Long-Term Care Regulation Provider Letter

Number: PL 2024-09
Title: Overview of G-tag Changes
Provider Types: Home and Community Support Services Agencies (HCSSA)
Date Issued: April 12, 2024

1.0 Subject and Purpose

The Centers for Medicare and Medicaid Services (CMS) have issued QSO-24-07-HHA regarding revised surveyor guidance for home health agencies. QSO-24-07-HHA notifies providers and surveyors of changes to the home health survey process, interpretive guidance, and tags.

The following attachment is an overview of the changes to the G-tags of Appendix B from the CMS State Operations Manual (SOM). Please read QSO-24-07-HHA and Appendix B of the SOM for a full description of changes.

2.0 Policy Details & Provider Responsibilities

CMS published these updates in Appendix B of the SOM to help surveyors, home health agencies and the public understand how compliance will be assessed. This update combines the survey protocol and interpretive guidelines into one document, updates Level 1 tags, and makes clarifications and technical corrections to other guidance areas.

Changes that have been made include but are not limited to:

- Adding the survey protocol to Part I of Appendix B;
- Revising Level 1 standards that surveyors assess during a standard survey;
- Revising tags to update regulatory language and adding interpretive language; and

- Adding survey procedures to multiple tags to assist surveyors in assessing compliance.

3.0 Background Information

With the release of QSO-24-07-HHA, several previously released memos are now retired. QSO-24-07-HHA and the associated Appendix B will supersede the expired memos below:

Memo Number	Memo Name
Admin Info 19-07-HHA (Expired effective 03/15/2024)	EXPIRED: Home Health Agency (HHA) Frequently Asked Questions
QSO-18-13-HHA (Expired effective 03/15/2024)	EXPIRED: Home Health Agency (HHA) Survey Protocol State Operations Manual (SOM) Appendix B Revised
QSO-18-25-HHA (Expired effective 03/15/2024)	EXPIRED: Home Health Agency (HHA) Interpretive Guidelines
Ref: S&C: 11-11-HHA (Expired 03/15/2024)	EXPIRED: Revised Home Health Survey Protocols
Ref: S&C: 12-15-HHA (Expired effective 03/15/2024)	EXPIRED: Revised Initial Certification Process for Home Health Agencies (HHAs)
Ref: S&C: 14-14-HHA (Expired effective 03/15/2024)	EXPIRED: Home Health Agency (HHA) State Operations Manual (SOM) revisions: Appendix B, HHA Enforcement Guidance and Revisions to Chapter 2, Certification Process
Ref: S&C: 15-51-HHA (Expired effective 03/15/2024)	EXPIRED: Home Health Agencies (HHAs): Change of Address Notification of the Medicare Administrative Contractor (MAC)
Ref: S&C: 15-52-HHA (Expired effective 03/15/2024)	EXPIRED: Home Health Agency (HHA) Survey Protocol Training Item Revised

4.0 Resources

QSO-24-07-HHA

For questions regarding QSO-24-07-HHA, please contact CMS at HHAsurveyprotocols@cms.hhs.gov.

5.0 Contact Information

If you have any questions about this letter, please contact the Policy and Rules Section by email at LTCRPolicy@hhs.texas.gov or call (512) 438-3161.

Overview of Appendix B and G-Tag Changes

Effective 03/15/2024

Please refer to Appendix B of the SOM for full details and complete understanding of the revisions.

***Please note that all new/revised language is in dark red.**

Page Number	Title	Summary of Changes
7 - 10	Types of HHA Surveys	This section provides information on the types of home health surveys including how a standard survey can become a partial extended survey based on compliance with Level 1 standards.
10	Compliance with Level 1 Standards	Non-compliance identified in any Level 1 standards warrants a partial extended survey. Level 2 standards are no longer identified.
10 – 11	Level 1 Tags/ Standards	This table shows the revised Level 1 tags/standards that will determine if a partial extended survey is warranted if out of compliance.
11 – 28	Tasks in the Survey Protocol	This section provides the various tasks in the survey protocol.
12	OASIS Reports	The surveyors are to review four OASIS reports as part of pre-survey preparation.
17	Survey Sample Table	Survey sample table includes the number of record review and home visits based on unduplicated admissions for the past 12 months.
23	Additional Survey Considerations	The surveyor should enter the total HHA's branch information in iQIES after every survey.
24	Additional Survey Considerations	Medicare certified agencies providing skilled care to non-Medicare beneficiaries must meet all CoPs for those beneficiaries.

G-Tag Revisions

Tag #	Summary of Changes
G325	New tag: §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.*
No tag	§484.2 Definitions *New definitions added.*
G370	Interpretive guidelines added. *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	Interpretive guidance revised. "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 comprehensive assessment and 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.
G376	Tag deleted and added to G378.
G378	Combined language from former G376 and added to interpretive guidelines. §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 *i*QIES. *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.*
G380	Tag deleted.
G382	Interpretive Guidelines includes transmission via iQIES. HHAs may directly transmit OASIS data (to the national data repository) via *iQIES* or other software that conforms to the FIPS 140-2.
G406	Interpretive Guidelines and Survey Procedures added to tag. ***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.*
G408	Tag deleted and added to G410.
G410	Combined language from former G408.

	§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:
G416	Survey Procedures added to tag. ***Survey Procedures: §484.50(a)(1)(iii)*** *Patient interview and clinical record review should confirm that the required privacy notice was provided.*
G418	Survey Procedures added to tag. ***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.*
G426	Tag deleted and added to G428.
G428	Combined language from former G426.
G430	Survey Procedures added to tag. **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.
G436	Survey Procedures added to tag. ***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	Survey Procedures added to tag. ***Survey procedures §484.50(c)(6)***

	Verify that the agency staff maintain the confidentiality of protected health information that they transport and use.
G440	Survey Procedures added to tag. ***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	Survey Procedures added to tag. ***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	Survey Procedures added to tag. ***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)).*
G448	Survey Procedures added to tag. ***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)).* Interpretive Guidelines changed language from "subsequent" to "after". **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.
G454	Added "allowed practitioner" to tag language and Interpretive Guidelines. **§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.
G458	Added "allowed practitioner" to tag language. **§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	Added "allowed practitioner" to Interpretive Guidelines. 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.
G464	Added "allowed practitioner" to tag language and Interpretive Guidelines. **§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.
G476	Deleted tag and added language to G478.
G478	Combined language from former G476, G480, and G482. ***§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.***
G480	Deleted tag and added language to G478.

G482	Deleted tag and added language to G478.
G484	Survey Procedures added to tag. ***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.*
G488	Revised Interpretive Guidelines. ***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.*
G510	Interpretive Guidelines added to tag. ***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.*
G512	Deleted tag and added language to G514.
G514	Combined language from former G512. Also added "allowed practitioner" to tag language. **§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. *(NOTE: CMS OASIS coding guidance1 for M0104 defines the referral date as the most recent date that verbal, written, or electronic authorization to begin or resume home care was received by the HHA.)* 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	Added language to tag. § 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.
G518	Deleted tag and added language to G520.
G520	Added language from former G518. ***§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.**
G522	Interpretive Guidelines and Survey Procedures added to tag. ***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	Language added to tag and Interpretive Guidelines. **§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.
G526	Tag deleted and added to G528.
G528	Added language from former G528. ***§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;**
G530	"Allowed practitioner" added to Interpretive Guidelines.

	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.
G534	Survey Procedures added to tag. ***Survey Procedures §484.55(c)(4)*** *Verify if the current comprehensive assessment accurately reflects the patient's current status.*
G536	Language added to Interpretive Guidelines and Survey Procedures added. **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.*
G548	Added "allowed practitioner" to tag language. ***[§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	Language added to Interpretive Guidelines. **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. *(NOTE: CMS OASIS coding guidance2 notes that a discharge comprehensive assessment including OASIS is required within two days of the patient's discharge date.)*
G560	Interpretive Guidelines added to tag. ***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	Interpretive Guidelines added to tag.

	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	#2 removed from tag and added to new tag G566. Interpretive Guidelines added. ***§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	New tag. Added #2 from G564. ***§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.***
G572	Added "allowed practitioner" to tag and Interpretive Guidelines. **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	Added "allowed practitioner" to tag and added language to Interpretive Guidelines. **§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	Added language to Interpretive Guidelines. **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.
G578	Deleted tag and added to G580.
G580	Added language from former G578 and added language to Interpretive Guidelines. **§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	Added physician assistant, nurse practitioner, clinical nurse specialist to tag and Interpretive Guidelines. Added "allowed practitioner" to Interpretive Guidelines. **§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	Added "allowed practitioner" to tag and Interpretive Guidelines. Added language to Interpretive Guidelines. **§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.*
G586	Tag deleted and language added to G588.
G588	Language from former G586 added to tag and also added "allowed practitioner". Interpretive Guidelines added. ***§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	"Allowed practitioner" added to tag and Interpretive Guidelines. **§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	Survey Procedures added. ***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	Survey Procedures added. ***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	"Allowed practitioner" added to tag and Interpretive Guidelines. **§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	"Allowed practitioner" added to tag and Interpretive Guidelines. **§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.
G600	Tag deleted and added to G602.

G602	Language from former G600 added to tag. "Allowed practitioner" added to tag and Interpretive Guidelines. ***§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	Added "allowed practitioner" to tag and Interpretive Guidelines. **§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*.
G608	Added Survey Procedures. ***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	Added Survey Procedures. ***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	Added "allowed practitioner" to Interpretive Guidelines.

	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.
G616	Added Survey Procedures. ***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.*
G640	Added Interpretive Guidelines. ***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.*
G644	Added Interpretive Guidelines. ***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	Added language from former G648, G650, and G652. Interpretive Guidelines removed from G656 and added to this tag. ***§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.
G648	Tag deleted and added language to G646.
G650	Tag deleted and added language to G646.
G652	Tag deleted and added language to G646.
G654	Added Interpretive Guidelines from G656 with additional language. ***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	Removed Interpretive Guidelines and added to G646 and G654.
G658	Added Survey Procedures. ***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	Added Interpretive Guidelines and Survey Procedures. **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	Added Interpretive Guidelines and Survey Procedures. ***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	Added language to Interpretive Guidelines.

	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),3 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).* 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	Added "allowed practitioner" to Interpretive Guidelines and additional language. **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).*
G686	Language added to Interpretive Guidelines and Survey Procedures added. **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	Added "allowed practitioner" to tag language and also added Survey Procedures. ***§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.*
G710	Added "allowed practitioner" to tag language. ***[§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	Added Survey Procedures. ***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	Added Survey Procedures. ***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)).*
G724	Added Survey Procedures. ***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	Added language to Interpretive Guidelines. **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.
G730	Added language to Interpretive Guidelines. **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 setting.*
G750	Interpretive Guidelines added. ***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.*
G752	Tag deleted and added language to G754.
G754	Language from former G752 added. ***§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.**
G756	Added Interpretive Guidelines. ***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).
G758	Tag deleted and language added to G760.
G760	Added language from former G758. Interpretive Guidelines added. ***§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.*
G764	Language added to Interpretive Guidelines. **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	Added Survey Procedures. ***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	Added language to Interpretive Guidelines. 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.*
G776	Language added to Interpretive Guidelines. **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	Added Survey Procedures. ***Survey Procedures §484.80(d)(2)*** *Review a sample of HHA personnel and training records to verify compliance.*
G780	Added language to Interpretive Guidelines. **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	Added language from former tags G784, G786, G788, G790, G792, G794, and G796. Interpretive Guidelines added. ***§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.*
G784	Deleted tag and added language to G782.
G786	Deleted tag and added language to G782.
G788	Deleted tag and added language to G782.
G790	Deleted tag and added language to G782.
G792	Deleted tag and added language to G782.
G794	Deleted tag and added language to G782.
G796	Deleted tag and added language to G782.
G798	Added standard language from former G796 and added language to ***§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	Added "allowed practitioner".

	§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	Changed Interpretive Guidelines language from "is able to manage" to "can manage". **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.
G804	Language added to Interpretive Guidelines. **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	Tag deleted and language added to G808.
G808	Language from former G806 added to tag. Added Interpretive Guidelines. ***§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	Language revised. **§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	Language revised. **§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	New tag with language from former G812. Added Interpretive Guidelines. ***§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	New language added to tag. **§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	Language added to tag. **§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.***
G820	Language added from former G822, G824, and G826. **§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.***
G822	Tag deleted and language added to G820.
G824	Tag deleted and language added to G820.
G826	Tag deleted and language added to G820.
G850	Language added from former G852, G854, G856, and G858. ***§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.***
G852	Tag deleted and language added to G850.
G854	Tag deleted and language added to G850.
G856	Tag deleted and language added to G850.
G858	Tag deleted and language added to G850.
G860	Standard language for §484.100(c) removed and added to G862. No other changes to tag.
G862	Added standard language from G860 to tag. Revised Interpretive Guidelines to state “provides assistance” to “assists”. *§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	Added Interpretive Guidelines. ***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).*
G942	Added Interpretive Guidelines. ***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).*
G944	Tag deleted and language added to G946.
G946	Language added from former G944 and Interpretive Guidelines added. ***§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	Added Interpretive Guidelines. ***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	Interpretive Guidelines from G952 added to tag. ***Interpretive Guidelines §484.105(b)(1)(iii)*** “Operating hours” include all hours which the HHA is open and providing care to patients.
G952	Interpretive Guidelines deleted and added to G950.
G954	Language added to Interpretive Guidelines. ***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).*
G958	Interpretive Guidelines from G968 added to tag. ***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.*
G968	Interpretive Guidelines deleted and added to G958.
G970	Tag deleted and language added to G972.
G972	Language added from former G970. Interpretive Guidelines added from G974. ***§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	Interpretive Guidelines language revised. Added Survey Procedures. **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	Standard language from §484.105(e) added to tag. ***§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)).**
G980	Reference to §484.105(d) added to Interpretive Guidelines. **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	Interpretive Guidelines added from G984. ***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	Change to Interpretive Guidelines language. **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	Language added to Interpretive Guidelines. **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.
G1008	Added "allowed practitioner" to tag and Interpretive Guidelines. ***§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.*
G1010	Tag deleted and language added to G1012.
G1012	Language added from former G1010. Also added "allowed practitioner" to tag. ***§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;
G1028	Language added to Interpretive Guidelines. Added Survey Procedures. **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.*
G1050	Added Interpretive Guidelines. ***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.*