CONDITIONS OF PARTICIPATION - HOME HEALTH AGENCIES

Updated 04/12/2024

§484.2	**Definitions.** As used in subparts A, B, and C of this part--
	Allowed practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as defined at this part.
	Branch office means an approved location or site from which a home health agency provides services within a portion of the total geographic area served by the parent agency. The parent home health agency must provide supervision and administrative control of any branch office. It is unnecessary for the branch office to independently meet the conditions of participation as a home health agency.
	Clinical note means a notation of a contact with a patient that is written, timed, and dated, and which describes signs and symptoms, treatment, drugs administered and the patient's reaction or response, and any changes in physical or emotional condition during a given period of time.
	Clinical nurse specialist means an individual as defined at §410.76(a) and (b) of this chapter, and who is working in collaboration with the physician as defined at §410.76(c)(3) of this chapter.
	In advance means that HHA staff must complete the task prior to performing any hands-on care or any patient education.
	Nurse practitioner means an individual as defined at §410.75(a) and (b) of this chapter, and who is working in collaboration with the physician as defined at §410.75(c)(3) of this chapter.
	Parent home health agency means the agency that provides direct support and administrative control of a branch.
	Physician is a doctor of medicine, osteopathy, or podiatric medicine, and who is not precluded from performing this function under paragraph (d) of this section. (A doctor of podiatric medicine may perform only plan of treatment functions that are consistent with the functions he or she is authorized to perform under State law.)
	Physician assistant means an individual as defined at §410.74(a) and (c) of this chapter.
	Primary home health agency means the HHA which accepts the initial referral of a patient, and which provides services directly to the patient or via another health care provider under arrangements (as applicable).
	Proprietary agency means a private, for-profit agency.
	Pseudo-patient means a person trained to participate in a role-play situation, or a computer-based mannequin device. A pseudo-patient must be capable of responding to and interacting with the home health aide trainee and must demonstrate the general characteristics of the primary patient population served by the HHA in key areas such as age, frailty, functional status, and cognitive status.
	Public agency means an agency operated by a state or local government.
	Quality indicator means a specific, valid, and reliable measure of access, care outcomes, or satisfaction, or a measure of a process of care.
	Representative means the patient's legal representative, such as a guardian, who makes health-care decisions on the patient's behalf, or a patient-selected representative who participates in making decisions related to the patient's care or well-being, including but not limited to, a family member or an advocate for the patient. The patient determines the role of the representative, to the extent possible.
	Simulation means a training and assessment technique that mimics the reality of the homecare environment, including environmental distractions and constraints that evoke or replicate substantial aspects of the real world in a fully interactive fashion, in order to teach and assess proficiency in performing skills, and to promote decision making and critical thinking.

§484.2	Definitions cont.
	Subdivision means a component of a multi-function health agency, such as the home care department of a hospital or the nursing division of a health department, which independently meets the conditions of participation for HHAs. A subdivision that has branch offices is considered a parent agency.
	Summary report means the compilation of the pertinent factors of a patient's clinical notes that is submitted to the patient's physician.
	Supervised practical training means training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while providing covered services to an individual under the direct supervision of either a registered nurse or a licensed practical nurse who is under the supervision of a registered nurse.
	Verbal order means a physician order that is spoken to appropriate personnel and later put in writing for the purposes of documenting as well as establishing or revising the patient's plan of care.

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G350	**§484.40 Condition of participation: Release of patient identifiable OASIS information.** The HHA and agent acting on behalf of the HHA in accordance with a written contract must ensure the confidentiality of all patient identifiable information contained in the clinical record, including OASIS data, and may not release patient identifiable OASIS information to the public.	**§484.40** An agent acting on behalf of the HHA is a person or organization, other than an employee of the agency that performs certain functions on behalf of, or provides certain services under contract or arrangement. HHAs often contract with specialized software vendors to submit OASIS data and are commonly referred to by the HHA as the Third-Party vendor. HHAs and their agents must develop and implement policies and procedures to protect the security of all patient identifiable information contained in electronic format that they create, receive, maintain, and transmit. The agreements between the HHA and OASIS vendors must address policies and procedures to protect the security of such electronic records in order to: • Ensure the confidentiality, integrity, and availability of all electronic records they create, receive, maintain, or transmit; • Identify and protect against reasonably anticipated threats to the security or integrity of the electronic records; • Protect against reasonably anticipated, impermissible uses or disclosures; and, • Ensure compliance by their workforce The HHA is ultimately responsible for compliance with these confidentiality requirements and is the responsible party if the agent does not meet the requirements. (See also §484.50(c)(6) Patient Rights)

Color Coded for Surveyor Use

Orange- Condition Level Look at during Standard Survey

Blue- Level 1 tag Look at during Standard Survey

Grey- All other Condition Level Tags

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G370	**§484.45 Condition of Participation: Reporting OASIS Information.** HHAs must electronically report all OASIS data collected in accordance with §484.55.	**§484.45** *The home health regulations at §484.55 require that each patient receive from the HHA a patient-specific, comprehensive assessment. As part of the comprehensive assessment of adult skilled patients, HHAs are required to use a standard core assessment data set, the OASIS.* The OASIS data collection set must include the data elements listed in §484.55 (c) (8) and be collected and updated per the requirements under §484.55(d).
G372	**§484.45(a) Standard: Encoding and transmitting OASIS data.** An HHA must encode and electronically transmit each completed OASIS assessment to the CMS system, regarding each beneficiary with respect to which information is required to be transmitted (as determined by the Secretary), within 30 days of completing the assessment of the beneficiary.	**§484.45(a)** "CMS system" means the national *internet* Quality Improvement Evaluation System, Assessment Submission and Processing (*i*QIES) system. "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.
G374	**§484.45(b) Standard: Accuracy of encoded OASIS data.** The encoded OASIS data must accurately reflect the patient's status at the time of assessment.	**§484.45(b)** "Accurate" means that the OASIS data transmitted to CMS is consistent with the current status of the patient at the time the OASIS was completed.

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G378	**§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.	**§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.*
G382	**§484.45(c)** ***Standard: Transmittal of OASIS data. An HHA must—*** (2) Transmit data using electronic communications software that complies with the Federal Information Processing Standard (FIPS 140-2, issued May 25, 2001) from the HHA or the HHA contractor to the CMS collection site.	**§484.45(c)(2)** HHAs may directly transmit OASIS data (to the national data repository) via *iQIES* or other software that conforms to the FIPS 140-2.
G384	**§484.45(c)** ***Standard: Transmittal of OASIS data. An HHA must—*** (3) Transmit data that includes the CMS-assigned branch identification number, as applicable.	
G386	**§484.45(d) Standard: Data Format.** The HHA must encode and transmit data using the software available from CMS or software that conforms to CMS standard electronic record layout, edit specifications, and data dictionary, and that includes the required OASIS data set.	

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G406	**§484.50 Condition of Participation: Patient Rights.** The patient and representative (if any), have the right to be informed of the patient's rights in a language and manner the individual understands. The HHA must protect and promote the exercise of these rights.	*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.*
G410	**§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:	**§484.50(a)(1)** The term "in advance" is defined at §484.2. "In advance" means that HHA staff must complete the task prior to performing any hands-on care or any patient education. A "legal representative" is an individual who has been legally designated or appointed as the patient's health care decision maker. When there is no evidence that a patient has a legal representative such as a guardianship, a power of attorney for health care decision-making, or a designated health care agent, the HHA must provide the information directly to the patient. The initial evaluation visit is the initial assessment visit that is conducted to determine the immediate care and support needs of the patient.
G412	***[§484.50(a) Standard: Notice of rights. The HHA must—(1) Provide the patient and the patient's legal representative (if any), the following information during the initial evaluation visit, in advance of furnishing care to the patient:]*** (i) Written notice of the patient's rights and responsibilities under this rule, and the HHA's transfer and discharge policies as set forth in paragraph (d) of this section. Written notice must be understandable to persons who have limited English proficiency and accessible to individuals with disabilities;	**§484.50(a)(1)(i)** We expect HHA patients to be able to confirm, upon interview, that their rights and responsibilities, as well as the transfer and discharge policies of the HHA, were understandable and accessible. To ensure patients receive appropriate notification: - Written notice to the patient or their representative of their rights and responsibilities under this rule should be provided via hard copy unless the patient requests that the document be provided electronically. - If a patient or his/her representative's understanding of English is inadequate for the patient's comprehension of his/her rights and responsibilities, the information must be provided in a language or format familiar to the patient or his/her representative. - Language assistance should be provided using competent bilingual staff, staff interpreters, contracts or formal arrangements with local organizations providing interpretation, translation services, or technology and telephonic interpretation services. All agency staff should be trained to identify patients with any language barriers which may

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G412 Cont.		prevent effective communication of the rights and responsibilities. Staff that have on-going contact with patients who have language barriers, should be trained in effective communication techniques, including the effective use of an interpreter. See §484.50(f) for discussion on communication of rights and responsibilities with patients who have disabilities that may hinder communication with the HHA.
G414	**§484.50(a)** ***Standard: Notice of rights. The HHA must—*** ***[(1) Provide the patient and the patient's legal representative (if any), the following information during the initial evaluation visit, in advance of furnishing care to the patient:]*** (ii) Contact information for the HHA administrator, including the administrator's name, business address, and business phone number in order to receive complaints.	
G416	**§484.50(a)** ***Standard: Notice of rights. The HHA must—*** ***[(1) Provide the patient and the patient's legal representative (if any), the following information during the initial evaluation visit, in advance of furnishing care to the patient:]*** (iii) An OASIS privacy notice to all patients for whom the OASIS data is collected.	**§484.50(a)(1)(iii)** Use of the OASIS Privacy Notice is required under the Federal Privacy Act of 1974 and must be used in addition to other notices that may be required by other privacy laws and regulations. The OASIS privacy notice is available in English and Spanish on the CMS web site. The OASIS Privacy Notice must be provided at the time of the initial evaluation visit.
G418	**§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:]*** (2) Obtain the patient's or legal representative's signature confirming that he or she has received a copy of the notice of rights and responsibilities.	
G420	**§484.50(a)** *(3)* ***[Reserved]***	
G422	**§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:]*** (4) Provide written notice of the patient's rights and responsibilities under this rule and the HHA's transfer and discharge policies as set forth in paragraph (d) of this section to a patient-selected representative within 4 business days of the initial evaluation visit.	

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G424	**§484.50(b) Standard: Exercise of rights.** (1) If a patient has been adjudged to lack legal capacity to make health care decisions as established by state law by a court of proper jurisdiction, the rights of the patient may be exercised by the person appointed by the state court to act on the patient's behalf. (2) If a state court has not adjudged a patient to lack legal capacity to make health care decisions as defined by state law, the patient's representative may exercise the patient's rights. (3) If a patient has been adjudged to lack legal capacity to make health care decisions under state law by a court of proper jurisdiction, the patient may exercise his or her rights to the extent allowed by court order.	**§484.50(b)** The HHA should obtain official documentation of: (1) any adjudication by a court that indicates that a patient lacks the legal capacity to make his/her own health care decisions and, (2) the name of any person identified by the court who may exercise the patient's rights.
G428	**§484.50(c) Standard: Rights of the patient.** The patient has the right to- (1) Have his or her property and person treated with respect;	**§484.50(c)(1)** Respect for Property: The patient has the right to expect the HHA staff will respect his/her property and person while in the patient's home. The HHA must ensure that during home visits the patient's property, both inside and outside the home, is not stolen, damaged, or misplaced by HHA staff. Respect for Person: The HHA must consider and accommodate any patient requests within the parameters of the assessment and plan of care, and the patient must be treated by the HHA as an active partner in the delivery of care. The HHA should make all reasonable attempts to respect the preferences of the patient regarding the services that will be delivered, such as the HHA visit schedule, which should be made at the convenience of the patient rather than of the agency personnel. The HHA must keep the patient informed of the visit schedule and timely and promptly notify the patient when scheduled services are changed.
G430	**§484.50(c) Standard: Rights of the patient.** The patient has the right to- (2) Be free from verbal, mental, sexual, and physical abuse, including injuries of unknown source, neglect and misappropriation of property;	**§484.50(c)(2)** The patient has a right to be free from abuse from the HHA staff and others in his/her home environment. The HHA should address any allegations or evidence of patient abuse to determine if immediate care is needed, a change in the plan of care is indicated, or if a referral to an appropriate agency is warranted. (State laws vary in the reporting requirements of abuse. HHAs should be knowledgeable of these laws and comply with the reporting requirements.) In addition, the HHA should intervene immediately if, as indicated by the circumstances, any injury is the result of an HHA staff member's actions. The HHA should also immediately remove staff from patient care if there are allegations of misconduct related

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G430 Cont.		to abuse or misappropriation of property. "Abuse" means the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. Abuse may be verbal, mental, sexual, or physical and include abuse facilitated or enabled through the use of technology. "Verbal abuse" refers to abuse perpetuated through any use of insulting, demeaning, disrespectful, oral, written or gestured language directed towards and in the presence of the client. "Mental abuse" is a type of abuse that includes, but is not limited to, humiliation, harassment, and threats of punishment or deprivation, sexual coercion and intimidation (e.g. living in fear in one's own home). "Sexual abuse" is a type of abuse that includes any incident where a beneficiary is coerced, manipulated, or forced to participate in any form of sexual activity for which the beneficiary did not give affirmative permission (or gave affirmative permission without the mental capacity required to give permission) or sexual assault against a beneficiary who is unable to defend him/herself. "Physical abuse" refers to abuse perpetrated through any action intended to cause physical harm or pain, trauma or bodily harm (e.g., hitting, slapping, punching, kicking, pinching, etc.). It includes the use of corporal punishment as well as the use of any restrictive, intrusive procedure to control inappropriate behavior for purposes of punishment. "Injury of unknown source" is an injury that was not witnessed by any person and the source of the injury could not be explained by the patient. "Misappropriation of property" is theft or stealing of items from a patient's home. The HHA staff must investigate and take immediate action on any allegations of misappropriation of patient property by HHA staff and refer to authorities when appropriate. Neglect means a failure to provide goods and/or services necessary to avoid physical harm, mental anguish or mental illness.
G432	**§484.50(c) Standard: Rights of the patient.** The patient has the right to- (3) Make complaints to the HHA regarding treatment or care that is (or fails to be) furnished, and the lack of respect for property and/or person by anyone who is furnishing services on behalf of the HHA;	**§484.50(c)(3)** The HHA should have written policies and procedures that address the acceptance, processing, review, and resolution of patient complaints, including complaint intake procedures, time frames for investigations, documentation, and potential outcomes and actions that the HHA may take to resolve patient complaints. See also §484.50(e) Investigation of complaints. The HHA should record in both the clinical record and the patient's home folder that the

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G432 Cont.		patient was provided with information regarding his or her right to lodge a complaint to the HHA.
G434	**§484.50(c) Standard: Rights of the patient.** The patient has the right to- (4) Participate in, be informed about, and consent or refuse care in advance of and during treatment, where appropriate, with respect to- (i) Completion of all assessments; (ii) The care to be furnished, based on the comprehensive assessment ; (iii) Establishing and revising the plan of care; (iv) The disciplines that will furnish the care; (v) The frequency of visits; (vi) Expected outcomes of care, including patient-identified goals, and anticipated risks and benefits; (vii) Any factors that could impact treatment effectiveness; and (viii) Any changes in the care to be furnished.	**§484.50(c)(4)** The patient's informed consent on the items (i)-(viii) is not intended to be recorded on a single signed form. Informed consent and patient participation takes place on an ongoing basis as the patient's care changes and evolves during his or her episodes of care. There must be evidence in the patient's medical record that, both initially and as changes occur in the patient's care, the patient was consulted and consented to planned services and care. "Participation" means that the patient is given options regarding care choices and preferences. For example, patient preferences should be respected in encouraging the patient to choose between a bath and a shower, unless there are physical restrictions or medical contraindications that limit patient choice. "Informed" means that all aspects of the planned care and services, and the way the care and services will be delivered, are reviewed by HHA staff with the patient and that, during such review, HHA staff solicits the patient's agreement or disagreement. When there is a change to the plan of care, whether initiated by the HHA/physician or at the request of the patient, documentation in the clinical record should indicate whether the patient was informed of and agreed to the changes.
G436	**§484.50(c) Standard: Rights of the patient.** The patient has the right to- (5) Receive all services outlined in the plan of care;	
G438	**§484.50(c) Standard: Rights of the patient.** The patient has the right to- (6) Have a confidential clinical record. Access to or release of patient information and clinical records is permitted in accordance with 45 CFR parts 160 and 164.	**§484.50(c)(6)** 45 CFR Part 160 and 164 pertain to requirements of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). The HIPAA Privacy Rule (45 CFR Part 160 and Subparts A and E of Part 164), Security Rule (45 CFR Part 160 and Subparts A and C of Part 164), and Breach Notification Rules (45 CFR 164 §164.400-414) protect the privacy and security of health information and provide individuals with certain rights regarding their health information as follows: • The Privacy Rule sets national standards for covered entities (health plans, health care clearinghouses, and health care providers that conduct certain health care transactions electronically) and their business associates, including appropriate safeguards to protect the privacy of protected health information (PHI) and the limits and conditions under which PHI is permitted or required to be used or disclosed; • The Security Rule specifies safeguards that covered entities and their business associates must implement to protect the confidentiality, integrity, and availability of electronic protected health information (ePHI); and • The Breach Notification Rule requires covered entities and their business associates to notify affected individuals, U.S. Department of Health & Human Services (HHS), and in some cases, the media of a breach of unsecured PHI.

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G438 Cont.		The HIPAA Privacy Rule also gives certain patients' rights over their health information, including rights to examine and obtain a copy of their health records, and to request corrections. HHAs have unique concerns and risks regarding staff and contractors who transport documents and/or electronic devices containing PHI such as during their visits to patient's homes. Compliance with §484.50(c)(6) is evidenced by documentation of HIPAA training for all staff and monitoring HIPAA compliance to manage the risk of inappropriate PHI disclosure or unsecured ePHI. Each covered entity and business associate is responsible for ensuring its compliance with the HIPAA Privacy, Security, and Breach Notification Rules, as applicable, including consulting appropriate counsel as necessary.
G440	**§484.50(c) Standard: Rights of the patient.** The patient has the right to- (7) Be advised orally and in writing of – (i) The extent to which payment for HHA services may be expected from Medicare, Medicaid, or any other Federally-funded or Federal aid program known to the HHA, (ii) The charges for services that may not be covered by Medicare, Medicaid, or any other Federally-funded or Federal aid program known to the HHA. (iii) The charges the individual may have to pay before care is initiated; and (iv) Any changes in the information provided in accordance with paragraph (c)(7) of this section when they occur. The HHA must advise the patient and representative (if any) of these changes as soon as possible, in advance of the next home health visit. The HHA must comply with patient notice requirements at 42 CFR 411.408(d)(2) and 42 CRF 411.408(f).	
G442	**§484.50(c) Standard: Rights of the patient.** The patient has the right to- (8) Receive proper written notice, in advance of a specific service being furnished, if the HHA believes that the service may be non-covered care; or in advance of the HHA reducing or terminating on-going care. The HHA must also comply with the requirements of 42 CFR 405.1200 through 405.1204.	**§484.50(c)(8)** §405.1200 through §405.1204 describe the expedited determination process which is a right that Medicare beneficiaries may exercise to dispute the termination of their Medicare covered services in certain settings including home health.
G444	**§484.50(c) Standard: Rights of the patient.** The patient has the right to- (9) Be advised of the state toll free home health telephone hot line, its contact information, its hours of operation, and that its purpose is to receive complaints or questions about local HHAs.	

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G446	**§484.50(c) Standard: Rights of the patient.** The patient has the right to- (10) Be advised of the names, addresses, and telephone numbers of the following Federally-funded and state-funded entities that serve the area where the patient resides; (i) Agency on Aging, (ii) Center for Independent Living, (iii) Protection and Advocacy Agency, (iv) Aging and Disability Resource Center; and (v) Quality Improvement Organization.	
G448	**§484.50(c) Standard: Rights of the patient.** The patient has the right to- (11) Be free from any discrimination or reprisal for exercising his or her rights or for voicing grievances to the HHA or an outside entity.	**§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.
G450	**§484.50(c) Standard: Rights of the patient.** The patient has the right to- (12) Be informed of the right to access auxiliary aids and language services as described in paragraph (f) of this section, and how to access these services.	
G452	**§484.50(d) Standard: Transfer and discharge.** The patient and representative (if any), have a right to be informed of the HHA's policies for transfer and discharge. The HHA may only transfer or discharge the patient from the HHA if:	
G454	**§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;	**§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

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G454 Cont.		acuity. Once the patient chooses an alternate entity, the HHA must contact that entity to facilitate a safe transfer. The HHA must ensure timely transfer of patient information to the alternate entity to facilitate continuity of care, i.e., the HHA must ensure that patient information is provided to the alternate entity prior to or simultaneously with the initiation of patient services at the new entity. Also see *the discharge planning requirements at §484.58 and the requirements at* §484.110(a)(6)(ii) regarding time frame for the transfer summary.
G456	**§484.50(d) Standard: Transfer and discharge.** ***[…The HHA may only transfer or discharge the patient from the HHA if:]*** (2) The patient or payer will no longer pay for the services provided by the HHA;	
G458	**§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	**§484.50(d) Standard: Transfer and discharge.** ***[…The HHA may only transfer or discharge the patient from the HHA if:]*** (4) The patient refuses services, or elects to be transferred or discharged;	**§484.50(d)(4)** A patient who occasionally declines a service is distinguished from a patient who refuses service altogether, or who habitually declines skilled care visits. It is the patient's right to refuse services. It is the agency's responsibility to educate the patient on the risks and potential adverse outcomes that can result from refusing services. In the case of patient refusals of skilled care, the HHA must document its communication with the physician or allowed practitioner, who is responsible for the patient's home health plan of care, as well as, the measures the HHA took to investigate the patient's refusal and the interventions the HHA attempted in order to obtain patient participation with the plan of care. The HHA may consider discharge if the patient's decision to decline services compromises the agency's ability to safely and effectively deliver care to the extent that the agency can no longer meet the patient's needs.
G462	**§484.50(d) Standard: Transfer and discharge.** ***[…The HHA may only transfer or discharge the patient from the HHA if:]*** (5) The HHA determines, under a policy set by the HHA for the	**484.50(d)(5)** "Disruptive, abusive behavior" includes verbal, non-verbal or physical threats, sexual harassment, or any incident in which agency staff feel threatened or unsafe resulting in a serious impediment to the agency's ability to operate safely and effectively in the delivery

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G462 Cont.	purpose of addressing discharge for cause that meets the requirements of paragraphs (d)(5)(i) through (D)(5)(iii) of this section, that the patient's (or other persons in the patient's home) behavior is disruptive, abusive, or uncooperative to the extent that delivery of care to the patient or the ability of the HHA to operate effectively is seriously impaired. The HHA must do the following before it discharges a patient for cause:	of care. "Uncooperative" is defined as the patient's repeated declination of services or persistent obstructive, hostile or contrary attitudes to agency caregivers that are counterproductive to the plan of care. The HHA must document in the patient's clinical record the behaviors and circumstances that warranted patient discharge for cause as well as the HHA's efforts to resolve the problems.
G464	**§484.50(d) Standard: Transfer and discharge.** ***[…The HHA may only transfer or discharge the patient from the HHA if:]*** (i) Advise the patient, the representative (if any), the physician(s) or allowed practitioner(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;	**§484.50(d)(5)(i)** The HHA must notify the patient, his or her representative (if any), the physician(s) or allowed practitioner(s) issuing orders for the home health care and the patient's primary care practitioner that the HHA is considering a discharge for cause. If the HHA can identify other health care professionals who may be involved in the patient's care after the discharge occurs, then the HHA should notify those individuals of the discharge when discharge becomes imminent.
G466	**§484.50(d) Standard: Transfer and discharge.** ***[…The HHA may only transfer or discharge the patient from the HHA if:]*** (5) (ii) Make efforts to resolve the problem(s) presented by the patient's behavior, the behavior of other persons in the patient's home, or situation;	
G468	**§484.50(d) Standard: Transfer and discharge.** ***[…The HHA may only transfer or discharge the patient from the HHA if:]*** (5) (iii) Provide the patient and representative (if any) with contact information for other agencies or providers who may be able to provide care; and	**§484.50(d)(5)(ii) and (iii)** The clinical record should reflect: • Identification of the problems encountered; • Assessment of the situation; • Communication among HHA management, patient care giver, legal representative and the physician responsible for the plan of care; • A plan to resolve the issues: and • Results of the plan implementation. Only in extreme situations when there is a serious imminent threat of physical harm to HHA staff, the HHA may take immediate action to discharge or transfer the patient without first making efforts to resolve the underlying issue. Evidence in the record should document that the HHA provided the patient and his or her

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G468 Cont.		representative (if any) with information including contact numbers for other community resources and names of other agencies or providers that may be able to provide services to the patient.
G470	**§484.50(d) Standard: Transfer and discharge.** ***[…The HHA may only transfer or discharge the patient from the HHA if:]*** (5) (iv) Document the problem(s) and efforts made to resolve the problem(s), and enter this documentation into its clinical records;	
G472	**§484.50(d) Standard: Transfer and discharge.** ***[…The HHA may only transfer or discharge the patient from the HHA if:]*** (6) The patient dies; or	
G474	**§484.50(d) Standard: Transfer and discharge.** ***[…The HHA may only transfer or discharge the patient from the HHA if:]*** (7)The HHA ceases to operate.	**§484.50(d)(7)** The agency must provide sufficient notice of its planned cessation of business to enable patients to select an alternative service provider and to enable the HHA to facilitate the safe transfer of its patients to other agencies.
G478	**§484.50(e) Standard: Investigation of complaints.** ***§484.50(e)(1) The HHA must—*** (i) Investigate complaints made by a patient, the patient's representative (if any), and the patient's caregivers and family, including, but not limited to, the following topics: *(A) Treatment or care that is (or fails to be) furnished, is furnished inconsistently, or is furnished inappropriately;* *(B) Mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and/or misappropriation of patient property by anyone furnishing services on behalf of the HHA.*	
G484	***§484.50(e)(1) The HHA must—*** (ii)Document both the existence of the complaint and the resolution of the complaint, and	

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G486	***§484.50(e)(1) The HHA must—*** (iii)Take action to prevent further potential violations, including retaliation, while the complaint is being investigated.	**§484.50(e)(1)** The HHA should have systems in place to record, track and investigate all complaints. Written policies and procedures on the acceptance, processing, review, and resolution of patient complaints should be developed and communicated to staff. These policies should include intake procedures, timeframes for investigations, documentation, and outcomes and actions that the HHA may take to resolve patient complaints. Complaint investigations should be incorporated into the agency's Quality Assurance Performance Improvement program. The HHA should be able to produce documentation for each complaint received that confirms that an investigation was conducted and records the investigation findings as well as the ultimate resolution of the complaint. The documentation should also describe any actions taken by the HHA to remove any risks to the patient while the complaint was being investigated.
G488	***§484.50(e)***(2) Any HHA staff (whether employed directly or under arrangements) in the normal course of providing services to patients, who identifies, notices, or recognizes incidences or circumstances of mistreatment, neglect, verbal, mental, sexual, and/or physical abuse, including injuries of unknown source, or misappropriation of patient property, must report these findings immediately to the HHA and other appropriate authorities in accordance with state law.	**§484.50(e)(2)** Immediately means reporting without delay, as soon as possible following the discovery. *States commonly have mandatory reporting requirements for providers, suppliers, and individuals making them legally responsible to report suspicions of abuse and neglect to appropriate State authorities. These entities and individuals should follow existing mandatory reporting requirements in their State in addition to any applicable Federal requirements. Action or inaction on the part of a provider or supplier to follow mandatory reporting requirements does not preclude an employee from fulfilling their reporting obligations.*
G490	**§484.50(f) Standard: Accessibility.** Information must be provided to patients in plain language and in a manner that is accessible and timely to— (1) Persons with disabilities, including accessible web sites and the provision of auxiliary aids and services at no cost to the individual in accordance with the Americans with Disabilities Act and Section 504 of the Rehabilitation Act. (2) Persons with limited English proficiency through the provision of language services at no cost to the individual, including oral interpretation and written translations.	**§484.50(f)(2)** "Plain language" (also referred to as "Plain English") is communication the patient and /or his or her representative (if any) can understand the first time they read or hear it. Language that is plain to one set of readers may not be plain to others. Written material is in plain language if the audience can: • Find what they need; • Understand what they find; and • Use what they find to meet their needs. Section 504 of the Rehabilitation Act and the Americans with Disabilities Act protect qualified individuals with disabilities from discrimination on the basis of disability in the provision of benefits and services. Concerns related to potential discrimination issues under 504 should be referred to the office of Civil Rights for further review. "Auxiliary Aids and Services" for individuals who are deaf or hard of hearing include services and devices such as, but not limited to: qualified interpreter services (on-site or through video remote interpreting (VRI)); note takers; real-time computer-aided

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G490 Cont.		transcription services; written materials; exchange of written notes; telephone handset amplifiers; assistive listening devices; assistive listening systems; telephones compatible with hearing aids; closed caption decoders; open and closed captioning, including real-time captioning; voice, text, and video-based telecommunications products and systems, including text telephones (TTYs), videophones, and captioned telephones, or equally effective telecommunications devices; videotext displays; accessible electronic and information technology. Auxiliary aids and services for individuals who are blind or have low vision include services and devices such as : qualified readers; taped texts; audio recordings; Braille materials and displays; screen reader software; magnification software; optical readers; secondary auditory programs (SAP); large print materials; accessible electronic and information technology. The patient's clinical record should include evidence that the HHA facilitated the availability of needed auxiliary aids and language services.

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G510	**§484.55 Condition of Participation: Comprehensive assessment of patients.** Each patient must receive, and an HHA must provide, a patient-specific, comprehensive assessment. For Medicare beneficiaries, the HHA must verify the patient's eligibility for the Medicare home health benefit including homebound status, both at the time of the initial assessment visit and at the time of the comprehensive assessment.	*A comprehensive assessment of the patient, in which patient needs are identified, is a crucial step in the establishment of a plan of care. In addition, a comprehensive assessment identifies patient progress toward desired outcomes or goals of the care plan.* *The manner and degree of noncompliance identified in relation to the standard level tags for §484.55 may result in substantial noncompliance with this CoP, requiring citation at the condition level.*
G514	**§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.	**§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 guidance[1] 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	**§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*	

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G516 Cont.	*initial assessment when occupational therapy is ordered with another qualifying rehabilitation therapy service (speech-language pathology or physical therapy) that* establishes program eligibility.	
G520	**§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.	**§484.55(b)(1)** The start of care date is the first visit where the HHA provides hands on, direct care services or treatments to the patient. If an initial assessment is completed without any direct care services being provided by the HHA during the assessment visit, the date of that initial assessment visit would not be the start of care date. The comprehensive assessment must be completed within 5 calendar days of the first visit where the HHA provides hands on, direct care services/treatments to the patient.
G522	**§484.55(b)** (2) Except as provided in paragraph (b)(3) of this section, a registered nurse must complete the comprehensive assessment and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status.	*The requirements for conducting the initial assessment visit and the comprehensive assessment for home health services are based on sections 181.4(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 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))*
G524	**§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.***	**§484.55(b)(3)** *In therapy-only cases*, a qualified therapist (registered and/or licensed by the State in which they practice) *may conduct* the comprehensive assessment for therapy services ordered.
G528	***§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;	**§484.55(c)(1)** Completion of the comprehensive assessment should provide the HHA with a complete picture of the patient's status to assist the HHA in developing the patient's plan of care. Assessment of the patient's current health status includes relevant past medical history as well as all active health and medical problems. Assessment of a patient's psychosocial status and his/her functional capacity within the community is intended to be a screening of the patient's relationships, living environment, impact on the delivery of services and ability to participate in his/ her own care.

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G528 Cont.		Assessment of a patient's functional status includes the patient's level of ability to function independently in the home such as activities of daily living. Assessment of a patient's cognitive status refers to an evaluation of the degree of his or her ability to understand, remember, and participate in developing and implementing the plan of care.
G530	***[*§484.55(c)*… The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:]*** (2) The patient's strengths, goals, and care preferences, including information that may be used to demonstrate the patient's progress toward achievement of the goals identified by the patient and the measurable outcomes identified by the HHA;	**§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 strengths to inform the plan of care and to set patient goals and measurable outcomes. Examples of patient strengths identified by HHAs through observation and by patient self-identification may include: awareness of disease status, knowledge of medications, motivation and readiness for change, motivation/ability to perform self-care, and/or implement a therapeutic exercise program, understanding of a dietary regimen for disease management, vocational interests/hobbies, interpersonal relationships and supports, and financial stability. The intent of assessing patient care preferences is to engage the patient to the greatest degree possible to take an active role in their home care rather than placing the patient in a passive recipient role by informing the patient what will be done for them and when). "Patient goal" is defined as a patient-specific objective, adapted to each patient based on the medical diagnosis, physician's or allowed practitioner's orders, comprehensive assessment, patient input, and the specific treatments provided by the agency. "Measurable outcome" is a change in health status, functional status, or knowledge which occurs over time in response to a health care intervention. Measurable outcomes may include end-result functional and physical health improvement/stabilization, health care utilization measures (hospitalization and emergency department use), and potentially avoidable events. Because the nature of the change can be positive, negative, or neutral, the actual change in patient health status can vary from patient to patient, ranging from decline, no change, to improvement in patient condition or functioning.
G532	***[*§484.55(c)*… The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:]*** (3) The patient's continuing need for home care;	**§484.55(c)(3)** Medicare does not limit the number of continuous 60-day episode recertifications for beneficiaries who continue to be eligible for the home health benefit. Therefore, the comprehensive assessment must clearly demonstrate the continuing need, i.e., eligibility, for the home health benefit.

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G534	***[*§484.55(c)*** ***… The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:]*** (4) The patient's medical, nursing, rehabilitative, social, and discharge planning needs;	
G536	***[*§484.55(c)*** ***… The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:]*** (5) A review of all medications the patient is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effect, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy,	**§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. T*he 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*.
G538	***[*§484.55(c)*** ***… The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:]*** **§484.55(c)**(6) The patient's primary caregiver(s), if any, and other available supports, including their; (i) Willingness and ability to provide care, and (ii) Availability and schedules;	
G540	***[*§484.55(c)*** ***… The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:]*** (7) The patient's representative (if any);	

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G542	***[*§484.55(c)*** ***… The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:]*** (8) Incorporation of the current version of the Outcome and Assessment Information Set (OASIS) items, using the language and groupings of the OASIS items, as specified by the Secretary. The OASIS data items determined by the Secretary must include: clinical record items, demographics and patient history, living arrangements, supportive assistance, sensory status, integumentary status, respiratory status, elimination status, neuro/emotional/behavioral status, activities of daily living, medications, equipment management, emergent care, and data items collected at inpatient facility admission or discharge only.	
G544	**§484.55(d) Standard: Update of the comprehensive assessment.** The comprehensive assessment must be updated and revised (including the administration of the OASIS) as frequently as the patient's condition warrants due to a major decline or improvement in the patient's health status, but not less frequently than—	**§484.55(d)** A marked improvement or worsening of a patient's condition, which changes, and was not anticipated in, the patient's plan of care would be considered a "major decline or improvement in the patient's health status" that would warrant update and revision of the comprehensive assessment.
G546	***[§484.55(d) Standard: Update of the comprehensive assessment…not less frequently than-]*** (1) The last 5 days of every 60 days beginning with the start-of-care date, unless there is a (i) Beneficiary elected transfer; (ii) Significant change in condition; or (iii) Discharge and return to the same HHA during the 60-day episode.	
G548	***[§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	***[§484.55(d) Standard: Update of the comprehensive assessment…not less frequently than-]*** (3) At discharge.	**§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.

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G560	**§484.58 Condition of Participation: Discharge planning.**	**§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	**§484.58 (a) Standard: Discharge planning.** A HHA must develop and implement an effective discharge planning process. For patients who are transferred to another HHA or who are discharged to a SNF, IRF or LTCH, the HHA must assist patients and their caregivers in selecting a post-acute care provider by using and sharing data that includes, but is not limited to HHA, SNF, IRF, or LTCH data on quality measures and data on resource use measures. The HHA must ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.	**§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	***§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.	*See also §484.110(a)(6) for discharge and transfer summary requirements.*
G566	***§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.*	

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G570	**§484.60 Condition of Participation: Care Planning, coordination of services, and quality of care.** Patients are accepted for treatment on the reasonable expectation that an HHA can meet the patient's medical, nursing, rehabilitative, and social needs in his or her place of residence. Each patient must receive an individualized written plan of care, including any revisions or additions. The individualized plan of care must specify the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, including identification of the responsible discipline(s), and the measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care. The individualized plan of care must also specify the patient and caregiver education and training. Services must be furnished in accordance with accepted standards of practice.	**§484.60** "Reasonable expectation that an HHA can meet the patient's medical, nursing, rehabilitative, and social needs in his or her place of residence" means that, in consideration of the patient's level of acuity, the HHA can effectively and safely provide the patient with the skilled services that the patient needs within the patient's home. "Accepted standards of practice" include guidelines and recommendations issued by nationally recognized organizations with expertise in the relevant field. The Agency for Health Research and Quality (AHRQ) maintains a National Guideline Clearinghouse as a public resource for summaries of evidence-based clinical practice guidelines. See §484.60(e) for written information that must be provided to the patient.
G572	**§484.60(a) Standard: Plan of care.** (1) Each patient must receive the home health services that are written in an individualized plan of care that identifies patient-specific measurable outcomes and goals, and which is established, periodically reviewed, and signed by a doctor of medicine, osteopathy, or podiatry or allowed practitioner acting within the scope of his or her state license, certification or registration. If a physician or allowed practitioner refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician or allowed practitioner is consulted to approve additions or modifications to the original plan.	**§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 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

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G572 (continued)		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	**§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.	**§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.*

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G576	**§484.60(a)(3)** All patient care orders, including verbal orders, must be recorded in the plan of care.	**§484.60(a)(3)** All patient care orders, including verbal orders are part of the plan of care. *The plan of care may include orders for treatment or services received from physicians other than the responsible physician.* The plan should be revised to reflect any verbal order received during the 60-day certification period so that all HHA staff are working from a current plan. It is not necessary for the physician *or allowed practitioner* to sign an updated plan of care until the patient is recertified to continue care and the plan of care is updated to reflect all current ongoing orders including any verbal orders received during the 60-day period. **NOTE**: Pulse oximetry is a ubiquitous assessment tool, often used as a part of routine vital signs across health care providers. Routine monitoring of vital signs, including pulse oximetry, do not require a physician order.
G580	**§484.60(b) Standard: Conformance with physician or allowed practitioner orders.** (1) Drugs, services, and treatments are administered only as ordered by a physician or allowed practitioner.	**§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	**§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.	**§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	**§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 HHAs' internal policies.	**§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

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G584 Cont.		particular system. A method must be established to identify the signer. *When verbal orders are added to the plan of care, it is not necessary for the physician or allowed practitioner to sign an updated plan of care until the patient is recertified.* *However, all verbal orders must be authenticated and dated by the physician or allowed practitioner in accordance with applicable state laws and regulations, as well as the HHA's internal policies.*
G588	**§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.	***See Tag G590 for Interpretive Guidelines for §484.60(c)(1).***
G590	**§484.60(c)** (i)…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.	**§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	**§484.60(c)(2)** A revised plan of care must reflect current information from the patient's updated comprehensive assessment, and contain information concerning the patient's progress toward the measurable outcomes and goals identified by the HHA and patient in the plan of care.	
G594	**§484.60(c)(3)** Revisions to the plan of care must be communicated as follows:	

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G596	**§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.	**§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	**§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).	**§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 representatives (if any), and the responsible physician or allowed practitioner. Other physicians or allowed practitioner(s) who contributed orders to the patient's plan of care must also be notified of changes to the patient's discharge plan.
G602	***§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.**	**§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	**§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.	**§484.60(d)(2)** The clinical manager or other staff designated by the HHA is responsible for integrating orders from all relevant physicians *or allowed practitioners* involved into the HHA plan of care and ensuring the orders are approved by the responsible physician *or allowed practitioner*.
G606	**§484.60(d)(3)** Integrate services, whether services are provided directly or under arrangement, to assure the identification of patient needs and factors that could affect patient safety and treatment effectiveness and the coordination of care provided by all disciplines.	**§484.60(d)(3)** The HHA must integrate services provided by various disciplines by: • Managing the scheduling of patients, taking into consideration the type of services that are being provided on a given day. For example, a patient may become fatigued after a HH aide visit assisting with a bath thus making a physical therapy session scheduled for directly after the HH aide visit less affective.

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G606 Cont.		• Managing pain during physical therapy or physical care (i.e. dressing changes or wound care) in order to minimize patient discomfort while maximizing the effectiveness of the therapy session. • Working with the patient to recommend and make safety modifications in the home. • Assuring that staff who provide care are communicating any patient concerns and patient progress toward the goals identified in the plan of care with others involved in the patient's care.
G608	**§484.60(d)(4)** Coordinate care delivery to meet the patient's needs, and involve the patient, representative (if any), and caregiver(s), as appropriate, in the coordination of care activities.	
G610	**§484.60(d)(5)** Ensure that each patient, and his or her caregiver(s) where applicable, receive ongoing education and training provided by the HHA, as appropriate, regarding the care and services identified in the plan of care. The HHA must provide training, as necessary, to ensure a timely discharge.	**§484.60(d)(5)** The comprehensive assessment, patient-centered plan of care and the goals identified therein inform the training and education objectives for each patient. The goals of the HHA episode are established at admission and revised as indicated by the patient's condition. With the discharge plan clearly identified, patient education and documentation of the patient response to the education begins upon admission and continues throughout the provision of HHA services. The HHA must monitor patient and caregiver responses to and comprehension of any training provided.
G612	***§484.60(e) Standard: Written information to the patient.*** The HHA must provide the patient and caregiver with a copy of written instructions outlining:	**§484.60(e)** The documents listed in (e)(1)-(5) must be provided to the patient and/or his/her caregiver and representative (if any) no later than the next visit after the plan of care has been approved by the physician *or allowed practitioner*. The written information should be updated as the plan of care changes. Clear written communication between the HHA and the patient and the patient's caregiver and representative (if any) helps ensure that patients and families understand what services to expect from the HHA, the purpose of each service and when to expect the services.
G614	***[The HHA must provide the patient and caregiver with a copy of written instructions outlining…]*** **§484.60(e)(1)** Visit schedule, including frequency of visits by HHA personnel and personnel acting on behalf of the HHA.	**§484.60(e)(1)** The HHA must ensure that the written visit schedule provided to the patient is consistent with the patient's most current plan of care.

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G616	***[The HHA must provide the patient and caregiver with a copy of written instructions outlining…]*** **§484.60(e)(2)** Patient medication schedule/instructions, including: medication name, dosage and frequency and which medications will be administered by HHA personnel and personnel acting on behalf of the HHA.	**§484.60(e)(1)** The HHA must prepare, and provide to the patient and his or her caregiver (if any) written information regarding the patient's medication regimen as based on the results of the medication review conducted at §484.55(c)(5). The medication administration instructions must be written in plain language that does not use medical abbreviations. The HHA must provide this information to the patient regardless of whether the patient is receiving only rehabilitation therapy services. See §484.55(c)(5) for communication between the therapist and the HHA nurse regarding medications.
G618	***[The HHA must provide the patient and caregiver with a copy of written instructions outlining…]*** **§484.60(e)(3)** Any treatments to be administered by HHA personnel and personnel acting on behalf of the HHA, including therapy services.	
G620	***[The HHA must provide the patient and caregiver with a copy of written instructions outlining…]*** **§484.60(e)(4)** Any other pertinent instruction related to the patient's care and treatments that the HHA will provide, specific to the patient's care needs.	
G622	***[The HHA must provide the patient and caregiver with a copy of written instructions outlining…]*** **§484.60(e)(5)** Name and contact information of the HHA clinical manager.	**§484.60(e)(5)** The name and contact information of the HHA's clinical manager, including the clinical manager's telephone number and, if the patient prefers electronic communication, email, must be provided to the patient. The HHA explains to the patient when the clinical manager should be contacted for discussion about their services.

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G640	***§484.65 Condition of participation: Quality assessment and performance improvement (QAPI).*** The HHA must develop, implement, evaluate, and maintain an effective, ongoing, HHA-wide, data-driven QAPI program. The HHA's governing body must ensure that the program reflects the complexity of its organization and services; involves all HHA services (including those services provided under contract or arrangement); focuses on indicators related to improved outcomes, including the use of emergent care services, hospital admissions and re-admissions; and takes actions that address the HHA's performance across the spectrum of care, including the prevention and reduction of medical errors. The HHA must maintain documentary evidence of its QAPI program and be able to demonstrate its operation to CMS.	**§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, regarding citation at the condition level.*
G642	**§484.65(a) Standard: Program scope.** (1) The program must at least be capable of showing measurable improvement in indicators for which there is evidence that improvement in those indicators will improve health outcomes, patient safety, and quality of care. (2) The HHA must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that enable the HHA to assess processes of care, HHA services, and operations.	**§484.65(a)(2)** The HHA selects the indicators that it will utilize in its QAPI program based upon identified adverse or negative patient outcomes or agency processes that the HHA wishes to monitor and measure. Each indicator must be measurable through data in order to evaluate any HHA change in procedure, policy or intervention. The HHA QAPI program must include procedures for measurement and analysis of indicators and address the frequency with which such measurement and analysis will occur. Per §484.70(b) the HHA must maintain a coordinated agency-wide program for the surveillance, investigation, identification, prevention, control and investigation of infectious and communicable diseases as an integral part of the QAPI program.
G644	**§484.65(b) Standard: Program data.** (1) The program must utilize quality indicator data, including measures derived from OASIS, where applicable, and other relevant data, in the design of its program. (2) The HHA must use the data collected to- (i) Monitor the effectiveness and safety of services and quality of care; and (ii) Identify opportunities for improvement.	

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G644 Cont.	(3) The frequency and detail of the data collection must be approved by the HHA's governing body.	***§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	**§484.65(c) 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.*	**§484.65(c)(1)(i)** "High risk" areas may include global concerns such as a type of service (e.g., pediatrics), geographic concerns (e.g., safety of a neighborhood served); or specific patient care services (e.g., administration of intravenous medications or tracheostomy care). All factors would be associated with significant risk to the health or safety of patients. "High volume" areas refers to care or service areas that are frequently provided by the HHA to a large patient population, thus possibly increasing the scope of the problem (e.g. laboratory testing, physical therapy, infusion therapy, diabetes management). "Problem-prone" areas refer to care or service areas that have the potential for negative outcomes and that are associated with a diagnosis or condition for a particular patient group or a particular component of the HHA operation or historical problem areas.
G654	**§484.65(c)(2)** Performance improvement activities must track adverse patient events, analyze their causes, and implement preventive actions.	**§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	**§484.65(c)(3)** The HHA must take actions aimed at performance improvement, and, after implementing those actions, the HHA must measure its success and track performance to ensure that improvements are sustained.	

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G658	**§484.65(d) Standard: Performance improvement projects.** Beginning July 13, 2018, HHAs must conduct performance improvement projects. (1) The number and scope of distinct improvement projects conducted annually must reflect the scope, complexity, and past performance of the HHA's services and operations. (2) The HHA must document the quality improvement projects undertaken, the reasons for conducting these projects, and the measurable progress achieved on these projects.	**§484.65(d)** The HHA should have at least one performance improvement project either in development, on-going or completed each calendar year. The HHA decides, based on the QAPI program activities and data, what projects are indicated and the priority of the projects.
G660	**§484.65(e) Standard: Executive responsibilities.** The HHA's governing body is responsible for ensuring the following: (1) That an ongoing program for quality improvement and patient safety is defined, implemented, and maintained; (2) That the HHA-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety, and that all improvement actions are evaluated for effectiveness; (3) That clear expectations for patient safety are established, implemented, and maintained; and (4) That any findings of fraud or waste are appropriately addressed.	***§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.

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G680	**§484.70 Condition of Participation: Infection prevention and control.** The HHA must maintain and document an infection control program which has as its goal the prevention and control of infections and communicable diseases.	***§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.*
G682	**§484.70(a) Standard: Prevention.** The HHA must follow accepted standards of practice, including the use of standard precautions, to prevent the transmission of infections and communicable diseases.	**§484.70(a)** *Federal and state agencies such as the Centers for Disease Control and Prevention (CDC) and state departments of health, national professional organizations, have all developed infection prevention and control standards of practice. Examples of national organizations that promulgate nationally recognized infection and communicable disease control guidelines, and/or recommendations include: the CDC, the Association for Professionals in Infection Control and Epidemiology (APIC), and the Society for Healthcare Epidemiology of America (SHEA). An HHA should identify the source of the standards it selects and be capable of explaining why those standards were chosen for incorporation into the HHA's infection prevention and control program (82 FR 4543).* Standard precautions must be used to prevent transmission of infectious agents. "Standard precautions" are a group of infection practices that apply to all patients regardless of suspected or confirmed infection status at the time health care is delivered. *These practices protect healthcare personnel and prevent healthcare personnel or the environment from transmitting infections to patients.* *For example,* the following are six (6) *core practices,* identified by the *CDC are based on the CDC's "Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings –Recommendations of The Healthcare Infection Control Practices Advisory Committee (HICPAC),*[1] *which is periodically updated. These are a core set of infection prevention and control practices that are recommended in all healthcare settings, regardless of the type of healthcare provided. Also, refer to "Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care" published by the National Center for Emerging and Zoonotic Infectious Diseases Division of Healthcare Quality Promotion, Version 2.3.*

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G682 Cont.		*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;

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G682 Cont.		• 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*.

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G684	**§484.70(b) Standard: Control.** The HHA must maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that is an integral part of the HHA's quality assessment and performance improvement (QAPI) program. The infection control program must include: (1) A method for identifying infectious and communicable disease problems; and (2) A plan for the appropriate actions that are expected to result in improvement and disease prevention.	**§484.70(b)** The HHA should have a program for the surveillance, identification, prevention, control and investigation of infectious and communicable diseases specific to care and services provided in the home setting. The CDC defines surveillance as "the ongoing, systematic collection, analysis, interpretation and evaluation of health data closely integrated with the timely dissemination of this data to those who need it." As part of its infection control program, the HHA should: 1) Observe and evaluate services from all disciplines to identify sources or causative factors of infection, track patterns and trends of infections; and 2) Establish a corrective plan for infection control (if appropriate) and monitor effectiveness of the corrective plan. Cross Reference to §484.65(a), QAPI Program Scope. **§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 transmissions of communicable diseases. *While not required by the regulation, CMS suggests HHAs have a way to receive alerts from the CDC Health Alert Network or local public health network as a means of staying up to date with alerts and information related to public health incidents (as seen with the 2019 Novel Coronavirus public health emergency).* **§484.70(b)(2)** The HHA must develop a*n* action plan to address or prevent infections or transmission of communicable diseases. Such plan should be based on surveillance findings, any identified root cause of infection or disease transmission, tracking data and analysis of data findings. Actions to facilitate improvements and disease prevention may include the following:

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G684 Cont.		• Policy, procedure or practice changes to improve care; • Education for patients, caregivers, and HHA personnel to prevent infections and transmissions of communicable diseases; and • The development of process or outcome measures which could be used to monitor and address identified issues (e.g., infection prevention and control observations for technique). The HHA must evaluate and revise the plan as needed.
G686	**§484.70(c) Standard: Education.** The HHA must provide infection control education to staff, patients, and caregiver(s).	**§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.

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G700	**§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.	**§484.75** *The manner and degree of noncompliance identified in relation to the standard level tags* for §484.75 *may result in substantial noncompliance with this CoP, requiring citation at the condition level.*
G702	**§484.75(a) Standard: Provision of services by skilled professionals.** Skilled professional services are authorized, delivered, and supervised only by health care professionals who meet the appropriate qualifications specified under §484.115 and who practice according to the HHA's policies and procedures.	
G704	**§484.75(b) Standard: Responsibilities of skilled professionals.** Skilled professionals must assume responsibility for, but not be restricted to, the following:	
G706	***[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]*** (1) Ongoing interdisciplinary assessment of the patient;	**§484.75(b)(1)** The term "interdisciplinary" refers to an approach to healthcare that includes a range of health service workers. "Ongoing interdisciplinary assessment" is the continual involvement of all skilled professional staff involved in the patient's plan of care from the initial assessment through discharge, which should include periodic discussions among the team regarding the patient's health status and recommendations for the plan of care. An interdisciplinary approach recognizes the contributions of various health care disciplines (MDs, RNs, *Licensed Professional/Vocational Nurses (*LPN/LVN, PT, OT, SLP, *Master of Social Work (*MSW, HH aides) and their interactions with each other to meet the patient's needs.
G708	***[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]*** (2) Development and evaluation of the plan of care in partnership with the patient, representative (if any), and caregivers(s);	
G710	***[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]***	

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G710 Cont.	(3) Providing services that are ordered by the physician or allowed practitioner as indicated in the plan of care;	
G712	***[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]*** (4) Patient, caregiver, and family counseling;	
G714	***[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]*** (5) Patient and caregiver education;	
G716	***[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]*** (6) Preparing clinical notes;	
G718	***[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]*** (7) Communication with all physicians involved in the plan of care and other health care practitioners (as appropriate) related to the current plan of care;	
G720	***[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]*** (8) Participation in the HHA's QAPI program; and	**§484.75(b)(8)** All skilled professional staff must provide input into and participate in the implementation of the HHA's QAPI program in order for the QAPI program to be effective. Every HHA skilled professional, regardless of whether the skilled professional is a direct employee or contractor of the HHA, is expected to contribute to all phases of the QAPI program. These contributions may include; identification of problem areas; recommendations to address problem areas; data collection; attendance at periodic QAPI meetings and participation in performance improvement projects.
G722	***[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]*** (9) Participation in HHA-sponsored in-service training.	

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G724	**§484.75(c) Standard: Supervision of skilled professional assistants.**	**§484.75(c)** Documentation in the clinical record should show how communication and oversight exist between the skilled professional and assistant regarding the patient's status, the patient's response to services furnished by the assistant, and the effectiveness of any written instructions provided by the skilled professional to the assistant. Any specific written instructions by skilled professionals to assistants are based on treatments prescribed in the patient's plan of care, patient assessments by the skilled professional, and accepted standards of professional practice. The skilled professional must periodically evaluate the effectiveness of the services furnished by the assistant to ensure the patient's needs are met.
G726	**§484.75(c)(1)** Nursing services are provided under the supervision of a registered nurse that meets the requirements of §484.115(k).	**§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 assessments, evaluations, care planning and discharge planning.
G728	**§484.75(c)(2)** Rehabilitative therapy services are provided under the supervision of an occupational therapist or physical therapist that meets the requirements of §484.115(f) or (h), respectively.	**§484.75(c)(2)** An assistant must be supervised by a skilled therapy professional for the assistant's respective therapy type. For example, only a physical therapist may supervise a physical therapist assistant and only an occupational therapist may supervise an occupational therapy assistant. The applicable therapist should monitor and evaluate the therapy assistant's performance *regarding* provision of treatments, patient education, communication with the therapist, and data collection regarding the patient's status and health needs (as delegated by the therapist). Only the skilled therapist may perform comprehensive assessments, patient evaluations, care planning and discharge planning.
G730	**§484.75(c)(3)** Medical social services are provided under the supervision of a social worker that meets the requirements of §484.115(m).	**§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.*

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G750	**§484.80 Condition of participation: Home health aide services.** All home health aide services must be provided by individuals who meet the personnel requirements specified in paragraph (a) of this section.	**§484.80** *The manner and degree of noncompliance identified in relation to the standard level tags for §484.80 may result in substantial noncompliance with this CoP, requiring citation at the condition level.*
G754	**§484.80(a) Standard: Home health aide qualification.** (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.	**§484.80(a)(1)** The regulation describes four methods by which a home health aide may become qualified. (1) The candidate may successfully complete a training and competency evaluation program offered by an HHA (except by an HHA specified in 484.80(f)). (2) The candidate may successfully complete a competency evaluation program only. This assumes that the candidate has had training in the past that addresses all or some of the topics in paragraph (b) of this section. The competency evaluation program must address all requirements in §484.80 (c). (3) A nurse aide who successfully completes a nurse aide training and competency evaluation program, and is found to be in good standing in the state nurse aide registry, is considered to have met the training and competency requirements for a HHA aide. See also 42 CFR Part 483, Subpart D for requirements for states and state agencies on Nurse Aide Training and Competency Evaluation. (4) The candidate may successfully complete a State administered program that licenses or certifies HH aides and that meets or exceeds the requirements under paragraphs (b) and (c) of this section. The HHA is responsible for ensuring that any HHA aide (whether employed directly or under arrangement), who provides home health aide services for the HHA meets the provisions of this regulation. Any state requirement regarding aide education, training, competency evaluations, or certification and supervision that is more stringent than the corresponding federal requirement takes precedence over the federal requirement. Likewise, any federal requirement that is more stringent than a corresponding state requirement takes precedence over the more lenient state requirement.
G756	**§484.80(a)(2)** A home health aide or nurse aide is not considered to have completed a program, as specified in paragraph (a)(1) of this section, if, since the individual's most recent completion of the program(s), there has been a continuous period of 24 consecutive months during which none of the services furnished by the individual as described in §409.40 of this chapter were for compensation. If	***§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*

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G756 Cont.	there has been a 24 month lapse in furnishing services for compensation, the individual must complete another program, as specified in paragraph (a)(1) of this section, before providing services.	*means monetary compensation, as set forth in section 1891(a)(3)(A) of the Act (as noted in 82 FR 4545 preamble discussion).*
G760	***§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.	***§484.80(b)(1)*** *Home health aide training must include classroom and supervised practical training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while providing services to an individual under the direct supervision of a registered nurse, or a licensed practical nurse who is under the supervision of a registered nurse. Alternative formats for classroom training, such as online course material or internet based interactive formats are acceptable delivery methods for the classroom training. These alternative formats should also provide an interactive component that permits students to ask questions and receive responses related to the training.*
G762	***[§484.80(b) Standard: Content and duration of home health aide classroom and supervised practical training.]*** **(2) A minimum of 16 hours of classroom training must precede a minimum of l6 hours of supervised practical training as part of the 75 hours.**	
G764	***[§484.80(b) Standard: Content and duration of home health aide classroom and supervised practical training.]*** (3) A home health aide training program must address each of the following subject areas: (i) Communication skills, including the ability to read, write, and verbally report clinical information to patients, representatives, and caregivers, as well as to other HHA staff. (ii) Observation, reporting, and documentation of patient status and the care or service furnished. (iii) Reading and recording temperature, pulse, and respiration. (iv) Basic infection prevention and control procedures. (v) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor. (vi) Maintenance of a clean, safe, and healthy environment. (vii) Recognizing emergencies and the knowledge of instituting emergency procedures and their application. (viii) The physical, emotional, and developmental needs of and ways to work with the populations served by the HHA, including the need for respect for the patient, his or her privacy, and his or her	

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G764 Cont.	property. (ix) Appropriate and safe techniques in performing personal hygiene and grooming tasks that include— (A) Bed bath; (B) Sponge, tub, and shower bath; (C) Hair shampooing in sink, tub, and bed; (D) Nail and skin care; (E) Oral hygiene; (F) Toileting and elimination; (x) Safe transfer techniques and ambulation; (xi) Normal range of motion and positioning; (xii) Adequate nutrition and fluid intake; (xiii) Recognizing and reporting changes in skin condition; and (xiv) Any other task that the HHA may choose to have an aide perform as permitted under state law. (xv) The HHA is responsible for training home health aides, as needed, for skills not covered in the basic checklist, as described in paragraph (b)(3)(ix) of this section.	**§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	***[§484.80(b) Standard: Content and duration of home health aide classroom and supervised practical training.]*** (b)(4) The HHA must maintain documentation that demonstrates that the requirements of this standard have been met.	
G768	***§484.80(c) Standard: Competency evaluation.*** An individual may furnish home health services on behalf of an HHA only after that individual has successfully completed a competency evaluation program as described in this section. **§484.80(c)(1)** The competency evaluation must address each of the subjects listed in paragraph (b)(3) of this section. Subject areas specified under paragraphs (b)(3)(i), (iii), (ix), (x), and (xi) of this section must be evaluated by observing an aide's performance of the task with a patient or pseudo-patient. The remaining subject areas may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient, or with a pseudo-patient as part of a simulation. **§484.80(c)(2)** A home health aide competency evaluation program may be offered by any organization, except as specified in paragraph (f) of this section.	**§484.80(c)** The HHA may not allow an aide to provide services to patients independently until they have successfully completed competency testing either at that HHA or at another training facility and successful completion is verified through documentation provided by the applicant or the training facility. **§484.80(c)(1)** The 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;

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G768 Cont.	**§484.80(c)(3)** The competency evaluation must be performed by a registered nurse in consultation with other skilled professionals, as appropriate.	(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 p*seudo-patient is a person who is trained to participate in a role-play situation, or a computer-based mannequin device. A pseudo-patient must be capable of responding to and interacting with the home health aide trainee, and must be similar in characteristics to the primary patient population served by the HHA in key areas such as age, frailty, functional status, and cognitive status.* *When pseudo-patients are used to test home health aide competency, the simulated environment must mimic the reality of the homecare environment, including environmental distractions and constraints that evoke or replicate substantial aspects of the real world in a fully interactive fashion, to assess proficiency in performing skills.*
G770	**§484.80(c)(4)** A home health aide is not considered competent in any task for which he or she is evaluated as unsatisfactory. An aide must not perform that task without direct supervision by a registered nurse until after he or she has received training in the task for which he or she was evaluated as "unsatisfactory," and has successfully completed a subsequent evaluation. A home health aide is not considered to have successfully passed a competency evaluation if the aide has an "unsatisfactory" rating in more than one of the required areas.	
G772	**§484.80(c)(5)** The HHA must maintain documentation which demonstrates that the requirements of this standard have been met.	**§484.80(c)(5)** Documentation of competency must: • Include a description of the competency evaluation program, including the qualifications of the instructors; • Confirm that competency was determined by direct observation and the results of those

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G772 Cont.		observations; • Distinguish between skills evaluated during patient care and those taught in a laboratory, e.g., skills evaluated through use of a volunteer or direct observation of patient care versus a skill lab demonstration; and • Describe how additional skills beyond the basic skills listed at §484.80(b)(3) were taught and tested. An HHA aide that is unable to provide the above documentation will be required to successfully complete a competency evaluation before providing care to patients *(§484.80(c)(4))*.
G774	**§484.80(d) Standard: In-service training.** A home health aide must receive at least l2 hours of in-service training during each 12-month period. In-service training may occur while an aide is furnishing care to a patient.	**§484.80(d)** The annual 12 hours of in-service training is met for the 12 months following successful completion of an HHA aide training and competency evaluation, unless the HHA introduces a new procedure that would indicate the need for further HHA aide in-service training. When conducting in-service training during patient care, the patient must first be informed of and consent to the training and be informed of how the training will be conducted; patient rights, respect for the patient's preferences, and potential for care disruption must always guide such training.
G776	**§484.80(d)(1) I**n-service training may be offered by any organization and must be supervised by a registered nurse.	**§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	**§484.80(d)(2)** The HHA must maintain documentation that demonstrates the requirements of this standard have been met.	
G780	***§484.80(e) Standard: Qualifications for instructors conducting classroom and supervised practical training.*** Classroom and supervised practical training must be performed by a registered nurse who possesses a minimum of 2 years nursing experience, at least 1 year of which must be in home health care, or by other individuals under the general supervision of the registered nurse.	**§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;

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G780 Cont.		• Speech-language pathologists; • Medical social workers; • LPN/LVNs; and • Nutritionists.
G782	***§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.*	***§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.

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G782 Cont.		*If an HHA loses the authority to operate a home health aide training and competency evaluation program, that does not preclude the HHA from using a contractor to acquire training (see 54 FR 33354, 33358 (Aug. 14, 1989)). If the HHA has its own training and competency lab onsite, it may be permissible for a contractor to conduct the training on the HHA premises. However, the HHA must have no influence or role in the conduct of the training and competency evaluation. The program must be independent of the HHA in all other regards.*
G798	***§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).	**§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	**§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	**§484.80(g)(3)** The duties of a home health aide include: (i) The provision of hands on personal care; (ii) The performance of simple procedures as an extension of therapy or nursing services; (iii) Assistance in ambulation or exercises; and (iv) Assistance in administering medications ordinarily self-administered.	**§484.80(g)(3)** "Self-administration of medications" means that the patient (or the patient's caregiver, if applicable) *can* manage all aspects of taking her or his medication, including safe medication storage, removing the correct dose of medication from the container, taking the medication at the correct time, and knowing how to contact the pharmacy for refills or other questions. "Assistance in administering medications," as referenced in this requirement, means that the HH aide may take only a passive role in this activity. Assistance may include items such as: • Bringing a medication to the patient either in a pill organizer or a medication container as requested by the patient or caregiver; • Providing fluids to take with the medication; • Reminding the patient to take a medication; • Applying a topical product, such as a non-prescription cream, to intact skin per home health aide instructions in how to apply it.

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G804	**§484.80(g)(4)** Home health aides must be members of the interdisciplinary team, must report changes in the patient's condition to a registered nurse or other appropriate skilled professional, and must complete appropriate records in compliance with the HHA's policies and procedures.	**§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.
G808	***§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.*	***§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	**§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.*	

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G812	**§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	***§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.*	***§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)(i*ii*), 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	**§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	**§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.*	

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G818	**§484.80(h)(4)** Home health aide supervision must ensure that aides furnish care in a safe and effective manner, including, but not limited to, the following elements: (i) Following the patient's plan of care for completion of tasks assigned to a home health aide by the registered nurse or other appropriate skilled professional; (ii) Maintaining an open communication process with the patient, representative (if any), caregivers, and family; (iii) Demonstrating competency with assigned tasks; (iv) Complying with infection prevention and control policies and procedures; (v) Reporting changes in the patient's condition; and (vi) Honoring patient rights.	**§484.80(h)(4)** During each supervisory visit the supervising registered nurse, or other appropriate skilled professional, should document his or her evaluation of the HH aide *regarding* each of the elements of this standard. **§484.80(h)(4)(ii)** "Maintaining an open communication process" means that the aide *can* explain what *they are* going to do with the patient, ask the patient open-ended questions, seek feedback from the patient, and respond to the needs and requests of the patient, representative (if any), caregivers, and family.
G820	**§484.80(h)(5)** If the home health agency chooses to provide home health aide services under arrangements, as defined in section 1861(w)(1) of the Act, the HHA's responsibilities also include, but are not limited to: *(i) Ensuring the overall quality of care provided by an aide;* *(ii) Supervising aide services as described in paragraphs (h)(l) and (2) of this section; and* *(iii) Ensuring that home health aides who provide services under arrangement have met the training or competency evaluation requirements, or both, of this part.*	
G828	***§484.80(i) Standard:*** *Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit.* An individual may furnish personal care services, as defined in §440.167 of this chapter, on behalf of an HHA. Before the individual may furnish personal care services, the individual must meet all qualification standards established by the state. The individual only needs to demonstrate competency in the services the individual is required to furnish.	

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G848	**§484.100 Condition of Participation: Compliance with Federal, State, and local laws and regulations related to the health and safety of patients.** The HHA and its staff must operate and furnish services in compliance with all applicable federal, state, and local laws and regulations related to the health and safety of patients. If state or local law provides licensing of HHAs, the HHA must be licensed.	**§484.100** Non-compliance with this condition includes: 1) the agency is not currently licensed per State requirements; or 2) the HHA has been cited by a Federal program (other than CMS), or a State or local authority for a non-compliance with licensing requirements. The Federal, State or local authority has made a final determination after all administrative procedures have been completed; all appeals have been finalized; and the findings of the noncompliance with the laws/regulations were upheld and enforced.
G850	***§484.100(a) Standard: Disclosure of ownership and management information.*** The HHA must comply with the requirements of part 420 subpart C, of this chapter. The HHA also must disclose the following information to the state survey agency at the time of the HHA's initial request for certification, for each survey, and at the time of any change in ownership or management: *(1) The names and addresses of all persons with an ownership or controlling interest in the HHA as defined in §420.201, §420.202, and §420.206 of this chapter.* *(2) The name and address of each person who is an officer, a director, an agent, or a managing employee of the HHA as defined in §420.20l, §420.202, and §420.206 of this chapter.* *(3) The name and business address of the corporation, association, or other company that is responsible for the management of the HHA, and the names and addresses of the chief executive officer and the chairperson of the board of directors of that corporation, association, or other company responsible for the management of the HHA.*	
G860	**§484.100(b) Standard: Licensing.** The HHA, its branches, and all persons furnishing services to patients must be licensed, certified, or registered, as applicable, in accordance with the state licensing authority as meeting those requirements.	
G862	**§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	**§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.

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G862 Cont.	its equipment for a patient's equipment when assisting with self-administered tests.	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	**§484.100(c)(2)** If the HHA refers specimens for laboratory testing, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of part 493 of this chapter.	***§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).*

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E0001	**§484.102 Condition of Participation: Emergency preparedness.** The Home Health Agency (HHA) must comply with all applicable Federal, State, and local emergency preparedness requirements. The HHA must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:	******* Guidance specific to HHAs from State Operations Manual Appendix Z******* ***§ 484.102*** *HHAs must comply with the applicable emergency preparedness requirements referenced in Appendix Z of the State Operations Manual. For all applicable requirements and guidance for Emergency Preparedness, please refer to Appendix Z. We note that compliance with the emergency preparedness requirements is assessed in accordance with the survey protocol outlined within Appendix Z.* Under this condition/requirement, facilities are required to develop an emergency preparedness program that meets all of the standards specified within the condition/requirement. The emergency preparedness program must describe a facility's comprehensive approach to meeting the health, safety, and security needs of their staff and patient population during an emergency or disaster situation. The program must also address how the facility would coordinate with other healthcare facilities, as well as the whole community during an emergency or disaster (natural, man-made, facility). The emergency preparedness program must be reviewed *every two years for all providers and suppliers, with the exception of LTC providers who must review their emergency program annually. All facilities are expected to make the appropriate changes to their emergency program in the event changes are required more frequently outside of their update cycles. ("Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care" Final Rule, 84 FR 51732, 51735, Sept. 30, 2019) ("Burden Reduction Rule").* A comprehensive approach to meeting the health and safety needs of a patient population should encompass the elements for emergency preparedness planning based on the "all-hazards" definition and specific to the location of the facility. For instance, a facility in a large flood zone, or tornado prone region, should have included these elements in their overall planning in order to meet the health, safety, and security needs of the staff and of the patient population. Additionally, if the patient population has limited mobility, facilities should have an approach to address these challenges during emergency events. The term "comprehensive" in this requirement is to ensure that facilities do not only choose one potential emergency that may occur in their area, but rather consider a multitude of events and be able to demonstrate that they have considered this during their development of the emergency preparedness plan. *As emerging infectious disease outbreaks may affect*

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E0001 Cont.		*any facility in any location across the country, a comprehensive emergency preparedness program should include emerging infectious diseases and pandemics during a public health emergency (PHE). The comprehensive emergency preparedness program emerging infectious disease planning should encompass how facilities will plan, coordinate and respond to a localized and widespread pandemic, similar to what is occurring with the 2019 Novel Coronavirus (COVID-19) PHE. Facilities should ensure their emergency preparedness programs are aligned with their State and local emergency plans/pandemic plans.* ***Documentation and Requirements*** ***The emergency preparedness program must be in writing.*** *The requirements under the emergency preparedness Final Rule allow for documentation flexibility. While facilities are required to meet all of the provisions applicable to their provider/supplier type, how they document their efforts is subject to their discretion. We are not requiring a hard copy/paper, electronic or any particular system for meeting the requirements. It is up to each individual facility to be able to demonstrate in writing their emergency preparedness program. We would also recommend, but are not requiring, facilities to develop a crosswalk as applicable for where their documents are located. For instance, if their emergency plan is located in a binder, specify this for surveyors. If there are policies and procedures to specific standards/requirements, identify where these are located.* *Providers and suppliers are encouraged to keep documentation and their written emergency preparedness program for a period of at least 2 years for inpatient providers and at least 4 years for outpatient providers. We are recommending this process due to the requirements related to training and testing exercises. Inpatient providers are required to have 2 exercises per year, therefore surveyors will review the current year and the previous year to determine compliance. For outpatient providers, testing exercises are required annually, however require full-scale exercises every other year, with the opposite years allowing for the exercise of choice. In order to determine compliance, surveyors will be required to review at least the past 2 cycles (generally 4 years) of emergency testing exercises.* *Additionally, we are not requiring approval of the Emergency Program or official "sign-off," however, we do recommend facilities check with their State Agencies and local emergency planning coordinators (LEPCs) as some states require approval of the emergency preparedness plans as part of state licensure.*
E0004	***§484.102 (a) Emergency plan.*** The HHA must develop and maintain an emergency preparedness plan that must be reviewed and update	***Emergency Plan- General*** Facilities are required to develop and maintain an emergency preparedness plan. The plan

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E0004 Cont.	at least every 2 years. The plan must do all of the following:	must include all of the required elements under the standard. The plan must be reviewed and updated at least *every 2 years, with the exception for LTC facilities which must review and update their plan on an annual basis*. This *periodic review* must be documented to include the date of the review and any updates made to the emergency plan based on the review. The format of the emergency preparedness plan that a facility uses is at its discretion. *While this 2-year review process (except for LTC facilities) provides more flexibilities for providers to update their program as they see fit, facilities are encouraged to continue to review and update their emergency preparedness plans and train their staff accordingly as the plan may change on a more frequent basis (84 FR at 51756).* An emergency plan is one part of a facility's emergency preparedness program. The plan provides the framework, which includes conducting facility-based and community-based risk assessments that will assist a facility in addressing the needs of their patient populations, along with identifying the continuity of business operations which will provide support during an actual emergency. ***Elements of the Emergency Plan*** In addition, the emergency plan supports, guides, and ensures a facility's ability to collaborate with local emergency preparedness officials. This approach is specific to the location of the facility and considers particular hazards most likely to occur in the surrounding area. These include, but are not limited to: • Natural disasters • Man-made disasters, • Facility-based disasters that include but are not limited to: o Care-related emergencies; o Equipment and utility failures, including but not limited to power, water, gas, etc.; o Interruptions in communication, including cyber-attacks; o Loss of all or portion of a facility; and o Interruptions to the normal supply of essential resources, such as water, food, fuel (heating, cooking, and generators), and in some cases, medications and medical supplies (including medical gases, if applicable). • Emerging infectious diseases (EIDs) such as Influenza, Ebola, Zika Virus and others. o These EIDs may require modifications to facility protocols to protect the health and safety of patients, such as isolation and personal protective equipment (PPE) measures. ***Emerging Infectious Diseases (EIDs)***

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E0004 Cont.		*As facilities develop or make revisions to their emergency preparedness plans, EID's are a potential threat which can impact the operations and continuity of care within a healthcare setting and should be considered. The type of infectious diseases to consider or the care-related emergencies that are a result of infectious diseases are not specified. Adding EID's within a facility's risk assessment ensures that facilities consider having infection prevention personnel involved in the planning, development and revisions to the emergency preparedness program, as these individuals would likely be coordinating activities within the facility during a potential surge of patients.* *Some examples of EID's may include, but are not limited to:* *o Hazardous Waste* *o Bioterrorism* *o Pandemic Flu* *o Highly Communicable Diseases (such as Ebola, Zika Virus, SARS, or novel COVID-19 or SARS-CoV-2)* *EID's may be localized to a certain community or be widespread (as seen with the COVID-19 PHE) and therefore plans for coordination with local, state, and federal officials are essential. Facilities should engage and coordinate with their local healthcare systems and healthcare coalitions, and their state and local health departments when deciding on ways to meet surge needs in their community.* ***Understanding the Terminology*** *CMS recognizes that there are differences in terminology used within the emergency preparedness industry pertaining to "continuity of operations" and "business continuity." We consider "continuity of business" to incorporate all continuity operations and business continuity, which involves planning to ensure business operations will continue even during a disaster. The concept of continuity is the facility's ability to continue operations or services related to patient care and to ensure patient safety and quality of care is continued in an emergency event. The emergency plan provides the framework, which includes conducting facility-based and community-based risk assessments that will assist a facility in addressing the needs of their patient populations, along with identifying the continuity of business operations which will provide support to services that are necessary during an actual emergency (81 FR 63875-63876). For additional information related to continuity of operations, please visit the Federal Emergency Management Agency's (FEMA's) Continuity Guidance Circular at https://www.fema.gov/sites/default/files/2020-07/Continuity-Guidance-Circular_031218.pdf.* *Essential Services and Continuity of Care*

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E004 Cont.		When evaluating potential interruptions to the normal supply of essential services, the facility should take into account the likely durations of such interruptions. Arrangements or contracts to re-establish essential utility services during an emergency should describe the timeframe within which the contractor is required to initiate services after the start of the emergency, how they will be procured and delivered in the facility's local area, and that the contractor will continue to supply the essential items throughout and to the end of emergencies of varying duration. *However, we recognize that contracts may be subject to some issues in itself as there are no guarantees in the event of a disaster that the contractor would be able to fulfill contract terms.* *Facilities should also be prepared to continue to provide care in a safe setting in the event that a contract is not able to be fulfilled during the event. The emergency plan should take into account contingency planning, such as evacuation triggers in the event essential resources provided by the contractor cannot be fulfilled.* *Finally, facilities should also include in their planning and revisions of existing plans, contracts and inventory of supply needs; availability of personal protective equipment (PPE); critical care equipment; and transportation options/needs to be prepared for surge events. NOTE: This is also further elaborated under the facility policies and procedures required by facilities under the emergency preparedness program.*
E0006	(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach. (2) Include strategies for addressing emergency events identified by the risk assessment.	***Risk Assessments Using All-Hazards Approach*** Facilities are expected to develop an emergency preparedness plan that is based on the facility-based and community-based risk assessment using an "all-hazards" approach. *Though a format is not specified, facilities* must document *the* risk assessment. An example consideration may include, but is not limited to, natural disasters prevalent in a facility's geographic region such as wildfires, tornados, flooding, etc. An all-hazards approach is an integrated approach to emergency preparedness planning that focuses on capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters, *including pandemics and EIDs as noted under E-0004.* This approach is specific to the location of the facility considering the types of hazards most likely to occur in the area*, but should also include unforeseen widespread communicable diseases*. Thus, all-hazards planning does not specifically address every possible threat or risk but ensures the facility will have the capacity to address a broad range of related emergencies. *Also, a risk assessment is facility-based, which, among other things, considers a facility's patient population and vulnerabilities. Facility-based and community-based risk assessments are intended to assist a facility in addressing the needs of their patient populations, along with identifying the continuity of business operations which will provide support during an actual emergency (81 FR 63876). For instance, if a facility has a population which is primarily*

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E0006 Cont.		*dependent on medical equipment and is not located near a nuclear power plant, the risk assessment would identify a higher risk for emergencies due to power failures than a potential for a nuclear disaster.* Facilities are encouraged to utilize the concepts outlined in the National Preparedness System, published by the United States Department of Homeland Security's Federal Emergency Management Agency (FEMA), as well as guidance provided by the Agency for Healthcare Research and Quality (AHRQ). ***Understanding Community-Based*** "Community" is not defined in order to afford facilities the flexibility in deciding which healthcare facilities and agencies it considers to be part of its community for emergency planning purposes. However, the term could mean entities within a state or multi-state region. The goal of the provision is to ensure that healthcare providers collaborate with other entities within a given community to promote an integrated response. Conducting integrated planning with state and local entities could identify potential gaps in state and local capabilities that can then be addressed in advance of an emergency. Facilities may rely on a community-based risk assessment developed by other entities, such as public health agencies, emergency management agencies, and regional health care coalitions or in conjunction with conducting its own facility-based assessment. If this approach is used, facilities are expected to have a copy of the community-based risk assessment and to work with the entity that developed it to ensure that the facility's emergency plan is in alignment. ***Development of Risk Assessments based on the Plan*** When developing an emergency preparedness plan, facilities are expected to consider, among other things, the following: • Identification of all business functions essential to the facility's operations that should be continued during an emergency; • Identification of all risks or emergencies that the facility may reasonably expect to confront; • Identification of all contingencies for which the facility should plan; • Consideration of the facility's location; • Assessment of the extent to which natural or man-made emergencies may cause the facility to cease or limit operations; and, • Determination of what arrangements may be necessary with other health care facilities, or other entities that might be needed to ensure that essential services could be provided during an emergency.

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E0006 Cont.		***Risk Assessment Considerations:*** *Based on the community threat and hazard identification process, facilities should select a comprehensive risk assessment tool that evaluates their risk and potential for hazards.. The comprehensive risk assessment should include all risks that could disrupt the facility's operations and necessitate emergency response planning to address the risk mitigation requirements and ensure continuity of care.* *Using an all-hazards approach helps facilities consider and prepare for a variety of risks which may impact their healthcare settings. Facilities should categorize the various probable risks and hazards identified by likelihood of occurrence and further create supplemental risk assessments based on the disaster or public health emergency. For example:* *• For power loss and potential disruptions of services: Facilities can consider using a heat index or heat risk assessment to identify situations which present concerns related to patient care and safety. Facilities are required to maintain safe temperatures under (b) policies and procedures (see Tag E-0015), therefore a heat risk assessment can be considered as an additional risk assessment, but is not required. Facilities may find it helpful to refer to ASPR TRACIE for the Natural Disasters Topic Collection at https://asprtracie.hhs.gov/technical-resources/36/natural-disasters/27.* ***NOTE:*** In situations where the facility does not own the structure(s) where care is provided, it is the facility's responsibility to discuss emergency preparedness concerns with the landlord to ensure continuation of care if the structure of the building and its utilities are impacted. • For public health emergencies, such as EIDs or pandemics: Facilities should consider risk assessments to include the needs of the patient population they serve in relation to a communicable or emerging infectious disease outbreak. Planning should include a process to evaluate the facility's needs based on the specific characteristics of an EID that includes, but is not limited to: o Influx in need for PPE; o Considerations for screening patients and visitors; which may also include testing considerations for staff, visitors and patients for infectious diseases; o Transfers and discharges of patients; o Home-based healthcare settings; o Physical Environment, including but not limited to changes needed for distancing, isolation, or capacity/surge. ***Planning for Staffing in Emergencies:***

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E0006 Cont.		Facilities must develop strategies for addressing emergency events that were identified during the development of the facility- and community-based risk assessments. Examples of these strategies may include, but are not limited to, developing a staffing strategy if staff shortages were identified during the risk assessment or developing a surge capacity strategy if the facility has identified it would likely be requested to accept additional patients during an emergency. Facilities will also want to consider evacuation plans. For example, a facility in a large metropolitan city may plan to utilize the support of other large community facilities as alternate care sites for its patients if the facility needs to be evacuated. The facility is also expected to have a backup evacuation plan for instances in which nearby facilities are also affected by the emergency and are unable to receive patients. ***NOTE:*** *Surveyors are not expected to analyze a facility's risk assessment to determine whether the identified risks are appropriate. Surveyors may take into consideration the geographic location and review the remaining standards to determine that the facility has addressed the hazards within their risk assessment through their policies and procedures. However, the intent is that surveyors review the risk assessments to determine if the facility has a risk assessment which is* ***facility-based and also community-based****. The facility's risk assessment should describe a process facilities use to assess and document potential hazards that are likely to impact their geographical region, community, facility and patient population. The ranking of priority of the hazards and the format of the risk assessment is at the discretion and expertise of the facility.*
E0007	(3) Address patient population including, but not limited to, the type of services the HHA has the ability to provide in an emergency; and continuity of operations, including delegation of authority and succession plans.	***Patient Population:*** The emergency plan must specify the population served within the facility, such as inpatients and/or outpatients, and their unique vulnerabilities in the event of an emergency or disaster. A facility's emergency plan must also address persons at-risk, except for plans of ASCs, hospices, PACE organizations, HHAs, CORFs, CMHCs, RHCs/FQHCs and ESRD facilities. As defined by the Pandemic and All-Hazards Preparedness Act (PAHPA) of 2006, members of at-risk populations may have additional needs in one or more of the following functional areas: maintaining independence, communication, transportation, supervision, and medical care. In addition to those individuals specifically recognized as at-risk in the PAHPA (children, senior citizens, and pregnant women), "at-risk populations" are also individuals who may need additional response assistance including those who have disabilities, live in institutionalized settings, are from diverse cultures and racial and ethnic backgrounds, have limited English proficiency or are non-English speaking, lack transportation, have chronic medical disorders, or have pharmacological dependency. At-risk populations would also include, but are not limited to, the elderly, persons in hospitals and nursing homes, people with physical and mental disabilities as well as others with access and functional needs, and infants and children. *At-risk populations, in the event of emerging infectious diseases and communicable diseases, may also include older adults and people of any age with underlying medical*

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E0007 Cont.		*conditions or who are immunocompromised, in which exposure may place them to be at higher risk for severe illnesses.* *Mobility & Transfers:* Mobility is an important part in effective and timely evacuations, and therefore facilities are expected to properly plan to identify patients who would require additional assistance, ensure that means for transport are accessible and available and that those involved in transport, as well as the patients and residents are made aware of the procedures to evacuate. For outpatient facilities, such as Home Health Agencies (HHAs), the emergency plan is required to ensure that patients with limited mobility are addressed within the plan. The plan should also address ways the facility will address identified patient needs that can't be addressed by in house services in an emergency, such as just in time contracts or emergency transfers. Ultimately, the delegations of authority and succession plans need to include plans on how the facility ensures patient safety is protected and patients will receive care at the facility or if transferred, under what circumstances transfers will occur. *Surge & Staffing* The emergency plan must also address the types of services that the facility would be able to provide in an emergency. The emergency plan must identify which staff would assume specific roles in another's absence through succession planning and delegations of authority. Succession planning is a process for identifying and developing internal people with the potential to fill key business leadership positions in the company. Succession planning increases the availability of experienced and capable employees that are prepared to assume these roles as they become available. During times of emergency, facilities must have employees who are capable of assuming various critical roles in the event that current staff and leadership are not available. At a minimum, there should be a qualified person who "is authorized in writing to act in the absence of the administrator or person legally responsible for the operations of the facility." *This does not mean that the facility must have documentation which lists each role and the designee for those roles within the same policy. Facilities may have a general plan which outlines the roles and responsibilities of the different individuals (e.g. incident commander, public information officer, patient liaison, etc.) and refers to those individuals by their titles. For example, a Facility Incident Commander may be the Facility Administrator. Also, an Emergency Department Charge Nurse of the Day may be the facility's identified person as the Safety Officer. However, if the facility chooses to follow this process without individual name identification, the individual serving in the role during the time of the survey should be able to adequately describe their role and responsibility during an emergency.*

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E0007 Cont.		*The emergency plan should also include ways the facility will respond to identified patient needs that cannot be addressed by in-house services in an emergency, such as use of just-in-time contracts or emergency transfers. As discussed under E-0001, CMS recognizes the variability in terminology in continuity of operations, business continuity, and other terms used by the emergency management industry. The intent behind this requirement is to ensure continuity of operations, including emergency preparedness succession planning, ultimately to ensure the facility has plans in place to continue functioning during an emergency and provide care in a safe setting, which may require some/all evacuations. Ultimately, the delegations of authority and succession plans, which are different from the "continuity" plans, are documented plans which outline the specific individuals and alternate/successors who can activate the facilities emergency plans to ensure patient safety is protected and patients will receive care at the facility or if transferred, under what circumstances transfers will occur.* ***General Considerations*** In addition to the facility- and community-based risk assessment, continuity of operations planning generally considers elements such as: essential personnel, essential functions, critical resources, vital records and IT data protection, alternate facility identification and location, and financial resources. Facilities are encouraged to refer to and utilize resources from various agencies such as FEMA and Assistant Secretary for Preparedness and Response (ASPR) when developing strategies for ensuring continuity of operations.
E0009	(4) Include a process for cooperation and collaboration with local, tribal, regional, State and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.	***Cooperation and Collaboration*** While the responsibility for ensuring a coordinated disaster preparedness response lies upon the state and local emergency planning authorities, the facility *must have a process to* engage in collaborative planning for an integrated emergency response. The facility must include this integrated response process in its emergency plan. Facilities are encouraged to participate in a healthcare coalition as it may provide assistance in planning and addressing broader community needs that may also be supported by local health department and emergency management resources. *While every detail of the cooperation and collaboration process is not required to be documented in writing, it is expected that the facility has documented sufficient details to support verification of the process.* *When deciding on ways to meet public health emergency needs in their community, facilities are expected to engage and coordinate with their local healthcare systems (including any emergency-related Alternate Care Sites), and their local and state health departments, and federal agency staff and also encouraged to engage with their healthcare coalitions, as applicable. Facility awareness of the state's emergency preparedness programs and pandemic plan ensures coordination occurs with the community. Coordination and*

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E0009 Cont.		*communications between facilities and their public health emergency officials is instrumental in ensuring a collaborative environment during a disaster. Coordination should be pre-planned and facility management should know the state and local emergency contacts (further defined within a facilities communication plan).* *We also note that under state licensure or their accreditation requirements, facilities may still be required to document their collaboration with local, tribal, regional, State, and Federal emergency preparedness officials. We recommend facilities contact their State Survey Agency (SA) and/or accrediting organizations (AO) to determine if any additional requirements exist.*
E0013	***§484.102 (b) Policies and procedures.*** The HHA must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:	Facilities must develop and implement policies and procedures per the requirements of this standard. The policies and procedures are expected to align with the identified hazards within the facility's risk assessment and the facility's overall emergency preparedness program. *We also recommend that facilities include strategies and succession planning as well as contingencies which support their response to any disaster or public health emergency (also see requirements at E-0024).* *Facilities should also consider updates to their emergency preparedness policies and procedures during a disaster, including planning for an emergency event with a duration longer than expected. For instance, during public health emergencies such as pandemics, the Centers for Disease Control and Prevention (CDC) and other public health agencies may issue event-specific guidance and recommendations to healthcare workers. Facilities should ensure their programs have policies in place to update or provide additional emergency preparedness procedures to staff. This may include a policy delegating an individual to monitor guidance by public health agencies and issuing directives and recommendations to staff such as use of PPE when entering the building; isolation of patients under investigation (PUIs); and, any other applicable guidance in a public health emergency.* We are not specifying where the facility must have the emergency preparedness policies and procedures. A facility may choose whether to incorporate the emergency policies and procedures within their emergency plan or to be part of the facility's Standard Operating Procedures or Operating Manual. *We are also not specifying the type of documentation- i.e. hard copy, electronic or other system-based emergency plans.* However, the facility must be able to demonstrate compliance upon survey, therefore we recommend that facilities have a central place to house the emergency preparedness program documents (to include all policies and procedures) to facilitate review. *Furthermore, since the format of the documentation is at the discretion of the facility, surveyors can identify a facility's reviews and updates of the emergency program through meeting minutes (facilities need to be clear if the entire program or any specific policy was reviewed and updated); through electronic or hard copy signatures on the table of contents of the emergency program documentation; or another manner. Facilities should clearly document the date of review and update and what*

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E0013 Cont.		*the update entailed.*
E0017	(1) The plans for the HHA's patients during a natural or man- made disaster. Individual plans for each patient must be included as part of the comprehensive patient assessment, which must be conducted according to the provision at §484.55.	HHAs must include policies and procedures in its emergency plan for ensuring all patients have an individualized plan in the event of an emergency. That plan must be included as part of the patient's comprehensive assessment. For example, discussions to develop individualized emergency preparedness plans could include potential disasters that the patient may face within the home such as fire hazards, flooding, tornados, *and EIDs*; and how and when a patient is to contact local emergency officials. Discussions may also include patient, care providers, patient representative, or any person involved in the clinical care aspects to educate them on steps that can be taken to improve the patient's safety. The individualized emergency plan should be in writing and could be as simple as a detailed emergency card to be kept with the patient. HHA personnel should document that these discussions occurred and also keep a copy of the individualized emergency plan in the patient's file as well as provide a copy to the patient and or their caregiver. *Additionally, HHAs should consider potential contingency operations within their policies. For example, how will the HHA ensure the appropriate discipline/staff perform the required initial and comprehensive assessments when access to residences may be hindered due to an emergency? While some contingency plans may include requests for Section 1135(b) emergency waiver flexibility during a declared public health emergency (requiring CMS pre-approval prior to use), HHAs are encouraged to plan ahead for the potential use of alternative staffing options/professions, acting in accordance with their state scope of practice laws.*
E0019	(2) The procedures to inform State and local emergency preparedness officials about HHA patients in need of evacuation from their residences at any time due to an emergency situation based on the patient's medical and psychiatric condition and home environment.	Home bound hospices, HHAs and PACE organizations are required to inform State and local emergency preparedness officials of the need for patient evacuations. These policies and procedures must address when and how this information is communicated to emergency officials and also include the clinical care needed for these patients. For instance, in the event an in-home hospice, PACE organization or HHA patient requires evacuation, the responsible agency should provide emergency officials with the appropriate information to facilitate the patient's evacuation and transportation. This should include, but is not limited to, the following: • Whether or not the patient is mobile. • What type of life-saving equipment does the patient require? • Is the life-saving equipment able to be transported? (E.g., Battery operated, transportable, condition of equipment, etc.) • Does the patient have special needs? (E.g., *electricity-dependent*, communication challenges, language barriers, intellectual disabilities, special dietary needs, etc.)

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E0019 Cont.		• *Is the patient a person under investigation (PUI), suspected exposure to or a confirmed case for any communicable diseases?* Since such policies and procedures include protected health information of patients, facilities must also ensure they are in compliance with, as applicable, the Health Insurance Portability and Accountability Act (HIPAA) Rules at 45 CFR parts 160 and 164, as appropriate. See (81 FR 63879, Sept. 16, 2016). *A level of pre-coordination activity with state and local emergency officials may be needed. Facilities should work with their state and local officials to determine how to coordinate the reporting of staff or patients who cannot be contacted. Emergency officials may include but are not limited to, emergency management departments/agencies (such as local FEMA or ASPR representatives), the state health department, CMS State Survey Agency or local response public emergency officials. (For additional information, please see standard (c)(2) [Tag E-0031] under the Communications Plan).* *Facilities should also account for contingency planning in the event that some staff are unaccounted for and how this relates to providing patient care.* *Finally, a facility's policies and procedures should also outline a contingency plan in the event patients require evacuation but are unable to be transferred due to a community-wide impacted emergency. See also, tag E-0022 for policy and procedure requirements addressing shelter in place.*
E0021	(3) The procedures to follow up with on-duty staff and patients to determine services that are needed, in the event that there is an interruption in services during or due to an emergency. The HHA must inform State and local officials of any on-duty staff or patients that they are unable to contact.	HHAs must include in its emergency plan, procedures required of this standard. During an emergency, if a patient requires care that is beyond the capabilities of the HHA, there is an expectation that care of the patient would be rearranged or suspended for a period of time, as most HHAs in general would not necessarily transfer patients to other HHAs during an emergency. HHAs policies and procedures should clearly outline what surrounding facilities, such as a hospital or a nursing home, it has a transfer arrangement with to ensure patient care is continued. Additionally, these policies and procedures should outline timelines for transferring patients or under what conditions patients would need to move. For instance, if the emergency is one which only is anticipated to have one or two days of disruption and does not pose immediate threat to patient health or safety (in which then the HHA should immediately transfer the patient); the HHA may rearrange services, whereas if a disaster is anticipated to last over one week or more, the HHA may need to initiate transfer of a patient as soon as possible. The policies and procedures should address these events. Additionally, the HHAs' policies and procedures must address what actions would be

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E0021 Cont.		required due to the inability to make contact with staff or patients and reporting capabilities to the local and State emergency officials. *Since HHAs must inform local and state officials of any on-duty staff or patients that they are unable to contact, the policies and procedures should align with the facility's communication plans outlined under §418.113(c). These policies and procedures should outline the timeframes for check-in with the facility's designated individual (e.g. staff check-in's every 2 or 4 hours while on shift, and every 8 while off-duty).* *A level of pre-coordination activity with state and local emergency officials may be needed. HHAs should work with their state and local officials to determine how to coordinate the reporting of staff or patients who cannot be contacted. HHAs should also accordingly account for contingency planning in the event that some staff are unaccounted for and how this relates to providing patient care.*
E0023	(4) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.	In addition to any existing requirements for patient records found in existing laws, under this standard, facilities are required to ensure that patient records are secure and readily available to support continuity of care during emergency. This requirement does not supersede or take away any requirements found under the provider/supplier's medical records regulations, but rather, this standard adds to such policies and procedures. These policies and procedures must also be in compliance with the Health Insurance Portability and Accountability Act (HIPAA), Privacy and Security Rules at 45 CFR parts 160 and 164, which protect the privacy and security of individual's personal health information.
E0024	(5) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.	*Surge Planning* *Emergencies, whether natural disasters, man-made disasters or infectious disease outbreaks, stress our healthcare systems through challenges with capacity and capability. While it is not possible to predict every scenario which could result in surge situations, healthcare facilities must have policies and procedures which include emergency staffing strategies and plan for emergencies. These strategies encompass procedures to preserve the healthcare system while continuing to provide care for all patients, at the appropriate level (e.g., home-based care, outpatient, urgent care, emergency room, or hospitalization).* *Facilities must have policies which address their ability to respond to a surge in patients requiring care. As required, these policies and procedures must be aligned with a facility's risk assessment, and should include planning for EIDs. Concentrated efforts will be required to mobilize all aspects of the healthcare system to reduce transmission of disease, direct*

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E0024 Cont.		*people to the right level of care, and decrease the burden on the healthcare system.* *Surge Planning During Natural Disasters* *In most circumstances, staffing strategies and surge planning surrounding natural disasters such as hurricanes are generally event specific and focus on evacuations, transfers, and staffing assistance from areas which are not impacted by the emergency. For instance, in response to Hurricane Sandy and Hurricane Katrina, while these events were considered large-scale natural disasters, assistance was more accessible in relation to staffing assistance, response assistance from local, state and federal partners as well as management of supplies.* *Surge Planning for Infectious Diseases/Pandemics* *Infectious diseases by nature may rise to the level of pandemic, causing severe impact on response and staffing strategies within the healthcare system. The primary goals in planning for infectious disease pandemics are to:* *• Reduce morbidity and mortality* *• Minimize disease transmission* *• Protect healthcare personnel* *• Preserve healthcare system functioning* *Surge Planning Considerations* *Facilities are encouraged to consider development of policies and procedures that could be implemented during an emergency to reduce non-essential healthcare visits and slow surge within the facility, such as:* *• Instructing patients to use available advice lines, patient portals, and/or on-line self-assessment tools;* *• Call options to speak to an office/clinic staff and identification of staff to conduct telephonic interactions with patients;* *• Development of protocols so that staff can triage and assess patients quickly;* *• Determine algorithms to identify which patients can be managed by telephone and advised to stay home, and which patients will need to be sent for emergency care or come to your facility.* ***NOTE:** Facilities are required to have a risk assessment in accordance with E-0004, however*

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E0024 Cont.		*we recommend that facilities also consider implications or evaluation of staffing needs. For instance, if a facility identifies a particular hazard, the facility should consider what staffing needs are required to ensure patients continue to receive care.* *Volunteers- Medical and Non-Medical* During an emergency, a facility may *also* need to accept volunteer support from individuals with varying levels of skills and training. The facility must have policies and procedures in place to facilitate this support. In order for volunteering healthcare professionals to be able to perform services within their scope of practice and training, facilities must include any necessary privileging and credentialing processes in its emergency preparedness plan policies and procedures. Non-medical volunteers would perform non-medical tasks. Facilities have flexibility in determining how best to utilize volunteers during an emergency as long as such utilization is in accordance with State law, State scope of practice rules, and facility policy. These may also include federally designated health care professionals, such as Public Health Service (PHS) staff, National Disaster Medical System (NDMS) medical teams, Department of Defense (DOD) Nurse Corps, Medical Reserve Corps (MRC), or personnel such as those identified in federally designated Health Professional Shortage Areas (HPSAs) to include licensed primary care medical, dental, and mental/behavioral health professionals. Facilities are also encouraged to collaborate with State-established volunteer registries, and where possible, State-based Emergency System for Advanced Registration of Volunteer Health Professionals (ESAR-VHP). Facilities are expected to include in its emergency plan a method for contacting off-duty staff during an emergency and procedures to address other contingencies in the event staff are not able to report to duty which may include, but are not limited to, utilizing staff from other facilities and state or federally-designated health professionals. *We would recommend that facilities include policies and procedures on the use of volunteers including if a facility chooses not to use volunteers, however at a minimum, the facility must have policies and procedures which address emergency staffing strategies. Providers and suppliers should have policies and guidelines for sheltering volunteers and any State and Federally designated health care professionals to address surge needs during an emergency. Facilities must determine their policies based on the emergency and the types of volunteers that may be present during and after an emergency (81 FR at 63881).* *Resources*

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E0024 Cont.		*Facilities are recommended to review the tools available related to planning for surge. ASPR TRACIE has developed multiple documents which could provide additional assistance during the development of policies and procedures, which include but are not limited to https://asprtracie.s3.amazonaws.com/documents/aspr-tracie-considerations-for-the-use-of-temporary-care-locations-for-managing-seasonal-patient-surge.pdf*
E0029	***§484.102 (c) Communication plan.*** The HHA must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:	Facilities must have a written emergency communication plan that contains how the facility coordinates patient care within the facility, across healthcare providers, and with state and local public health departments. The communication plan should include how the facility interacts and coordinates with emergency management agencies and systems to protect patient health and safety in the event of a disaster. The development of a communication plan will support the coordination of care. The plan must be reviewed annually and updated as necessary. We are allowing facilities flexibility in how they formulate and operationalize the requirements of the communication plan. Although *the requirement for documentation of collaboration with state and local officials was removed (see 84 FR 51817, Sept. 30, 2019), facilities should still continue to collaborate with state and local emergency officials. During the creation process for communication plans, facilities should also consult their applicable state and local emergency and pandemic plans.* Facilities in rural or remote areas with limited connectivity to communication methodologies such as the Internet, World Wide Web, or cellular capabilities need to ensure their communication plan addresses how they would communicate and comply with this requirement in the absence of these communication methodologies. For example, if a facility is located in a rural area, which has limited or no Internet and phone connectivity during an emergency, it *should* address what alternate means are available to alert local and State emergency officials. Optional communication methods facilities may consider include satellite phones, radios and short wave radios.
E0030	(1) Names and contact information for the following: (i) Staff. (ii) Entities providing services under arrangement. (iii) Patients' physicians. (iv) Volunteers.	A facility must have the contact information for those individuals and entities outlined within the standard. The requirement to have contact information for "other facilities" requires a provider or supplier to have the contact information for another provider or supplier of the same type as itself. For instance, hospitals should have contact information for other hospitals and CORFs should have contact information for other CORFs, etc. While not required, facilities may also find it prudent to have contact information for other facilities not of the same type. For instance a hospital may find it appropriate to have the contact information of LTC facilities within a reasonable geographic area, which could assist in facilitating patient transfers. Facilities have discretion in the formatting of this

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E0030 Cont.		information, however it should be readily available and accessible to leadership, *at a minimum, to the individual(s) designated as the emergency preparedness coordinator or person(s) responsible for the facility's emergency preparedness program and management during an emergency event,* during an emergency event. Facilities which utilize electronic data storage should be able to provide evidence of data back-up with hard copies or demonstrate capability to reproduce contact lists or access this data during emergencies. All contact information must be reviewed and updated as necessary at least *every 2 years, annually for LTC facilities*. Contact information contained in the communication plan must be accurate and current. Facilities must update contact information for incoming new staff and departing staff throughout the year and any other changes to information for those individuals and entities on the contact list. ***NOTE**: For Home Health Agencies, contact information should also include patient's physicians or allowed practitioners. Section 484.60 requires that each patient's written plan of care specify the care and services necessary to meet the patient specific needs identified in the comprehensive assessment. Accordingly, additional practitioners at HHAs should also be notified to reflect the interdisciplinary, coordinated approach to home health care delivery consistent with the HHA regulations.*
E0031	(2) Contact information for the following: (i) Federal, State, tribal, regional, and local emergency preparedness staff. (ii) Other sources of assistance.	A facility must have the contact information for those individuals and entities outlined within the standard. *Emergency management officials may include, but are not limited to, emergency management agencies which may be local to the community as well as local officials who support the Incident Command System depending on the nature of the disaster (e.g. fire, police, public health, etc.). Additionally, emergency management officials also include the state public health departments and State Survey Agencies as well as federal emergency preparedness officials (FEMA, ASPR, DHS, CMS, etc.) and tribal emergency officials, as applicable*. Facilities have discretion in the formatting of this information, however it should be readily available and accessible to leadership during an emergency event. Facilities are encouraged but not required to maintain these contact lists both in electronic format and hard-copy format in the event that network systems to retrieve electronic files are not accessible. All contact information must be reviewed and updated *at least every 2 years.* **NOTE:** *Even though the communications plan must include contact information, it does not specifically require the facility to have an individual contact for emergency management agencies. For instance, a state emergency management agency may have a specific phone*

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E0031 Cont.		*line or contact method and not a specific individual person.*
E0032	(3) Primary and alternate means for communicating with the following: (i) HHA's staff. (ii) Federal, State, tribal, regional, and local emergency management agencies.	Facilities are required to have primary and alternate means of communicating with staff, Federal, State, tribal, regional, and local emergency management agencies. Facilities have the discretion to utilize alternate communication systems that best meets their needs. However, it is expected that facilities would consider pagers, cellular telephones, radio transceivers (that is, walkie-talkies), and various other radio devices such as the NOAA Weather Radio and Amateur Radio Operators' (HAM Radio) systems, as well as satellite telephone communications systems. We recognize that some facilities, especially in remote areas, may have difficulty using some communication systems, such as cellular phones, even in non-emergency situations, which should be outlined within their risk assessment and addressed within the communications plan. It is expected these facilities would address such challenges when establishing and maintaining a well-designed communication system that will function during an emergency. The communication plan should include procedures regarding when and how alternate communication methods are used, and who uses them. In addition the facility should ensure that its selected alternative means of communication is compatible with communication systems of other facilities, agencies and state and local officials it plans to communicate with during emergencies. For example, if State X local emergency officials use the SHAred RESources (SHARES) High Frequency (HF) Radio program and facility Y is trying to communicate with RACES, it may be prudent to consider if these two alternate communication systems can communicate on the same frequencies. *Facilities should identify their primary and alternate means of communication in their emergency preparedness communication plan. For instance, a primary means of communication may be cellular phones, hard wire lines and the facilities intercom system, whereas the facilities alternate means (given interruption of primary means) may be the SHAred RESources.* Facilities may seek information about the National Communication System (NCS), which offers a wide range of National Security and Emergency Preparedness communications services, the Government Emergency Telecommunications Services (GETS), the Telecommunications Service Priority (TSP) Program, Wireless Priority Service (WPS), and SHARES. Other communication methods could include, but are not limited to, satellite phones, radio, and short wave radio. The Radio Amateur Civil Emergency Services (RACES)

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E0032 Cont.		is an integral part of emergency management operations.
E0033	(4) A method for sharing information and medical documentation for patients under the HHA's care, as necessary, with other health providers to maintain the continuity of care. (5) A means of providing information about the general condition and location of patients under the HHA's care as permitted under 45 CFR 164.510(b)(4).	Facilities are required to develop a method for sharing information and medical documentation for patients under the facility's care, as necessary, with other health care providers to maintain continuity of care. Such a system must ensure that information necessary to provide patient care is sent with an evacuated patient to the next care provider and would also be readily available for patients being sheltered in place. While the regulation does not specify timelines for delivering patient care information, facilities are expected to provide patient care information to receiving facilities during an evacuation, within a timeframe that allows for effective patient treatment and continuity of care. Facilities should not delay patient transfers during an emergency to assemble all patient reports, tests, etc. to send with the patient. Facilities should send all necessary patient information that is readily available and should include at least, patient name, age, DOB, allergies, current medications, medical diagnoses, current reason for admission (if inpatient), blood type, advance directives and next of kin/emergency contacts. There is no specified means (such as paper or electronic) for how facilities are to share the required information. HIPAA requirements are not suspended during a national or public health emergency. However, the HIPAA Privacy Rule specifically permits certain uses and disclosures of protected health information in emergency circumstances and for disaster relief purposes. Section 164.510 ''Uses and disclosures requiring an opportunity for the individual to agree to or to object,'' is part of the ''Standards for Privacy of Individually Identifiable Health Information,'' commonly known as ''The Privacy Rule.'' HIPAA Privacy Regulations at 45 CFR 164.510(b)(4), ''Use and disclosures for disaster relief purposes,'' establishes requirements for disclosing patient information to a public or private entity authorized by law or by its charter to assist in disaster relief efforts for purposes of notifying family members, personal representatives, or certain others of the patient's location or general condition.
E0034	(6) A means of providing information about the HHA's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.	Facilities, except for transplant *programs*, must have a means of providing information about the facility's needs and its ability to provide assistance to the authority having jurisdiction (local and State emergency management agencies, local and state public health departments, the Incident Command Center, the Emergency Operations Center, or designee). *Reporting of a Facility's Needs*

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E0034 Cont.		*Generally, in small community emergency disasters, reporting the facility's needs will be coordinated through developed processes to report directly to local and state emergency officials. Reporting needs may include but are not limited to: shortages in PPE; need to evacuate or transfer patients; requests for assistance in transport; temporarily loss of part or all facility function; and, staffing shortages.* *In large scale emergency disasters or pandemics, reporting of needs specific to a facility may be altered by local, state and federal public health and emergency management officials due to the potential volume of requests. Some emergency management officials at all levels of governance may require facilities to report specific data or slow reporting to manage volume. It is recommended that facilities verify their reporting requirements with their local Incident Command Structures or State Agencies.* *Dependent on the emergency event and the anticipated longevity, facilities may need to report select criteria such as in an EID outbreak or the number of patients' positive or persons under investigation (PUI). The facility's process should include monitoring by the facility's emergency management coordinator or designee of reporting requirements issued by CMS or other agencies with jurisdiction. Additional monitoring and reporting may be required by local and state public health agencies due to contact tracing requirements for extended periods of time or for time specific intervals. Facilities should identify local and state policies for reporting and contract tracing to ensure they have appropriate information to address requirements.* *Facilities should actively engage with their healthcare coalitions, associations, accrediting organizations and other stakeholders during the onset of any wide-spread emergency. As state and federal emergency organizations may become overwhelmed with requests, these stakeholders may be able to reconcile needs-requests for specific providers and suppliers. In situations in which a Presidential Declaration and a Public Health Emergency (PHE) have been declared, and Section 1135 Waivers may be granted, these stakeholders (healthcare coalitions, associations, accrediting organizations and others) may have the ability to request and streamline 1135 waiver requests for their members, dependent on the severity of the emergency.* *<u>Reporting of a Facility's Ability to Provide Assistance</u>* *During widespread disasters, reporting a facility's ability to provide assistance is critical within a community. Pre-planning and collaborating with emergency officials before an*

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E0034 Cont.		*emergency to determine what assistance may be necessary directly supports surge planning within a community. For instance, in preparation for a natural disaster such as a hurricane, pre-planning reporting criteria such as the facility's response-- e.g. closing the outpatient services in a forecasted natural disaster-- may facilitate the Incident Command as they would be aware of the operating status of the facility. Reporting the ability to provide assistance would also include pre-planning with public health and emergency officials in the local community to make them aware of what capabilities are available within the specific facility, e.g. number of beds, critical care equipment, staffing, etc.* *During widespread disasters, facilities may be required to report the following to local officials:* • *Ability to care for patients requiring transfer from different healthcare settings;* • *Availability of PPE;* • *Availability of staff who may be able to assist in a mass casualty incident;* • *Availability of electricity-dependent medical and assistive equipment, such as ventilators and other oxygen equipment (BiPAP, CPAP, etc.), renal replacement therapy machines (e.g., home and facility-based hemodialysis, peritoneal dialysis, continuous renal replacement therapy and other machines, etc.), and wheelchairs and beds.* **NOTE:** As defined by the Federal Emergency Management Administration (FEMA), an Incident Command System (ICS) is a management system designed to enable effective and efficient domestic incident management by integrating a combination of facilities, equipment, personnel, procedures, and communications operating within a common organizational structure. (FEMA, 2016). The industry, as well as providers/suppliers, use various terms to refer to the same function and we have used the term ''Incident Command Center'' to mean ''Emergency Operations Center'' or ''Incident Command Post.'' Local, State, Tribal and Federal emergency preparedness officials, as well as regional healthcare coalitions, can assist facilities in the identification of their Incident Command Centers and reporting requirements dependent on an emergency.
E0036	***§484.102 (d) Training and testing.*** The HHA must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.	*Training and Testing Program- General* An emergency preparedness training and testing program as specified in this requirement must be documented, reviewed and updated. The training and testing program must reflect the risks identified in the facility's risk assessment and be included in their emergency plan. For example, a facility that identifies flooding as a risk should also include policies and procedures in their emergency plan for closing or evacuating their facility and include these in their training and testing program. This would include, but is not limited to, training and

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E0036 Cont.		testing on how the facility will communicate the facility closure to required individuals and agencies, testing patient tracking systems and testing transportation procedures for safely moving patients to other facilities. Additionally, for facilities with multiple locations, such as multi-campus or multi-location hospitals, the facility's training and testing program must reflect the facility's risk assessment for each specific location. *Training Component* *Training refers to a facility's responsibility to provide education and instruction to staff, contractors, and facility volunteers to ensure all individuals are aware of the emergency preparedness program. For training requirements, the facility must have a process outlined within its emergency preparedness program which encompasses staff and volunteer training complementing the risk assessment. The training for staff should at a minimum include training related to the facility's policies and procedures. Facilities must maintain documentation of the training so that surveyors are able to clearly identify staff training and testing conducted. For example, facilities may have a sign-in roster of training conducted within their training files or inclusion of this training in their training program, or individual training certificates of completion within personnel records. A surveyor should be able to ask for a list of employees and to verify training on the emergency preparedness requirements as required under E-0037 (subsection (d)(1)(iii).* *Testing Component* *Testing requirements vary based on the provider type. Inpatient providers are required to conduct two testing exercises annually. Outpatient providers are required to conduct one testing exercise annually (that at least every two years their exercise must be a full-scale exercise)- Refer to E-0039 (subsection (d)(2)).* Testing is the concept in which training is operationalized and the facility is able to evaluate the effectiveness of the training as well as the overall emergency preparedness program. Testing includes conducting drills and/or exercises to test the emergency plan to identify gaps and areas for improvement. *Additionally, facilities should establish a process which includes participation of all staff in testing exercises over a period of time. Facilities are encouraged to consider their scheduled exercises and the appropriate departments to be included. For instance, if a clinically-relevant testing exercise is not necessarily applicable to some other departments or staff, then the staff which did not participate in one year should participate in the next testing exercise to ensure that over a period of time all shifts are*

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E0036 Cont.		*incorporated. Additionally, we are not specifying a facility to utilize all required equipment in the testing (drills) or a percentage of the patients/residents that would be included in these drills, however facilities should test their exercises according to how they would respond to the emergency would it be an actual real emergency.* *Under this standard, surveyors are to assess whether or not the facility has a training and testing program based on the facility's risk assessment and has incorporated its policies and procedures, as well as its communication plan within training required for staff and its testing exercises.*
E0037	(1) Training program. The HHA must do all of the following: (i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles. (ii) Provide emergency preparedness training at least every 2 years. (iii) Maintain documentation of all emergency preparedness training. (iv) Demonstrate staff knowledge of emergency procedures. (v) If the emergency preparedness policies and procedures are significantly updated, the [facility] must conduct training on the updated policies and procedures.	*Training Program- General* Facilities are required to provide initial training in emergency preparedness policies and procedures that are consistent with their roles in an emergency to all new and existing staff, individuals providing services under arrangement, and volunteers. This includes individuals who provide services on a per diem basis such as agency nursing staff and any other individuals who provide services on an intermittent basis and would be expected to assist during an emergency. *The training provided by the facility must be based on the facility's risk assessment policies and procedures as well as the communication plan. The intent is that staff, volunteers and individuals providing services at the facility are familiar and trained on the facility's processes for responding to an emergency. Training should include individual-based response activities in the event of a natural disasters, such as what the process is for staff in the event of a forecasted hurricane. It should also include the policies and procedures on how to shelter-in-place or evacuate. Training should include how the facility manages the continuity of care to its patient population, such as triage processes and transfer/discharge during mass casualty or surge events.* *Furthermore, the facility must train staff based on the facility's risk assessment. Training for staff should mirror the facility's emergency plan and should include training staff on procedures that are relevant to the hazards identified. For example, for EID's this may include proper use of PPE, assessing needs of patients and how to screen patients and provide care based on the facility's capacity and capabilities and communications regarding reporting and providing information on patient status with caregiver and family members.* Facilities should provide **initial emergency training during orientation** (or shortly thereafter) to ensure initial training is not delayed.

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E0037 Cont.		*Continued Training* *After the initial training has been conducted for staff, facilities must provide training on their facility's emergency plan at least every 2 years (except for LTC facilities which will still be required to provide training annually).* Facilities have the flexibility to determine the focus of their *initial and 2-year* training, as long as it aligns with the emergency plan and risk assessment. *Initial and subsequent* training should be modified *as needed and if the facility updates the policies and procedures to include but not limited to* incorporating any lessons learned from the most recent exercises *and* real-life emergencies that occurred in and during the review of the facility's emergency program, *we would expect the facility be able to demonstrate how they have updated the training as well*. For example, *the 2 year subsequent* training could include training staff on new evacuation procedures that were identified as a best practice and documented in the facility "After Action Report" (AAR) during the last emergency drill and were incorporated into the emergency plan during the program's review. While facilities are required to provide *initial and subsequent (at least every 2 years except for LTC facilities which will still be required to provide training annually)* training to all staff, it is up to the facility to decide what level of training each staff member will be required to complete based on an individual's involvement or expected role during an emergency. There may be core topics that apply to all staff, while certain clinical staff may require additional topics. For example, dietary staff who prepare meals may not need to complete annual training that is focused on patient evacuation procedures. Instead, the facility may provide training that focuses on the proper preparation and storage of food in an emergency. In addition, depending on specific staff duties during an emergency, a facility may determine that documented external training is sufficient to meet some or all of the facility's training requirements. For example, staff who work with radiopharmaceuticals may attend external training that teach staff how to handle radiopharmaceutical emergencies. It is up to the facility to decide if the external training meets the facility's requirements. *Facilities must also be able to demonstrate additional training when the emergency plan is significantly updated. Facilities which may have changed their emergency plan should plan to conduct initial training to all staff on the new or revised sections of the plan. If a facility determines the need to add additional policies and procedures based on a new risk identified in the facility's risk assessment, the facility must train all staff on the new policies and procedures and the staff responsibilities. Facilities are not required to re-train staff on the entire emergency plan, but can choose to train staff on the new or revised element of the*

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E0037 Cont.		*emergency preparedness program. For example, a facility identifies during an influenza outbreak that additional policies and procedures and adjustments to the risk assessment are needed to address a significant influx of patients/clients/residents. The facility identifies clinical locations in which contagious patients can be triaged in a manner to minimize exposure to non-infected individuals. The training for this new or revised policy can be done without needing to re-train staff on the entire program.* *Documentation Requirements* Facilities must maintain documentation of the *initial and subsequent (at least every 2 years except for LTC facilities which will still be required to provide training annually)* training for all staff. The documentation must include the specific training completed as well as the methods used for demonstrating knowledge of the training program. Facilities have flexibility in ways to demonstrate staff knowledge of emergency procedures. The method chosen is likely based on the training delivery method. For example: computer-based or printed self-learning packets may contain a test to demonstrate knowledge. If facilities choose instructor-led training, a question and answer session could follow the training. Regardless of the method, facilities must maintain documentation that training was completed and that staff are knowledgeable of emergency procedures. ***NOTE:** For ease of demonstrating compliance that the facility has updated its training program at least every 2 years, we recommend that facilities retain at a minimum, the past 2 cycles (generally 4 years) of emergency training documentation for both training and exercises for surveyor verification.*
E0039	**(2) Testing. The HHA must conduct exercises to test the emergency plan at least annually. The HHA must do the following:** (i) Participate in a full-scale exercise that is community-based; or (A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise every 2 years; or (B) If the HHA experiences an actual or man-made emergency that requires activation of the emergency plan, the HHA is exempt from engaging in its next required full-scale community-based or individual; facility-based functional exercise following the on-set of the emergency event. (ii) Conduct an additional exercise every 2 years, opposite the year of the full scale exercise or functional exercise under paragraph	*For outpatient providers: Facilities are required to only conduct one testing exercise on an annual basis, which may be either one community-based full-scale exercise, if available, or an individual facility-based functional exercise. The opposite years (every other year opposite of the full-scale exercises), these providers may choose the testing exercise of their choice, which can include either another full-scale, individual facility-based, a mock disaster drill (using mock patients), tabletop exercise or workshop which includes a facilitator.* *Understanding Exercises and Terminology* *Similar to the training expectations outlined under E-0037 or (d)(1), such as hospitals at 482.15(d)(1), a facility's testing exercises require they be based on the individual facility's risk assessment, policies and procedures, and communication plan and support the patient population it serves. Testing exercises should vary, based on the facility's requirements, by*

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E0039 Cont.	(d)(2)(i) of this section is conducted, that may include, but is not limited to the following: (A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or (B) A mock disaster drill; or (C) A tabletop exercise or workshop that is led by a facilitator and included a group discussion, using a narrated, clinically relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. (iii) Analyze the HHA's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the HHA's emergency plan as needed.	*cycles and frequency of testing. The intent is that testing exercise provide a comprehensive testing and training for staff, volunteers, and individuals providing services under arrangement as well community partners. Testing exercises must be based on the facility's identified hazards, to include natural or man-made disasters. This should include EID outbreaks.* *Facilities are expected to test their response to emergency events as outlined within their comprehensive emergency preparedness program. Testing exercises should not test the same scenario year after year or the same response processes. The intent is to identify gaps in the facility's emergency program as it relates to responding to various emergencies and ensure staff are knowledgeable on the facility's program. In the event gaps are identified, facilities should update their emergency programs as outlined within the requirements for After-Action Review (AAR).* *Full-Scale and Community Based Exercises* As the term full-scale exercise may vary by sector, facilities are not required to conduct a full-scale exercise as defined by FEMA or DHS's Homeland Security Exercise and Evaluation Program (HSEEP). For the purposes of this requirement, a full scale exercise is defined and accepted as any operations-based exercise (drill, functional, or full-scale exercise) that assesses a facility's functional capabilities by simulating a response to an emergency that would impact the facility's operations and their given community. *Full-scale exercises in the industry setting are large exercises in which multiple agencies participate and may only be available every three to five years; while functional exercises are similar in nature, but may not involve as many participants and in which each agency can choose its priorities to test within the confines of the exercise. Therefore, full-scale can include what is known as a "functional" exercise or drill in the industry and according to HSEEP.* A full-scale exercise is also an operations-based exercise that typically involves multiple agencies, jurisdictions, and disciplines performing functional or operational elements. There is also definition for "community" as it is subject to variation based on geographic setting, (e.g. rural, suburban, urban, etc.), state and local agency roles and responsibilities, types of providers in a given area in addition to other factors. In doing so, facilities have the flexibility to participate in and conduct exercises that more realistically reflect the risks and composition of their communities. Facilities are expected to consider their physical location, agency and other facility responsibilities and needs of the community when planning or participating in their exercises. The term could, however, mean entities within a state or multi-state region.

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E0039 Cont.		In many areas of the country, State and local agencies (emergency management agencies and health departments) and some regional entities, such as healthcare coalitions may conduct an annual full-scale, community-based exercise in an effort to more broadly assess community-wide emergency planning, potential gaps, and the integration of response capabilities in an emergency. Facilities should actively engage these entities to identify potential opportunities, as appropriate, as they offer the facility the opportunity to not only assess their emergency plan but also better understand how they can contribute to, coordinate with, and integrate into the broader community's response during an emergency. They also provide a collective forum for assessing their communications plans to ensure they have the appropriate contacts and understand how best to engage and communicate with their state and local public health and emergency management agencies and other relevant partners, such as a local healthcare coalition, during an emergency. Facilities are expected to contact their local and state agencies and healthcare coalitions, where appropriate, to determine if an opportunity exists and determine if their participation would fulfill this requirement. It is also important to note that agencies and or healthcare coalitions conducting these exercises will not have the resources to fulfill individual facility requirements and thus will only serve as a conduit for broader community engagement and coordination prior to, during and after the full-scale community-based exercise. Facilities are responsible for resourcing their participation and ensuring that all requisite documentation is developed and available to demonstrate their compliance with this requirement. Facilities are encouraged to engage with their area Health Care Coalitions (HCC) (partnerships between healthcare, public health, EMS, and emergency management) to explore integrated opportunities. Health Care Coalitions (HCCs) are groups of individual health care and response organizations who collaborate to ensure each member has what it needs to respond to emergencies and planned events. HCCs plan and conduct coordinated exercises to assess the health care delivery systems readiness. There is value in participating in HCCs for participating in strategic planning, information sharing and resource coordination. HCC's do not coordinate individual facility exercises, but rather serve as a conduit to provide an opportunity for other provider types to participate in an exercise. HCCs should communicate exercise plans with local and state emergency preparedness agencies and HCCs will benefit the entire community's preparedness. In addition, CMS does not regulate state and local government disaster planning agencies. It is the sole responsibility of the facility to be in compliance. *Facilities which determine that a full-scale community-based exercise will be planned for the*

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E0039 Cont.		*facility's exercise requirement must also ensure that the exercise scenario developed is identified within the facility's risk assessment. While generally local and state emergency officials plan emergency exercises which could occur within the geographic location or community, facilities must ensure that participation in the exercise would adequately test the facility's emergency program (specifically its policies and procedures and communication plan). For instance, in the event the local or state full-scale exercise is testing the response to a major multiple car accident requiring airlift transfers of patients, a LTC facility or ESRD facility may not be impacted by this type of disaster or require activation of its emergency program, therefore the exercise may not be as appropriate. In this case, the facility could document that the scenario offered in this full-scale community based exercise and that the facility conducted an individual facility-based exercise to test its emergency program instead. However, if the state or local exercise is testing an EID outbreak, all facilities in the community may be impacted, therefore participation would be strongly recommended.* *The intent behind full-scale and community based exercises is to ensure the facility's emergency program and response capabilities complement the local and state emergency plans and support an integrated response while protecting the health and safety of patients.* *Individual Facility-Based Exercises:* Facilities that are not able to identify a full-scale community-based exercise, can instead fulfill this part of their requirement by either conducting an individual facility-based exercise, documenting an emergency that required them to fully activate their emergency plan, or by conducting a smaller community-based exercise with other nearby facilities. Facilities that elect to develop a small community-based exercise have the opportunity to not only assess their own emergency preparedness plans but also better understand the whole community's needs, identify critical interdependencies and or gaps and potentially minimize the financial impact of this requirement. For example, a LTC facility, a hospital, an ESRD facility, and a home health agency, all within a given area, could conduct a small community-based exercise to assess their individual facility plans and identify interdependencies that may impact facility evacuations and or address potential surge scenarios due to a prolonged disruption in dialysis and home health care services. Those that elect to conduct a community-based exercise should make an effort to contact their local/state emergency officials and healthcare coalitions, where appropriate, and offer them the opportunity to attend as they can provide valuable insight into the broader emergency planning and response activities in their given area. *Community partners are considered any emergency management officials (fire, police, emergency medical services, etc.) for full-scale and community-based exercises, however can also mean community partners that assist in an*

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E0039 Cont.		*emergency, such as surrounding providers and suppliers.* *Participation* *While the regulations do not specify a minimum number of staff, or the roles of staff in the exercises, it is strongly encouraged that facility leadership and department heads participate in exercises. If an exercise is conducted at the individual facility-based level and is testing a particular clinical area, staff who work in this clinical area should participate in the exercise for a clear understanding of their roles and responsibilities.* *Additionally, facilities can review which members of staff participated in the previous exercise, and include those who did not participate in the subsequent exercises to ensure all staff members have an opportunity to participate and gain insight and knowledge. Facilities can use a sign-in roster for the exercise to substantiate staff participation. A sufficient number of staff should participate in the exercise to test the scenario and thoroughly assess the risk, policy, procedure, or plan being tested.* Facilities that conduct an individual facility-based exercise will need to demonstrate how it addresses any risk(s) identified in its risk assessment. For example, an inpatient facility might test their policies and procedures for a flood that may require the evacuation of patients to an external site or to an internal safe "shelter-in-place" location (e.g. foyer, cafeteria, etc.) and include requirements for patients with access and functional needs and potential dependencies on life-saving electricity-dependent medical equipment. An outpatient facility, such as a home health provider, might test its policies and procedures for a flood that may require it to rapidly locate its on-duty staff, assess the acuity of its patients to determine those that may be able to shelter-in-place or require hospital admission, communicate potential evacuation needs to local agencies, and provide medical information to support the patient's continuity of care. *If the facility uses fire drills based on their risk assessment (e.g. wild fires) as a full-scale community based exercise in one given year (which is also a requirement for some providers/suppliers under Life Safety Code), the facility is encouraged to choose in the following year a different hazard in their risk assessment to conduct an exercise in order to ensure variability in the training and testing program. The intent of the requirements under the emergency preparedness condition for participation/condition for coverage, or requirement for LTC, is to test the facility's ability to respond to any emergency outlined within their risk assessment. The purpose of testing the facility's emergency program is to identify gaps in response which could result in adverse events for patients and staff and to adjust plans, policies and procedures to ensure patient and staff safety is maintained*

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E0039 Cont.		*regardless of the type of emergency which occurs.* *Table-Top Exercise and Workshops* *Facilities are also required to conduct an "exercise of choice" or, for some, only conduct a table-top exercise (TTX) or workshop. Please refer back to the definition section above. TTX's or workshops are expected to be group discussions led by a facilitator. We are not defining whether or not the facilitator must be a staff member or contracted service. Some facilities may find that a specific department lead may be best suited dependent on the scenario being tested, while other facilities may find an outside facilitator may be more appropriate to facilitate.* *The intent behind TTX's or workshops is to test an exercise based on the facility's risk assessment. Some facilities may find it prudent to conduct a TTX or workshop prior to a full-scale or individual-facility based exercise in order to identify potential gaps or challenges and then update the policies and procedures accordingly to resolve the potential issue. This would allow for facilities to test their adjustments during a full-scale or individual facility-based exercise to determine if the corrective action was appropriate.* *After-Action Reviews* Each facility is responsible for documenting their compliance and ensuring that this information is available for review at any time for a period of no less than three (3) years. Facilities should also document the lessons learned following their tabletop and full-scale exercises and real-life emergencies and demonstrate that they have incorporated any necessary improvements in their emergency preparedness program. Facilities may complete an after action review process to help them develop an actionable after action report (AAR). The process includes a roundtable discussion that includes leadership, department leads and critical staff who can identify and document lessons learned and necessary improvements in an official AAR. The AAR, at a minimum, should determine 1) what was supposed to happen; 2) what occurred; 3) what went well; 4) what the facility can do differently or improve upon; and 5) a plan with timelines for incorporating necessary improvement. Lastly, facilities that are a part of a healthcare system, can elect to participate in their system's integrated and unified emergency preparedness program and exercises. However, those that do will still be responsible for documenting and demonstrating their individual facility's compliance with the exercise and training requirements.

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E0039 Cont.		*Exemption based on Actual Emergency* Finally, an actual emergency event or response of sufficient magnitude that requires activation of the relevant emergency plans meets the *full-scale* exercise requirement and exempts the facility for engaging in *their next required community-based full-scale exercise or individual, facility-based exercise* for following the actual event; and facilit*ies* must be able to demonstrate this through written documentation. *With the changed requirements as a result of the 2019 Burden Reduction final rule (81 FR 63859) for outpatient providers required to conduct full-scale exercises only every other year, opposite of their exercises of choice, these facilities are exempt from their next required full-scale or individual facility-based exercise. For inpatient providers, the full-scale exercise would be annually. The intent is to ensure that facilities conduct at least one exercise per year.* *For example, in the event an outpatient provider conducts a required full-scale community based exercise in January 2019, and completed the optional exercise of its choice in January 2020, and experiences an actual emergency in March 2020, the outpatient provider is exempt from next required full-scale community based or individual facility based exercise in January 2021. If the outpatient provider conducts a required full-scale community based exercise in January 2020, and has the optional exercise of its choice scheduled for January 2021, and experiences an actual emergency in March 2020, the outpatient provider is exempt from next required full-scale community based or individual facility based exercise in January 2022, but must still conduct the required exercise of choice in January 2021. The exemption is based on the facility's required full-scale exercise, not the exercise of choice, therefore the exemption may not be applicable until two years following the activation of the emergency plan, dependent on the cycle the facility has determined and the actual emergency event.* *The exercises of choice, which allow facilities to choose one (e.g., another full-scale/individual facility based; mock disaster drill; or table top exercises) are not considered as the required full-scale community based or individual facility based exercises. Facilities which may have schedule full-scale exercises annually as part of their licensure or accrediting organizations requirements, would be exempt from their next required annual full-scale exercise. Facilities which have a full-scale exercise scheduled as part of their exercise of choice for the opposite years would be exempt from their next scheduled exercise following an emergency, which would still be July 2021 (using the above example).* *Facilities must document that they had activated their emergency program based on an actual emergency. Documentation may include, but is not limited to: a section 1135 waiver*

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E0039 Cont.		*issued to the facility (time limited and event-specific); documentation alerting staff of the emergency; documentation of facility closures; meeting minutes which addressed the time and event specific information. The facility must also complete an after action review and integrated corrective actions into their emergency preparedness program.* *Resources* For additional information and tools, please visit the CMS *Quality, Safety & Oversight Group* Emergency Preparedness website at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/index.html or ASPR TRACIE. ***NOTE:*** *We recommend facilities to retain, at a minimum, the past 2 cycles (generally 2 years for inpatient providers and 4 years for outpatient providers of emergency testing exercise documentation. This would allow surveyors to assess compliance on the cycle of testing required for outpatient providers.*
E0042	***§484.102 (e) Integrated healthcare systems.*** If a HHA is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the HHA may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following; (1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program. (2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered. (3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program. (4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a) (2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include all of the following: (i) A documented community-based risk assessment,	Healthcare systems that include multiple facilities that are each separately certified as a Medicare-participating provider or supplier have the option of developing a unified and integrated emergency preparedness program that includes all of the facilities within the healthcare system instead of each facility developing a separate emergency preparedness program. If an integrated healthcare system chooses this option, each certified facility in the system may elect to participate in the system's unified and integrated emergency program or develop its own separate emergency preparedness program. It is important to understand that healthcare systems are not required to develop a unified and integrated emergency program. Rather it is a permissible option. In addition, the separately certified facilities within the healthcare system are not required to participate in the unified and integrated emergency preparedness program. It is simply an option for each facility. If this option is taken, the healthcare system's unified emergency preparedness program should be updated each time a facility enters or leaves the healthcare system's program. If a healthcare system elects to have a unified emergency preparedness program, the integrated program must demonstrate that each separately certified facility within the system that elected to participate in the system's integrated program actively participated in the development of the program. Therefore, each facility should designate personnel who will collaborate with the healthcare system to develop the plan. The unified and integrated plan should include documentation that verifies each facility participated in the development of the plan. This could include the names of personnel at each facility who assisted in the development of the plan and the minutes from planning meetings. All

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E0042 Cont.	utilizing an all-hazards approach. (ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach. (5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that met the requirements of paragraphs (c) and (d) of this section, respectively.	components of the emergency preparedness program that are required to be reviewed and updated at least *every 2 years* must include all participating facilities. Again, each facility must be able to prove that it was involved in the annual reviews and updates of the program. The healthcare system and each facility must document each facility's active involvement with the reviews and updates, as applicable. A unified program must be developed and maintained in a manner that takes into account the unique circumstances, patient populations, and services offered at each facility participating in the integrated program. For example, for a unified plan covering both a hospital and a LTC facility, the emergency plan must account for the residents in the LTC facility as well as those patients within a hospital, while taking into consideration the difference in services that are provided at a LTC facility and a hospital. The unique circumstances that should be addressed at each facility would include anything that would impact operations during an emergency, such as the location of the facility, resources such as the availability of staffing, medical supplies, subsistence, patients' and residents' varying acuity and mobility at the different types of facilities in a unified healthcare system, etc. Each separately certified facility must be capable of demonstrating during a survey that it can effectively implement the emergency preparedness program and demonstrate compliance with all emergency preparedness requirements at the individual facility level. Compliance with the emergency preparedness requirements is the individual responsibility of each separately certified facility. The unified emergency preparedness program must include a documented community–based risk assessment and an individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach. This is especially important if the facilities in a healthcare system are located across a large geographic area with differing weather conditions. Lastly, the unified program must have a coordinated communication plan and training and testing program. For example, if the unified emergency program incorporates a central point of contact at the "system" level who assists in coordination and communication, such as during an evacuation, each facility must have this information outlined within its individual plan. This type of integrated healthcare system emergency program should focus the training and exercises to ensure communication plans and reporting mechanisms are seamless to the

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E0042 Cont.		emergency management officials at state and local levels to avoid potential miscommunications between the system and the multiple facilities under its control. The training and testing program in a unified emergency preparedness program must be developed considering all of the requirements of each facility type. For example, if a healthcare system includes, hospitals, LTC facilities, ESRD facilities and ASCs, then the unified training and testing programs must meet all of the specific regulatory requirements for each of these facility types. Because of the many different configurations of healthcare systems, from the different types of facilities in the system, to the varied locations of the facilities, it is not possible to specify how unified training and testing programs should be developed. There is no "one size fits all" model that can be prescribed. However, if the system decides to develop a unified and integrated training and testing program, the training and testing must be developed based on the community and facility based hazards assessments at each facility that is participating in the unified emergency preparedness program. Each facility must maintain individual training records of staff and records of all required training exercises.

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G940	**§484.105 Condition of Participation: Organization and administration of Services.** The HHA must organize, manage, and administer its resources to attain and maintain the highest practicable functional capacity, including providing optimal care to achieve the goals and outcomes identified in the patient's plan of care, for each patient's medical, nursing, and rehabilitative needs. The HHA must assure that administrative and supervisory functions are not delegated to another agency or organization, and all services not furnished directly are monitored and controlled. The HHA must set forth, in writing, its organizational structure, including lines of authority, and services furnished.	**§484.105** The roles of the governing body, administrator and clinical manager may not be delegated. In other words, an HHA must ensure that the responsibilities of the governing body, administrator and clinical manager (for the day-to-day operation of the HHA) are not relinquished to another person or organization on an on-going basis. This does not apply to periodic "acting" employees in the absence of the administrator or clinical manager. In addition, the use of payroll services, OASIS transmission contractors, and personnel training programs are not considered to be delegation of administrative and supervisory functions; these are service contracts that the agency may use to optimize administrative and supervisory efficiencies.
G942	**§484.105(a) Standard: Governing body.** A governing body (or designated persons so functioning) must assume full legal authority and responsibility for the agency's overall management and operation, the provision of all home health services, fiscal operations, review of the agency's budget and its operational plans, and its quality assessment and performance improvement program.	***§484.105(a)*** *An HHA may establish a governing body composed of individuals of its choosing. The individuals that comprise the governing body are those who have the legal authority to assume responsibility for assuring that management and operation of the HHA is effective and operating within all legal bounds (as noted in 82 FR 4548).*
G946	***§484.105(b)(1) Standard: Administrator. The administrator must:*** (i) Be appointed by and report to the governing body;	***§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	***[§484.105(b)(1) The administrator must:]*** (ii) Be responsible for all day-to-day operations of the HHA;	***§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	***[§484.105(b)(1) The administrator must:]*** (iii) Ensure that a clinical manager as described in paragraph (c) of this section is available during all operating hours;	**§484.105(b)(1)(iii)** "Operating hours" include all hours which the HHA is open and providing care to patients.
G952	***[§484.105(b)(1) The administrator must:]*** (iv) Ensure that the HHA employs qualified personnel, including assuring the development of personnel qualifications and policies.	

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G954	**§484.105(b)(2)** When the administrator is not available, a qualified, pre-designated person, who is authorized in writing by the administrator and the governing body, assumes the same responsibilities and obligations as the administrator. The pre-designated person may be the clinical manager as described in paragraph (c) of this section.	**§484.105(b)(2)** "Pre-designation" means that the individual who is responsible for fulfilling the role of the administrator in his/her absence is established in advance and approved by the governing body. *Pre-designation needs to be by both the administrator and the governing body. The goal of this requirement is to provide management continuity within the HHA to the greatest degree possible. HHA staff should know and be able to verbalize upon interview who the pre-designated individual(s) is/are for this role (82 FR 4549).*
G956	**§484.105(b)(3)** The administrator or a pre-designated person is available during all operating hours.	**§484.105(b)(3)** "Available" means physically present at the agency or able to be contacted via telephone or other electronic means.
G958	**§484.105(c) Standard: Clinical manager.** One or more qualified individuals must provide oversight of all patient care services and personnel. Oversight must include the following-	**§484.105(c)** *§484.115(c) provides that a clinical manager must be a licensed physician, physical therapist, speech-language pathologist, occupational therapist, audiologist, social worker, or a registered nurse.*
G960	***[§484.105(c) Standard: Clinical manager…Oversight must include the following-]*** (1) Making patient and personnel assignments,	
G962	***[§484.105(c) Standard: Clinical manager…Oversight must include the following-]*** (2) Coordinating patient care,	
G964	***[§484.105(c) Standard: Clinical manager…Oversight must include the following-]*** (3) Coordinating referrals,	
G966	***[§484.105(c) Standard: Clinical manager…Oversight must include the following-]*** (4) Assuring that patient needs are continually assessed, and	
G968	***[§484.105(c) Standard: Clinical manager…Oversight must include the following-]*** (5) Assuring the development, implementation, and updates of the individualized plan of care.	
G972	**§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.	**§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.*

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G974	(2) The parent HHA provides direct support and administrative control of its branches.	**§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.
G976	**§484.105(e) Standard: Services under arrangement.** (1) The HHA must ensure that all services furnished under arrangement provided by other entities or individuals meet the requirements of this part and the requirements of section 1861(w) of the Act (42 U.S.C. 1395x(w)).	
G978	**§484.105(e)(2)** An HHA must have a written agreement with another agency, with an organization, or with an individual when that entity or individual furnishes services under arrangement to the HHA's patients. The HHA must maintain overall responsibility for the services provided under arrangement, as well as the manner in which they are furnished. The agency, organization, or individual providing services under arrangement may not have been: (i) Denied Medicare or Medicaid enrollment; (ii) Been excluded or terminated from any federal health care program or Medicaid; (iv) Been debarred from participating in any government program.	
G980	**§484.105(e)(3)** The primary HHA is responsible for patient care, and must conduct and provide, either directly or under arrangements, all services rendered to patients.	**§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-

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G980 Cont.		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	**§484.105(f) Standard: Services furnished.** (1) Skilled nursing services and at least one other therapeutic service (physical therapy, speech-language pathology, or occupational therapy; medical social services; or home health aide services) are made available on a visiting basis, in a place of residence used as a patient's home. An HHA must provide at least one of the services described in this subsection directly, but may provide the second service and additional services under arrangement with another agency or organization.	**§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	**§484.105(f)(2)** All HHA services must be provided in accordance with current clinical practice guidelines and accepted professional standards of practice.	**§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	**§484.105(g) Standard: Outpatient physical therapy or speech-language pathology services.** An HHA that furnishes outpatient physical therapy or speech-language pathology services must meet all of the applicable conditions of this part and the additional health and safety requirements set forth in §485.711, §485.713, §485.715, §485.719, §485.723, and §485.727 of this chapter to implement section 1861(p) of the Act.	**§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.*

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G986 Cont.		If an HHA provides outpatient physical therapy services or speech-language pathology services it must also meet the conditions of the regulations summarized below*, among others*, as applicable: §485.711 Condition of participation: Plan of care and physician involvement: For each patient in need of outpatient physical therapy or speech pathology services, there is a written plan of care established and periodically reviewed by a physician, or by a physical therapist or speech pathologist respectively. §485.713 Condition of participation: Physical therapy services: If the HHA offers physical therapy services, it provides an adequate program of physical therapy and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives. §485.715 Condition of participation: Speech pathology services: If speech pathology services are offered, the HHA provides an adequate program of speech pathology and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives. §485.719 Condition of participation: Arrangements for physical therapy and speech pathology services to be performed by other than salaried organization personnel *The following two CoPs, §485.723 and §485.727,* are applicable when specialized rehabilitation space and equipment is owned, leased, operated, contracted for, or arranged for at sites under the HHA's control and when the HHA bills the Medicare/Medicaid programs for services rendered at these sites.] §485.723 Condition of participation: Physical environment. The building housing the HHA is constructed, equipped, and maintained to protect the health and safety of patients, personnel, and the public and provides a functional, sanitary, and comfortable environment. §485.727 Condition of participation: Emergency preparedness. The HHA must establish and maintain an emergency preparedness program.
G988	**§484.105(h) Standard: Institutional planning.** The HHA, under the direction of the governing body, prepares an overall plan and a budget that includes an annual operating budget and capital expenditure plan. (1) *Annual operating budget.* There is an annual operating budget that includes all anticipated income and expenses related to items that	

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G988 Cont.	would, under generally accepted accounting principles, be considered income and expense items. However, it is not required that there be prepared, in connection with any budget, an item by item identification of the components of each type of anticipated income or expense. (2) *Capital expenditure plan.* (i) There is a capital expenditure plan for at least a 3-year period, including the operating budget year. The plan includes and identifies in detail the anticipated sources of financing for, and the objectives of, each anticipated expenditure of more than $600,000 for items that would under generally accepted accounting principles, be considered capital items. In determining if a single capital expenditure exceeds $600,000, the cost of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition, improvement, modernization, expansion, or replacement of land, plant, building, and equipment are included. Expenditures directly or indirectly related to capital expenditures, such as grading, paving, broker commissions, taxes assessed during the construction period, and costs involved in demolishing or razing structures on land are also included. Transactions that are separated in time, but are components of an overall plan or patient care objective, are viewed in their entirety without regard to their timing. Other costs related to capital expenditures include title fees, permit and license fees, broker commissions, architect, legal, accounting, and appraisal fees; interest, finance, or carrying charges on bonds, notes and other costs incurred for borrowing funds. (ii) If the anticipated source of financing is, in any part, the anticipated payment from title V (Maternal and Child Health Services Block Grant) or title XVIII (Medicare) or title XIX (Medicaid) of the Social Security Act, the plan specifies the following: (A) Whether the proposed capital expenditure is required to conform, or is likely to be required to conform, to current standards, criteria, or plans developed in accordance with the Public Health Service Act or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963. (B) Whether a capital expenditure proposal has been submitted to the designated planning agency for approval in accordance with section 1122 of the Act (42 U.S.C. 1320a-1) and implementing regulations. (C) Whether the designated planning agency has approved or disapproved the proposed capital expenditure if it was presented to that agency.	

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G988 Cont.	(3) *Preparation of plan and budget.* The overall plan and budget is prepared under the direction of the governing body of the HHA by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff (if any) of the HHA. (4) *Annual review of plan and budget.* The overall plan and budget is reviewed and updated at least annually by the committee referred to in paragraph (i)(3) of this section under the direction of the governing body of the HHA.	

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G1008	**§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.	***§484.110*** *The HHA must use the information contained in each medical record to assure that safe care is delivered to each HHA patient. In accordance with the provisions of the Patient rights Condition at §484.50(c)(6), the HHA must ensure the confidentiality of each patient's clinical record.* *The manner and degree of noncompliance identified in relation to the standard level tags for §484.110 may result in substantial noncompliance with this CoP, requiring citation at the condition level.*
G1012	***§484.110(a) Standard: Contents of clinical record. The record must include:*** (1) The patient's current comprehensive assessment, including all of the assessments from the most recent home health admission, clinical notes, plans of care, and physician or allowed practitioner orders;	
G1014	***[§484.110(a) Standard: Contents of clinical record. The record must include:]*** (2) All interventions, including medication administration, treatments, and services, and responses to those interventions;	**§484.110(a)(2)** "All interventions" refers to those interventions performed by the HHA.
G1016	***[§484.110(a) Standard: Contents of clinical record. The record must include:]*** (3) Goals in the patient's plans of care and the patient's progress toward achieving them;	
G1018	***[§484.110(a) Standard: Contents of clinical record. The record must include:]*** (4) Contact information for the patient, the patient's representative (if any), and the patient's primary caregiver(s);	
G1020	***[§484.110(a) Standard: Contents of clinical record. The record must include:]*** (5) Contact information for the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA; and	**§484.110(a)(5)** If the patient identifies an attending physician (whether it is the responsible HHA physician or another physician) who will resume their care after the HHA episode, the contact information of the physician should be included in the clinical record.
G1022	***[§484.110(a) Standard: Contents of clinical record. The record must include:]*** (6)(i) A completed discharge summary that is sent to the primary care practitioner or other health care professional who will	**§484.110(a)(6)** Discharge summaries typically contain the following items: • Admission and discharge dates; • Physician responsible for the home health plan of care;

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G1022 Cont.	be responsible for providing care and services to the patient after discharge from the HHA (if any) within 5 business days of the patient's discharge; or (ii) A completed transfer summary that is sent within 2 business days of a planned transfer, if the patient's care will be immediately continued in a health care facility; or (iii) A completed transfer summary that is sent within 2 business days of becoming aware of an unplanned transfer, if the patient is still receiving care in a health care facility at the time when the HHA becomes aware of the transfer.	• Reason for admission to home health; • Type of services provided and frequency of services; • Laboratory data; • Medications the patient is on at the time of discharge; • Patient's discharge condition; • Patient outcomes in meeting the goals in the plan of care; and • Patient and family post-discharge instructions. A discharge summary must be sent to the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any) within five (5) business days of the date of the order for discharge from the responsible physician. The contents of a transfer summary typically contain the same components as a discharge summary.
G1024	**§484.110(b) Standard: Authentication.** All entries must be legible, clear, complete, and appropriately authenticated, dated, and timed. Authentication must include a signature and a title (occupation), or a secured computer entry by a unique identifier, of a primary author who has reviewed and approved the entry.	
G1026	**§484.110(c) Standard: Retention of records.** (1) Clinical records must be retained for 5 years after the discharge of the patient, unless state law stipulates a longer period of time. (2) The HHA's policies must provide for retention of clinical records even if it discontinues operation. When an HHA discontinues operation, it must inform the state agency where clinical records will be maintained.	
G1028	**§484.110(d) Standard: Protection of records.** The clinical record, its contents, and the information contained therein must be safeguarded against loss or unauthorized use. The HHA must be in compliance with the rules regarding personal health information set out at 45 CFR parts 160 and 164.	**§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*

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G1028 Cont.		*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, a*ll 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.*
G1030	**§484.110(e) Standard: Retrieval of clinical records.** A patient's clinical record (whether hard copy or electronic form) must be made available to a patient, free of charge, upon request at the next home visit, or within 4 business days (whichever comes first).	

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G1050	**§484.115 Condition of Participation: Personnel qualifications** HHA staff are required to meet the following standards:	***§484.115*** *The manner and degree of noncompliance identified in relation to the standard level tags for §484.115 may result in substantial noncompliance with this CoP, requiring citation at the condition level.*
G1052	**§484.115(a) Standard: Administrator, home health agency.** (1) For individuals that began employment with the HHA prior to July 13, 2017, a person who: (i) Is a licensed physician; (ii) Is a registered nurse; or (iii) Has training and experience in health service administration and at least 1 year of supervisory administrative experience in home health care or a related health care program. (2) For individuals that begin employment with an HHA on or after July 13, 2017, a person who: (i) Is a licensed physician, a registered nurse, or holds an undergraduate degree; and (ii) Has experience in health service administration, with at least 1 year of supervisory or administrative experience in home health care or a related health care program.	**§484.115(a)(2)** An "undergraduate degree" means a bachelor's degree or an associate's degree.
G1054	**§484.115(b) Standard: Audiologist.** A person who: (1) Meets the education and experience requirements for a Certificate of Clinical Competence in audiology granted by the American Speech-Language-Hearing Association; or (2) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.	
G1056	**§484.115(c) Standard: Clinical manager.** A person who is a licensed physician, physical therapist, speech-language pathologist, occupational therapist, audiologist, social worker, or a registered nurse.	
G1058	**§484.115(d) Standard: Home health aide.** A person who meets the qualifications for home health aides specified in section 1891(a) (3) of the Act and implemented at §484.80.	

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G1060	**§484.115(e) Standard: Licensed practical (vocational) nurse.** A person who has completed a practical (vocational) nursing program, is licensed in the state where practicing, and who furnishes services under the supervision of a qualified registered nurse.	
G1062	**§484.115(f) Standard: Occupational therapist. A person who –** (1) (i) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the state in which practicing, unless licensure does not apply; (ii) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA), or successor organizations of ACOTE; and (iii) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT). (2) On or before December 31, 2009— (i) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the state in which practicing; or (ii) When licensure or other regulation does not apply— (A) Graduated after successful completion of an occupational therapist education program accredited by the accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or successor organizations of ACOTE; and (B) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc., (NBCOT). (3) On or before January 1, 2008— (i) Graduated after successful completion of an occupational therapy program accredited jointly by the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or (ii) Is eligible for the National Registration Examination of the American Occupational Therapy Association or the National Board for	

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G1062 Cont.	Certification in Occupational Therapy. (4) On or before December 31, 1977— (i) Had 2 years of appropriate experience as an occupational therapist; and (ii) Had achieved a satisfactory grade on an occupational therapist proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service. (5) If educated outside the United States, must meet both of the following: (i) Graduated after successful completion of an occupational therapist education program accredited as substantially equivalent to occupational therapist entry level education in the United States by one of the following: (A) The Accreditation Council for Occupational Therapy Education (ACOTE). (B) Successor organizations of ACOTE. (C) The World Federation of Occupational Therapists. (D) A credentialing body approved by the American Occupational Therapy Association. (E) Successfully completed the entry level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT). (ii) On or before December 31, 2009, is licensed or otherwise regulated, if applicable, as an occupational therapist by the state in which practicing.	
G1064	**§484.115(g) Standard: Occupational therapy assistant. A person who—** (1) Meets all of the following: (i) Is licensed or otherwise regulated, if applicable, as an occupational therapy assistant, by the state in which practicing, unless licensure does apply; or (ii) Graduated after successful completion of an occupational therapy assistant education program accredited by the Accreditation Council for Occupational Therapy Education, (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or its successor organizations. (iii) Is eligible to take or successfully completed the entry-level	

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G1064 Cont.	certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT). (2) On or before December 31, 2009— (i) Is licensed or otherwise regulated as an occupational therapy assistant, if applicable, by the state in which practicing; or any qualifications defined by the state in which practicing, unless licensure does not apply; or (ii) Must meet both of the following: (A) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association. (B) After January 1, 2010, meets the requirements in paragraph (f)(1) of this section. (3) After December 31, 1977 and on or before December 31, 2007— (i) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association; or (ii) Completed the requirements to practice as an occupational therapy assistant applicable in the state in which practicing. (4) On or before December 31, 1977— (i) Had 2 years of appropriate experience as an occupational therapy assistant; and (ii) Had achieved a satisfactory grade on an occupational therapy assistant proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service. (5) If educated outside the United States, on or after January 1, 2008— (i) Graduated after successful completion of an occupational therapy assistant education program that is accredited as substantially equivalent to occupational therapist assistant entry level education in the United States by— (A) The Accreditation Council for Occupational Therapy Education (ACOTE). (B) Its successor organizations.	

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G1064 Cont.	(C) The World Federation of Occupational Therapists. (D) By a credentialing body approved by the American Occupational Therapy Association; and (E) Successfully completed the entry level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT). (ii) [Reserved]	
G1066	**§484.115(h) Standard: Physical therapist.** A person who is licensed, if applicable, by the state in which practicing, unless licensure does not apply and meets one of the following requirements: (1)(i) Graduated after successful completion of a physical therapist education program approved by one of the following: (A) The Commission on Accreditation in Physical Therapy Education (CAPTE). (B) Successor organizations of CAPTE. (C) An education program outside the United States determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or an organization identified in 8 CFR 212.15(e) as it relates to physical therapists. (ii) Passed an examination for physical therapists approved by the state in which physical therapy services are provided. (2) On or before December 31, 2009— (i) Graduated after successful completion of a physical therapy curriculum approved by the Commission on Accreditation in Physical Therapy Education (CAPTE); or (ii) Meets both of the following: (A) Graduated after successful completion of an education program determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified in 8 CFR 212.15(e) as it relates to physical therapists. (B) Passed an examination for physical therapists approved by the state in which physical therapy services are provided.	

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G1066 Cont.	(3) Before January 1, 2008 graduated from a physical therapy curriculum approved by one of the following: (i) The American Physical Therapy Association. (ii) The Committee on Allied Health Education and Accreditation of the American Medical Association. (iii) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association. (4) On or before December 31, 1977 was licensed or qualified as a physical therapist and meets both of the following: (i) Has 2 years of appropriate experience as a physical therapist. (ii) Has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service. (5) Before January 1, 1966— (i) Was admitted to membership by the American Physical Therapy Association; (ii) Was admitted to registration by the American Registry of Physical Therapists; or (iii) Graduated from a physical therapy curriculum in a 4-year college or university approved by a state department of education. (6) Before January 1, 1966 was licensed or registered, and before January 1, 1970, had 15 years of fulltime experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy. (7) If trained outside the United States before January 1, 2008, meets the following requirements: (i) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy. (ii) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.	

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G1068	**§484.115(i) Standard: Physical therapist assistant.** A person who is licensed, registered or certified as a physical therapist assistant, if applicable, by the state in which practicing, unless licensure does not apply and meets one of the following requirements: (1)(i) Graduated from a physical therapist assistant curriculum approved by the Commission on Accreditation in Physical Therapy Education of the American Physical Therapy Association; or if educated outside the United States or trained in the United States military, graduated from an education program determined to be substantially equivalent to physical therapist assistant entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified at 8 CFR 212.15(e); and (ii) Passed a national examination for physical therapist assistants. (2) On or before December 31, 2009, meets one of the following: (i) Is licensed, or otherwise regulated in the state in which practicing. (ii) In states where licensure or other regulations do not apply, graduated before December 31, 2009, from a 2-year college-level program approved by the American Physical Therapy Association and after January 1, 2010, meets the requirements of paragraph (h)(1) of this section. (3) Before January 1, 2008, where licensure or other regulation does not apply, graduated from a 2-year college level program approved by the American Physical Therapy Association. (4) On or before December 31, 1977, was licensed or qualified as a physical therapist assistant and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.	
G1070	**§484.115(j) Standard: Physician.** A person who meets the qualifications and conditions specified in section 1861(r) of the Act and implemented at §410.20(b) of this chapter.	
G1072	**§484.115(k) Standard: Registered nurse.** A graduate of an approved school of professional nursing who is licensed in the state where practicing.	

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G1074	**§484.115(l) Standard: Social Work Assistant.** A person who provides services under the supervision of a qualified social worker and: (1) Has a baccalaureate degree in social work, psychology, sociology, or other field related to social work, and has had at least 1 year of social work experience in a health care setting; or (2) Has 2 years of appropriate experience as a social work assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that the determinations of proficiency do not apply with respect to persons initially licensed by a state or seeking initial qualification as a social work assistant after December 31, 1977.	
G1076	**§484.115(m) Standard: Social worker.** A person who has a master's or doctoral degree from a school of social work accredited by the Council on Social Work Education, and has 1 year of social work experience in a health care setting.	
G1078	**§484.115(n) Standard: Speech-language pathologist.** A person who has a master's or doctoral degree in speech-language pathology, and who meets either of the following requirements: (1) Is licensed as a speech-language pathologist by the state in which the individual furnishes such services; or (2) In the case of an individual who furnishes services in a state which does not license speech-language pathologists: (i) Has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating supervised clinical experience); (ii) Performed not less than 9 months of supervised full-time speech-language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field; and (iii) Successfully completed a national examination in speech-language pathology approved by the Secretary.	