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

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(Rev. 245; Issued: 08-05-26)

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Survey Protocol for Home Health Agencies

Part I

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

I. – Introduction

Home health agencies (HHAs) are required to meet the definition of an HHA as stated in section 1861(o) of the Social Security Act (the Act) and comply with the federal requirements set forth in the Medicare Conditions of Participation (CoPs) in order to be certified by the Medicare program. The HHA survey process evaluates compliance with the CoPs set forth at section 1891 of the Act and 42 CFR Part 484 to ensure that the HHA meets minimum health and safety standards.

The HHA survey process incorporates an approach that is patient-focused and outcome-oriented, making it effective and efficient in assessing, monitoring, and evaluating the quality of care delivered by an HHA.

The purpose of the survey protocols and interpretive guidelines (IGs) is to provide a standardized methodology for conducting the survey. Surveyors conduct the HHA survey in accordance with the appropriate protocols, which are intended to promote consistency in the survey process.

Compliance with the CoPs is evaluated from information gathered during observations of the HHA's performance and practices as well as clinical record reviews and interviews with the HHA's patients, patients' caregivers and HHA staff.

All mandatory requirements for HHAs are set forth in relevant provisions of the Social Security Act and in the Code of Federal Regulations (CFR). Although surveyors use the information contained in the IGs to help to make a determination about compliance with the requirements, the IGs are not binding and do not replace or supersede the law or regulations.

The IGs contain authoritative interpretations and clarification of statutory and regulatory requirements and are used to assist surveyors in making determinations about an HHA's compliance, however IGs may not be used alone as the sole basis for a citation.

A. Survey Team Size and Composition

Surveyor qualifications are specified at 42 CFR §488.735. Surveyors must successfully complete the Centers for Medicare & Medicaid Services (CMS)-sponsored Basic HHA Surveyor Training Course and any associated course prerequisites before they may serve on an HHA survey team (except as a trainee). Surveyor trainees may participate in an HHA survey under the supervision of an

experienced surveyor. Each HHA survey team must include at least one Registered Nurse (RN).

The survey team size will vary depending on the size of the agency. Survey team size is determined by the State Survey Agency (SA) (or the CMS Location for federal teams) and influenced by the following factors:

- **The HHA patient census, number of unduplicated admissions, and number of branches at the time of the last survey;**
- **A pattern of past serious deficiencies or complaints.**

Home health agency surveys will also vary in duration, based on the patient census, the number of branches and their locations, number of home visits and travel time, as well as the number and complexity of concerns that are identified during the survey.

<u>Prohibition of Conflicts of Interest</u>

Prior to finalizing the survey team, SAs, federal teams, and Accreditation Organizations (AO) must ensure that no conflicts of interest are present between surveyors and the HHA being surveyed. Section 488.735(b) sets out the circumstances that would disqualify a surveyor from surveying a particular agency.

Any of the following circumstances disqualifies a surveyor from surveying an HHA.

- **The surveyor currently works for, or, within the past two years, has worked with the HHA to be surveyed as a direct employee, employment agency staff at the agency, or officer, consultant, or agent for the agency to be surveyed.**
- **The surveyor has a financial interest or an ownership interest in the HHA to be surveyed.**
- **The surveyor has a family member who has a relationship with the HHA to be surveyed.**
- **The surveyor has an immediate family member who is a patient of the HHA to be surveyed.**

B. Types of Home Health Agency Surveys

All agencies that seek to participate or are participating as HHAs in Medicare are subject to the following unannounced surveys:

1. Initial Certification Survey

Initial certification surveys are conducted when an agency seeks to participate in the Medicare program as an HHA. SAs or AOs with CMS deeming authority, may

conduct the initial certification survey. The initial certification survey reviews all CoPs for compliance with the requirements.

Before the initial certification survey can be conducted, the prospective HHA must obtain Medicare Administrative Contractor (MAC) approval of the application for enrollment (CMS 855-A). The HHA must also meet the following criteria for an initial survey listed below:

- **Provide skilled nursing and at least one other therapeutic service (physical therapy, speech language pathology, occupational therapy, medical social services or home health aide) - See §484.105(f)(1); and**
- **Have provided care to a minimum of 10 skilled patients receiving care (not required to be Medicare beneficiaries) that is consistent with the CoPs. At least 7 of the 10 required patients should be receiving skilled care from the prospective HHA at the time of the initial certification survey. If the prospective HHA has not provided skilled care to at least 10 patients, the SA or the AO must contact the CMS Location to determine if the agency is in a medically underserved area (MUA). In making such a determination, the CMS locations may use the MUA Find search tool (https://data.hrsa.gov/tools/shortage-area/mua-find) developed by the Health Resources & Services Administration (HRSA). In this situation, the CMS Location may reduce the minimum number of skilled patients from 10 to 5. In such situations, at least 2 of the 5 required patients should be receiving skilled care from the prospective HHA at the time of the initial Medicare survey.**

Change of Ownership (CHOW)

HHAs that undergo a change in majority ownership by sale within three years of the effective date of its initial Medicare enrollment, or within three years of its most recent change in majority ownership, must enroll in the Medicare program as a new HHA provider (initial certification) under 42 CFR §424.550(b)(1) unless an exception under §424.550(b)(2) applies. Therefore, the HHA must undergo an initial certification survey by the SA or an AO with deeming authority. This is necessary to ensure that newly-sold HHAs are compliant with the CoPs.

2. Recertification Survey

Each HHA must be surveyed not later than 36 months after the last day of the previous standard survey as specified in 42 CFR §488.730. Recertification surveys begin as a standard survey, but may, as needed, be converted to a partial extended or an extended survey as outlined below in Part I, Section C. Survey Protocols: Standard, Partial Extended, and Extended Surveys.

3. Abbreviated Standard Survey

The abbreviated standard survey is a highly focused survey that evaluates an HHA's compliance with specific standards within a CoP or the CoP itself, as determined by the reason or purpose of the survey. 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.

Types of Abbreviated standard surveys include:

a. <u>Complaint Survey (Investigation)</u>

A complaint investigation is conducted to investigate specific allegations of noncompliance. Refer to the State Operations Manual (SOM), Chapter 5, for additional guidance regarding complaint surveys.

b. <u>Post-Survey Revisit (Follow-up Survey)</u>

When deficiencies have been cited during any type of survey, the surveyor may, as necessary, conduct a post-survey revisit to determine if the agency has made significant corrections to meet the requirements for participation for those cited deficiencies. However, the existence of condition-level deficiencies in any CoP requires an onsite post-survey revisit to determine if the HHA has corrected these deficiencies. See also, SOM, Chapter 2, for information on revisit surveys.

4. Validation Survey for Deemed HHAs

Section 1865(a)(1) of the Act permits providers and suppliers "accredited" by a CMS-approved program of a national AO to be exempt from routine surveys by SAs to determine compliance with CoPs if they apply for deemed status. These deemed status HHAs may be subject to validation surveys authorized by CMS, as a component of CMS's oversight of an AO's deeming program.

C. Survey Protocols: Standard, Partial Extended, and Extended Surveys

Section 1891(c)(2) of the Act establishes the requirements for surveying HHAs to determine whether they meet the Medicare conditions of participation. These requirements are reflected in the definitions at 42 CFR §488.705 for the standard survey, the partial extended survey, and extended survey as well as in the regulations at 42 CFR part 488, Subpart I.

1. Standard Survey

CMS has identified a select number of standards, called Level 1 standards, most closely related to the agency's ability to deliver quality patient care and services as

required under the CoPs. Compliance with these Level 1 standards is associated with positive outcomes for patient care. See Table 1 for the Level 1 standards.

The standard survey focuses on the Level 1 standards and utilizes information from clinical record reviews, observational home visits, and patient and staff interviews. Staff interviews are conducted as indicated to gain more information based on the findings from other information gathering tasks.

If no deficiencies are identified during home visits, clinical record reviews, and interviews with patients and staff, and no other concerns are identified, the HHA is considered to be compliant with the CoPs. Surveyors may conclude the survey and exit the HHA.

When noncompliance is identified with any Level 1 standard, the survey must be expanded to a partial extended survey to further investigate the noncompliance. If it is obvious during a survey that noncompliance exists at the condition-level, the surveyor may immediately advance to an extended survey that examines all conditions of participation. The requirement to encode and transmit Outcome and Assessment Information Set (OASIS) data (§484.45(a)) is not designated as a Level 1 standard, however it is evaluated during the pre-survey preparation. A deficiency cited for this requirement does not trigger a partial extended or extended survey.

2. Partial Extended Survey

A partial extended survey is conducted when noncompliance is identified in any Level 1 standard. CMS no longer identifies specific Level 2 standards, instead, all remaining standards within the CoP that contains a Level 1 standard deficiency are evaluated and a determination must be made as to the compliance with the condition.

3. Extended Survey

Substandard care means noncompliance with one or more of the eight CoPs reviewed in the standard survey, including deficiencies which could result in actual or potential harm to patients of the HHA (see Table 1). When a standard or partial extended survey reveals substandard care, the surveyor must extend the survey to review all 15 CoPs. The extended survey may be conducted at any time at the discretion of the AO, SA or CMS Location, but must always be conducted when substandard care is identified.

The extended survey should be initiated immediately upon a finding of substandard care. Unless there are extenuating circumstances (for example, weather, scheduling, etc.), the extended survey should be completed without interruption. However, no longer than 14 calendar days can lapse before the extended survey is completed.

For example, when a complaint investigation identifies condition-level noncompliance, the extended survey must be completed within 14 days.

Noncompliance with Requirements other than Level 1 Standards during the Standard or Partial Extended Survey

A surveyor may discover noncompliance unrelated to Level 1 standards during a standard or partially extended survey. In this case, the surveyor would determine any additional standards and conditions to examine based on findings of noncompliance. If noncompliance is identified in a non-Level 1 standard, the finding is documented on the Form CMS -2567 and the survey may continue as a standard survey.

Condition-level non-compliance in CoPs that do not contain Level 1 standards does not trigger an extended survey. However, at the discretion of the SA or CMS Location, the survey may be elevated to an extended survey at any time.

Table 1. Standard Survey Conditions of Participation and Tags that are Level 1 Standards

Condition of Participation	Level 1 Tags
§484.50 Patient Rights	G412, G414, G416, G418, G422, G428, G430, G432, G434, G436, G438, G442, G444, G448, G454, G464, G478, G484, G486, G488, G490
§484.55 Comprehensive Assessment of Patients	G514, G516, G520, G528, G530, G532, G534, G536, G544, G546
§484.60 Care planning, coordination of services, and quality of care.	G572, G574, G576, G580, G582, G584, G588, G590, G592, G596, G598, G602, G604, G606, G608, G610, G612, G614, G616, G618, G620, G622
§484.70 Infection prevention and control	G682, G686
§484.75 Skilled Professional Services	G704, G706, G708, G710, G712, G714, G716, G718, G724, G726, G728, G730
§484.80 Home Health Aide Services	G768, G772, G798, G800, G802, G804, G808, G810, G812, G816, G818
§484.102 Emergency Preparedness	E-0004, E-0013, E-0036

***See Appendix Z for details**	
§484.105 Organization and Administration of Services	**G982, G984**
§484.110 Clinical Records	**G1012, G1014, G1016, G1018, G1022, G1024, G1028**

Part II – The Survey Tasks

The HHA survey process consists of seven standard tasks, listed below:

• Task 1 Pre-Survey Preparation;
• Task 2 Entrance Conference;
• Task 3 Survey Sample Selection;
• Task 4 Information Gathering
• Task 5 Preliminary Decision Making and Analysis of Findings;
• Task 6 Exit Conference; and
• Task 7 Post-Survey Activities.

Task 1 - Pre-Survey Preparation

The objectives of the pre-survey preparation are to review historical information about the HHA that may assist in identifying areas of potential concern during the survey and to establish the plan for the logistics of the survey. The primary pre-survey activities include:

A. Reviewing background information about the HHA;
B. Generating and printing OASIS Reports; and
C. Printing surveyor worksheets.

A. Reviewing Background Information

In preparation for the survey/resurvey, review documents of record including licensure records, previous survey reports including complaint investigations, media reports about the facility, and other publicly available information about the facility (e.g., the HHA's website; CMS Care Compare – HHAs). The background material that is reviewed in the SA and AO's files assists in determining the composition of the survey team and the time that may be required for the survey, as well as identifying potential concerns for a focused review. Review the following files:

- **The most recent form CMS-1572, Home Health Agency Survey Report; this provides information of the HHA from the last survey conducted as well as general information such as location, name of the administrator, staffing, services provided, and branches. This information can assist in the planning of**

the survey, for example, if branches need to be visited and determining the potential number of home visits.

- **The most recent Form CMS-2567, Statement of Deficiencies and Plan of Correction; and**
- **All complaint investigations since the last recertification survey to evaluate for patterns of deficient practice.**

B. OASIS Reports

During the pre-survey preparation, four reports are downloaded from the CMS national data system for review:

1. **The Potentially Avoidable Event Report (12 months);**
2. **The Potentially Avoidable Event Report: Patient Listing (12 months);**
3. **The Agency Patient Related Characteristics Report (12 months); and**
4. **The HHA Error Summary by Agency (12 months).**

The reports are created from OASIS data elements. The requirements at §484.45, Reporting OASIS Information, specify that an HHA transmit OASIS elements to the CMS system. This data is utilized to populate the internet Quality Improvement & Evaluation System (iQIES) and generate reports.

The reports contain information that may assist the surveyor in identifying potential areas of concern that may need to be emphasized during the survey to help focus the survey, as well as identifying potential patients for the survey sample. OASIS coordinators can assist with providing available OASIS reports to surveyors.

1. The Potentially Avoidable Event Report
This report contains outcome measures that address potentially avoidable events, defined as outcomes that may or may not have been influenced by the care and services provided by the HHA. This report is used in conjunction with the Potentially Avoidable Event Patient Listing Report to select patients for closed record review.

2. The Potentially Avoidable Event Patient Listing Report
This report is a companion to the above Potentially Avoidable Event Report and provides the names of the patients who experienced the events noted in that report.

3. The Agency Patient-Related Characteristics (formerly Case Mix) Report
This report compiles several OASIS data elements into one report that provides a high-level overview of the HHA patient demographics, home care diagnoses, and agency statistics. The report displays the types of patients for whom the agency is providing care, their characteristics at the start of care, as well as outcome and discharge information. The agency's data is compared to a national reference sample, and to the HHA's own data from a prior reporting period. This data may inform the active sample selection. For example, the home visit sample may be

influenced by high rates of recertification of care or clinically complex patient care services that might require increased coordination of care needs.

4. The HHA Error Summary by Agency Report
This report compiles OASIS submission errors to iQIES. While this report displays any warning or fatal errors encountered in OASIS records processed by iQIES for a user-specified time; the focus for this report should be on one specific error, -3330, "Record Submitted Late: The submission date is more than 30 days after M0090 (Date Assessment Completed) on this new record." The date criteria for this report is the prior calendar year. If an HHA shows a pattern of multiple assessments with error -3330 on this report, surveyors should investigate compliance with G372, Encoding and transmitting OASIS data (§484.45(a)).

C. Surveyor Forms

The forms for HHA surveys include:

- **Home Health Agency Survey Report, Form CMS-1572;**
- **Home Visit Consent Form CMS-36;**
- **Surveyor Notes Worksheet, Form CMS-807 (optional);**
- **HHA Survey Investigation Worksheet: Calendar (optional).**

Task 2 – Entrance Conference

The objectives of this task are to generally inform the HHA administrator or designee of the survey activities that will take place and request specific information that will be needed to conduct the survey. Surveyors must be professional, organized, prepared, and courteous. The entrance conference should be informative, concise, and brief. If the HHA is not open when the surveyor arrives, the SA should be contacted for further guidance. See also State Operations Manual (SOM) Chapter 2 for additional details on entrance protocol.

Upon entrance, the survey team will:

- **Present identification;**
- **Introduce the survey team to the administrator or designee;**
- **Explain the purpose of the survey; and**
- **Provide the estimated survey duration.**

For all surveys, request assistance with the following from the administrator (or designee):

- **A private space for the survey team to work;**
- **Location of a copier and operation instructions;**

- **An assigned HHA staff person(s) who will be a resource to respond to the surveyor's questions and can obtain information for the surveyor;**
- **HHA staff who are most knowledgeable about clinical supervision, in-service training, and home health aide supervision;**
- **Orientation to the electronic and/or paper clinical records that includes:**
  - **The comprehensive assessment, the plan of care, physician's orders, progress notes and home visits, supervisory visits, case conferences, medication lists, medication administration records;**
  - **How to use electronic health records (EHR);**
  - **The designated individual who will respond to any questions or assist the surveyor as needed in accessing the EHR in a timely fashion; and**
  - **Computer terminals where the surveyors may access the electronic health records, if applicable.**

For a standard survey, request that the HHA provide the following documentation:

- **The number of unduplicated skilled care admissions from the 12 months prior to the survey, including all payer sources and all HHA locations, i.e. parent and all branch locations. The unduplicated skilled admission total is used to determine the survey sample size. Unduplicated means that patients are counted only once in 12 months for the number of skilled care admissions;**
- **A complete list of active skilled care patients (all payer sources) for the parent HHA and its branches containing, at a minimum, the following information for each patient:**
  - **Patient names;**
  - **Patient certification dates (start of care/resumption of care dates);**
  - **Admitting diagnosis;**
  - **Services provided by discipline (i.e. skilled nurse (SN), physical therapy (PT), occupational therapy (OT), speech-language pathology (SLP), or social worker (SW));**
  - **Clinically complex, specialized services or treatments, for example, infusion therapies, pediatrics, anticoagulant therapy management, mechanical ventilation, tracheostomy care, wound care, or pressure ulcer care.**

- **The schedule of home visits that will be performed during the survey for all locations including parent and branches; and**

- **A complete list of all discharged patients in the past six months with start of care and discharge dates, diagnoses, services provided, and the disposition of the patient.**

Request the agency provide the following additional information:

- **Current list of all direct and contracted employees including job title and date of hire;**
- **Whether outpatient therapy is provided at the parent or any of its branches; if so, contact the SA for guidance on including evaluation of the service during the survey;**
- **An updated Form CMS-1572, Home Health Agency Survey Report, by the end of the first day of the survey;**
- **Organizational chart for parent and branches;**
- **Admission packet;**
- **Complaint log; and**
- **Abuse tracking log, if available.**

When an extended survey is conducted, any additional information required may be requested at the time of the entrance (if it is a planned extended survey, e.g. initial), or when the survey is expanded to an extended survey.

- **Home health aide training records and/or competency evaluations and in-service training;**
- **The identity of, and governing body authorization for, the person who is authorized in writing to act on behalf of the administrator;**
- **The Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver for the agency and CLIA licenses for clinical laboratories where the agency sends specimens;**

- **The Quality Assessment and Program Improvement (QAPI) program activities and performance improvement projects including infection control; and**
- **The Emergency Preparedness Plan.**

Task 3 – Survey Sample Selection

The objective of this task is to select a case-mix stratified patient sample that represents the range of skilled services provided to a selection of home health patients from all operating locations (parent and branch). "Case-mix" means the sample contains a range of admitting diagnoses, and "stratified" means the sample includes patients who receive a variety of skilled services including: nursing, physical therapy (PT), speech language pathology (SLP), occupational therapy (OT), medical social services, and home health aide services.

The sample consists of both closed (discharged) and active (current) patients for all payer sources. The active patient sample is comprised of two groups: record review only and record review with home visit.

Documents and Information Utilized for Sample Selection:

- **The list of unduplicated skilled care admissions in the 12 months prior to the survey from all payer sources and all HHA branches. The number of unduplicated skilled admissions determines the total patient sample size;**
- **The complete census of all active (current) skilled care patients (all payer sources) in the parent HHA and all branches;**
- **The list of patients receiving clinically complex services or treatments;**
- **The home visit schedule during the survey for all skilled services in all locations including parent and branches;**
- **The list of all discharged patients in the six months prior to the survey;**
- **iQIES Reports: Potentially Avoidable Event Report and Potentially Avoidable Event Patient Listing Report; and**
- **iQIES Report: Agency Patient-Related Characteristics (Case Mix) Report.**

A. Patient Sample Selection Protocol

Based on the number of unduplicated skilled service admissions, use Table 2, Survey Sample Table (below) to determine the minimum sample size for closed record review, active patient home visit with record review, and active patient record review only. The sample may be expanded per surveyor discretion at any point in the survey as needed to further investigate findings.

If the HHA has had a very low census of skilled admissions in the past 12 months and does not meet the minimum sample size (i.e. less than 7), the surveyor may use the skilled admissions since the last certification survey from which to pull the sample. For instance, if the HHA only has one skilled admission in the past 12 months, the surveyor should extend the period beyond 12 months to obtain additional skilled admissions for review. In these instances, the sample will be reduced to those skilled admissions that are available for review. The sample must, however, include patients receiving skilled services and the surveyor may not substitute non-skilled home health aide personal care observations to complete the home visit patient sample.

Table 2. Survey Sample Table

Number of Unduplicated Skilled Admissions for the Past 12 Months	Closed Record Review (Discharged)	Active Sample: Home Visit with Record Review	Active Sample: Record Review Only	Total Patient Sample (Minimum)
Less than 300	2	3	2	7
301 - 500	3	4	3	10
501 - 700	4	5	4	13
701 or more	5	7	5	17

For abbreviated surveys (complaint and revisit), surveyors should select at least 3 records for review to ensure the HHA is in compliance with the applicable CoP. Record review and the number of records is dependent upon the nature of the complaint and investigation or revisit follow up and may require more or less than 3 records based on observations, interviews, home visits, etc. Some abbreviated surveys may not require record review if the Medicare condition does not require medical record documentation. For complaint surveys, it is important to note that surveyors must assess the entire CoP related to the complaint allegation and therefore it is not enough to look only at the medical record for the complaint case when conducting a complaint investigation.

If surveyors find the HHA has no patients on the current patient roster (for any payment source) and has not provided care to any patients for twelve months or more, they should discuss with the appropriate CMS location whether continuing the survey is possible. The determination should be made whether to proceed with the survey and lead to possible enforcement actions or to allow the HHA to voluntary terminate based on cessation of business (see also 42 CFR 489.52(b)(3)). Please note that the twelve-month period is guidance to surveyors about when they should contact CMS locations about cessation of services. It does not limit CMS's ability to terminate a provider that has not provided services for a shorter period of time. Pursuant to section 1866(b)(2)(B) of the Act, CMS has the discretion to terminate a provider when it no longer meets the definition of an HHA at section 1861(o)(1). [42 CFR 489.53(a)(1).] CMS has the discretion to decide how long a cessation of services is too long, and may determine that a shorter period is appropriate in some cases.

B. Closed Record Sample Criteria

1. Potentially Avoidable Event Reports Review Procedure

The Potentially Avoidable Event Report and the Potentially Avoidable Event Patient Listing Report are used to select the closed record sample. Potentially avoidable events are outcomes that can be influenced, although not necessarily totally avoided, by following best practices in providing care. Utilize the reports as follows:

- **Review the Potentially Avoidable Event report for all outcomes greater than the national "observation" (language used in the OASIS Case Mix Report);**
- **In areas where the HHA exceeds the national observation, refer to the Potentially Avoidable Event Patient Listing Report to select the patients for the closed record sample; and**
- **Patients listed under one or more measures should be selected for the closed record review sample due to having more potentially avoidable events.**

Request the records for the patients selected from the report after the entrance conference to expedite the retrieval of these clinical records for review.

If there are no patients listed in the Potentially Avoidable Event, Patient Listing Report, or there is an insufficient number of patients to meet the required closed record sample size, complete the closed record sample using the discharged patient list, as well as the complaint log obtained during the entrance conference. When using the discharged patient list provided by the HHA, randomly select the patients from the list who had different discharge dispositions such as hospitalization, transfer to another provider, or routine discharge as planned.

Occasionally, the patients in the Potentially Avoidable Event reports have not yet been discharged from the HHA. When this occurs, consider adding that patient to the active sample, and replace with another patient to complete the closed record sample.

2. Agency Patient-Related Characteristics (Case Mix) Report Review Procedure

Review the Patient Diagnostic Information for:

- **Acute and Chronic Conditions;**
- **Home Care Diagnoses; and**
- **Active Diagnoses.**

Note the diagnoses where the HHA's observation exceeds the national average (as noted in the OASIS Case Mix Report data). For example, identify the type of patients the agency treats on a regular basis, such as orthopedic, neurological, musculoskeletal, wound care, and diabetes mellitus. Consider this information to assist in case mix stratification when selecting a sample that is representative of the HHA's patient population.

C. Active Patient Criteria

The active patient sample includes:

1) Active patient home visits with record review; and
2) Active patient record reviews only.

Use the following criteria for the active patient sample selection:

- **Include patients who receive more than one HHA service to assess for coordination of care across the disciplines;**
  - **The Agency Patient Characteristics Report can provide additional information on the type of patients where the HHA observation exceeds the national average to include in the sample.**
- **Include patients from all branches of the HHA in addition to the parent location;**

- **Include patients who receive clinically complex services or treatments, for example:**
  - **Infusion therapies;**
  - **Wound and ulcer care, including negative pressure wound therapy;**
  - **Pediatric care;**
  - **Anticoagulant therapy management;**
  - **Diabetes management;**
  - **Congestive heart failure monitoring;**
  - **Enteral and parenteral nutrition;**
  - **Tracheostomy care;**
  - **Bi-level positive airway pressure (BiPap), and other respiratory therapy devices; and/or**
  - **Therapy modalities such as ultrasound and electrical muscle stimulation (e-stim).**

Active Patient Home Visit with Record Review Sample Selection

Surveyors may conduct home visits to any patients of the HHA who have given their permission for the surveyor to directly observe care and services. The surveyor selects the patients according to the sample criteria, rather than the HHA selecting the home visit sample. The home visit sample should represent the variety of services that the HHA provides. Home visits to patients being served by branch locations should be made whenever possible.

Use the Survey Sample Table (Table 2) to determine the number of active patients for home visits with record review. It is recommended to select a few more patients than the number of required home visits to accommodate possible refusals. Provide the HHA with the home visit sample as soon as possible so that the agency may begin to contact the patients to request their permission. Additional home visits may be made to address any concerns initially identified by survey findings.

For a small agency with a low skilled patient census, enough home visits may not be available during the survey to meet the home visit sample requirement. At least one home visit must be conducted to evaluate compliance with the CoPs. Additionally, the surveyor may substitute active record reviews as a first option, or closed records to review for a range of skilled services to meet the minimum sample size.

Record Review Only

Use the same criteria for record review only that is used for the home visit sample. If a home visit cannot be made to all branches, this is the opportunity to include patients from all branch location(s) in the record review sample and expand the sample as needed to ensure that at least one patient from each branch is included in

the active sample record review. Select patients who are not receiving a home visit during the survey, but meet the active sample with home visit criteria.

Task 4: Information Gathering

Information gathering is an organized, systematic, and consistent process designed to assist surveyors to make findings concerning the HHA's compliance with the CoPs during a survey. The information gathering activities in the home health agency survey consist of:

A. Home Visit and Patient Interview Procedures
B. Clinical Record Review Procedures
C. Interviews with Agency Staff
D. Other HHA Documentation Review
E. Guidance for Evaluating Compliance with Level 1 Standards: Home Visit Observation and Interview, Clinical Record Review, and Other HHA Documentation Review
F. Home Visit Follow-Up Procedures

Surveyors gather information by focusing on home visit observations, interviews, and clinical record reviews. Surveyors assess for compliance with the Level 1 standards to determine if patient outcomes were negatively influenced by non-compliance with the CoPs by the HHA. The findings determine whether the survey is elevated to a partial extended or extended survey as well as identifying possible areas for further investigation. Surveyors will validate any findings with additional document review and/or interviews.

The closed clinical record review is a review of agency services and patient care outcomes from admission through discharge. Closed record review differs from active record review in that surveyors will also evaluate whether the discharge and transfer summaries were completed as required per §484.110(a)(6), and evaluate the HHA's compliance with the 60-day recertification of care. The records are assessed for compliance with the CoPs to determine if the agency provided the necessary care and services to meet the patients' health needs.

A. Home Visit and Patient Interview Procedures

<u>Objective of Home Visits</u>

The purpose of the home visit is to evaluate whether the care being provided by the HHA meets the health and safety standards of the Medicare program (i.e., CoPs) and to confirm that the agency follows the patient's plan of care. The home visit is the only opportunity for the surveyor to observe direct care being provided by the HHA personnel and is thus the most important means of information gathering

during the HHA survey. The surveyor uses observational and interview skills to assess the HHA's adherence to the requirements.

Planning the Home Visit with the Agency

After sample selection by the survey team, the HHA should contact the patient, family, or caregiver to request permission and make the arrangements for the home visit. If the patient refuses to allow the surveyor to visit, the surveyor should select an alternate patient.

Clinical records should be reviewed prior to and after the home visit. Prior to the home visit, obtain the information most relevant for the home visit, such as copies of the most current version of the plan of care, medication list, and aide instructions.

Conducting Home Visits and Patient Interviews

The surveyor must always be cognizant that as a guest in a patient's home or place of residence, courtesy, respect, and sensitivity to the patient's clinical status (physical and emotional) are necessary. Explain to the patient that the purpose of the visit is to ensure that the care being provided to them by the HHA meets the health and safety standards of the Medicare program and is provided in accordance with the plan of care ordered by the patient's physician or allowed practitioner. Prior to asking the patient to sign the home visit consent, confirm with the beneficiary that the HHA explained that the home visit and interview is voluntary and refusal would not affect their home health benefits.

Ask the patient or caregiver to sign a Consent for Home Visit (Form CMS-36) in a language and manner the individual(s) understands. Provide a copy of the signed consent form to the patient, a copy to the HHA for the patient's clinical record, and retain a copy for the survey file.

Observe, but do not interfere with, the delivery of care and the interactions between the HHA representative and the patient/family and/or caregiver. Home visit observations and the plan of care determine the focus and depth of questions asked of the patient and HHA staff by the surveyor. It may be appropriate to ask questions during patient care if it does not interfere with care or disturb the rapport of the HHA staff with the patient. The surveyor should ask the patient's permission to review the patient's information packet and written information that the HHA provided to the patient at the start of care and subsequent updates. The patient may not be able to locate the information readily, and if that is the case, do not press the issue with the patient and continue the visit.

The surveyor should end the interview or home visit if the patient expressly requests or indicates through body language a desire to conclude the interview or home visit. The surveyor should attempt to address any potential concerns of the patient by inquiring if the surveyor's presence is problematic and reassuring the patient of the role of the observational home visit. The surveyor should be alert to signals from the

patient, such as displaying reluctance to speak in front of staff, appearing fatigued or distressed, that may be an indication of an unexpressed concern or unwillingness to participate. Surveyors should remain (if the opportunity presents) after the HHA staff leave to give the patient and family an opportunity to share information with them confidentially.

If conditions in the patient's home raise concerns for the surveyor's physical safety, the surveyor should discontinue the visit.

B. Clinical Record Review Procedures

The clinical record review is used to verify that HHA documentation thoroughly and accurately reflects the care and services provided by the HHA and confirms that services are provided in compliance with the plan of care and CoPs.

The surveyor should review the clinical record only in enough detail prior to the home visit to allow the surveyor to be prepared to observe the care and services that will be provided (e.g. the most current plan of care, medication list, and aide instructions). The surveyor should review the record in more detail after the home visit to address any concerns for non-compliance identified during the home visit and further evaluate the requirements of Level 1 standards included in the standard survey.

C. Interviews with Agency Staff

Interviews provide another method to collect information, and to verify and validate information obtained through observations, record reviews, and/or patient interviews. The depth of the interview and the number of interviewees is determined by the issues identified.

Informal interviews are conducted throughout the duration of the survey. The information obtained from interviews may be used to determine what additional observations, interviews, and record reviews are necessary to determine compliance or noncompliance with the CoPs.

Interviews should be focused on obtaining detailed information regarding a specific event, how a care task was completed or not completed, or action or inaction by the HHA. Ask open-ended questions whenever possible to elicit staff knowledge rather than questions that lead the staff member to certain responses. Interview agency staff, including the administrator, clinical managers, skilled professional staff, home health aides, and other HHA staff, only as necessary, to address concerns identified. For example, if concerns are identified with clinical record confidentiality during transport of records, the surveyor may ask the staff how they transport and secure protected health information while outside the HHA parent or branch office.

D **Other HHA Documentation Review**

When surveyors identify concerns that indicate actual or potential findings of noncompliance, surveyors should review additional documentation to assist the surveyor in making a compliance determination. Non-clinical record materials, such as personnel records, service contracts, policies and procedures, clinical practice guidelines, documentation of home health aide training and/or competency evaluation, documentation of complaint investigation and resolution, CLIA waiver, and/or other materials, are not routinely reviewed unless the surveyor identifies concerns during HHA staff interviews, patient/caregiver interviews, home visits, and clinical record reviews.

E. Home Visit Follow-Up Procedures

If the surveyor has any questions or concerns based on the home visit observation, the agency staff that was observed may also be interviewed following the home visit. Additionally, if the surveyor identifies concerns or potential noncompliance during the home visit, the surveyor may conduct additional record review and staff interviews as necessary to investigate findings.

If the patient or caregiver reports having lodged a complaint, review the complaint log to investigate how the HHA addressed the issue.

F. Additional Survey Considerations

<u>Onsite Review of Approved Branches by the SA During Survey</u>

The Form CMS-1572, the Home Health Agency Survey and Deficiencies Report, includes a field where the HHA indicates the total number of branches and the name and address of each branch location. The surveyor should enter this information regarding the HHA's branches into the national survey data system (iQIES as appropriate) after every survey as part of the survey kit.

As surveys are conducted, SAs, AOs and federal surveyors should verify that the information on branch locations is current and accurate. During a survey, if a surveyor finds that services are being provided from an unapproved location that is not listed on the CMS 1572, the surveyor must investigate this location to determine if it is a CMS-approved branch.

<u>Application of Home Health Agency Conditions of Participation to Patients Who Do Not Receive Skilled Services</u>

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 Medicare certified HHAs choose to offer non-skilled services through various Medicaid state programs including:

- **Personal care services, such as help with activities of daily living (ADLs) like bathing, dressing, eating, getting in or out of bed, moving around, and using the bathroom;**
- **Housekeeping services;**
- **General household chores; or**
- **Family and caregiver support services.**

The HHA may offer these services to individuals who choose to pay for them privately, and/or individuals who are provided these services from other state programs.

Two standards in the HHA CoP home health aide services, at 42 CFR §484.80, apply to beneficiaries who receive non-skilled services only:

- **42 CFR §484.80(h)(2) - see also G814**
- **42 CFR §484.80(i) - see also G828**

Review of these two requirements during survey is conducted through a separate sample than the sample used to evaluate compliance with skilled services requirements for HHA patients.

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 is considering to receive non-skilled services that Medicare does not pay for those services. For additional information, see the interpretive guidance and survey procedures at §484.50.

<u>Agencies Serving Medicaid Waiver and State Plan Patients</u>

If a Medicare certified HHA provides <u>skilled</u> care services to non-Medicare beneficiaries under a Medicaid Waiver or State Plan, the HHA must meet all CoPs for these beneficiaries including the comprehensive assessment and OASIS data reporting requirements.

Task 5 - Preliminary Decision Making and Analysis of Findings

A. General

The general objectives of this task are to integrate findings, review and analyze all information collected from observations, interviews, and record reviews, and to determine whether the HHA is in compliance with the CoPs. The information analysis process requires surveyors to review the information gathered during the survey and make judgments about the compliance of the HHA. An evaluation of whether a finding constitutes a standard-level deficiency or whether a condition-

level deficiency exists should not be made until all necessary information has been collected. Survey activities and investigations including the record review, home visit observations and interviews substantiate and support any findings of non-compliance with the CoPs.

B. Analysis

<u>Guidance for Citing Standard- versus Condition-Level Noncompliance</u>

The regulations at 42 CFR §488.26(b) state in part, "The decision as to whether there is compliance with a particular requirement, condition of participation, or condition for coverage depends upon the manner and degree to which the provider or supplier satisfies the various standards within each condition."

When noncompliance with a particular standard within the CoP is noted, the determination of whether the lack of compliance is at the standard- or condition-level depends upon the nature of the noncompliance – i.e., how serious is the deficiency in terms of its potential or actual harm to patients – and the extent of noncompliance – e.g., how many different regulatory requirements within a CoP are being cited for noncompliance, or how widespread was a given noncompliant practice, etc. One instance of noncompliance with a standard that poses a serious threat to patient health and safety is enough to find condition-level noncompliance. Likewise, when an HHA has multiple standard-level deficiencies in a CoP, the extent of the non-compliance could be enough to find condition-level noncompliance.

When deficiencies are found during a survey, the surveyor should explain the noncompliance to the provider during the Exit Conference. It is not the surveyor's responsibility to provide consultation on how to fix the deficiencies. Surveyors should maintain their role as representatives of a regulatory agency. Although non-consultative information may be provided to the HHA upon request, the surveyor is not a consultant and may not provide consulting services to the HHA. See also SOM Chapter 2 and 4 for additional information related to the regulatory role of surveyors.

<u>Guidance for Level 1 Standards and Survey Type (Standard, Partial Extended, Extended)</u>

During a standard survey, surveyors review Level 1 standards only. Because the Level 1 standards are identified as those most closely related to the delivery of high-quality patient care, a single finding may support a determination of noncompliance with the standard (i.e., standard level noncompliance), and warrant the move to a partial extended survey to investigate noncompliance at the condition level. However, if it is obvious that the noncompliance exists at the condition-level during a standard survey, the surveyor may immediately advance to an extended survey that examines all conditions of participation without expanding to a partial extended survey first.

The partial extended survey may be conducted at any time at the discretion of CMS, the SA, or AO, but must be conducted when a Level 1 finding indicates that a condition may be out of compliance. During a partial extended survey, all standards within the condition of participation that contains one or more Level 1 standards are evaluated. If a surveyor determines that noncompliance exists at the condition-level during a partial extended survey, the surveyor advances to an extended survey to review all conditions of participation. Advanced CMS Location approval is not required to extend the survey.

An extended survey may be conducted at any time at the discretion of CMS, the SA, or AO, but will always 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 identified on a standard survey, including deficiencies that could result in actual or potential harm to patients of an HHA. The HHA standard survey evaluates compliance with eight of the 15 HHA CoPs and noncompliance with any of these eight conditions would constitute substandard care. When substandard care is identified, the extended survey reviews and identifies the HHA's policies, procedures, and practices that produced the substandard care.

The extended survey should be initiated immediately upon finding substandard care. Unless there are extenuating circumstances, the extended survey should be completed without interruption. However, no longer than 14 calendar days may elapse before the extended survey is completed. For example, when a complaint investigation identifies condition-level noncompliance, the extended survey must be completed within 14 days.

If the surveyor identifies or suspects an immediate jeopardy (IJ) situation, they must immediately follow the guidelines in SOM Appendix Q, including use of the IJ template. Immediate jeopardy means a situation in which the provider's or supplier's non-compliance with one or more requirements, conditions of participation, conditions for coverage, or conditions for certification has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident or patient. [see 42 CFR 488.805 Definitions.] As noted in Appendix Q, if an IJ is identified, surveyors must notify the administrator (or appropriate staff member who has full authority to act on behalf of the entity) that IJ has been identified and provide a copy of the completed IJ template to the entity

Non-Level 1 Deficiencies: A surveyor may discover noncompliance unrelated to Level 1 standards during a standard or partially extended survey. In this case, the surveyor determines the additional standards and/or conditions to examine based on the finding of noncompliance. If noncompliance is identified in a non-Level 1 standard, the finding is documented on the Form CMS -2567 and the survey may continue as a standard survey. Condition-level noncompliance with CoPs that do not contain Level 1 standards does not trigger an extended survey. However, at the

discretion of the SA/CMS location the survey may be elevated to an extended survey at any time.

The requirement to encode and transmit OASIS data (§484.45(a)), while not a Level 1 standard, is evaluated during a standard survey. Deficiencies cited with this requirement do not trigger a partial or extended survey.

Task 6 - Exit Conference

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 where the HHA is not generally aware of the surveyor concerns prior to the exit conference. If the HHA asks for the specific regulatory basis for a finding of noncompliance, surveyors may provide the preliminary regulatory citation.

Additionally, surveyors will:

- **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;**
- **Describe the regulatory requirements that the HHA does not meet and the preliminary findings that substantiate these deficiencies. Do not refer to any specific iQIES software data tag numbers when describing deficiency findings. In the process of writing up the findings the SA or AO will finalize just which tags/regulatory text to cite for each finding, so it would be premature to make such statements during the exit conference;**
- **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;**
- **Answer questions regarding the findings and accept further pertinent information from the HHA for the surveyors to consider offsite prior to the completion of the Form CMS-2567;**
- **Respond to any HHA procedural questions with accurate survey process information (e.g., the timeframe for receiving Form CMS-2567 and submitting a plan of correction to the SA in response to the written citations); and**
- **Inform the HHA that the Form CMS-2567 will be provided in accordance with the State agency's policy, but generally no later than 10 working days after the exit conference.**

Discontinuation of an Exit Conference

CMS' general policy is to conduct an exit conference at the conclusion of all types of surveys as a courtesy to the provider/supplier and to promote timely remediation of quality of care for safety problems. However, there are some rare situations that justify refusal to conduct or continue an exit conference. For example, as noted in SOM Chapter 2:

> **• Surveyors may refuse to conduct or may discontinue the exit conference if the HHA is represented by an attorney who is present at the conference and the attorney attempts to turn it into an evidentiary hearing; or**
> **• If HHA staff /administration create an environment that is hostile, intimidating, or inconsistent with the informal and preliminary nature of an exit conference.**

Under such circumstances, it is suggested that the surveyor stop the exit conference and call the SA or AO for further direction. If a survey team is on-site, the Team Coordinator should take the above actions.

Recording the Exit Conference

If the facility wishes to audio tape the conference, it must provide two tapes and tape recorders, recording the meeting simultaneously. The surveyor or Team Coordinator should select one of the tapes at the conclusion of the exit conference to take back to the SA/AO. If the recording is electronic, a copy must be submitted to the surveyor immediately upon ending the conference. Videotaping is also permitted, if: 1) the surveyor/team agrees to this, and 2) a copy is provided the surveyor/team at the conclusion of the conference. The surveyor or survey team is under no obligation to consent to videotaping and is not required to offer a reason if it refuses to permit videotaping.

Task 7 – Post-Survey Activities

The general objective of this task is to complete the survey and certification requirements, in accordance with the regulations found at 42 CFR Part 488.

General Procedures

Each SA and CMS location must follow the instructions in the SOM including:

• Timelines for completing each step of the process;
• Responsibilities for completing the Form CMS 2567, "Statement of Deficiencies and Plan of Correction;"
• Notification to the HHA regarding survey results;

• Additional survey activities based on the survey results (e.g., revisit, forwarding documents to the CMS location for further action/direction, such as concurrence with findings for deemed HHAs); and
• Compilation of documents for the HHA's file.

Statement of Deficiencies Report & Plan of Correction

The Statement of Deficiencies Report and Plan of Correction (Form CMS-2567) is the official document that communicates the determination of compliance or noncompliance with federal requirements. Also, it is the form that the HHA will use to submit a plan to achieve compliance. Form CMS-2567 is an official record and is available to the public upon request. See SOM, Chapter 2 for information related to preparation of the Statement of Deficiencies and Plan of Correction. Refer to the document "Principles of Documentation" in SOM Chapter 9, Exhibit 7A, for detailed instructions on completing the Form CMS-2567.

Regulations and Interpretive Guidelines for Home Health Agencies

Subpart A--General Provisions

G325

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.1 Basis and Scope

(a) Basis. This part is based on:

(1) Sections 1861(o) and 1891 of the Act, which establish the conditions that an HHA must meet in order to participate in the Medicare program and which, along with the additional requirements set forth in this part, are considered necessary to ensure the health and safety of patients; and

(2) Section 1861(z) of the Act, which specifies the institutional planning standards that HHAs must meet.

(b) Scope. The provisions of this part serve as the basis for survey activities for the purpose of determining whether an agency meets the requirements for participation in the Medicare program.

Interpretive Guidelines §484.1

To qualify for a provider agreement as a home health agency under Medicare and Medicaid, an entity must meet and continue to meet all the statutory provisions of

§1861(o), 1891 and 1861(z) of the Act, including the Condition of Participation (CoP) requirements.

This, in part, means the HHA:

- **is primarily engaged in providing skilled nursing services and other therapeutic services [§1861(o)(1) of the Act; 42 CFR 484.105, Organization and administration of services];**

- **has policies to govern the services which it provides and provides for supervision of such services [§1861(o)(2) of the Act; 42 CFR 484.75, Skilled professional services and § 484.65 Quality assessment and performance improvement (QAPI). See also 82 FR 4542];**

- **maintains clinical records on all patients [§1861(o)(3) of the Act; 42 CFR 484.110, Clinical records];**

- **for any HHA in a state or local jurisdiction with a law that requires agencies or organizations like HHAs to be licensed, is licensed pursuant to such law, or is approved, by the State or local agency responsible for licensing agencies or organizations of this nature, as meeting the standards established for such licensing [§1861(o)(4) of the Act; 42 CFR 484.100, Compliance with Federal, State and local laws and regulations related to health and safety of patients];**

- **has in effect an overall plan and budget [§1861(o)(5) of the Act; 42 CFR 484.105, Organization and administration of services];**

- **meets the conditions of participation specified in section 1891(a) and such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such agency or organization [§1861(o)(6) of the Act; 42 CFR 484.1, Basis and Scope, et seq.];**

- **provides the Secretary with a surety bond [§1861(o)(7) of the Act; 42 CFR Part 489, Subpart F];**

- **meets such additional requirements (including conditions relating to bonding or establishing of escrow accounts as the Secretary finds necessary for the financial security of the program) as the Secretary finds necessary for the effective and efficient operation of the program [§1861(o)(8) of the Act; 42 CFR 484.1, Basis and Scope, et seq.];**

- **except that for purposes of part A "home health agency" shall not include any agency or organization which is primarily for the care and treatment of mental diseases. The Secretary may waive the requirement of a surety bond under paragraph (7) in the case of an agency or organization that provides a comparable surety bond under State law [§1861(o) of the Act; 42 CFR 484.1, Basis and Scope, et seq.].**

CMS is required to determine whether an HHA is complying substantially with the Medicare participation requirements established by the Act and regulations. Section 1866(b)(2)(B) of the Act states in part that a provider's participation agreement may be terminated if CMS determines that "the provider fails substantially to meet the applicable provisions of section 1861." To remain a Medicare participating HHA, the HHA must remain in substantial compliance with all conditions of participation.

No Tag

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.2 Definitions.

As used in subparts A, B, and C, of this part--

Allowed practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as defined at this part.

Branch office means an approved 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 parent home health agency must provide supervision and administrative control of any branch office. It is unnecessary for the branch office to independently meet the conditions of participation as a home health agency.

Clinical note means a notation of a contact with a patient that is written, timed, and dated, and which describes signs and symptoms, treatment, drugs administered and the patient's reaction or response, and any changes in physical or emotional condition during a given period of time.

Clinical nurse specialist means an individual as defined at §410.76(a) and (b) of this chapter, and who is working in collaboration with the physician as defined at §410.76(c)(3) of this chapter.

In advance means that HHA staff must complete the task prior to performing any hands-on care or any patient education.

Nurse practitioner means an individual as defined at §410.75(a) and (b) of this chapter, and who is working in collaboration with the physician as defined at §410.75(c)(3) of this chapter.

Parent home health agency means the agency that provides direct support and administrative control of a branch.

Physician is a doctor of medicine, osteopathy, or podiatric medicine, and who is not precluded from performing this function under paragraph (d) of this section. (A doctor of podiatric medicine may perform only plan of treatment functions that are consistent with the functions he or she is authorized to perform under State law.)

Physician assistant means an individual as defined at §410.74(a) and (c) of this chapter.

Primary home health agency means the HHA which accepts the initial referral of a patient, and which provides services directly to the patient or via another health care provider under arrangements (as applicable).

Proprietary agency means a private, for-profit agency.

Pseudo patient means a person trained to participate in a role-play situation, or a computer-based mannequin device. A pseudo-patient must be capable of responding to and interacting with the home health aide trainee, and must demonstrate the general characteristics of the primary patient population served by the HHA in key areas such as age, frailty, functional status, and cognitive status.

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

Quality indicator means a specific, valid, and reliable measure of access, care outcomes, or satisfaction, or a measure of a process of care.

Representative means the patient's legal representative, such as a guardian, who makes health-care decisions on the patient's behalf, or a patient-selected representative who participates in making decisions related to the patient's care or well-being, including but not limited to, a family member or an advocate for the patient. The patient determines the role of the representative, to the extent possible.

Simulation means a training and assessment technique that mimics the reality of the homecare environment, including environmental distractions and constraints that evoke or replicate substantial aspects of the real world in a fully interactive fashion, in order to teach and assess proficiency in performing skills, and to promote decision making and critical thinking.

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 branch offices is considered a parent agency.

Summary report means the compilation of the pertinent factors of a patient's clinical notes that is submitted to the patient's physician, physician assistant, nurse practitioner, or clinical nurse specialist.

Supervised practical training means training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while providing covered services to an individual under the direct supervision of either a registered nurse or a licensed practical nurse who is under the supervision of a registered nurse.

Verbal order means a physician, physician assistant, nurse practitioner, or clinical nurse specialist order that is spoken to appropriate personnel and later put in writing for the purposes of documenting as well as establishing or revising the patient's plan of care.

Subpart B--Patient Care

G350

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.40 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 OASIS information to the public.

Interpretive Guidelines §484.40

An agent acting on behalf of the HHA is a person or organization, other than an employee of the agency that performs certain functions on behalf of, or provides certain services under contract or arrangement. HHAs often contract with specialized software vendors to submit OASIS data and are commonly referred to by the HHA as the Third-Party vendor.

HHAs and their agents must develop and implement policies and procedures to protect the security of all patient identifiable information contained in electronic format that they create, receive, maintain, and transmit. The agreements between the HHA and OASIS vendors must address policies and procedures to protect the security of such electronic records in order to:

- **Ensure the confidentiality, integrity, and availability of all electronic records they create, receive, maintain, or transmit;**
- **Identify and protect against reasonably anticipated threats to the security or**

integrity of the electronic records;

- **Protect against reasonably anticipated, impermissible uses or disclosures; and,**
- **Ensure compliance by their workforce**

The HHA is ultimately responsible for compliance with these confidentiality requirements and is the responsible party if the agent does not meet the requirements. (See also §484.50(c)(6) Patient Rights)

G370

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.45 Condition of participation: Reporting OASIS information.

HHAs must electronically report all OASIS data collected in accordance with §484.55.

Interpretive Guidelines §484.45

The home health regulations at §484.55 require that each patient receive from the HHA a patient-specific, comprehensive assessment. As part of the comprehensive assessment of adult skilled patients, HHAs are required to use a standard core assessment data set, the OASIS. The OASIS data collection set must include the data elements listed in §484.55(c)(8) and be collected and updated per the requirements under §484.55(d).

G372

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.45(a) Standard: Encoding and transmitting OASIS data. An HHA must encode and electronically transmit each completed OASIS assessment to the CMS system, regarding each beneficiary with respect to which information is required to be transmitted (as determined by the Secretary), within 30 days of completing the assessment of the beneficiary.

Interpretive Guidelines §484.45(a)

"CMS system" means the national internet Quality Improvement Evaluation System (iQIES).

"Encode" means to enter OASIS information into a computer.

"Transmit" means electronically send OASIS information, from the HHA directly to the CMS system.

An HHA must transmit a completed OASIS to the CMS system for all Medicare patients, Medicaid patients, and patients utilizing any federally funded health plan options that are part of the Medicare program (e.g., Medicare Advantage (MA) plans). An HHA must also transmit an OASIS assessment for all Medicaid patients receiving services under a waiver program receiving services subject to the Medicare Conditions of Participation as determined by the State.

Exceptions to the transmittal requirements are patients:

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

The OASIS reporting regulations are not applicable to patients receiving personal care only services, regardless of payor source.

As long as the submission time frame is met, HHAs are free to develop schedules for transmission of the OASIS assessments that best suit their needs.

G374

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.45(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 §484.45(b)

"Accurate" means that the OASIS data transmitted to CMS is consistent with the status of the patient at the time the OASIS was completed.

G378

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.45(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 §484.45(c)(1)

Successful transmission of OASIS data is verified through validation and feedback reports from iQIES. Although not required by the regulation, it is recommended that the HHA keep copies of the electronic validation records, that indicate

transmission was successful, for twelve months, or until the next set of reports are available. The validation reports may be needed as evidence if the HHA receives a denial from the Medicare Administrative Contractor (MAC) for missing OASIS assessments.

G382

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.45(c) Standard: Transmittal of OASIS data. An HHA must—

(2) Transmit data using electronic communications software that complies with the Federal Information Processing Standard (FIPS 140-2, issued May 25, 2001) from the HHA or the HHA contractor to the CMS collection site.

Interpretive Guidelines §484.45(c)(2)

HHAs may directly transmit OASIS data (to the national data repository) via iQIES or other software that conforms to the FIPS 140-2.

G384

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.45(c) Standard: Transmittal of OASIS data. An HHA must—

(3) Transmit data that includes the CMS-assigned branch identification number, as applicable.

G386

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.45(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.

G406

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50 Condition of participation: Patient rights.

The patient and representative (if any), have the right to be informed of the patient's rights in a language and manner the individual understands. The HHA must protect and promote the exercise of these rights.

Interpretive Guidelines §484.50

Ensuring that patients (and representative, if any) are aware of their rights and how to exercise them is vital to quality of care and patient satisfaction. HHAs must inform patients of their rights and protect and promote the exercise of these rights, e.g., by informing the patient how to exercise those rights.

The manner and degree of noncompliance identified in relation to the standard level tags for §484.50 may result in substantial noncompliance with this CoP, requiring citation at the condition level.

Survey Procedures: §484.50

When there is a team surveying the HHA, survey of the Patient rights Condition should be coordinated by one surveyor. However, each surveyor, as they conduct their survey assignments, should assess the HHA's compliance with the Patient rights regulatory requirements. It is particularly important for the surveyor who will be conducting home visits to observe how the HHA's actions protect and promote those patients' exercise of their rights.

• Determine whether the HHA provides patients (or their representatives, if any), with notice of their rights, consistent with the standards under this condition. Review documents in the home provided by the HHA to the patient if the patient (or authorized representative) can provide them.

• Determine whether the HHA promotes the patients' exercise of their rights (or their representatives, as applicable), consistent with the standards under this condition. Interview the patient (or authorized representative) to assess whether they were informed that they are entitled to certain rights.

G410

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(a) Standard: Notice of rights. The HHA must—

(1) Provide the patient and the patient's legal representative (if any), the following information during the initial evaluation visit, in advance of furnishing care to the patient:

Interpretive Guidelines §484.50(a)(1)

The term "in advance" is defined at §484.2. "In advance" means that HHA staff must complete the task prior to performing any hands-on care or any patient education.

A "legal representative" is an individual who has been legally designated or appointed as the patient's health care decision maker. When there is no evidence that a patient has a legal representative, such as a guardianship, a power of attorney for health care decision-making, or a designated health care agent, the HHA must provide the information directly to the patient.

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

G412

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.50(a) Standard: Notice of rights. The HHA must—(1) Provide the patient and the patient's legal representative (if any), the following information during the initial evaluation visit, in advance of furnishing care to the patient:]

(i) Written notice of the patient's rights and responsibilities under this rule, and the HHA's transfer and discharge policies as set forth in paragraph (d) of this section. Written notice must be understandable to persons who have limited English proficiency and accessible to individuals with disabilities;

Interpretive Guidelines §484.50(a)(1)(i)

We expect HHA patients to be able to confirm, upon interview, that their rights and responsibilities, as well as the transfer and discharge policies of the HHA, were understandable and accessible.

To ensure patients receive appropriate notification:

- **Written notice to the patient or their representative of their rights and responsibilities under this rule should be provided via hard copy unless the patient requests that the document be provided electronically.**

- **If a patient or his/her representative's understanding of English is inadequate for the patient's comprehension of his/her rights and responsibilities, the information must be provided in a language or format familiar to the patient or his/her representative.**

- **Language assistance should be provided using competent bilingual staff, staff interpreters, contracts or formal arrangements with local organizations providing interpretation, translation services, or technology and telephonic interpretation services.**

• All agency staff should be trained to identify patients with any language barriers which may prevent effective communication of the rights and responsibilities. Staff that have on-going contact with patients who have language barriers, should be trained in effective communication techniques, including the effective use of an interpreter.

See §484.50(f) for discussion on communication of rights and responsibilities with patients who have disabilities that may hinder communication with the HHA.

G414

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(a) Standard: Notice of rights. The HHA must—

[(1) Provide the patient and the patient's legal representative (if any), the following information during the initial evaluation visit, in advance of furnishing care to the patient:]

(ii) Contact information for the HHA administrator, including the administrator's name, business address, and business phone number in order to receive complaints.

G416

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(a) Standard: Notice of rights. The HHA must—

[(1) Provide the patient and the patient's legal representative (if any), the following information during the initial evaluation visit, in advance of furnishing care to the patient:]

(iii) An OASIS privacy notice to all patients for whom the OASIS data is collected.

Interpretive Guidelines §484.50(a)(1)(iii)

Use of the OASIS Privacy Notice is required under the Federal Privacy Act of 1974 and must be used in addition to other notices that may be required by other privacy laws and regulations. The OASIS privacy notice is available in English and Spanish on the CMS website. The OASIS Privacy Notice must be provided at the time of the initial evaluation visit.

Survey Procedures: §484.50(a)(1)(iii)

Patient interview and clinical record review should confirm that the required privacy notice was provided.

G418
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(a) Standard: Notice of rights. The HHA must—

(2) Obtain the patient's or legal representative's signature confirming that he or she has received a copy of the notice of rights and responsibilities.

Survey Procedures: §484.50(a)(2)

Clinical record review should confirm that the required written notice of patient rights and responsibilities was provided to the patient. Note if the patient/legal representative's signature was obtained as required.

G420
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(a)(3)- Reserved for Future Use

G422
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(a) Standard: Notice of rights. The HHA must—

(4) Provide written notice of the patient's rights and responsibilities under this rule and the HHA's transfer and discharge policies as set forth in paragraph (d) of this section to a patient-selected representative within 4 business days of the initial evaluation visit.

G424
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(b) Standard: Exercise of rights.

(1) If a patient has been adjudged to lack legal capacity to make health care decisions as established by state law by a court of proper jurisdiction, the rights of the patient may be exercised by the person appointed by the state court to act on the patient's behalf.

(2) If a state court has not adjudged a patient to lack legal capacity to make health care decisions as defined by state law, the patient's representative may exercise the patient's rights.

(3) If a patient has been adjudged to lack legal capacity to make health care decisions under state law by a court of proper jurisdiction, the patient may exercise his or her rights to the extent allowed by court order.

Interpretive Guidelines §484.50(b)

The HHA should obtain official documentation of: (1) any adjudication by a court that indicates that a patient lacks the legal capacity to make his or her own health care decisions; and (2) the name of any person identified by the court who may exercise the patient's rights.

G428

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(c) Standard: Rights of the patient. The patient has the right to—

(1) Have his or her property and person treated with respect;

Interpretive Guidelines §484.50(c)(1)

Respect for Property: The patient has the right to expect the HHA staff will respect his or her property and person while in the patient's home. The HHA must ensure that during home visits the patient's property, both inside and outside the home, is not stolen, damaged, or misplaced by HHA staff.

Respect for Person: The HHA must consider and accommodate any patient requests within the parameters of the assessment and plan of care, and the patient must be treated by the HHA as an active partner in the delivery of care. The HHA should make all reasonable attempts to respect the preferences of the patient regarding the services that will be delivered, such as the HHA visit schedule, which should be made at the convenience of the patient rather than of the agency personnel. The HHA must keep the patient informed of the visit schedule and timely and promptly notify the patient when scheduled services are changed.

G430

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(c) Standard: Rights of the patient. The patient has the right to—

(2) Be free from verbal, mental, sexual, and physical abuse, including injuries of unknown source, neglect and misappropriation of property;

Interpretive Guidelines §484.50(c)(2)

The patient has a right to be free from abuse from the HHA staff and others in his or her home environment. The HHA should address any allegations or evidence of

patient abuse to determine if immediate care is needed, a change in the plan of care is indicated, or if a referral to an appropriate agency is warranted. (State laws vary in the reporting requirements of abuse. HHAs should be knowledgeable of these laws and comply with the reporting requirements.) In addition, the HHA should intervene immediately if, as indicated by the circumstances, any injury is the result of an HHA staff member's actions. The HHA should also immediately remove staff from patient care if there are allegations of misconduct related to abuse or misappropriation of property.

"Abuse" means the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. Abuse may be verbal, mental, sexual, or physical and includes abuse facilitated or enabled through the use of technology.

"Verbal abuse" refers to abuse perpetrated through any use of insulting, demeaning, disrespectful, oral, written or gestured language directed toward and in the presence of the client.

"Mental abuse" is a type of abuse that includes, but is not limited to, humiliation, harassment, and threats of punishment or deprivation, sexual coercion and intimidation (e.g. living in fear in one's own home).

"Sexual abuse" is a type of abuse that includes any incident where a beneficiary is coerced, manipulated, or forced to participate in any form of sexual activity for which the beneficiary did not give affirmative permission (or gave affirmative permission without the mental capacity required to give permission), or sexual assault against a beneficiary who is unable to defend him/herself.

"Physical abuse" refers to abuse perpetrated through any action intended to cause physical harm or pain, trauma or bodily harm (e.g., hitting, slapping, punching, kicking, pinching, etc.). It includes the use of corporal punishment as well as the use of any restrictive, intrusive procedure to control inappropriate behavior for purposes of punishment.

"Injury of unknown" source is an injury that was not witnessed by any person and the source of the injury cannot be explained by the patient.

"Misappropriation of property" is theft or stealing of items from a patient's home. The HHA staff must investigate and take immediate action on any allegations of misappropriation of patient property by HHA staff and refer to authorities when appropriate.

Neglect means a failure to provide goods and/or services necessary to avoid physical harm, mental anguish or mental illness.

Survey Procedures: §484.50(c)(2)

Examine the extent to which the HHA has a system in place to protect patients from abuse, neglect, and misappropriation of property of all forms, whether from staff or from other persons. Determine the extent to which the HHA addresses the following issues:

- **How does the HHA staff conduct themselves in the patient's home in regards to demonstrating respect for persons and property?**

- **Does the HHA have policies and procedures for investigating allegations of abuse, neglect and misappropriation of property?**

- **Interview staff to determine if staff members know what to do if they witness abuse, neglect or misappropriation of property.**

- **Ask the HHA if it has had any allegations of patient abuse or neglect from any source during the past year. If it has, ask the HHA to provide the files and to describe how the matter was handled. Review the HHA records to see if the appropriate agencies were notified in accordance with State and federal laws regarding incidents of substantiated abuse and neglect.**

G432

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(c) Standard: Rights of the patient. The patient has the right to—

(3) Make complaints to the HHA regarding treatment or care that is (or fails to be) furnished, and the lack of respect for property and/or person by anyone who is furnishing services on behalf of the HHA;

Interpretive Guidelines §484.50(c)(3)

The HHA should have written policies and procedures that address the acceptance, processing, review, and resolution of patient complaints, including complaint intake procedures, timeframes for investigations, documentation, and potential outcomes and actions that the HHA may take to resolve patient complaints. See also §484.50(e) Investigation of complaints.

The HHA should record, in both the clinical record and the patient's home folder, that the patient was provided with information regarding his or her right to lodge a complaint to the HHA.

G434

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(c) Standard: Rights of the patient. The patient has the right to—

(4) Participate in, be informed about, and consent or refuse care in advance of and during treatment, where appropriate, with respect to –

(i) Completion of all assessments;
(ii) The care to be furnished, based on the comprehensive assessment;
(iii) Establishing and revising the plan of care;
(iv) The disciplines that will furnish the care;
(v) The frequency of visits;
(vi) Expected outcomes of care, including patient-identified goals, and anticipated risks and benefits;
(vii) Any factors that could impact treatment effectiveness; and
(viii) Any changes in the care to be furnished.

Interpretive Guidelines §484.50(c)(4)

The patient's informed consent on the items (i)-(viii) is not intended to be recorded on a single signed form. Informed consent and patient participation take place on an ongoing basis as the patient's care changes and evolves during his or her episodes of care. There must be evidence in the patient's medical record that, both initially and as changes occur in the patient's care, the patient was consulted and consented to planned services and care.

"Participation" means that the patient is given options regarding care choices and preferences. For example, patient preferences should be respected in encouraging the patient to choose between a bath and a shower, unless there are physical restrictions or medical contraindications that limit patient choice.

"Informed" means that all aspects of the planned care and services, and the way the care and services will be delivered, are reviewed by HHA staff with the patient and that, during such review, HHA staff solicits the patient's agreement or disagreement. When there is a change to the plan of care, whether initiated by the HHA/physician or at the request of the patient, documentation in the clinical record should indicate whether the patient was informed of and agreed to the changes.

G436

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(c) Standard: Rights of the patient. The patient has the right to—

(5) Receive all services outlined in the plan of care.

Survey Procedures: §484.50(c)(5)

Clinical record review and patient interview should confirm that the HHA is providing the services identified in the patient's individualized plan of care (see also §484.60(a)).

G438

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(c) Standard: Rights of the patient. The patient has the right to—

(6) Have a confidential clinical record. Access to or release of patient information and clinical records is permitted in accordance with 45 CFR parts 160 and 164.

Interpretive Guidelines §484.50(c)(6)

45 CFR Part 160 and 164 pertain to requirements of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). The HIPAA Privacy Rule (45 CFR Part 160 and Subparts A and E of Part 164), Security Rule (45 CFR Part 160 and Subparts A and C of Part 164), and Breach Notification Rule (45 CFR §§ 164.400–414) protect the privacy and security of health information and provide individuals with certain rights regarding their health information as follows:

- **The Privacy Rule sets national standards for covered entities (health plans, health care clearinghouses, and health care providers that conduct certain health care transactions electronically) and their business associates, including appropriate safeguards to protect the privacy of protected health information (PHI) and the limits and conditions under which PHI is permitted or required to be used or disclosed;**

- **The Security Rule specifies safeguards that covered entities and their business associates must implement to protect the confidentiality, integrity, and availability of electronic protected health information (ePHI)**

- **The Breach Notification Rule requires covered entities and their business associates to notify affected individuals, U.S. Department of Health & Human Services (HHS), and in some cases, the media of a breach of unsecured PHI.**

The HIPAA Privacy Rule also gives certain patients' rights over their health information, including rights to examine and obtain a copy of their health records, and to request corrections.

HHAs have unique concerns and risks regarding staff and contractors who transport documents and/or electronic devices containing PHI, such as during their visits to patient's homes. Compliance with §484.50(c)(6) is evidenced by documentation of HIPAA training for all staff and monitoring HIPAA compliance

to manage the risk of inappropriate PHI disclosure or unsecured ePHI. Each covered entity and business associate is responsible for ensuring its compliance with the HIPAA Privacy, Security, and Breach Notification Rules, as applicable, including consulting appropriate counsel as necessary.

Survey procedures §484.50(c)(6)

Verify that the agency staff maintain the confidentiality of protected health information that they transport and use.

G440

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(c) Standard: Rights of the patient. The patient has the right to—

(7) Be advised, orally and in writing, of—

- **(i) The extent to which payment for HHA services may be expected from Medicare, Medicaid, or any other federally-funded or federal aid program known to the HHA,**
- **(ii) The charges for services that may not be covered by Medicare, Medicaid, or any other federally-funded or federal aid program known to the HHA,**
- **(iii) The charges the individual may have to pay before care is initiated; and**
- **(iv) Any changes in the information provided in accordance with paragraph (c)(7) of this section when they occur. The HHA must advise the patient and representative (if any), of these changes as soon as possible, in advance of the next home health visit. The HHA must comply with the patient notice requirements at 42 CFR 411.408(d)(2) and 42 CFR 411.408(f).**

Survey Procedures §484.50(c)(7)

Ask the patient or legal representative (if any) about whether the HHA informed them if there were any services that may not be covered by Medicare and, if so, how that would be addressed. If a notice of Medicare non-coverage was provided to the patient, confirm that it was received prior to the care being provided. Surveyors are not to advise the patient about finances, or coverage, or payment issues, but rather confirm if the HHA provided this information.

G442

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(c) Standard: Rights of the patient. The patient has the right to—

(8) Receive proper written notice, in advance of a specific service being furnished, if the HHA believes that the service may be non-covered care; or in advance of the HHA reducing or terminating on-going care. The HHA must also comply with the requirements of 42 CFR 405.1200 through 405.1204.

Interpretive Guidelines §484.50(c)(8)

§405.1200 through §405.1204 describe the expedited determination process, which is a right that Medicare beneficiaries may exercise to dispute the termination of Medicare-covered services in certain settings including home health.

Survey Procedures §484.50(c)(8)

Surveyors are not to advise the patient about finances, or coverage, or payment issues, but rather confirm if the HHA provided this information.

G444

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(c) Standard: Rights of the patient. The patient has the right to—

(9) Be advised of the state toll free home health telephone hot line, its contact information, its hours of operation, and that its purpose is to receive complaints or questions about local HHAs.

Survey Procedures §484.50(c)(9)

Determine if the patient is aware of the state home health hotline to lodge a complaint if dissatisfied with the care provided by the HHA. Inquire if the patient filed any complaints directly with the HHA and if the care and services were negatively affected by this action (see also §484.50(c)(11)).

G446

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(c) Standard: Rights of the patient. The patient has the right to—

(10) Be advised of the names, addresses, and telephone numbers of the following Federally-funded and state-funded entities that serve the area where the patient resides:

(i) Agency on Aging

(ii) Center for Independent Living

(iii)Protection and Advocacy Agency,
(iv)(iv) Aging and Disability Resource Center; an

(v) (v) Quality Improvement Organization.

G448
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(c) Standard: Rights of the patient. The patient has the right to—

(11) Be free from any discrimination or reprisal for exercising his or her rights or for voicing grievances to the HHA or an outside entity.

Interpretive Guidelines §484.50(c)(11)

"Discrimination or reprisal against a patient for exercising his or her rights or for voicing grievances" is defined as treating a patient differently from other patients after receipt by the HHA of a patient complaint, without a medical justification for such different treatment.

Examples of discrimination or reprisal include, but are not limited to, a reduction of current services, a complete discontinuation of services, or discharge from the HHA after receipt by the HHA of a patient complaint, without a medical justification for the change of services or discharge.

Survey Procedures §484.50(c)(11)

Inquire if the patient filed any complaints directly with the HHA and if the care and services were negatively affected by this action. Determine if the patient is aware of the state HHA hotline to lodge a complaint if dissatisfied with the care provided by the HHA (§484.50(c)(9)).

G450
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(c) Standard: Rights of the patient. The patient has the right to—

(12) Be informed of the right to access auxiliary aids and language services as described in paragraph (f) of this section, and how to access these services.

G452
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(d) Standard: Transfer and discharge.

The patient and representative (if any), have a right to be informed of the HHA's policies for transfer and discharge. The HHA may only transfer or discharge the patient from the HHA if:

G454

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(d) Standard: Transfer and discharge.

[…The HHA may only transfer or discharge the patient from the HHA if:]

(1) The transfer or discharge is necessary for the patient's welfare because the HHA and the physician or allowed practitioner who is responsible for the home health plan of care agree that the HHA can no longer meet the patient's needs, based on the patient's acuity. The HHA must arrange a safe and appropriate transfer to other care entities when the needs of the patient exceed the HHA's capabilities;

Interpretive Guidelines §484.50(d)(1)

When a patient's care needs change to require more than intermittent services or require specialized services not provided by the agency, the HHA must inform the patient, patient representative (if any), and the physician or allowed practitioner who is responsible for the patient's home health plan of care that the HHA cannot meet the patient's needs without potentially adverse outcomes. (As noted in §484.2, "allowed practitioner" means a physician assistant, nurse practitioner, or clinical nurse specialist as defined at this part.) The HHA should assist the patient and his or her representative (if any) in choosing an alternative entity by identifying those entities in the patient's geographic area that may be able to meet the patient's needs based on the patient's acuity. Once the patient chooses an alternate entity, the HHA must contact that entity to facilitate a safe transfer. The HHA must ensure timely transfer of patient information to the alternate entity to facilitate continuity of care, i.e., the HHA must ensure that patient information is provided to the alternate entity prior to or simultaneously with the initiation of patient services at the new entity.

Also see the discharge planning requirements at §484.58 and the requirements at §484.110(a)(6)(ii) regarding time frame for the transfer summary.

G456

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(d) Standard: Transfer and discharge.

[…The HHA may only transfer or discharge the patient from the HHA if:]

(2) The patient or payer will no longer pay for the services provided by the HHA;

G458

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(d) Standard: Transfer and discharge.

[…The HHA may only transfer or discharge the patient from the HHA if:]

(3) The transfer or discharge is appropriate because the physician or allowed practitioner who is responsible for the home health plan of care and the HHA agree that the measurable outcomes and goals set forth in the plan of care in accordance with §484.60(a)(2)(xiv) have been achieved, and the HHA and the physician or allowed practitioner who is responsible for the home health plan of care agree that the patient no longer needs the HHA's services;

G460

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(d) Standard: Transfer and discharge.

[…The HHA may only transfer or discharge the patient from the HHA if:]

(4) The patient refuses services, or elects to be transferred or discharged;

Interpretive Guidelines §484.50(d)(4)

A patient who occasionally declines a service is distinguished from a patient who refuses services altogether, or who habitually declines skilled care visits. It is the patient's right to refuse services. It is the agency's responsibility to educate the patient on the risks and potential adverse outcomes that can result from refusing services. In the case of patient refusals of skilled care, the HHA must document its communication with the physician or allowed practitioner who is responsible for the patient's home health plan of care, as well as the measures the HHA took to investigate the patient's refusal and the interventions the HHA attempted in order to obtain patient participation with the plan of care.

The HHA may consider discharge if the patient's decision to decline services compromises the agency's ability to safely and effectively deliver care to the extent that the agency can no longer meet the patient's needs.

G462

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(d) Standard: Transfer and discharge.

[…The HHA may only transfer or discharge the patient from the HHA if:]

(5) The HHA determines, under a policy set by the HHA for the purpose of addressing discharge for cause that meets the requirements of paragraphs (d)(5)(i) through (d)(5)(iii) of this section, that the patient's (or other persons in the patient's home) behavior is disruptive, abusive, or uncooperative to the extent that delivery of care to the patient or the ability of the HHA to operate effectively is seriously impaired. The HHA must do the following before it discharges a patient for cause:

Interpretive Guidelines §484.50(d)(5)

"Disruptive, abusive behavior" includes verbal, non-verbal or physical threats, sexual harassment, or any incident in which agency staff feel threatened or unsafe, resulting in a serious impediment to the agency's ability to operate safely and effectively in the delivery of care.

"Uncooperative" is defined as the patient's repeated declination of services or persistent obstructive, hostile or contrary attitudes to agency caregivers that are counterproductive to the plan of care.

The HHA must document in the patient's clinical record the behaviors and circumstances that warranted patient discharge for cause as well as the HHA's efforts to resolve the problems.

G464

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(d) Standard: Transfer and discharge.

[…The HHA must do the following before it discharges a patient for cause:]

(5)(i) Advise the patient, the representative (if any), the physician(s) or allowed practitioners(s) issuing orders for the home health plan of care, and the patient's primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any) that a discharge for cause is being considered;

Interpretive Guidelines §484.50(d)(5)(i)

The HHA must notify the patient, his or her representative (if any), the physician(s) or allowed practitioners(s) issuing orders for the home health care and the patient's primary care practitioner that the HHA is considering a discharge for cause. If the HHA can identify other health care professionals who may be involved in the

patient's care after the discharge occurs, then the HHA should notify those individuals of the discharge when discharge becomes imminent.

G466

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(d) Standard: Transfer and discharge.

[…The HHA must do the following before it discharges a patient for cause:]

(5)(ii) Make efforts to resolve the problem(s) presented by the patient's behavior, the behavior of other persons in the patient's home, or situation;

G468

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(d) Standard: Transfer and discharge.

[…The HHA must do the following before it discharges a patient for cause:]

(5)(iii) Provide the patient and representative (if any), with contact information for other agencies or providers who may be able to provide care; and

Interpretive Guidelines §484.50(d)(5)(ii) and (iii)

The clinical record should reflect:

- **Identification of the problems encountered;**
- **Assessment of the situation;**
- **Communication among HHA management, patient caregiver, legal representative and the physician responsible for the plan of care;**
- **A plan to resolve the issues; and**
- **Results of the plan implementation.**

Only in extreme situations when there is a serious imminent threat of physical harm to
HHA staff, the HHA may take immediate action to discharge or transfer the patient without first making efforts to resolve the underlying issue.

Evidence in the record should document that the HHA provided the patient and his or her representative (if any) with information including contact numbers for other community resources and names of other agencies or providers that may be able to provide services to the patient.

G470

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(d) Standard: Transfer and discharge.

[…The HHA must do the following before it discharges a patient for cause:]

(5)(iv) Document the problem(s) and efforts made to resolve the problem(s), and enter this documentation into its clinical records;

G472

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(d) Standard: Transfer and discharge.

[…The HHA may only transfer or discharge the patient from the HHA if:]

(6) The patient dies; or

G474

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(d) Standard: Transfer and discharge.

[…The HHA may only transfer or discharge the patient from the HHA if:]

(7) The HHA ceases to operate.

Interpretive Guidelines §484.50(d)(7)

The agency must provide sufficient notice of its planned cessation of business to enable patients to select an alternative service provider and to enable the HHA to facilitate the safe transfer of its patients to other agencies.

G478

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(e) Standard: Investigation of complaints.

§484.50(e)(1) The HHA must—

(i) Investigate complaints made by a patient, the patient's representative (if any), and the patient's caregivers and family, including, but not limited to, the following topics:

(A) Treatment or care that is (or fails to be) furnished, is furnished inconsistently, or is furnished inappropriately;

(B) Mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and/or misappropriation of patient property by anyone furnishing services on behalf of the HHA.

G484

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(e)(1) The HHA must—

(ii) Document both the existence of the complaint and the resolution of the complaint; and

Survey Procedures §484.50(e)(1)(ii)

Obtain the complaint log (or other format used for documenting complaints) to verify that the HHA is tracking complaints received from receipt of complaint through resolution.

G486

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(e)(1) The HHA must—

(iii) Take action to prevent further potential violations, including retaliation, while the complaint is being investigated.

Interpretive Guidelines §484.50(e)(1)

The HHA should have systems in place to record, track and investigate all complaints. Written policies and procedures on the acceptance, processing, review, and resolution of patient complaints should be developed and communicated to staff. These policies should include intake procedures, timeframes for investigations, documentation, and outcomes and actions that the HHA may take to resolve patient complaints. Complaint investigations should be incorporated into the agency's Quality Assurance Performance Improvement program.

The HHA should be able to produce documentation for each complaint received that confirms that an investigation was conducted and records the investigation

findings as well as the ultimate resolution of the complaint. The documentation should also describe any actions taken by the HHA to remove any risks to the patient while the complaint was being investigated.

G488

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(e)(2) Any HHA staff (whether employed directly or under arrangements) in the normal course of providing services to patients, who identifies, notices, or recognizes incidences or circumstances of mistreatment, neglect, verbal, mental, sexual, and/or physical abuse, including injuries of unknown source, or misappropriation of patient property, must report these findings immediately to the HHA and other appropriate authorities in accordance with state law.

Interpretive Guidelines §484.50(e)(2)

Immediately means reporting without delay, as soon as possible following the discovery.
States commonly have mandatory reporting requirements for providers, suppliers, and individuals making them legally responsible to report suspicions of abuse and neglect to appropriate State authorities. These entities and individuals should follow existing mandatory reporting requirements in their State in addition to any applicable Federal requirements. Action or inaction on the part of a provider or supplier to follow mandatory reporting requirements does not preclude an employee from fulfilling their reporting obligations.

G490

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.50(f) Standard: Accessibility. Information must be provided to patients in plain language and in a manner that is accessible and timely to—

(1) Persons with disabilities, including accessible web sites and the provision of auxiliary aids and services at no cost to the individual in accordance with the Americans with Disabilities Act and Section 504 of the Rehabilitation Act.

(2) Persons with limited English proficiency through the provision of language services at no cost to the individual, including oral interpretation and written translations.

Interpretive Guidelines §484.50(f)

"Plain language" (also referred to as "Plain English") is communication the patient and/or his or her representative (if any) can understand the first time they read or hear it. Language that is plain to one set of readers may not be plain to others. Written material is in plain language if the audience can:

- **Find what they need;**
- **Understand what they find; and**
- **Use what they find to meet their needs.**

Section 504 of the Rehabilitation Act and the Americans with Disabilities Act protect qualified individuals with disabilities from discrimination on the basis of disability in the provision of benefits and services. Concerns related to potential discrimination issues under 504 should be referred to the Office of Civil Rights for further review.

"Auxiliary aids and services" for individuals who are deaf or hard of hearing include services and devices such as, but not limited to: qualified interpreter services (on-site or through video remote interpreting (VRI)); note takers; real-time computer-aided transcription services; written materials; exchange of written notes; telephone handset amplifiers; assistive listening devices; assistive listening systems; telephones compatible with hearing aids; closed caption decoders; open and closed captioning, including real-time captioning; voice, text, and video-based telecommunications products and systems, including text telephones (TTYs), videophones, and captioned telephones, or equally effective telecommunications devices; videotext displays; and accessible electronic and information technology. Auxiliary aids and services for individuals who are blind or have low vision include services and devices such as: qualified readers; taped texts; audio recordings; Braille materials and displays; screen reader software; magnification software; optical readers; secondary auditory programs (SAP); large print materials; and accessible electronic and information technology.

The patient's clinical record should include evidence that the HHA facilitated the availability of needed auxiliary aids and language services.

G510

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.55 Condition of participation: Comprehensive assessment of patients.

Each patient must receive, and an HHA must provide, a patient-specific, comprehensive assessment. 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.

Interpretive Guidelines §484.55

A comprehensive assessment of the patient, in which patient needs are identified, is a crucial step in the establishment of a plan of care. In addition, a comprehensive

assessment identifies patient progress toward desired outcomes or goals of the care plan.

The manner and degree of noncompliance identified in relation to the standard level tags for §484.55 may result in substantial noncompliance with this CoP, requiring citation at the condition level.

G514

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§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. 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- or allowed practitioner-ordered start of care date.

Interpretive Guidelines §484.55(a)(1)

For patients receiving only nursing services or both nursing and rehabilitation therapy services, a registered nurse must conduct the initial assessment visit. For patients receiving rehabilitation therapy services only, the initial assessment may be made by the applicable rehabilitation skilled professional rather than the registered nurse. See §484.55(a)(2).

The initial assessment bridges the gap between when the first patient encounter occurs and when a plan of care can be implemented. "Immediate care and support needs" are those items and services that will maintain the patient's health and safety through this interim period, i.e., until the HHA can complete the comprehensive assessment and implement the plan of care. "Immediate care and support needs" may include medication, mobility aids for safety, skilled nursing treatments, and items to address fall risks and nutritional needs.

The clinical record must demonstrate that homebound status/eligibility for the Medicare home health benefit was determined and documented during the initial visit.

An HHA that is unable to complete the initial assessment within 48 hours of referral or the patient's return home, shall not request a different start of care date from the ordering physician to ensure compliance with the regulation or to accommodate the convenience of the agency.

In instances where the patient requests a delay in the start of care date, the HHA would need to contact the physician to request a change in the start of care date and such change would need to be documented in the medical record.

G516

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§ 484.55(a)(2) When rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician or allowed practitioner who is responsible for the home health plan of care, the initial assessment visit may be made by the appropriate rehabilitation skilled professional. For Medicare patients, an occupational therapist may complete the initial assessment when occupational therapy is ordered with another qualifying rehabilitation therapy service (speech-language pathology or physical therapy) that establishes program eligibility.

G520

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§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 start of care date is the first visit where the HHA provides hands on, direct care services or treatments to the patient. If an initial assessment is completed without any direct care services being provided by the HHA during the assessment visit, the date of that initial assessment visit would not be the start of care date. The comprehensive assessment must be completed within 5 calendar days of the first visit where the HHA provides hands on, direct care services/treatments to the patient.

G522

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§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 requirements for conducting the initial assessment visit and the comprehensive assessment for home health services are based on sections 1814(a)(2)(c) and 1835(a)(2)(A) of the Act regarding eligibility and payment for home health services. The requirements for these assessments are based on the professional disciplines that will be involved in, and coordinating, care for the patient. When nursing is assigned to the case, it is likely the patient will have a greater need for nursing services than other services and therefore skilled nurses should conduct the initial assessment visit and initiate the comprehensive assessment (86 FR 62240, 62351 (Nov. 9, 2021)).

Survey Procedures §484.55(b)(2)

- **Through clinical record review, verify the initial assessment was conducted by a registered nurse unless the patient is receiving therapy services only.**

- **Through home visit observation, verify if the current comprehensive assessment and plan of care were completed and accurately reflect the patient's status.**

G524

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.55(b)(3) When physical therapy, speech-language pathology, or occupational therapy is the only service ordered by the physician or allowed practitioner, 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. For Medicare patients, the occupational therapist may complete the comprehensive assessment when occupational therapy is ordered with another qualifying rehabilitation therapy service (speech-language pathology or physical therapy) that establishes program eligibility.

Interpretive Guidelines §484.55(b)(3)

In therapy-only cases, a qualified therapist (registered and/or licensed by the State in which they practice) may conduct the comprehensive assessment for therapy services ordered.

G528

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.55(c) Standard: Content of the comprehensive assessment. The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:

(1) The patient's current health, psychosocial, functional, and cognitive status;

Interpretive Guidelines §484.55(c)(1)

Completion of the comprehensive assessment should provide the HHA with a complete picture of the patient's status to assist the HHA in developing the patient's plan of care.

Assessment of the patient's current health status includes relevant past medical history as well as all active health and medical problems.

Assessment of a patient's psychosocial status and his/her functional capacity within the community is intended to be a screening of the patient's relationships, living environment, impact on the delivery of services and ability to participate in his/her own care. Assessment of a patient's functional status includes the patient's level of ability to function independently in the home such as activities of daily living.

Assessment of a patient's cognitive status refers to an evaluation of the degree of his or her ability to understand, remember, and participate in developing and implementing the plan of care.

G530

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.55(c) … The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:]

(2) The patient's strengths, goals, and care preferences, including information that may be used to demonstrate the patient's progress toward achievement of the goals identified by the patient and the measurable outcomes identified by the HHA;

Interpretive Guidelines §484.55(c)(2)

Consistent with the principles of patient-centered care, the intent in identifying patient strengths is to empower the patient to take an active role in his or her care. The HHA must ask the patient to identify her or his own strengths and must also independently identify the patient's strengths to inform the plan of care and to set patient goals and measurable outcomes. Examples of patient strengths identified by HHAs through observation and by patient self-identification may include: awareness of disease status, knowledge of medications, motivation and readiness for change, motivation/ability to perform self-care and/or implement a therapeutic exercise program, understanding of a dietary regimen for disease management, vocational interests/hobbies, interpersonal relationships and supports, and financial stability.

The intent of assessing patient care preferences is to engage the patient to the greatest degree possible to take an active role in their home care rather than placing

the patient in a passive recipient role by informing the patient what will be done for them and when.

"Patient goal" is defined as a patient-specific objective, adapted to each patient based on the medical diagnosis, physician's or allowed practitioner's orders, comprehensive assessment, patient input, and the specific treatments provided by the agency.

"Measurable outcome" is a change in health status, functional status, or knowledge, which occurs over time in response to a health care intervention. Measurable outcomes may include end-result functional and physical health improvement/stabilization, health care utilization measures (hospitalization and emergency department use), and potentially avoidable events. Because the nature of the change can be positive, negative, or neutral, the actual change in patient health status can vary from patient to patient, ranging from decline, no change, to improvement in patient condition or functioning.

G532

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.55(c) … The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:]

(3) The patient's continuing need for home care;

Interpretive Guidelines §484.55(c)(3)

Medicare does not limit the number of continuous 60-day episode recertifications for beneficiaries who continue to be eligible for the home health benefit. Therefore, the comprehensive assessment must clearly demonstrate the continuing need, i.e., eligibility, for the home health benefit.

G534

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.55(c) … The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:]

(4) The patient's medical, nursing, rehabilitative, social, and discharge planning needs;

Survey Procedures §484.55(c)(4)

Verify if the current comprehensive assessment accurately reflects the patient's current status.

G536

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.55(c) … The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:]

(5) 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)(5)

The patient's clinical record should identify all medications that the patient is taking, both prescription and non-prescription (e.g., over-the-counter drugs, herbal remedies, and other alternative treatments that could affect drug therapy), as well as the dose, route, frequency, or time of administration when indicated on the prescription or order. The skilled professional performing the comprehensive assessment should consider, and the clinical record should document, that the skilled professional considered each medication the patient is currently taking for possible side effects and the list of medications in its entirety for possible drug interactions. Each agency must determine the capabilities of current staff members to perform comprehensive assessments, considering professional standards or practice acts specific to the State. No specific discipline is identified as exclusively able to perform the medication review. However, only Registered Nurses (RNs), Physical Therapists (PTs), Occupational Therapists (OTs) and Speech-Language Pathologists (SLPs) are qualified to perform comprehensive assessments (see also §484.55(b)). While only the assessing clinician is responsible for accurately completing and signing a comprehensive assessment, the agency may develop a policy where clinicians may collaborate to collect data for all OASIS items. For example, to assess potential side effects and drug interactions, the agency may wish to have RNs or practical (vocational) nurses, as defined in §484.115, review the mediation lists.

HHA should have policies that guide staff in the event there is a concern identified with a patient's medication that should be reported to the physician or allowed practitioner.

Survey Procedures §484.55(c)(5)

Through home visit observation and record review, confirm the medications the patient identifies they are taking against the medical record documentation to verify that the HHA identified all medications, both prescription and non-prescription.

G538
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.55(c) … The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:]

§484.55(c)(6) The patient's primary caregiver(s), if any, and other available supports, including their:

(i) Willingness and ability to provide care, and

(ii) Availability and schedules;

G540
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.55(c) … The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:]

(7) The patient's representative (if any);

G542
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.55(c) … The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:]

(8) Incorporation 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. The OASIS data items determined by the Secretary 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.

G544
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§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)

A marked improvement or worsening of a patient's condition, which changes, and was not anticipated in, the patient's plan of care would be considered a "major decline or improvement in the patient's health status" that would warrant update and revision of the comprehensive assessment.

G546
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.55(d) Standard: Update of the comprehensive assessment…not less frequently than-]

(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.

G548
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.55(d) Standard: Update of the comprehensive assessment…not less frequently than-]

(2) Within 48 hours of the patient's return to the home from a hospital admission of 24 hours or more for any reason other than diagnostic tests, or on physician or allowed practitioner -ordered resumption date;

G550
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.55(d) Standard: Update of the comprehensive assessment…not less frequently than-]

(3) At discharge.

Interpretive Guidelines § 484.55(d)(3)

The update of the comprehensive assessment at discharge would include a summary of the patient's progress in meeting the care plan goals.

G560
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§ 484.58 Condition of participation: Discharge planning.

Interpretive Guidelines § 484.58

The manner and degree of noncompliance identified in relation to the standard level tags for §484.58 may result in substantial noncompliance with this CoP, requiring citation at the condition level.

G562
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.58(a) Standard: Discharge planning.

A home health agency must develop and implement an effective discharge planning process. For patients who are transferred to another HHA or who are discharged to a SNF, IRF or LTCH, the HHA must assist patients and their caregivers in selecting a post-acute care provider by using and sharing data that includes, but is not limited to HHA, SNF, IRF, or LTCH data on quality measures and data on resource use measures. The HHA must ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.

Interpretive Guidelines §484.58(a)

The goal of discharge planning is to prepare patients and caregivers to be active partners in post-discharge care, to effectively transition the patient from HHA to post-HHA care, and to reduce the factors that often lead to preventable readmissions.

Data on quality and resource use measures are available on the CMS.gov web site to assist consumers in making informed decisions about the performance of HHA and other providers including skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), long term care hospitals (LTCHs) and hospices.

G564
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.58(b) Standard: Discharge or transfer summary content.

(1) The HHA must send all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, to the receiving facility or health care practitioner to ensure the safe and effective transition of care.

Interpretive Guidelines §484.58(b)(1)

See also §484.110(a)(6) for discharge and transfer summary requirements.

G566

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.58(b) Standard: Discharge or transfer summary content.

(2) The HHA must comply with requests for additional clinical information as may be necessary for treatment of the patient made by the receiving facility or health care practitioner.

G570

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.60 Condition of participation: Care planning, coordination of services, and quality of care.

Patients are accepted for treatment on the reasonable expectation that an HHA can meet the patient's medical, nursing, rehabilitative, and social needs in his or her place of residence. Each patient must receive an individualized written plan of care, including any revisions or additions. The individualized plan of care must specify the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, including identification of the responsible discipline(s), and the measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care. The individualized plan of care must also specify the patient and caregiver education and training. Services must be furnished in accordance with accepted standards of practice.

Interpretive Guidelines §484.60

"Reasonable expectation that an HHA can meet the patient's medical, nursing, rehabilitative, and social needs in his or her place of residence" means that, in consideration of the patient's level of acuity, the HHA can effectively and safely provide the patient with the skilled services that the patient needs within the patient's home.

"Accepted standards of practice" include guidelines and recommendations issued by nationally recognized organizations with expertise in the relevant field. The

Agency for Healthcare Research and Quality (AHRQ) maintains a National Guideline Clearinghouse as a public resource for summaries of evidence-based clinical practice guidelines.

See §484.60(e) for written information that must be provided to the patient.

G572

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.60(a) Standard: Plan of care.

(1) Each patient must receive the home health services that are written in an individualized plan of care that identifies patient-specific measurable outcomes and goals, and which is established, periodically reviewed, and signed by a doctor of medicine, osteopathy, or podiatry acting within the scope of his or her state license, certification, or registration. If a physician or allowed practitioner refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician or allowed practitioner is consulted to approve additions or modifications to the original plan.

Interpretive Guidelines §484.60(a)(1)

"Patient-specific measurable outcome" is a change in health status, functional status, or knowledge, which occurs over time in response to a health care intervention that provides end-result functional and physical health improvement/stabilization.

Patient-specific goals must be individualized to the patient based on the patient's medical diagnosis, physician or allowed practitioner orders, comprehensive assessment and patient input. Progress/non-progress toward achieving the goals is evaluated through measurable outcomes. The HHA must include goals for the patient, as well as patient preferences and service schedules, as a part of the plan of care (See §484.60(a)(2) below).

"Periodically reviewed" means every 60 days or more frequently when indicated by changes in the patient's condition (see §484.60(c)(1)).

The patient's physician or allowed practitioner orders for treatments and services are the foundation of the plan of care. If the HHA misses a visit or a treatment or service as required by the plan of care, the HHA should make every attempt to reschedule the missed visit. If the visit cannot be rescheduled, the responsible physician or allowed practitioner should be notified, and the HHA should document the potential clinical impact of missed treatments or services. The HHA should advise and educate the patient on the potential impacts of missed visits.

If the patient or the patient's representative refuses care that could impact the patient's clinical wellbeing (such as dressing changes or essential medication) on more than one occasion, then the HHA must attempt to identify the reason for the refusal. If the HHA is unable to identify and address the reason for the refusal, then the HHA must communicate with the patient's responsible physician or allowed practitioner to discuss how to proceed with patient care.

The physician or allowed practitioner should not be approached to reduce the frequency of services based solely on the availability of HHA staff.

In instances where the HHA receives a general referral from a physician or allowed practitioner that requests HHA services but does not provide the actual plan of care components (i.e., treatments and observations) for the patient, the HHA will not be able to create a comprehensive plan of care to include goals and services until a home visit is done and sufficient information is obtained to communicate with and receive approval from the physician or allowed practitioner.

G574

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.60(a)(2) The individualized plan of care must include the following:

(i) All pertinent diagnoses;

(ii) The patient's mental, psychosocial, and cognitive status;

(iii) The types of services, supplies, and equipment required;

(iv) The frequency and duration of visits to be made;

(v) Prognosis;

(vi) Rehabilitation potential;

(vii) Functional limitations;

(viii) Activities permitted;

(ix) Nutritional requirements;

(x) All medications and treatments;

(xi) Safety measures to protect against injury;

(xii) A description of the patient's risk for emergency department visits and hospital re-admission, and all necessary interventions to address the underlying risk factors.

(xiii) Patient and caregiver education and training to facilitate timely discharge;

(xiv) Patient-specific interventions and education; measurable outcomes and goals identified by the HHA and the patient;

(xv) Information related to any advanced directives; and

(xvi) Any additional items the HHA or physician or allowed practitioner may choose to include.

Interpretive Guidelines §484.60(a)(2)

A detailed, individualized plan of care is critical to both the quality and safety of patient care and therefore each of the required elements must be included.

- **In general, pertinent diagnoses include, but are not limited to, the chief reason the patient is receiving home care and the diagnosis most related to the current home health plan of care. Additionally, comorbid conditions that exist at the time of the assessment, that are actively addressed in the patient's Plan of Care, or that have the potential to affect the patient's responsiveness to treatment and rehabilitative prognosis should be considered and documented.**

- **Mental status is generally screened by asking the patient questions on orientation to time, place and person.**

- **Psychosocial status, as relevant to the patient's plan of care, may include but is not limited to, interpersonal relationships in the immediate family, financial status, homemaker/household needs, vocational rehabilitation needs, family social problems and transportation needs.**

- **In general, the plan of care should list the required supplies and equipment which are non-routine and medically necessary for the patient's care. Examples include, but are not limited to, shower chairs, catheters, tube feeding supplies, and ostomy bags.**

G576

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.60(a)(3) All patient care orders, including verbal orders, must be recorded in the plan of care.

Interpretive Guidelines §484.60(a)(3)

All patient care orders, including verbal orders are part of the plan of care. The plan of care may include orders for treatment or services received from physicians other than the responsible physician. The plan should be revised to reflect any verbal order received during the 60-day certification period so that all HHA staff are working from a current plan. It is not necessary for the physician or allowed practitioner to sign an updated plan of care until the patient is recertified to continue care and the plan of care is updated to reflect all current ongoing orders including any verbal orders received during the 60-day period.

NOTE: Pulse oximetry is a ubiquitous assessment tool, often used as a part of routine vital signs across health care providers. Routine monitoring of vital signs, including pulse oximetry, do not require a physician order.

G580

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.60(b) Standard: Conformance with the physician or allowed practitioner orders.

(1) Drugs, services, and treatments are administered only as ordered by a physician or allowed practitioner.

Interpretive Guidelines §484.60(b)(1)

Drugs, services and treatments must be administered in accordance with the orders of a physician or allowed practitioner that establishes and periodically reviews the plan of care. See also §484.60(a)(1).

G582

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.60(b)(2) Influenza and pneumococcal vaccines may be administered per agency policy developed in consultation with a physician, physician assistant, nurse practitioner, or clinical nurse specialist, and after an assessment of the patient to determine for contraindications.

Interpretive Guidelines §484.60(b)(2)

The HHA, in consultation with a physician, physician assistant, nurse practitioner, or clinical nurse specialist must develop a written policy that addresses vaccination screening for safety exclusions and assessing contraindications prior to administration of a vaccine, as well as written policies and procedures that address vaccine administration, including managing adverse reactions. No individual physician or allowed practitioner order is required for a vaccine. The administration of these vaccines is an exception to §484.60(b)(1).

G584

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.60(b)(3) Verbal orders must be accepted only by personnel authorized to do so by applicable state laws and regulations and by the HHA's internal policies.

§484.60(b)(4) When services are provided on the basis of a physician or allowed practitioner's verbal orders, a nurse acting in accordance with state licensure requirements, or other qualified practitioner responsible for furnishing or supervising the ordered services, in accordance with state law and the HHA's policies, must document the orders in the patient's clinical record, and sign, date, and time the orders. Verbal orders must be authenticated and dated by the physician or allowed practitioner in accordance with applicable state laws and regulations, as well as the HHA's internal policies.

Interpretive Guidelines §484.60(b)(4)

When services are furnished based on a physician or allowed practitioner's verbal order, the order must be put into writing by personnel authorized to do so by applicable state laws as well as by the HHA's internal policies. The orders must be signed and dated with the date of receipt by the nurse or qualified therapist (i.e., physical therapist, speech-language pathologist, occupational therapist, or medical social worker) responsible for furnishing or supervising the ordered services.

In the absence of a state requirement, the HHA should establish a timeframe for physician or allowed practitioner authentication, i.e. for obtaining a physician or allowed practitioner signature for verbal/telephone orders received. The signature may be written or in electronic form following the requirements of the particular system. A method must be established to identify the signer.

When verbal orders are added to the plan of care, it is not necessary for the physician or allowed practitioner to sign an updated plan of care until the patient is recertified. However, all verbal orders must be authenticated and dated by the physician or allowed practitioner in accordance with applicable state laws and regulations, as well as the HHA's internal policies.

G588

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.60(c) Standard: Review and revision of the plan of care.

(1) The individualized plan of care must be reviewed and revised by the physician or allowed practitioner who is responsible for the home health plan of care and the HHA as frequently as the patient's condition or needs require, but no less frequently than once every 60 days, beginning with the start of care date. . . .

Interpretive Guidelines §484.60(c)(1)

See Tag G590 for Interpretive Guidelines for §484.60(c)(1).

G590

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.60(c)(1)
. . . The HHA must promptly alert the relevant physician(s) or allowed practitioner(s) to any changes in the patient's condition or needs that suggest that outcomes are not being achieved and/or that the plan of care should be altered.

Interpretive Guidelines §484.60(c)(1) (Tags G588 and G590)

For "responsible physician" see §484.60(a)(1).

The signature and date of the review by the responsible physician or allowed practitioner verifies the interval between plan of care reviews.

In the event of a change in patient condition or needs that suggest outcomes are not being achieved and/or that the patient's plan of care should be altered, the HHA should notify both the responsible physician or allowed practitioner and the physician(s) or allowed practitioner(s) associated with the relevant aspect of care.

Changes in physician or allowed practitioner orders during the plan of care certification period do not automatically restart the timeframe for physician or allowed practitioner review of the plan of care.

G592

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.60(c)(2) A revised plan of care must reflect current information from the patient's updated comprehensive assessment, and contain information concerning the patient's progress toward the measurable outcomes and goals identified by the HHA and patient in the plan of care.

Survey Procedures §484.60(c)(2)

The clinical record should demonstrate that patients are assessed throughout the episode of care to assure that HHA services meet the needs of the patient; changes in a patient's status are consistently communicated; and the plan of care is updated as needed.

G594
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.60(c)(3) Revisions to the plan of care must be communicated as follows:

Survey Procedures §484.60(c)(3)

Ask the HHA to explain how changes to the plan of care are consistently communicated and verify through record review that communications occur.

G596
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.60(c)(3)(i) Any revision to the plan of care due to a change in patient health status must be communicated to the patient, representative (if any), caregiver, and all physicians or allowed practitioners issuing orders for the HHA plan of care.

Interpretive Guidelines §484.60(c)(3)(i)

There must be evidence in the clinical record that the HHA explained to the patient that a change to the plan of care has occurred and how the change will impact the care delivered by the HHA. The clinical record must also document that the revised plan of care was shared with all relevant physicians or allowed practitioners providing care to the patient.

G598
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.60(c)(3)(ii) Any revisions related to plans for the patient's discharge must be communicated to the patient, representative, caregiver, all physicians or allowed practitioners issuing orders for the HHA plan of care, and the patient's primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any).

Interpretive Guidelines §484.60(c)(3)(ii)

Discharge planning begins early in the provision of care and must be revised as the patient's condition or life circumstances change. There must be evidence in the clinical record that the HHA discussed any such changes with the patient, his or her representative (if any) and the responsible physician or allowed practitioner. Other physicians or allowed practitioner(s) who contributed orders to the patient's plan of care must also be notified of changes to the patient's discharge plan

G602
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.60(d) Standard: Coordination of Care. The HHA must:

(1) Assure communication with all physicians or allowed practitioners involved in the plan of care.

Interpretive Guidelines §484.60(d)(1)

The physician or allowed practitioner who initiated home health care is responsible for the ongoing plan of care; however, to assure the development and implementation of a coordinated plan of care, HHA communication with all physicians or allowed practitioner involved in the patient's care is often necessary. While a patient may see several physicians or allowed practitioner(s) for various medical problems, not all the physicians or allowed practitioner(s) would necessarily be involved in the skilled services defined in the patient's home health plan of care. Regarding this requirement, "physicians or allowed practitioners involved in the plan of care" means those physicians or allowed practitioners who give orders that are directly related to home health skilled services.

G604

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.60(d)(2) Integrate orders from all physicians or allowed practitioners involved in the plan of care to assure the coordination of all services and interventions provided to the patient.

Interpretive Guidelines §484.60(d)(2)

The clinical manager or other staff designated by the HHA is responsible for integrating orders from all relevant physicians or allowed practitioners involved into the HHA plan of care and ensuring the orders are approved by the responsible physician or allowed practitioner.

G606

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.60(d)(3) Integrate services, whether services are provided directly or under arrangement, to assure the identification of patient needs and factors that could affect patient safety and treatment effectiveness and the coordination of care provided by all disciplines.

Interpretive Guidelines §484.60(d)(3)

The HHA must integrate services provided by various disciplines by:

- **Managing the scheduling of patients, taking into consideration the type of services that are being provided on a given day. For example, a patient may**

become fatigued after a HH aide visit assisting with a bath, thus making a physical therapy session scheduled for directly after the HH aide visit less effective.

- **Managing pain during physical therapy or physical care (i.e. dressing changes or wound care) to minimize patient discomfort while maximizing the effectiveness of the therapy session.**
- **Working with the patient to recommend and make safety modifications in the home.**
- **Assuring that staff who provide care are communicating any patient concerns and patient progress toward the goals identified in the plan of care with others involved in the patient's care.**

G608

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.60(d)(4) Coordinate care delivery to meet the patient's needs, and involve the patient, representative (if any), and caregiver(s), as appropriate, in the coordination of care activities.

Survey Procedures §484.60(d)(4)

Determine through interview if the patient, representative, and caregiver, as applicable and appropriate, are involved in care coordination. For example, were individual schedules considered and accommodated as able?

G610

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.60(d)(5) Ensure that each patient, and his or her caregiver(s) where applicable, receive ongoing education and training provided by the HHA, as appropriate, regarding the care and services identified in the plan of care. The HHA must provide training, as necessary, to ensure a timely discharge.

Interpretive Guidelines §484.60(d)(5)

The comprehensive assessment, patient-centered plan of care and the goals identified therein inform the training and education objectives for each patient. The goals of the HHA episode are established at admission and revised as indicated by the patient's condition. With the discharge plan clearly identified, patient education and documentation of the patient response to the education begins upon admission and continues throughout the provision of HHA services. The HHA must monitor patient and caregiver responses to and comprehension of any training provided.

Survey Procedures §484.60(d)(5)

If education was conducted, did the HHA staff provide education and training to the patient and any caregivers, when appropriate, and according to the plan of care? Look for evidence that the education was conducted by reviewing the written information in the patient's home and/or interviewing the patient and HHA staff.

G612

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.60(e) Standard: Written information to the patient.

The HHA must provide the patient and caregiver with a copy of written instructions outlining:

Interpretive Guidelines §484.60(e)

The documents listed in (e)(1)-(5) must be provided to the patient and/or their his/her caregiver and representative (if any) no later than the next visit after the plan of care has been approved by the physician or allowed practitioner. The written information should be updated as the plan of care changes. Clear written communication between the HHA and the patient and the patient's caregiver and representative (if any) helps ensure that patients and families understand what services to expect from the HHA, the purpose of each service and when to expect the services.

G614

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[The HHA must provide the patient and caregiver with a copy of written instructions outlining…]

§484.60(e)(1) Visit schedule, including frequency of visits by HHA personnel and personnel acting on behalf of the HHA.

Interpretive Guidelines §484.60(e)(1)

The HHA must ensure that the written visit schedule provided to the patient is consistent with the patient's most current plan of care.

G616

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[The HHA must provide the patient and caregiver with a copy of written instructions outlining…]

§484.60(e)(2) Patient medication schedule/instructions, including: medication name, dosage and frequency and which medications will be administered by HHA personnel and personnel acting on behalf of the HHA.

Interpretive Guidelines §484.60(e)(2)

The HHA must prepare, and provide to the patient and his or her caregiver (if any) written information regarding the patient's medication regimen as based on the results of the medication review conducted at §484.55(c)(5). The medication administration instructions must be written in plain language that does not use medical abbreviations.

The HHA must provide this information to the patient regardless of whether the patient is receiving only rehabilitation therapy services. See §484.55(c)(5) for communication between the therapist and the HHA nurse regarding medications.

Survey Procedures §484.60(e)(2)

Review the most current medication list that the HHA personnel provided to the patient. Determine if the medications match those listed in the comprehensive assessment, the plan of care, and the written information to the patient. Investigate any discrepancies for additions or deletions to the medications since the information was last updated by the HHA.

G618

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[The HHA must provide the patient and caregiver with a copy of written instructions outlining…]

§484.60(e)(3) Any treatments to be administered by HHA personnel and personnel acting on behalf of the HHA, including therapy services.

G620

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[The HHA must provide the patient and caregiver with a copy of written instructions outlining…]

§484.60(e)(4) Any other pertinent instruction related to the patient's care and treatments that the HHA will provide, specific to the patient's care needs.

G622

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[The HHA must provide the patient and caregiver with a copy of written instructions outlining…]

§484.60(e)(5) Name and contact information of the HHA clinical manager.

Interpretive Guidelines §484.60(e)(5)

The name and contact information of the HHA's clinical manager, including the clinical manager's telephone number and, if the patient prefers electronic communication, e-mail, must be provided to the patient. The HHA explains to the patient when the clinical manager should be contacted for discussion about their services.

G640

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.65 Condition of participation: Quality assessment and performance improvement (QAPI).

The HHA must develop, implement, evaluate, and maintain an effective, ongoing, HHA-wide, data-driven QAPI program. The HHA's governing body must ensure that the program reflects the complexity of its organization and services; involves all HHA services (including those services provided under contract or arrangement); focuses on indicators related to improved outcomes, including the use of emergent care services, hospital admissions and re-admissions; and takes actions that address the HHA's performance across the spectrum of care, including the prevention and reduction of medical errors. The HHA must maintain documentary evidence of its QAPI program and be able to demonstrate its operation to CMS.

Interpretive Guidelines § 484.65

The manner and degree of noncompliance identified in relation to the standard level tags for §484.65 may result in substantial noncompliance with this CoP, requiring citation at the condition level.

G642

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.65(a) Standard: Program scope.

(1) The program must at least be capable of showing measurable improvement in indicators for which there is evidence that improvement in those indicators will improve health outcomes, patient safety, and quality of care.

(2) The HHA must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that enable the HHA to assess processes of care, HHA services, and operations.

Interpretive Guidelines §484.65(a)

The HHA selects the indicators that it will utilize in its QAPI program based upon identified adverse or negative patient outcomes or agency processes that the HHA wishes to monitor and measure. Each indicator must be measurable through data to evaluate any HHA change in procedure, policy or intervention.

The HHA QAPI program must include procedures for measurement and analysis of indicators and address the frequency with which such measurement and analysis will occur.

Per §484.70(b) the HHA must maintain a coordinated agency-wide program for the surveillance, investigation, identification, prevention, control and investigation of infectious and communicable diseases as an integral part of the QAPI program.

G644

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.65(b) Standard: Program data.

(1) The program must utilize quality indicator data, including measures derived from OASIS, where applicable, and other relevant data, in the design of its program.

(2) The HHA must use the data collected to-

(i) Monitor the effectiveness and safety of services and quality of care; and

(ii) Identify opportunities for improvement.

(3) The frequency and detail of the data collection must be approved by the HHA's governing body.

Interpretive Guidelines §484.65(b)(1)-(3)

HHAs seeking initial enrollment in the Medicare program are unlikely to have collected extensive data for their QAPI program indicators, since they likely have been in operation for a relatively brief time. Nevertheless, these initial applicants must have a QAPI program in place, and must be able to describe how the program functions, including which indicators/measures are being tracked, at what intervals, and how the information will be used by the HHA to improve quality and safety.

G646

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.65(c) Standard: Program activities.

(1) The HHA's performance improvement activities must—

(i) Focus on high risk, high volume, or problem-prone areas;
(ii) Consider incidence, prevalence, and severity of problems in those areas; and
(iii) Lead to an immediate correction of any identified problem that directly or potentially threaten the health and safety of patients.

Interpretive Guidelines §484.65(c)(1)

"High risk" areas may include global concerns such as a type of service (e.g., pediatrics), geographic concerns (e.g., safety of a neighborhood served); or specific patient care services (e.g., administration of intravenous medications or tracheostomy care). All factors would be associated with significant risk to the health or safety of patients.

"High volume" areas refers to care or service areas that are frequently provided by the HHA to a large patient population, thus possibly increasing the scope of the problem (e.g. laboratory testing, physical therapy, infusion therapy, diabetes management).

"Problem-prone" areas refer to care or service areas that have the potential for negative outcomes and that are associated with a diagnosis or condition for a particular patient group or a particular component of the HHA operation or historical problem areas.

G654

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.65(c)(2) Performance improvement activities must track adverse patient events, analyze their causes, and implement preventive actions.

Interpretive Guidelines §484.65(c)(2)

"Adverse patient events" are those patient events that are negative and unexpected, impact a patient's HHA plan of care, and have the potential to cause a decline in a patient's condition.

HHAs must track all adverse patient events, to determine through subsequent analysis whether they were the result of errors that should have been preventable, to

reduce the likelihood of such events in the future. HHAs should also consider a way to identify errors that result in near misses, since such errors have the potential to cause future adverse events.

G656

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.65(c)(3) The HHA must take actions aimed at performance improvement, and, after implementing those actions, the HHA must measure its success and track performance to ensure that improvements are sustained.

G658

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.65(d) Standard: Performance improvement projects.

Beginning January 13, 2018 HHAs must conduct performance improvement projects.

> **(1) The number and scope of distinct improvement projects conducted annually must reflect the scope, complexity, and past performance of the HHA's services and operations.**
>
> **(2) The HHA must document the quality improvement projects undertaken, the reasons for conducting these projects, and the measurable progress achieved on these projects.**

Interpretive Guidelines §484.65(d)

The HHA should have at least one performance improvement project either in development, on-going or completed each calendar year.

The HHA decides, based on the QAPI program activities and data, what projects are indicated and the priority of the projects.

Survey Procedures §484.65(d)

• Ask the HHA to show you documentation for performance improvement projects currently underway, as well as those completed in the prior year.

• Does the HHA's documentation indicate the rationale for undertaking each project? Does the HHA have data indicating it had a problem in the area targeted for improvement, or could the HHA point to recommendations from a nationally recognized expert organization suggesting the activities?

• Does the documentation for the completed project(s) include the project's results? If a project was unsuccessful, ask the HHA what actions it took because of that information. If the project was successful, ask the HHA how it is sustaining the improvement.

G660

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.65(e) Standard: Executive responsibilities.

The HHA's governing body is responsible for ensuring the following:

> **(1) That an ongoing program for quality improvement and patient safety is defined, implemented, and maintained;**
>
> **(2) That the HHA-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety, and that all improvement actions are evaluated for effectiveness;**
>
> **(3) That clear expectations for patient safety are established, implemented, and maintained; and**
>
> **(4) That any findings of fraud or waste are appropriately addressed.**

Interpretive Guidelines §484.65(e)(1)-(4)

The governing body must assume overall responsibility for ensuring that the QAPI program reflects the complexity of the HHA and its services, involves all services (including those provided under contract or arrangement), focuses on indicators related to improved outcomes, and takes actions that address the HHA's performance across the spectrum of care. Additionally, the HHA's governing body must appropriately address any findings of fraud or waste in order to assure that resources are appropriately used for patient care activities and that patients are receiving the right care to meet their needs (82 FR 4504, 4510, 4561 (Jan. 13, 2017)). If the HHA identifies or otherwise learns of an action by an HHA employee, contractor or responsible or relevant physician or allowed practitioner that may be illegal, the HHA should report the action to the appropriate authorities in accordance with applicable law.
Survey Procedures §484.65(e)(1)-(4)

- **Ask the HHA for information about its governing body. If there are questions about who constitutes the HHA's governing body, it may help to review the information the HHA reported on its CMS Form 855A application, identifying those individuals with ownership interest or managing control of the HHA.**

- **Ask to see meeting minutes or other evidence of how the governing body exercises ongoing oversight of and accountability for the HHA's QAPI program.**

G680
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.70 Condition of participation: Infection prevention and control.

The HHA must maintain and document an infection control program which has as its goal the prevention and control of infections and communicable diseases.

Interpretive Guidelines § 484.70

The home health setting presents unique challenges for infection control, because: care is delivered in the home environment, not a structured facility; sterile supplies are transported by staff and may need to be stored and protected in the home; and patients may not have access to basic hygiene necessities in their home. It is essential that HHAs have a comprehensive and effective infection control program, because the consequences of poor infection prevention and control can be very serious.

The manner and degree of noncompliance identified in relation to the standard level tags for §484.70 may result in substantial noncompliance with this CoP, requiring citation at the condition level.

Survey Procedures § 484.70

- **Surveyors will focus their observation of infection control practices by the HHA during home visits.**
- **Determine whether the policies and procedures of the HHA's infection control program are implemented correctly based on observations of care.**
- **Determine that there is an ongoing, documented program for the prevention and control of infections and communicable diseases among patients and HHA personnel.**

G682
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.70(a) Standard: Prevention

The HHA must follow accepted standards of practice, including the use of standard precautions, to prevent the transmission of infections and communicable diseases.

Interpretive Guidelines §484.70(a)

Federal and state agencies such as the Centers for Disease Control and Prevention (CDC) and state departments of health, national professional organizations, have all developed infection prevention and control standards of practice. Examples of national organizations that promulgate nationally recognized infection and communicable disease control guidelines, and/or recommendations include: the CDC, the Association for Professionals in Infection Control and Epidemiology (APIC), and the Society for Healthcare Epidemiology of America (SHEA). An HHA should identify the source of the standards it selects and be capable of explaining why those standards were chosen for incorporation into the HHA's infection prevention and control program (82 FR 4543).

Standard precautions must be used to prevent transmission of infectious agents. "Standard precautions" are a group of infection practices that apply to all patients regardless of suspected or confirmed infection status at the time health care is delivered. These practices protect healthcare personnel and prevent healthcare personnel or the environment from transmitting infections to patients.

For example, the following are six (6) core practices, identified by the CDC are based on the CDC's "Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings –Recommendations of The Healthcare Infection Control Practices Advisory Committee (HICPAC),[1] which is periodically updated. These are a core set of infection prevention and control practices that are recommended in all healthcare settings, regardless of the type of healthcare provided. Also, refer to "Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care" published by the National Center for Emerging and Zoonotic Infectious Diseases Division of Healthcare Quality Promotion, Version 2.3.

1. Hand Hygiene

HHAs and surveyors are advised to review the most current CDC's hand hygiene recommendations for correct procedures. Hand Hygiene should be performed:

• Before and after contact with a patient;
• Before performing an aseptic task (e.g., insertion of IV, preparing an injection, performing wound care);
• After contact with blood, body fluids or contaminated surfaces;
• After contact with the patient's immediate environment;
• When moving from a contaminated body site to a clean body site during patient care; and
• After removal of personal protective equipment (e.g., gloves, gown, facemask).

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[1] *https://www.cdc.gov/hicpac/pdf/core-practices.pdf.*

The term "hand hygiene" includes both handwashing with either plain or antiseptic-containing soap and water, and use of alcohol-based products (gels, rinses, foams) that do not require the use of water. In the absence of visible soiling of hands, approved alcohol-based products for hand disinfection are preferred over antimicrobial or plain soap and water because of their superior microbiocidal activity, reduced drying of the skin, and convenience. The HHA must ensure that supplies necessary for adherence to hand hygiene are provided.

2. Environmental cleaning and disinfection

Environmental cleaning and disinfection presents a unique challenge for HHA personnel. The HHA staff have little control over the home environment but must protect their equipment and supplies during the home visit. Examples of how this might be accomplished include but are not limited to: Cleaning and disinfecting or placing a clean barrier on the surface in the home where clean equipment will be placed and/or preparation of injectable medications will be performed. Additionally, items that are taken from one home to another should be cleaned and disinfected in accordance with accepted standards of practice, which include manufacturer's instructions for use.

3. Injection and Medication Safety

Safe injection practices include but are not limited to:

• Use of aseptic technique when preparing and administering medications;
• Not reusing needles, lancets, lancet holding devices, or syringes for more than one use on one patient; using single-dose vials for parenteral medications whenever possible;
• Not administering medications from a single-dose vial or ampule to multiple patients;
• Use of fluid infusion and administration sets (i.e., intravenous bags, tubing and connectors) for one patient only and disposal appropriately after use;
• Considering a syringe or needle/cannula contaminated once it has been used to enter or connect to patient's intravenous infusion bag or administration set;
• Entering medication containers with a new needle and a new syringe even when obtaining additional doses for the same patient;
• Insulin pens are dedicated for a single patient and never shared even if the needle is changed; and,
• Sharps disposal complies with applicable state and local laws and regulations.

4. Appropriate Use of Personal Protective Equipment

Appropriate Use of Personal Protective Equipment (PPE) is the use of specialized clothing or equipment worn for protection and as a barrier against infectious materials or any potential infectious exposure. PPE protects the caregiver's skin, hands, face, respiratory tract, and/or clothing from exposure. Examples of PPE

include: gloves, gowns, face protection (facemask and goggles or face shields). The selection and use of PPE is determined by the nature of patient interaction and potential for exposure to blood, body fluids and/or infectious materials.

5. Minimizing Potential Exposures

Minimizing Potential Exposures in the home health setting focuses on prevention of reducing the exposure and transmission of respiratory infections. HHA staff should also be careful to minimize potential exposures to infectious agents while transporting medical specimens and medical waste, such as sharps.

6. Reprocessing, Storage, Transport, and Usage/Operation of Equipment or Devices Used for Patient Care

Cleaning and disinfecting of medical equipment is essential. Staff should follow the manufacturer's instructions for reprocessing (i.e., cleaning and disinfection or cleaning and sterilization) and use and current standards of practice for transport and storage of patient care equipment. Single-use equipment is discarded after use according to the manufacturer's instructions for proper disposal. Reusable medical equipment (e.g., blood glucose meters and other point-of-care meters, blood pressure cuffs, oximeter probes) are reprocessed prior to use on another patient and when soiled. The HHA must ensure that HHA staff are trained to maintain separation between clean and soiled equipment to prevent cross contamination in the patient care environment and during transport.

G684

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.70(b) Standard: Control.

The HHA must maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that is an integral part of the HHA's quality assessment and performance improvement (QAPI) program. The infection control program must include:

Interpretive Guidelines §484.70(b)

The HHA should have a program for the surveillance, identification, prevention, control and investigation of infectious and communicable diseases specific to care and services provided in the home setting. The CDC defines surveillance as "the ongoing, systematic collection, analysis, interpretation and evaluation of health data closely integrated with the timely dissemination of this data to those who need it."

As part of its infection control program the HHA should: (1) observe and evaluate services from all disciplines to identify sources or causative factors of infection, track patterns and trends of infections; and (2) establish a corrective plan for

infection control (if appropriate) and monitor the effectiveness of the corrective plan. Cross Reference to §484.65(a), QAPI Program Scope.

§484.70(b)(1) A method for identifying infectious and communicable disease problems; and

Interpretive Guidelines §484.70(b)(1)

The HHA must develop a procedure for the identification of infections or risk of infections among patients. It is the prerogative of the HHA to determine the methodology to be used for such identification. Example methodologies include, but are not limited to:

- **Clinical record review;**
- **Staff reporting procedures;**
- **Review of laboratory results;**
- **Data analysis of physician or allowed practitioner and emergency room visits for symptoms of infection; and**
- **Identification of root cause of infection through evaluation of HHA personnel technique and self-care technique by patients or caregivers.**

Analysis of surveillance data should be used to improve care practices and control infections and transmission of communicable diseases.

While not required by the regulation, CMS suggests HHAs have a way to receive alerts from the CDC Health Alert Network or local public health network as a means of staying up to date with alerts and information related to public health incidents (as seen with the 2019 Novel Coronavirus public health emergency).

§484.70(b)(2) A plan for the appropriate actions that are expected to result in improvement and disease prevention.

Interpretive Guidelines §484.70(b)(2)

The HHA must develop an action plan to address or prevent infections or transmission of communicable diseases. Such plan should be based on surveillance findings, any identified root cause of infection or disease transmission, tracking data and analysis of data findings.

Actions to facilitate improvements and disease prevention may include the following:
- **Policy, procedure or practice changes to improve care;**
- **Education for patients, caregivers, and HHA personnel to prevent infections and transmission of communicable diseases; and**

• The development of process or outcome measures which could be used to monitor and address identified issues (e.g., infection prevention and control observations for technique).

The HHA must evaluate and revise the plan as needed.

G686

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.70(c) Standard: Education.

The HHA must provide infection control education to staff, patients, and caregiver(s).

Interpretive Guidelines §484.70(c)

The regulation does not specify the form or content of education regarding infection prevention and control. However, in accordance with requirements under §484.60, patients and caregivers must be provided with education and training specific to the individualized plan of care. HHAs should also take into consideration the patient's and caregiver(s)' health conditions and individual learning needs. The HHA should review training information with the patient and his or her representative (if any), including information on how to clean and care for equipment (e.g., blood glucose meters or reusable catheters), at sufficient intervals to reinforce comprehension of the training.

Additionally, HHAs must provide infection control education to staff.

HHA staff infection control education should include the following:

• Information on appropriate use, transport, storage, and cleaning methods of patient care equipment according to manufacturer guidelines/instructions for use;
• Job-specific, infection prevention education and training to all health care personnel for all of their respective tasks;
• Processes to ensure that all health care personnel understand and are competent to adhere to infection prevention requirements as they perform their roles and responsibilities;
• Written infection prevention policies and procedures that are widely available, current, and based on current standards of practice;
• Training before individuals are allowed to perform their duties and periodic refresher training as designated by HHA policy;
• Additional training in response to recognized lapses in adherence and to address newly recognized infection transmission threats (e.g., introduction of new equipment or procedures);
• Infection control education provided to staff at periodic intervals consistent with accepted standards of practice. Such education must be provided at orientation,

annually, and as needed to meet the staff's learning needs to provide adequate care; identify infection signs and symptoms; identify routes of infection transmission; appropriately disinfect/sanitize/transport equipment and devices used for patient care; and use proper medical waste disposal techniques. Such education must include instructions on how to implement current infection prevention/treatment practices in the home setting.

Survey Procedures §484.70(c)

- **Review the clinical record for evidence of patient/caregiver infection control education pertinent to the patient's condition and per the plan of care (see also §484.60).**

- **Ask the staff what training they received in infection control. Based on interview responses, follow up through HHA policy review and training records to ensure evidence of compliance.**

G700

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.75 Condition of participation: Skilled professional services.

Skilled professional services include skilled nursing services, physical therapy, speech-language pathology services, and occupational therapy, as specified in §409.44 of this chapter, and physician or allowed practitioner and medical social work services as specified in §409.45 of this chapter. Skilled professionals who provide services to HHA patients directly or under arrangement must participate in the coordination of care.

Interpretive Guidelines § 484.75

The manner and degree of noncompliance identified in relation to the standard level tags for §484.75 may result in substantial noncompliance with this CoP, requiring citation at the condition level.

G702

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.75(a) Standard: Provision of services by skilled professionals.

Skilled professional services are authorized, delivered, and supervised only by health care professionals who meet the appropriate qualifications specified under §484.115 and who practice according to the HHA's policies and procedures.

G704

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.75(b) Standard: Responsibilities of skilled professionals.

Skilled professionals must assume responsibility for, but not be restricted to, the following:

G706

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]

(1) Ongoing interdisciplinary assessment of the patient;

Interpretive Guidelines §484.75(b)(1)

The term "interdisciplinary" refers to an approach to healthcare that includes a range of health service workers.

"Ongoing interdisciplinary assessment" is the continual involvement of all skilled professional staff involved in a patient's plan of care from the initial assessment through discharge, which should include periodic discussions among the team regarding the patient's health status and recommendations for the plan of care.

An interdisciplinary approach recognizes the contributions of various health care disciplines (MDs, RNs, Licensed Practical/Vocational Nurses (LPN/LVN), PT, OT, SLP, Master of Social Work (MSW), HH aides) and their interactions with each other to meet the patient's needs.

G708

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]

(2) Development and evaluation of the plan of care in partnership with the patient, representative (if any), and caregiver(s);

G710

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]

(3) Providing services that are ordered by the physician or allowed practitioner as indicated in the plan of care;

G712

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]

(4) Patient, caregiver, and family counseling;

Survey Procedures §484.75(b)(4)

Home visit observations with direct care observation and patient interview should assist in determining compliance with this requirement. The clinical record should reflect the education and counseling provided by skilled professionals to the patient, caregiver, and family (see also §484.75(b)(5)).

G714

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]

(5) Patient and caregiver education;

Survey Procedures §484.75(b)(5)

Home visit observations with direct care observation and patient interview should assist in determining compliance with this requirement. The clinical record should reflect the education and counseling provided by skilled professionals to the patient, caregiver, and family (see also §484.75(b)(4)).

G716

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]

(6) Preparing clinical notes;

G718

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]

(7) Communication with all physicians involved in the plan of care and other health care practitioners (as appropriate) related to the current plan of care;

G720

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]

(8) Participation in the HHA's QAPI program; and

Interpretive Guidelines §484.75(b)(8)

All skilled professional staff must provide input into and participate in the implementation of the HHA's QAPI program for the QAPI program to be effective. Every HHA skilled professional, regardless of whether the skilled professional is a direct employee or contractor of the HHA, is expected to contribute to all phases of the QAPI program. These contributions may include: identification of problem areas; recommendations to address problem areas; data collection; attendance at periodic QAPI meetings; and participation in performance improvement projects.

G722

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]

(9) Participation in HHA-sponsored in-service training.

G724

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.75(c) Standard: Supervision of skilled professional assistants.

Interpretive Guidelines §484.75(c)

Documentation in the clinical record should show how communication and oversight exist between the skilled professional and assistant regarding the patient's status, the patient's response to services furnished by the assistant, and the effectiveness of any written instructions provided by the skilled professional to the assistant.

Any specific written instructions by skilled professionals to assistants are based on treatments prescribed in the patient's plan of care, patient assessments by the

skilled professional, and accepted standards of professional practice. The skilled professional must periodically evaluate the effectiveness of the services furnished by the assistant to ensure the patient's needs are met.

Survey Procedures §484.75(c)

Documentation in the clinical record should demonstrate evidence that the skilled professionals supervise professional assistants as per HHA policy. Supervision of the skilled assistants must be conducted by the same discipline as the skilled professional that developed the assistant's instructions. Look for evidence in the clinical record that the skilled professional remains active in the ongoing plan of care through periodic supervisory follow-up. Review clinical notes to verify that professional assistants adhere to the instructions established by the skilled professional and that they document the treatment and patient response to the treatment.

G726

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.75(c)(1) Nursing services are provided under the supervision of a registered nurse that meets the requirements of §484.115(k).

Interpretive Guidelines §484.75(c)(1)

The HHA should identify a registered nurse (RN) to supervise the care provided by licensed practical/vocational nurses (LPN/LVNs). §484.115(k) requires the RN be a graduate of an approved school of professional nursing who is licensed in the state where practicing.

The identified RN must in turn monitor and evaluate LPN/LVN performance in the provision of services, provision of treatments, patient education, communication with the RN, and data collection regarding the patient's status and health needs (as delegated by the RN). Only a registered nurse may perform comprehensive assessment, evaluations, care planning and discharge planning.

G728

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.75(c)(2) Rehabilitative therapy services are provided under the supervision of an occupational therapist or physical therapist that meets the requirements of §484.115(f) or (h), respectively.

Interpretive Guidelines §484.75(c)(2)

An assistant must be supervised by a skilled therapy professional for the assistant's respective therapy type. For example, only a physical therapist may supervise a physical therapist assistant and only an occupational therapist may supervise an occupational therapy assistant. The applicable therapist should monitor and evaluate the therapy assistant's performance regarding provision of treatments, patient education, communication with the therapist, and data collection regarding the patient's status and health needs (as delegated by the therapist). Only the skilled therapist may perform comprehensive assessments, patient evaluations, care planning and discharge planning.

G730

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.75(c)(3) Medical social services are provided under the supervision of a social worker that meets the requirements of §484.115(m).

Interpretive Guidelines §484.75(c)(3)

Any social service provided by a social work assistant must be supervised by a social worker who has a master's degree or doctoral 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

G750

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.80 Condition of participation: Home health aide services.

All home health aide services must be provided by individuals who meet the personnel requirements specified in paragraph (a) of this section.

Interpretive Guidelines §484.80

The manner and degree of noncompliance identified in relation to the standard level tags for §484.80 may result in substantial noncompliance with this CoP, requiring citation at the condition level.

G754

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.80(a) Standard: Home health aide qualifications.

(1) A qualified home health aide is a person who has successfully completed:

(i) A training and competency evaluation program as specified in paragraphs (b) and (c) respectively of this section; or

(ii) A competency evaluation program that meets the requirements of paragraph (c) of this section; or

(iii)A nurse aide training and competency evaluation program approved by the state as meeting the requirements of §483.151 through §483.154 of this chapter, and is currently listed in good standing on the state nurse aide registry; or

(iv) The requirements of a state licensure program that meets the provisions of paragraphs (b) and (c) of this section.

Interpretive Guidelines §484.80(a)(1)

The regulation describes four methods by which a home health aide may become qualified:

- **The candidate may successfully complete a training and competency evaluation program offered by an HHA (except by an HHA specified in §484.80(f)).**

- **The candidate may successfully complete a competency evaluation program only. The competency evaluation program must address all requirements in §484.80(c).**

- **A nurse aide who successfully completes a nurse aide training and competency evaluation program, and is found to be in good standing in the state nurse aide registry, is considered to have met the training and competency requirements for an HHA aide. See also 42 CFR Part 483, Subpart D for requirements for states and state agencies on Nurse Aide Training and Competency Evaluation.**

- **The candidate may successfully complete a State administered program that licenses or certifies HHA aides and that meets or exceeds the requirements under paragraphs (b) and (c) of this section.**

The HHA is responsible for ensuring that any HHA aide (whether employed directly or under arrangement) who provides home health aide services for the HHA meets the provisions of this regulation.

Any state requirement regarding aide education, training, competency evaluations, or certification and supervision that is more stringent that the corresponding federal requirement takes precedence over the federal requirement. Likewise, any

federal requirement that is more stringent than a corresponding state requirement takes precedence over the more lenient state requirement

G756

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.80(a)(2) A home health aide or nurse aide is not considered to have completed a program, as specified in paragraph (a)(1) of this section, if, since the individual's most recent completion of the program(s), there has been a continuous period of 24 consecutive months during which none of the services furnished by the individual as described in §409.40 of this chapter were for compensation. If there has been a 24 month lapse in furnishing services for compensation, the individual must complete another program, as specified in paragraph (a)(1) of this section, before providing services.

Interpretive Guidelines §484.80(a)(2)

If an individual has a 24 consecutive month lapse in furnishing aide services for compensation, regardless of the circumstances surrounding the lapse, the aide will be required to complete a new training and competency evaluation program, or a competency evaluation program, prior to providing aide services on behalf of the HHA. Compensation as it relates to home health aide means monetary compensation, as set forth in section 1891(a)(3)(A) of the Act (as noted in 82 FR 4545 preamble discussion).

G760

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.80(b) Standard: Content and duration of home health aide classroom and supervised practical training.

(1) Home health aide training must include classroom and supervised practical training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while providing services to an individual under the direct supervision of a registered nurse, or a licensed practical nurse who is under the supervision of a registered nurse. Classroom and supervised practical training must total at least 75 hours.

Interpretive Guidelines §484.80(b)(1)

Home health aide training must include classroom and supervised practical training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while providing services to an individual under the direct supervision of a registered nurse, or a licensed practical nurse who is under the supervision of a registered nurse. Alternative formats for classroom training, such as online course material or internet based interactive formats are acceptable delivery methods for the classroom training. These alternative formats should also provide an interactive component that permits students to ask questions and receive responses related to the training.

G762

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.80(b) Standard: Content and duration of home health aide classroom and supervised practical training.]

(2) A minimum of 16 hours of classroom training must precede a minimum of l6 hours of supervised practical training as part of the 75 hours.

G764

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.80(b) Standard: Content and duration of home health aide classroom and supervised practical training.]

(3) A home health aide training program must address each of the following subject areas:

> **(i) Communication skills, including the ability to read, write, and verbally report clinical information to patients, representatives, and caregivers, as well as to other HHA staff.**
>
> **(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 prevention and 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 the knowledge of instituting emergency procedures and their application.

(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 performing personal hygiene and grooming tasks that include—

(A) Bed bath;
(B) Sponge, tub, and shower bath;
(C) Hair shampooing in sink, tub, and 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) Recognizing and reporting changes in skin condition; and

(xiv) Any other task that the HHA may choose to have an aide perform as permitted under state law.

(xv) The HHA is responsible for training home health aides, as needed, for skills not covered in the basic checklist, as described in paragraph (b)(3)(ix) of this section.

Interpretive Guidelines §484.80(b)(3)

Two requirements were added to 484.80(b)(3) in 2017 (82 FR 4504) that must be included in HHA training beginning on January 13, 2018:

1. **Communication skills in regard to the aide's ability to read, write, and verbally report clinical information to patients, representatives, and caregivers, as well as to other HHA staff; and**
2. **Recognizing and reporting changes in skin condition.**

For individuals who met the qualification requirements for HHA aides prior to January 13, 2018, new training content in these requirements may be completed via in-service training.

G766
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.80(b) Standard: Content and duration of home health aide classroom and supervised practical training.]

(b)(4) The HHA must maintain documentation that demonstrates that the requirements of this standard have been met.

Survey Procedures §484.80(b)(4)

When aide services are observed during the surveyor home visit, or are included in the patient sample, review documentation of the HHA aide competency testing for those home health aides to confirm that it was completed. The competency evaluation consists of those subject areas specified in §484.80(b)(3).

G768
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.80(c) Standard: Competency evaluation.

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

Interpretive Guidelines §484.80(c)

The HHA may not allow an aide to provide services to patients independently until they have successfully completed competency testing either at that HHA or at another training facility and successful completion is verified through documentation provided by the applicant or the training facility.

§484.80(c)(1) The competency evaluation must address each of the subjects listed in paragraph (b)(3) of this section. Subject areas specified under paragraphs (b)(3)(i), (iii), (ix), (x), and (xi) of this section must be evaluated by observing an aide's performance of the task with a patient or pseudo-patient. The remaining subject areas may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient, or with a pseudo-patient as part of a simulation.

§484.80(c)(2) A home health aide competency evaluation program may be offered by any organization, except as specified in paragraph (f) of this section.

§484.80(c)(3) The competency evaluation must be performed by a registered nurse in consultation with other skilled professionals, as appropriate.

Interpretive Guidelines §484.80(c)(1)

The following skills must be evaluated by observing the aide's performance while carrying out the task with a patient or pseudo-patient.

(i) Communication skills, including the ability to read, write, and verbally report clinical information to patients, representatives, and caregivers, as well as to other HHA staff;

(iii) Reading and recording temperature, pulse, and respiration;

(ix) Appropriate and safe techniques in performing personal hygiene and grooming tasks that include—

(A) Bed bath;
(B) Sponge, tub, and shower bath;
(C) Hair shampooing in sink, tub, and 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.

In accordance with §484.80(c)(3), a registered nurse, in consultation with other skilled professionals (as appropriate), must observe the HHA aide candidate perform each of the tasks above in its entirety to confirm the competence of the candidate.

HHA aides who successfully completed a competency evaluation prior to January 13, 2018, do not need to repeat the portions of the competency evaluation required to be done while providing services to a patient under §§484.80 (b) (i), (iii), (ix), (x), and (xi). For all HHA aides who receive a competency evaluation after January 13, 2018, however, these skills must be tested while the aide is providing care to a patient or pseudo-patient. A pseudo-patient is a person who is trained to participate in a role-play situation, or a computer-based mannequin device. A pseudo-patient must be capable of responding to and interacting with the home health aide trainee, and must be similar in characteristics to the primary patient population served by the HHA in key areas such as age, frailty, functional status, and cognitive status.

When pseudo-patients are used to test home health aide competency, the simulated environment must mimic the reality of the homecare environment, including environmental distractions and constraints that evoke or replicate substantial aspects of the real world in a fully interactive fashion, to assess proficiency in performing skills.

G770

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.80(c)(4) A home health aide is not considered competent in any task for which he or she is evaluated as unsatisfactory. An aide must not perform that task without direct supervision by a registered nurse until after he or she has received training in the task for which he or she was evaluated as "unsatisfactory," and has successfully completed a subsequent evaluation. 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.

G772

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.80(c)(5) The HHA must maintain documentation which demonstrates that the requirements of this standard have been met.

Interpretive Guidelines §484.80(c)(5)

Documentation of competency must:

- **Include a description of the competency evaluation program, including the qualifications of the instructors;**
- **Confirm that competency was determined by direct observation and the results of those observations;**
- **Distinguish between skills evaluated during patient care and those taught in a laboratory, e.g., skills evaluated through use of a volunteer or direct observation of patient care versus a skill lab demonstration; and**
- **Describe how additional skills beyond the basic skills listed at §484.80(b)(3) were taught and tested.**

An HHA aide that is unable to provide the above documentation will be required to successfully complete a competency evaluation before providing care to patients (§484.80(c)(4)).

G774

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.80(d) Standard: In-service training.

A home health aide must receive at least l2 hours of in-service training during each 12-month period. In-service training may occur while an aide is furnishing care to a patient.

Interpretive Guidelines §484.80(d)

The annual 12 hours of in-service training is met for the 12 months following successful completion of an HHA aide training and competency evaluation, unless the HHA introduces a new procedure that would indicate the need for further HHA aide in-service training.

When conducting in-service training during patient care, the patient must first be informed of and consent to the training and be informed of how the training will be conducted; patient rights, respect for the patient's preferences, and potential for care disruption must always guide such training.

G776

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.80(d)(1) In-service training may be offered by any organization and must be supervised by a registered nurse.

Interpretive Guidelines §484.80(d)(1)

RN supervision means that the RN approves the content of and attends the in-service training to ensure the content is consistent with the HHA's policies and procedures. It would be permissible for HHAs to use in-service education through another organization, if it is under the supervision of an RN (82 FR 4545).

G778

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.80(d)(2) The HHA must maintain documentation that demonstrates the requirements of this standard have been met.

Survey Procedures §484.80(d)(2)

Review a sample of HHA personnel and training records to verify compliance.

G780

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.80(e) Standard: Qualifications for instructors conducting classroom and supervised practical training.

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

Interpretive Guidelines §484.80(e)

**The required 2 years of nursing experience for the RN 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. At least 1 year of experience must be in home health care.**

"Other individuals" who may help with home health aide training would include health care professionals such as:

- **Physicians;**
- **Physical therapists;**
- **Occupational therapists;**
- **Speech-language pathologists;**
- **Medical social workers,**
- **LPN/LVNs; and**
- **Nutritionists.**

G782

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.80(f) Standard: Eligible training and competency evaluation organizations.

A home health aide training program and competency evaluation program may be offered by any organization except by an HHA that, within the previous 2 years:

> **(1) Was out of compliance with the requirements of paragraphs (b), (c), (d), or (e) of this section; or**
>
> **(2) Permitted an individual who does not meet the definition of a "qualified home health aide" as specified in paragraph (a) of this section to furnish home health aide services (with the exception of licensed health professionals and volunteers); or**
>
> **(3) Was subjected to an extended (or partially extended) survey as a result of having been found to have furnished substandard care (or for other reasons as determined by CMS or the state); or**
>
> **(4) Was assessed a civil monetary penalty of $5,000 or more as an intermediate sanction; or**
>
> **(5) Was found to have compliance deficiencies that endangered the health and safety of the HHA's patients, and had temporary management appointed to oversee the management of the HHA; or**

(6) Had all or part of its Medicare payments suspended; or

(7) Was found under any federal or state law to have:

(i) Had its participation in the Medicare program terminated; or

(ii) Been assessed a penalty of $5,000 or more for deficiencies in federal or state standards for HHAs; or

(iii) Been subjected to a suspension of Medicare payments to which it otherwise would have been entitled; or

(iv) Operated under 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

(v) Been closed, or had its patients transferred by the state; or

(vi) Been excluded from participating in federal health care programs or debarred from participating in any government program.

Interpretive Guidelines §484.80(f)

The home health aide training and competency evaluation program may be offered by any HHA, except an HHA that falls under one of the exceptions specified in the regulation. These exceptions include, but are not limited to, agencies that have been found out of compliance with the home health aide requirements any time in the last 2 years, agencies that permitted an unqualified individual to function as a home health aide, and agencies that have been found to have compliance deficiencies that endangered patient health and safety. The full list of exceptions is included in the regulatory text.

"Substandard care" is defined as care that is noncompliant with federal HHA regulations at a condition-level.

If an HHA chooses to use volunteers to provide patient care services, the volunteer must either: (1) be licensed by the State to provide the service (RN/LPN/LVN/physical therapist, occupational therapist or speech therapist); or (2) have successfully completed any training and competency requirements applicable to the service performed.

The most reliable source of information to assure that an HHA has not been excluded from participating in federal health care programs is the List of Excluded Individuals and Entities on the HHS Office of Inspector General (OIG) website: https://oig.hhs.gov/exclusions/. In addition, a reliable source to confirm whether an HHA has been debarred (in accordance with the debarment regulations at 2 CFR

180.300) is the System for Award Management (SAM), an official website of the U.S. government: https://www.sam.gov/portal/SAM/##11#1.

Prohibition/Loss of Home Health Aide Training and Competency Evaluation Program

If a partially extended survey is conducted, but no condition-level deficiency is found, then the HHA would not be precluded from offering its own aide training and/or competency evaluation program. If a condition-level deficiency is found during a partially extended or extended survey, then the HHA may complete any training course and competency evaluation program that is in progress; however, the HHA may not: (1) accept new candidates into the program; or (2) begin a new program for two years after receipt of written notice from the CMS Regional Office of such condition-level deficiency. Correction of the condition-level deficiency does not lift the two-year restriction identified in this standard.

If an HHA loses the authority to operate a home health aide training and competency evaluation program, that does not preclude the HHA from using a contractor to acquire training (see 54 FR 33354, 33358 (Aug. 14, 1989)). If the HHA has its own training and competency lab onsite, it may be permissible for a contractor to conduct the training on the HHA premises. However, the HHA must have no influence or role in the conduct of the training and competency evaluation. The program must be independent of the HHA in all other regards.

G798

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.80(g) Standard: Home health aide assignments and duties.

(1) Home health aides are assigned to a specific patient by a registered nurse or other appropriate skilled professional, with written patient care instructions for a home health aide prepared by that registered nurse or other appropriate skilled professional (that is, physical therapist, speech-language pathologist, or occupational therapist).

Interpretive Guidelines §484.80(g)(1)

The act of assigning a "specific patient" to a HH aide should be an intentional and deliberate decision that takes into consideration the skills of the aide, the availability of the aide for patient care continuity, patient preference (when possible), and other considerations as determined by the patient's care needs.

Most generally, HH aide services are provided in conjunction with, and as an adjunct to, a skilled nursing service. When both nursing and therapy services are

involved, either skilled professional may assign home health aides and develop written patient care instructions.

G800

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.80(g)(2) A home health aide provides services that are:

(i) Ordered by the physician or allowed practitioner;
(ii) Included in the plan of care;
(iii) Permitted to be performed under state law; and
(iv) Consistent with the home health aide training

G802

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.80(g)(3) The duties of a home health aide include:

(i) The provision of hands on personal care;
(ii) The performance of simple procedures as an extension of therapy or nursing services;
(iii) Assistance in ambulation or exercises; and
(vi) Assistance in administering medications ordinarily self-administered.

Interpretive Guidelines §484.80(g)(3)

"Self-administration of medications" means that the patient (or the patient's caregiver, if applicable) can manage all aspects of taking her or his medication, including safe medication storage, removing the correct dose of medication from the container, taking the medication at the correct time, and knowing how to contact the pharmacy for refills or other questions.

"Assistance in administering medications," as referenced in this requirement, means that the HH aide may take only a passive role in this activity. Assistance may include items such as:

- **Bringing a medication to the patient either in a pill organizer or a medication container as requested by the patient or caregiver;**
- **Providing fluids to take with the medication;**
- **Reminding the patient to take a medication;**
- **Applying a topical product, such as a non-prescription cream, to intact skin per home health aide instructions in how to apply it.**

G804

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.80(g)(4) Home health aides must be members of the interdisciplinary team, must report changes in the patient's condition to a registered nurse or other appropriate skilled professional, and must complete appropriate records in compliance with the HHA's policies and procedures.

Interpretive Guidelines §484.80(g)(4)

As noted in 82 FR 4532, interdisciplinary teams work together, each member contributing their knowledge and skills, interacting with and building upon each other, to enhance patient care. The interdisciplinary team model is the foundation of care in other health care providers, such as hospices and complex chronic care management practices. HHAs may choose to develop interdisciplinary team models based on the experiences and knowledge developed by these similar care providers, or may develop their own strategies and structures to create effective interdisciplinary teams. The term "interdisciplinary" refers to an approach to healthcare that includes a range of health service workers, which may include but is not limited to, MDs, RNs, LPN/LVN, PT & Physical Therapy Assistant (PTA), OT & Occupational Therapy Assistant (OTA), SLP, MSW, and HH aides.

During interdisciplinary team meetings, all HHA staff involved in the patient's care must be present for, and, where appropriate, should contribute to, any discussion regarding the patient's care. Since home health aides play an integral role in the delivery of HHA services and have frequent and/or prolonged encounters with patients, their input as members of the interdisciplinary team is important for information sharing and their participation in the team should be reflected in the visit notes of the clinical record. The HHA aide may participate in person, electronically or via telephone.

G806

(Rev. 182, Issued: 09-28-18, Effective: 09-28-18, Implementation: 09-28-18)

§484.80(h) Standard: Supervision of home health aides.
§484.80(h)(1)

G808

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.80(h) Standard: Supervision of home health aides.

(1)(i) If home health aide services are provided to a patient who is receiving skilled nursing, physical or occupational therapy, or speech language pathology services—

(A) A registered nurse or other appropriate skilled professional who is familiar with the patient, the patient's plan of care, and the written patient care instructions described in paragraph (g) of this section, must complete a supervisory assessment of the aide services being provided no less frequently than every 14 days; and

(B) The home health aide does not need to be present during the supervisory assessment described in paragraph (h)(1)(i)(A) of this section.

Interpretive Guidelines §484.80(h)(1)(i)

An occupational therapist may conduct a home health initial assessment visit and complete a comprehensive assessment under the Medicare program, but only when occupational therapy is on the home health plan of care, with either physical therapy or speech therapy, and when skilled nursing services are not initially in the plan of care (86 FR 62242).

G810

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.80(h)(1)(ii) The supervisory assessment must be completed onsite (that is, an in person visit), or on the rare occasion by using two-way audio-video telecommunications technology that allows for real-time interaction between the registered nurse (or other appropriate skilled professional) and the patient, not to exceed 1 virtual supervisory assessment per patient in a 60-day episode.

G812

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.80(h)(1)(iii) If an area of concern in aide services is noted by the supervising registered nurse or other appropriate skilled professional, then the supervising individual must make an on-site visit to the location where the patient is receiving care in order to observe and assess the aide while he or she is performing care.

G813

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.80(h)(1)(iv) A registered nurse or other appropriate skilled professional must make an annual on-site visit to the location where a patient is receiving care in order to observe and assess each aide while he or she is performing care.

Interpretive Guidelines §484.80(h)(1)(iv)

In addition to the regularly-scheduled 14-day supervisory assessment and as-needed observation visits for aides providing care to patients receiving skilled services, HHAs are required to make an annual on-site, in person, visit to a patient's home to directly observe and assess each home health aide while he or she is performing patient care activities. The HHA is required to observe each home health aide annually with at least one patient (86 FR 62347). The skilled professional who supervises aide services should be familiar with the patient, the patient's plan of care, and the written patient care instructions.

If, during a supervisory visit described in §484.80(h)(1)(iii), a concern is identified at a patient's home, but the aide is not present, then the skilled professional must go on-site with the aide at the next scheduled visit to observe and assess the aide while he or she is performing care.

G814

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.80(h)(2)(i) 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, —

> **(A) The registered nurse must make an onsite, in person visit every 60 days to assess the quality of care and services provided by the home health aide and to ensure that services meet the patient's needs; and**
>
> **(B) The home health aide does not need to be present during this visit.**

(ii) Semi-annually the registered nurse must make an on-site visit to the location where each patient is receiving care in order to observe and assess each home health aide while he or she is performing non-skilled care.

G816

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.80(h)(3) If a deficiency in aide services is verified by the registered nurse or other appropriate skilled professional during an on-site visit, then the agency must conduct, and the home health aide must complete, retraining and a competency evaluation for the deficient and all related skills.

G818

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.80(h)(4) Home health aide supervision must ensure that aides furnish care in a safe and effective manner, including, but not limited to, the following elements:

(i) Following the patient's plan of care for completion of tasks assigned to a home health aide by the registered nurse or other appropriate skilled professional;
(ii) Maintaining an open communication process with the patient, representative (if any), caregivers, and family;
(iii) Demonstrating competency with assigned tasks;
(iv) Complying with infection prevention and control policies and procedures;
(v) Reporting changes in the patient's condition; and
(vi) Honoring patient rights.

Interpretive Guidelines §484.80(h)(4)

During each supervisory visit the supervising registered nurse, or other appropriate skilled professional, should document his or her evaluation of the HH aide regarding each of the elements of this standard.

§484.80(h)(4)(ii) "Maintaining an open communication process" means that the aide can explain what they are going to do with the patient, ask the patient open-ended questions, seek feedback from the patient, and respond to the needs and requests of the patient, representative (if any), caregivers, and family.

G820
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.80(h)(5) If the home health agency chooses to provide home health aide services under arrangements, as defined in section 1861(w)(1) of the Act, the HHA's responsibilities also include, but are not limited to:

(i) Ensuring the overall quality of care provided by an aide;
(ii) Supervising aide services as described in paragraphs (h)(l) and (2) of this section; and
(iii) Ensuring that home health aides who provide services under arrangement have met the training or competency evaluation requirements, or both, of this part.

G828
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.80(i) Standard: Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit.

An individual may furnish personal care services, as defined in §440.167 of this chapter, on behalf of an HHA. Before the individual may furnish personal care services, the individual must meet all qualification standards established by the

state. The individual only needs to demonstrate competency in the services the individual is required to furnish.

Subpart C--Organizational Environment

G848

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.100 Condition of participation: Compliance with Federal, State, and local laws and regulations related to the health and safety of patients.

The HHA and its staff must operate and furnish services in compliance with all applicable federal, state, and local laws and regulations related to the health and safety of patients. If state or local law provides licensing of HHAs, the HHA must be licensed.

Interpretive Guidelines §484.100

Non-compliance with this condition includes: 1) the agency is not currently licensed per State requirements; or 2) the HHA has been cited by a Federal program (other than CMS), or a State or local authority for a non-compliance with licensing requirements. The Federal, State or local authority has made a final determination after all administrative procedures have been completed; all appeals have been finalized; and the findings of the noncompliance with the laws/regulations were upheld and enforced.

G850

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.100(a) Standard: Disclosure of ownership and management information.

The HHA must comply with the requirements of part 420 subpart C, of this chapter. 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 names and addresses of all persons with an ownership or controlling 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 §420.20l, §420.202, and §420.206 of this chapter.**

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

G860

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.100(b) Standard: Licensing.

The HHA, its branches, and all persons furnishing services to patients must be licensed, certified, or registered, as applicable, in accordance with the state licensing authority as meeting those requirements.

G862

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.100(c) 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 Food and Drug Administration, the testing must be in compliance with all applicable requirements of part 493 of this chapter. The HHA may not substitute its equipment for a patient's equipment when assisting with self-administered tests.

Interpretive Guidelines §484.100(c)(1)

If an HHA nurse or other HHA employee only assists a patient who has her or his own glucose meter, then a Clinical Laboratory Improvement Amendment (CLIA) certificate is not required. If the HHA nurse or HHA employee conducts the test, regardless of whether the patient's equipment or the HHA's equipment is used, then a CLIA certificate (specifically a Certificate of Waiver) is required.

The HHA may not substitute its equipment for a patient's equipment when assisting with self-administered tests, except that an HHA may allow a patient to use HHA testing equipment for a short, defined period of time until the patient has obtained his or her own testing equipment. As a part of the care planning process, HHAs are expected to help patients identify and obtain resources to secure the equipment needed for self-testing.

G864

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.100(c)(2) If the HHA refers specimens for laboratory testing, 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 §484.100(c)(2)

HHAs may refer to Appendix C of the CMS State Operations Manual for regulations and interpretive guidelines for Part 493 (Laboratory Requirements).

REFER TO E-TAGS (Appendix Z)
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.102 Condition of participation: Emergency preparedness.

Interpretive Guidelines: § 484.102

HHAs must comply with the applicable emergency preparedness requirements referenced in Appendix Z of the State Operations Manual. For all applicable requirements and guidance for Emergency Preparedness, please refer to Appendix Z. We note that compliance with the emergency preparedness requirements is assessed in accordance with the survey protocol outlined within Appendix Z.

G940

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.105 Condition of participation: Organization and administration of services.

The HHA must organize, manage, and administer its resources to attain and maintain the highest practicable functional capacity, including providing optimal care to achieve the goals and outcomes identified in the patient's plan of care, for each patient's medical, nursing, and rehabilitative needs. The HHA must assure that administrative and supervisory functions are not delegated to another agency or organization, and all services not furnished directly are monitored and controlled. The HHA must set forth, in writing, its organizational structure, including lines of authority, and services furnished.

Interpretive Guidelines §484.105

The roles of the governing body, administrator and clinical manager may not be delegated. In other words, an HHA must ensure that the responsibilities of the governing body, administrator and clinical manager (for the day-to-day operation of the HHA) are not relinquished to another person or organization on an on-going basis. This does not apply to periodic "acting" employees in the absence of the administrator or clinical manger. In addition, the use of payroll services, OASIS transmission contractors, and personnel training programs are not considered to be

delegation of administrative and supervisory functions; these are service contracts that the agency may use to optimize administrative and supervisory efficiencies.

G942

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.105(a) Standard: Governing body.

A governing body (or designated persons so functioning) must assume full legal authority and responsibility for the agency's overall management and operation, the provision of all home health services, fiscal operations, review of the agency's budget and its operational plans, and its quality assessment and performance improvement program.

Interpretive Guidelines §484.105(a)

An HHA may establish a governing body composed of individuals of its choosing. The individuals that comprise the governing body are those who have the legal authority to assume responsibility for assuring that management and operation of the HHA is effective and operating within all legal bounds (as noted in 82 FR 4548).

G946

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.105(b)(1) Standard: Administrator. The administrator must:

(i) Be appointed by and report to the governing body;

Interpretive Guidelines §484.105(b)(1)(i)

The administrator is actively involved in the daily responsibilities of running the HHA. The administrator must be appointed by and accountable to the governing body; acting as a liaison between the daily functions of the HHA and the governing body (as noted in 82 FR 4548).

G948

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.105(b)(1) The administrator must:]

(ii) Be responsible for all day-to-day operations of the HHA;

Interpretive Guidelines §484.105(b)(1)(ii)

The HHA administrator is required, among other things, to be responsible for all day-to-day operations of the HHA and to be available to patients, representatives, and caregivers to receive complaints (§ 484.50(a)(1)(ii) and (c)(3)). The administrator should be actively involved in the daily responsibilities of running the HHA, and each HHA should be able to demonstrate such involvement upon survey (as noted in 82 FR 4548).

G950

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.105(b)(1) The administrator must:]

(iii) Ensure that a clinical manager as described in paragraph (c) of this section is available during all operating hours;

Interpretive Guidelines §484.105(b)(1)(iii)

"Operating hours" include all hours which the HHA is open and providing care to patients.

G952

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.105(b)(1) The administrator must:]

(iv) Ensure that the HHA employs qualified personnel, including assuring the development of personnel qualifications and policies.

G954

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.105(b)(2) When the administrator is not available, a qualified, pre-designated person, who is authorized in writing by the administrator and the governing body, assumes the same responsibilities and obligations as the administrator. The pre-designated person may be the clinical manager as described in paragraph (c) of this section.

Interpretive Guidelines §484.105(b)(2)

"Pre-designation" means that the individual who is responsible for fulfilling the role of the administrator in his/her absence is established in advance and approved by the governing body.

Pre-designation needs to be by both the administrator and the governing body. The goal of this requirement is to provide management continuity within the HHA to the

greatest degree possible. HHA staff should know and be able to verbalize upon interview who the pre-designated individual(s) is/are for this role (82 FR 4549).

G956
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.105(b)(3) The administrator or a pre-designated person is available during all operating hours.

Interpretive Guidelines §484.105(b)(3)

"Available" means physically present at the agency or able to be contacted via telephone or other electronic means.

G958
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.105(c) Standard: Clinical manager.

One or more qualified individuals must provide oversight of all patient care services and personnel. Oversight must include the following-

Interpretive Guidelines §484.105(c)

§484.115(c) provides that a clinical manager must be a licensed physician, physical therapist, speech-language pathologist, occupational therapist, audiologist, social worker, or a registered nurse.

G960
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.105(c) Standard: Clinical manager…Oversight must include the following-]

(1) Making patient and personnel assignments,

G962
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.105(c) Standard: Clinical manager…Oversight must include the following-]

(2) Coordinating patient care,

G964
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.105(c) Standard: Clinical manager…Oversight must include the following-]

(3) Coordinating referrals,

G966
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.105(c) Standard: Clinical manager…Oversight must include the following-]

(4) Assuring that patient needs are continually assessed, and

G968
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.105(c) Standard: Clinical manager…Oversight must include the following-]

(5) Assuring the development, implementation, and updates of the individualized plan of care.

G972
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.105(d) Standard: Parent-branch relationship.

(1) The parent HHA is responsible for reporting all branch locations of the HHA to the state survey agency at the time of the HHA's request for initial certification, at each survey, and at the time the parent proposes to add or delete a branch.

Interpretive Guidelines §484.105(d)(1)

A "branch" is an approved location or site (physically separate from its parent's location) from which an HHA provides services within a portion of the total geographic area served by the parent agency. A branch provides services under the same CMS certification number (CCN) as its parent agency. See Chapter 2 of the State Operations Manual for additional information on HHA Branch CMS Certification Numbers.

G974
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

(2) The parent HHA provides direct support and administrative control of its branches.

Interpretive Guidelines §484.105(d)(2)

The parent location must provide supervision and administrative control of its branches daily to the extent that the branches depend upon the parent's supervision and administrative functions to meet the CoPs, and could not do so as independent entities. The parent agency must be available to meet the needs of any situation and respond to issues that could arise with respect to patient care or administration of a branch. A violation of a CoP in a branch would apply to the entire HHA. Therefore, it is essential for the parent to exercise adequate control, supervision, and guidance for all branches under its leadership.

"Direct support and administrative control" of a branch includes that the parent agency maintains responsibility for:

- **The governing body oversight of the branch;**
- **Any branch contracts for services;**
- **The branch's quality assurance and performance improvement plan;**
- **Policies and procedures implemented in the branch;**
- **How and when management and direct care staff are shared between the parent and branch, particularly in the event of staffing shortfalls or leave coverage;**
- **Human resource management at the branch;**
- **Assuring the appropriate disposition of closed clinical records at the branch; and**
- **Ensuring branch personnel training requirements are met.**

Survey Procedures §484.105(d)(2)

HHAs must demonstrate compliance through evidence of established policies and procedures to ensure adequate control, supervision, and guidance for all branches under an HHA's leadership.

G976
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.105(e) Standard: Services under arrangement.

(1) The HHA must ensure that all services furnished under arrangement provided by other entities or individuals meet the requirements of this part and the requirements of section 1861(w) of the Act (42 U.S.C. 1395x(w)).

G978

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.105(e)(2) An HHA must have a written agreement with another agency, with an organization, or with an individual when that entity or individual furnishes services under arrangement to the HHA's patients. The HHA must maintain overall responsibility for the services provided under arrangement, as well as the manner in which they are furnished. The agency, organization, or individual providing services under arrangement may not have been:

(i) Denied Medicare or Medicaid enrollment;

(ii) Been excluded or terminated from any federal health care program or Medicaid;

(iii) Had its Medicare or Medicaid billing privileges revoked; or

(iv) Been debarred from participating in any government program.

G980

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.105(e)(3) The primary HHA is responsible for patient care, and must conduct and provide, either directly or under arrangements, all services rendered to patients.

Interpretive Guidelines §484.105(e)

The HHA retains overall responsibility for all services provided, whether provided directly by the HHA or through arrangements (i.e., under contract). For example, in contracting for a service such as physical therapy, an HHA may require the contracted party to do the day-to-day professional evaluation component of the therapy service. The HHA may not, however, delegate its overall administrative and supervisory responsibilities (see also §484.105(d)). All HHA contracts for services should specify how HHA supervision will occur.

G982

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.105(f) Standard: Services furnished.

(1) Skilled nursing services and at least one other therapeutic service (physical therapy, speech-language pathology, 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 services described in this subsection directly, but may provide the second service and additional services under arrangement with another agency or organization.

Interpretive Guidelines §484.105(f)

The HHA must provide skilled nursing services and at least one other therapeutic service. However, only one service must be provided directly by the HHA.

An HHA is considered to provide a service "directly" when the persons providing the service for the HHA are HHA employees. An individual who works for the HHA on an hourly or per-visit basis may be considered an HHA employee if the HHA is required to issue a form W-2 on the individual's behalf with no intermediaries. 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.

Contracted staffing may supplement, but may not be used in lieu of, HHA staffing for services provided directly by the HHA. In addition, the use of contracted staff in a service provided directly by the HHA may occur only on a temporary basis to provide coverage for unexpected HHA staffing shortages, or to provide a specialized service that HHA employees cannot provide.

G984

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.105(f)(2) All HHA services must be provided in accordance with current clinical practice guidelines and accepted professional standards of practice.

Interpretive Guidelines §484.105(f)(2)

Accepted standards of practice include guidelines or recommendations issued by nationally recognized organizations with expertise in the field. Clinical practice guidelines and accepted professional standards of practice may be found in, but are not limited to:

- **State practice acts;**
- **Standards established by national organizations, boards, and councils (e.g., the American Nurses' Association standards); and**
- **The HHA's own policies and procedures.**

HHAs should consider identifying the clinical practice guideline or standard of practice used when developing and updating care policies and procedures.

G986

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.105(g) Standard: Outpatient physical therapy or speech-language pathology services.

An HHA that furnishes outpatient physical therapy or speech-language pathology services must meet all of the applicable conditions of this part and the additional health and safety requirements set forth in §485.711, §485.713, §485.715, §485.719, §485.723, and §485.727 of this chapter to implement section 1861(p) of the Act.

Interpretive Guidelines §484.105(g)

In general, this guidance is for situations where a patient would be coming to the premises of the HHA for outpatient therapy services. The patient would not be receiving HHA services and OPT services at the same time and therefore not all the HHA CoPs would apply. For example, the patient could have a total joint operation and be discharged home to get HHA services inclusive of therapy. Then when the patient is doing better, they could transition to outpatient services provided by the HHA on the premises of the HHA where the HHA has a therapy gym.

If an HHA provides outpatient physical therapy services or speech-language pathology services it must also meet the conditions of the regulations summarized below, among others, as applicable:

§485.711 Condition of participation: Plan of care and physician involvement: For each patient in need of outpatient physical therapy or speech pathology services, there is a written plan of care established and periodically reviewed by a physician, or by a physical therapist or speech pathologist respectively.

§485.713 Condition of participation: Physical therapy services: If the HHA offers physical therapy services, it provides an adequate program of physical therapy and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.

§485.715 Condition of participation: Speech pathology services: If speech pathology services are offered, the HHA provides an adequate program of speech pathology and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.

§485.719 Condition of participation: Arrangements for physical therapy and speech pathology services to be performed by other than salaried organization personnel

The following two CoPs, §485.723 and §485.727, are applicable 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.]

§485.723 Condition of participation: Physical environment. The building housing the HHA is constructed, equipped, and maintained to protect the health and safety of patients, personnel, and the public and provides a functional, sanitary, and comfortable environment.

§485.727 Condition of participation: Emergency preparedness. The HHA must establish and maintain an emergency preparedness program.

G988

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.105(h) 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.

(1) 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.

(2) 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 Services Block Grant) 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.

(3) 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.

(4) 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.

G990

(Rev. 245; Issued: 08-05-26; Effective: 08-05-26; Implementation:08-05-26)

§484.105(i) Standard: HHA acceptance to service.

An HHA must do both of the following:

(1) Develop, implement, and maintain through an annual review, a patient acceptance-to-service policy that is applied consistently to each prospective patient referred for home health care, which addresses criteria related to the HHA's capacity to provide patient care, including, but not limited to, all of the following:

(i) Anticipated needs of the referred prospective patient.

(ii) Case load and case mix of the HHA.

(iii) Staffing levels of the HHA.

(iv) Skills and competencies of the HHA staff.

Interpretive Guidelines §484.105(i)(1):

Admission to HHA services is a critical step in ensuring patients receive timely, appropriate care to meet their needs. As part of this process, agencies must develop, implement, and maintain a patient acceptance-to-service policy that is applied equally and consistently when evaluating each prospective patient referred for home health care.

The acceptance-to-service policy includes four minimum requirements related to the HHA's capacity to provide patient care that are clinical factors that influence whether an HHA should accept or decline a referral, ensuring the health and safety of the referred patient by matching HHA services to patient needs. The policy must be reviewed annually and include, at a minimum, the following information:

- *the anticipated needs of the referred prospective patient;*
- *the HHA's case load and case mix, which generally means the number (volume) and types of patients (complexity) of patients currently receiving care at the HHA which informs what the HHA expects it can reasonably care for at any time;*
- *the HHA's staffing levels; and*
- *the skills and competencies of the HHA staff.*

These elements inform an HHA's assessment of its capacity and determine its suitability to meet the anticipated needs of the prospective patient referred for HHA services. Within this structure, HHAs may tailor their policy to address additional concerns, procedural delays, and challenges that they typically face in the referral and acceptance process. It is the responsibility of the HHA to work with its referral sources by educating them on the HHA's acceptance-to-service policy and the services it offers, with the goal of minimizing communication gaps (see the related requirement at G992).

While all of a prospective patient's needs may not be known at the time of referral, general information regarding the patient's diagnosis and recent hospitalization (as appropriate), and specific orders from the patient's medical provider should provide a reasonable basis for HHAs to anticipate the overall needs of the patient and determine whether, in light of the described elements that must be present in the policy, the prospective patient is or is not appropriate for the HHA to accept for service.

- *Surveyors must review the HHA's acceptance to service policy to ensure it meets all the elements within this regulation.*
- *Surveyors should confirm the HHA's acceptance to service policy includes at a minimum the four criteria listed in this requirement:*
    - *Anticipated needs of the referred prospective patient.*

- *Case load and case mix of the HHA.*
- *Staffing levels of the HHA.*
- *Skills and competencies of the HHA staff.*

This policy is HHA-specific and separate and distinct from the patient's individualized plan of care at §484.60.

G992
(Rev. 245; Issued: 08-05-26; Effective: 08-05-26; Implementation:08-05-26)

§484.105(i) Standard: HHA acceptance to service.

[An HHA must do both of the following: ...]

(2)(i) Make available to the public accurate information regarding the services offered by the HHA and any limitations related to types of specialty services, service duration, or service frequency.

(ii) Review the information specified in paragraph (i)(2)(i) of this section as frequently as the services are changed, but no less often than annually.

Interpretive Guidelines §484.105(i)(2):

HHAs must make the specified information available to the public; however, CMS does not specify a method for public availability (89 FR at 88455 (Nov. 7, 2024)). HHAs provide information regarding their services in multiple formats (for example, Care Compare, agency websites, brochures). To ensure that the information presented to the public is accurate, we are requiring HHAs to review publicly facing information whenever services are changed, but no less often than annually. We expect HHAs to update information on the services they provide and any service limitations if they anticipate not having a service available for 3 to 6 months. Changing a service means the HHA has formally altered the services it offers, whether by adding, discontinuing, temporarily pausing, or restricting a service. For example, a change in service may include an employee taking an extended leave of absence (that is, care for a family member, recovery from a serious illness or procedure, maternity leave) or the addition of a new contract employee that provides speech language pathology services, which an HHA may not have provided before.

CMS extracts information about an HHA's services offered (including whether they provide Skilled Nursing Care, Physical Therapy, Occupational Therapy, Speech Therapy, Medical Social Worker Services, and Home Health Aides) from the CMS-1572 survey report form, where the "Services Provided" information is captured directly from facility staff. The information from this form is entered into the CMS iQIES database and serves as the source for certain CMS public reporting, such as the CMS Care Compare website. This form is completed and updated during a CMS initial and recertification survey.

States may also create these forms outside a survey cycle. HHAs should ensure this information is completed in PECOS, then outreach to their OASIS Education Coordinator or OASIS Automation Coordinator to request that their data in iQIES be updated.

Surveyors should note that updates to home health agency provider demographic information do not occur in real time and may take up to six months to appear on Care Compare. Therefore, as long as the HHA can provide you with evidence that they requested corrections/updates, this would not trigger a citation if Care Compare was incorrect.

G1008

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.110 Condition of participation: Clinical records.

The HHA must maintain a clinical record containing past and current information for every patient accepted by the HHA and receiving home health services. Information contained in the clinical record must be accurate, adhere to current clinical record documentation standards of practice, and be available to the physician(s) or allowed practitioner(s) issuing orders for the home health plan of care, and appropriate HHA staff. This information may be maintained electronically.

Interpretive Guidelines §484.110

The HHA must use the information contained in each medical record to assure that safe care is delivered to each HHA patient. In accordance with the provisions of the Patient rights Condition at §484.50(c)(6), the HHA must ensure the confidentiality of each patient's clinical record.

The manner and degree of noncompliance identified in relation to the standard level tags for §484.110 may result in substantial noncompliance with this CoP, requiring citation at the condition level.

G1012

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.110(a) Standard: Contents of clinical record. The record must include:

(1) The patient's current comprehensive assessment, including all of the assessments from the most recent home health admission, clinical notes, plans of care, and physician or allowed practitioner orders;

G1014
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.110(a) Standard: Contents of clinical record. The record must include:]

(2) All interventions, including medication administration, treatments, and services, and responses to those interventions;

Interpretive Guidelines §484.110(a)(2)

"All interventions" refers to those interventions performed by the HHA.

G1016
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.110(a) Standard: Contents of clinical record. The record must include:]

(3) Goals in the patient's plans of care and the patient's progress toward achieving them;

G1018
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.110(a) Standard: Contents of clinical record. The record must include:]

(4) Contact information for the patient, the patient's representative (if any), and the patient's primary caregiver(s);

G1020
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.110(a) Standard: Contents of clinical record. The record must include:]

(5) Contact information for the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA; and

Interpretive Guidelines §484.110(a)(5)

If the patient identifies an attending physician (whether it is the responsible HHA physician or another physician) who will resume their care after the HHA episode, the contact information of the physician should be included in the clinical record.

G1022

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

[§484.110(a) Standard: Contents of clinical record. The record must include:]

(6)(i) A completed discharge summary that is sent to the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any) within 5 business days of the patient's discharge; or

(ii) A completed transfer summary that is sent within 2 business days of a planned transfer, if the patient's care will be immediately continued in a health care facility; or

(iii) A completed transfer summary that is sent within 2 business days of becoming aware of an unplanned transfer, if the patient is still receiving care in a health care facility at the time when the HHA becomes aware of the transfer.

Interpretive Guidelines §484.110(a)(6)

Discharge summaries typically contain the following items:

- **Admission and discharge dates;**
- **Physician responsible for the home health plan of care;**
- **Reason for admission to home health;**
- **Type of services provided and frequency of services;**
- **Laboratory data;**
- **Medications the patient is on at the time of discharge;**
- **Patient's discharge condition;**
- **Patient outcomes in meeting the goals in the plan of care; and**
- **Patient and family post-discharge instructions.**

A discharge summary must be sent to the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any) within five (5) business days of the date of the order for discharge from the responsible physician.

The contents of a transfer summary typically contain the same components as a discharge summary.

G1024

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.110(b) Standard: Authentication.

All entries must be legible, clear, complete, and appropriately authenticated, dated, and timed. Authentication must include a signature and a title (occupation), or a secured computer entry by a unique identifier, of a primary author who has reviewed and approved the entry.

G1026

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.110(c) Standard: Retention of records.

(1) Clinical records must be retained for 5 years after the discharge of the patient, unless state law stipulates a longer period of time.

(2) The HHA's policies must provide for retention of clinical records even if it discontinues operation. When an HHA discontinues operation, it must inform the state agency where clinical records will be maintained.

G1028

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.110(d) Standard: Protection of records.

The clinical record, its contents, and the information contained therein must be safeguarded against loss or unauthorized use. The HHA must be in compliance with the rules regarding personal health information set out at 45 CFR parts 160 and 164.

Interpretive Guidelines §484.110(d)

HHA staff (whether employed directly or under arrangement) who carry documents and/or electronic devices containing Protected Health Information from patient's homes to the HHA office, or to and from the HHA staff member's home, create additional confidentiality/protection concerns with patient records.

Section 45 CFR Parts 160 and 164, generally known as the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security rules, establish standards for health care providers and suppliers that conduct covered electronic transactions, such as HHAs, among others, for the privacy of protected health information (PHI), as well as for the security of electronic phi (ePHI).

In accordance with 45 CFR 164.530, all HHA staff must receive comprehensive and periodic training on the protection of patient clinical records. HHAs must also

establish policies and procedures to ensure the security of clinical records and the privacy of information contained within such records to prevent loss or unauthorized use in the patient's home, in transit, in the office setting, or any other location.

Survey Procedures §484.110(d)

During the home visit, observe how agency staff maintain the confidentiality of protected health information that they transport and use for patient care encounters as well as safeguard it against loss or unauthorized use.

CMS does not interpret or enforce the HIPAA Privacy and Security Rules, which fall under the jurisdiction of the Office for Civil Rights (OCR). Because there are a number of scenarios that allow for using or disclosing PHI in full compliance with the HIPAA Privacy and Security Rules, surveyors must defer to OCR on whether the manner in which the HHA uses, discloses, maintains or destroys PHI is consistent with these requirements. Information on how to file a HIPAA Privacy or Security complaint with OCR may be found at http://www.hhs.gov/ocr/privacy/hipaa/complaints/index.html.

G1030

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.110(e) Standard: Retrieval of clinical records.

A patient's clinical record (whether hard copy or electronic form) must be made available to a patient, free of charge, upon request at the next home visit, or within 4 business days (whichever comes first).

G1050

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.115 Condition of participation: Personnel qualifications.

HHA staff are required to meet the following standards:

Interpretive Guidelines §484.115

The manner and degree of noncompliance identified in relation to the standard level tags for §484.115 may result in substantial noncompliance with this CoP, requiring citation at the condition level.

G1052

(Rev. 245; Issued: 08-05-26; Effective: 08-05-26; Implementation:08-05-26)

§484.115(a) Standard: Administrator, home health agency.

(1) For individuals who began employment with the HHA before January 13, 2018, a person who:

(i) Is a licensed physician;

(ii) Is a registered nurse; or

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

(2) For individuals who begin employment with an HHA on or after January 13, 2018, a person who:

(i) Is a licensed physician, a registered nurse, or holds an undergraduate degree; and

(ii) Has experience in health service administration, with at least 1 year of supervisory or administrative experience in home health care or a related health care program.

Interpretive Guidelines §484.115(a)

*As noted in the 2017 Final Rule revising the HHA CoPs (82 FR at 4556 (Jan. 13, 2017), individuals acting in the administrator role with the HHA before the effective date of the rule (January 13, 2018), must meet the requirements in standard §484.115(a)(1) to continue in their current role as administrator. Individuals hired into the administrator role after January 13, 2018, must meet the requirements in standard §484.115(a)(2). We note that a*n "undergraduate degree" means a bachelor's or associate degree.

G1054

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.115(b) Standard: Audiologist. A person who:

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

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

G1056
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.115(c) Standard: Clinical manager.

A person who is a licensed physician, physical therapist, speech-language pathologist, occupational therapist, audiologist, social worker, or a registered nurse.

G1058
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.115(d) Standard: Home health aide.

A person who meets the qualifications for home health aides specified in section 1891(a)(3) of the Act and implemented at §484.80.

G1060
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.115(e) Standard: Licensed practical (vocational) nurse.

A person who has completed a practical (vocational) nursing program, is licensed in the state where practicing, and who furnishes services under the supervision of a qualified registered nurse.

G1062
(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.115(f) Standard: Occupational therapist. A person who—

(1)(i) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the state in which practicing, unless licensure does not apply; or
(ii) 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
(iii) 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).

(2) On or before December 31, 2009—
(i) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the state in which practicing; or
(ii) When licensure or other regulation does not apply—

> **(A) 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**
> **(B) 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).**

(3) On or before January 1, 2008—
(i) 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
(ii) Is eligible for the National Registration Examination of the American Occupational Therapy Association or the National Board for Certification in Occupational Therapy.

(4) On or before December 31, 1977—
(i) Had 2 years of appropriate experience as an occupational therapist; and
(ii) Had achieved a satisfactory grade on an occupational therapist proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(5) If educated outside the United States, must meet both of the following:
(i) 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:

> **(A) The Accreditation Council for Occupational Therapy Education (ACOTE).**
> **(B) Successor organizations of ACOTE.**
> **(C) The World Federation of Occupational Therapists.**
> **(D) A credentialing body approved by the American Occupational Therapy Association.**
> **(E) Successfully completed the entry level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).**

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

G1064

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.115(g) Standard: Occupational therapy assistant. A person who—

(1) Meets all of the following:

(i) Is licensed or otherwise regulated, if applicable, as an occupational therapy assistant, by the state in which practicing, unless licensure does apply; or

(ii) 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.

(iii) 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).

(2) On or before December 31, 2009—

(i) 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

(ii) Must meet both of the following:

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

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

G1066

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.115(h) Standard: 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:

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

(A) The Commission on Accreditation in Physical Therapy Education (CAPTE).
(B) Successor organizations of CAPTE.
(C) 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.

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

(2) On or before December 31, 2009—

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

(ii) Meets both of the following:
(A) 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.
(B) Passed an examination for physical therapists approved by the state in which physical therapy services are provided.

(3) Before January 1, 2008 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.

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

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

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

(5) Before January 1, 1966—

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

(ii) Was admitted to registration by the American Registry of Physical Therapists; or
(iii) Graduated from a physical therapy curriculum in a 4-year college or university approved by a state department of education.

(6) Before January 1, 1966 was licensed or registered, and before January 1, 1970, had 15 years of fulltime 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.

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

(i) 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.

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

G1068

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.115(i) Standard: Physical therapist assistant.

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

(1)(i) 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

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

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

(i) Is licensed, or otherwise regulated in the state in which practicing.

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

(3) 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.

(4) 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.

G1070

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.115(j) Standard: Physician.

A person who meets the qualifications and conditions specified in section 1861(r) of the Act and implemented at §410.20(b) of this chapter.

G1072

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.115(k) Standard: Registered nurse.

A graduate of an approved school of professional nursing who is licensed in the state where practicing.

G1074

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.115(l) Standard: Social Work Assistant.

A person who provides services under the supervision of a qualified social worker and:

(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 the 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.

G1076

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.115(m) Standard: Social worker.

A person who has a master's or doctoral 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.

G1078

(Rev. 219; Issued: 04-12-24; Effective: 04-12-24; Implementation: 04-12-24)

§484.115(n) Standard: Speech-language pathologist.

A person who has a master's or doctoral degree in speech-language pathology, and who meets either of the following requirements:

(1) Is licensed as a speech-language pathologist by the state in which the individual furnishes such services; or

(2) In the case of an individual who furnishes services in a state which does not license speech-language pathologists:

(i) Has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating supervised clinical experience);

(ii) Performed not less than 9 months of supervised full-time speech-language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field; and

(iii) Successfully completed a national examination in speech-language pathology approved by the Secretary.

Transmittals Issued for this Appendix

Rev #	Issue Date	Subject	Impl Date	CR#
R245SOMA	08/05/2026	Revised Appendix B, Interpretive Guidelines for Home Health Agencies: New Acceptance-to-Service requirements for home health agencies at 42 CFR 484.105(i).	08/05/2026	N/A
R219SOMA	04/12/2024	Revisions to the State Operations Manual (SOM) Appendix B – Home Health Agencies	04/12/2024	N/A
R200SOMA	02/21/2020	Revisions to the State Operations Manual (SOM) Appendix A - Hospitals, Appendix AA – Psychiatric Hospitals, Appendix B – Home Health Agency, Appendix D - Portable X-Ray, Appendix G - Rural Health Clinics/Federally Qualified Health Centers, Appendix H- End Stage Renal Disease Facilities (ESRD), Appendix K – Comprehensive Outpatient Rehabilitation Facility, Appendix L - Ambulatory Surgical Centers, Appendix M – Hospice, Appendix U - Religious Nonmedical Healthcare Institutions, Appendix W - Critical Access Hospitals (CAHs), Appendix X - Organ Transplant Program and Appendix Z - Emergency Preparedness	02/21/2020	N/A
R182SOMA	09/28/2018	Revisions to State Operation Manual (SOM), Appendix B - Guidance to Surveyors for Home Health Agencies	09/28/2018	N/A
R011SOM	08/12/2005	Revised Chapter 2, Sections 2180E thru 200F and Appendix B	08/12/2005	N/A
R01SOM	05/21/2004	Initial Release of Pub. 100-07	N/A	N/A