these guidelines during the exit conference:

- Clarify the names and positions of all HHA personnel or other individuals attending the meeting.
- Summarize the facts of the onsite evaluation (team size, composition, days onsite, the sample size for record review and home visits) to set the tone for understanding the overall recommendations that the SA will make to CMS regarding compliance determinations.
- Present findings regarding citations of deficient practice(s) in a straightforward, 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 (i.e., recertification status: the timeframe for receiving Form CMS-2567 and submitting a PoC to the SA in response to the written citations). Clarify any areas for which further deficiency citations may be made offsite after further analysis with team members or the SA supervisor.
- Provide instructions and timeframe necessary for submitting a PoC as referenced in [§2724](#).
- Describe the procedures that are not in compliance with regulations and the findings that substantiate the deficiencies, identifying specific regulatory references in response to questions raised by staff.

Present Form CMS-2567 onsite or in accordance with the SA's policy, but no later than 10 **working** days after the exit conference.

NOTE: Surveyors should refer to [§2724](#) 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.

2200F - Task 6 - Formation of the Statement of Deficiencies

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

Write the deficiency statement in terms specific enough to allow a reasonably knowledgeable person to understand the aspects of each requirement not met. The [§2728](#) provides detailed instructions on the effective completion of Form CMS-2567.

G115

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

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

Interpretive Guidelines §484.10(e)

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

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

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

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

Probes §484.10(e)

- 1. What process is followed by the HHA to inform the patient of home care charges and probable payment sources, patient's payment liability (if any), and of changes in payment sources and patient liabilities?*
 - 2. What documentation in the clinical record indicates that the HHA informed the patient of Federally-funded or aided covered and non-covered services?*
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G120

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

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

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

Interpretive Guidelines §484.12(b)

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

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

Probes §484.12(b)

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

2. How does the HHA implement its policy or procedure for reporting changes in ownership and management information to the State?
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G162

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

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

Interpretive Guidelines §484.18(a)

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

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

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

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

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

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

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

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

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

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

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

Probes §484.18(a)

1. How does an HHA evaluate whether the plan of care, and the coordination of services, help the patient attain and maintain his or her highest practicable functional capacity based on medical, nursing, and rehabilitative needs?
 2. How does the HHA monitor the delivery of services, including those provided under arrangement or contract, to ensure compliance with the specificity and frequency of services ordered in the plan of care?
 3. If a range of visits is ordered, how does the HHA ensure that the frequency of visits meets the clinical needs of the patient?
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G164

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

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

Interpretive Guidelines §484.18(b)

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

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

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

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

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

§484.18(c) Standard: Conformance with Physician Orders

G165

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

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

G166

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

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

Interpretive Guidelines §484.18(c)

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

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

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

Probes §484.18(c)

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

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

§484.20 Condition of Participation: Reporting OASIS Information

G320

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

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

Interpretive Guidelines §484.20

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

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

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

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

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

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

HHAs or contracted entities acting on behalf of the HHA can report OASIS data to the State agency using the HAVEN software CMS provides free of charge or by using

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

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

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

G213

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

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

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

G214

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

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

G230

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

§484.36(d)(3)

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

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

Interpretive Guidelines §484.36(d)

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

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

Probes §484.36(d)

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

§484.48 Condition of Participation: Clinical Records

G236

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

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

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

Interpretive Guidelines §484.48

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

Questionable patterns, rather than isolated instances, in clinical records are an indicator that the quality of care provided by the HHA needs to be carefully assessed for compliance with the plan of care, coordination of service, concurrence with the HHA's stated policies and procedures, and evaluations of patient outcomes. However, isolated instances, depending on their nature and severity, can serve as the basis of a deficiency and enforcement action (e.g., immediate and serious threat as outlined in Appendix Q).

Electronic Signatures

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

Physician's Rubber Stamp Signatures

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

Correction of Clinical Records

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

When a comprehensive assessment is corrected, the HHA must maintain the original assessment record as well as all subsequent corrected assessments in the patient's

clinical record for five years, or longer, in accordance with the clinical record requirements at 42 CFR 484.48. If maintained electronically, the HHA must be capable of retrieving and reproducing a hard copy of these assessments upon request. It is acceptable to have multiple corrected assessments for an OASIS assessment, as long as the OASIS and the clinical record are documented in accordance with the requirements at 42 CFR 484.48, Clinical records.

Clinical Implications of Corrected Assessment Records

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

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

G303

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

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

Interpretive Guidelines §484.48

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

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

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

Probes §484.48

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

G330

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

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

Interpretive Guidelines §484.55

The comprehensive assessment includes the collection of OASIS data items for most patients, as described below, by a qualified clinician, i.e., an RN, physical therapist, occupational therapist, or speech language pathologist. For Medicare patients, there are some additional requirements. HHAs are expected to conduct a comprehensive assessment of each patient that accurately reflects the patient's current health status and includes information to establish and monitor a plan of care. The plan of care must be

reviewed and updated at least every 60 days or as often as the severity of the patient's condition requires, per the requirements at [42 CFR 484.18 \(a\) and \(b\)](#).

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

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

- Under age 18;
- Receiving maternity services;
- Receiving housekeeping or chore services only; or
- Receiving only personal care services until further notice.
- Patients for whom Medicare or Medicaid insurance is not billed

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

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

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

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

- *HHAs must continue to comply with the aspects of the regulation at 42 CFR 484.55 regarding the comprehensive assessment of patients. HHAs must provide each agency patient, regardless of payment source, with a patient-specific comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward the achievement of desired outcomes. The comprehensive assessment must also identify the patient's continuing need for home care, medical, nursing, rehabilitative, social, and discharge planning needs.*
- *HHAs may continue to collect OASIS data on their non-Medicare/non-Medicaid patients for their own use.*
- *Surveyors must continue to examine the completeness of the comprehensive assessment for all patients during a survey. However, surveyors must not investigate whether the HHA included the specific OASIS items in its patient-specific comprehensive assessments of non-Medicare/non-Medicaid patients, nor cite deficiencies based solely on this finding.*
- *HHAs must continue to collect, encode, and transmit OASIS data for their non-maternity Medicare and Medicaid patients that are age 18 and over and receiving skilled services.*

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

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

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

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

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

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

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