

FINAL RULE ENTITLED “MEDICARE AND MEDICAID PROGRAMS:  
CONDITIONS OF PARTICIPATION FOR HOME HEALTH AGENCIES”

Published in Federal Register on January 13, 2017

Tag Number	Regulation	Guidance To Surveyors
	<p><b><u>§484.40 Condition of Participation: Release of patient identifiable OASIS Information</u></b></p> <p>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.</p>	
	<p><b><u>§484.45 Condition of Participation: Reporting OASIS Information</u></b></p> <p>HHAs must electronically report all OASIS data collected in accordance with § 484.55.</p>	
	<p><b><u>§484.45(a) Standard: Encoding and transmitting OASIS data</u></b></p> <p>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.</p>	
	<p><b><u>§484.45(b) Standard: Accuracy of encoded OASIS data</u></b></p> <p>The encoded OASIS data must accurately reflect the patient’s status at the time of assessment.</p>	

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	<p><b>§484.45(c) Standard: Transmittal of OASIS data</b></p> <p>An HHA must—</p> <ol style="list-style-type: none"><li>(1) For all completed assessments, transmit OASIS data in a format that meets the requirements of paragraph (d) of this section.</li><li>(2) Successfully transmit test data to the QIES ASAP System or CMS OASIS contractor.</li><li>(3) 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.</li><li>(4) Transmit data that includes the CMS-assigned branch identification number, as applicable.</li></ol>	
	<p><b>§484.45(d) Standard: Data Format</b></p> <p>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.</p>	
	<p><b>§484.50 Condition of Participation: Patient Rights</b></p> <p>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.</p>	
	<p><b>§484.50(a) Standard: Notice of rights</b></p> <p>The HHA must—</p> <ol style="list-style-type: none"><li>(1) Provide the patient and the patient’s legal representative (if any), the following information during the initial evaluation visit,</li></ol>	

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	<p>in advance of furnishing care to the patient:</p> <ul style="list-style-type: none"><li>(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;</li><li>(ii) Contact information for the HHA administrator, including the administrator’s name, business address, and business phone number in order to receive complaints.</li><li>(iii) An OASIS privacy notice to all patients for whom the OASIS data is collected.</li></ul> <p>(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.</p> <p>(3) Provide verbal notice of the patient’s rights and responsibilities in the individual’s primary or preferred language and in a manner the individual understands, free of charge, with the use of a competent interpreter if necessary, no later than the completion of the second visit from a skilled professional as described in § 484.75.</p> <p>(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.</p>	
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	<p><b>§484.50(b) Standard: Exercise of rights</b></p> <p>(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.</p> <p>(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.</p> <p>(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.</p>	
	<p><b>§484.50(c) Standard: Rights of the patient</b></p> <p>The patient has the right to –</p> <p>(1) Have his or her property and person treated with respect;</p> <p>(2) Be free from verbal, mental, sexual, and physical abuse, including injuries of unknown source, neglect and misappropriation of property;</p> <p>(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;</p> <p>(4) Participate in, be informed about, and consent or refuse care in advance of and during treatment, where appropriate, with respect to-</p> <p>(i) Completion of all assessments;</p> <p>(ii) The care to be furnished, based on the comprehensive assessment ;</p> <p>(iii) Establishing and revising the plan of care;</p> <p>(iv) The disciplines that will furnish the care;</p>	

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	<p>(v) The frequency of visits;</p> <p>(vi) Expected outcomes of care, including patient-identified goals, and anticipated risks and benefits;</p> <p>(vii) Any factors that could impact treatment effectiveness; and</p> <p>(viii) Any changes in the care to be furnished</p> <p>(5) Receive all services outlined in the plan of care;</p> <p>(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.</p> <p>(7) Be advised of –</p> <p>(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,</p> <p>(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.</p> <p>(iii) The charges the individual may have to pay before care is initiated; and</p> <p>(iv) Any changes in the information provided in accordance with paragraph (c) (7) of this section when they occur. The HHA must advise the patient and representative (if any) of these changes as soon as possible, in advance of the next home health visit. The HHA must comply with the patient notice requirements at 42 CFR 411.408(d) (2) and 42 CFR 411.408(f).</p> <p>(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.</p> <p>(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.</p> <p>(10) Be advised of the names, addresses, and telephone numbers of the following federally-funded and state-</p>	
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	<p>funded entities that serve the area where the patient resides;</p> <ul style="list-style-type: none"> <li>(i) Agency on Aging,</li> <li>(ii) Center for Independent Living,</li> <li>(iii) Protection and Advocacy Agency,</li> <li>(iv) Aging and Disability resource Center; and</li> <li>(v) Quality Improvement Organization.</li> </ul> <p>(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.</p> <p>(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.</p>	
	<p><b>484.50(d) Standard: Transfer and discharge</b></p> <p>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:</p> <ul style="list-style-type: none"> <li>(1) The transfer or discharge is necessary for the patient’s welfare because the HHA and the physician 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;</li> <li>(2) The patient or payer will no longer pay for the services provided by the HHA;</li> <li>(3) The transfer or discharge is appropriate because the physician 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 who is responsible for the home health plan of care agree that the patient no longer needs the HHA’s services;</li> <li>(4) The patient refuses services, or elects to be</li> </ul>	

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	<p>transferred or discharged;</p> <p>(5) The HHA determines, under a policy set by the HHA for the purpose of addressing discharge for cause that meets the requirements of paragraphs (d) (5) (i) through (D) (5) (iii) of this section, that the patient’s (or other persons in the patient’s home) behavior is disruptive, abusive, or uncooperative to the extent that delivery of care to the patient or the ability of the HHA to operate effectively is seriously impaired. The HHA must do the following before it discharges a patient for cause:</p> <p>(i) Advise the patient, representative (if any), the physician(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;</p> <p>(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;</p> <p>(iii) Provide the patient and representative (if any) with contact information for other agencies or providers who may be able to provide care; and</p> <p>(iv) Document the problem(s) and efforts made to resolve the problem(s), and enter this documentation into its clinical records;</p> <p>(6) The patient dies; or</p> <p>(7) The HHA ceases to operate.</p>	
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**484.50(e) Standard: Investigation of complaints**

- (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; and
    - (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.
  - (ii) Document both the existence of the complaint and the resolution of the complaint, and
  - (iii) Take action to prevent further potential violations, including retaliation, while the complaint is being investigated.
- (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.



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	<p><b>484.50(f) Standard: Accessibility</b></p> <p>Information must be provided to patients in plain language and in a manner that is accessible and timely to—</p> <ol style="list-style-type: none"><li>(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.</li><li>(2) Persons with limited English proficiency through the provision of language services at no cost to the individual, including oral interpretation and written translations.</li></ol>	
	<p><b><u>§484.55 Condition of Participation: Comprehensive assessment of patients</u></b></p> <p>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.</p>	
	<p><b>484.55(a) Standard: Initial assessment visit</b></p> <ol style="list-style-type: none"><li>(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-ordered start of care date.</li><li>(2) When rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician who is</li></ol>	

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	<p>responsible for the home health plan of care, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate rehabilitation skilled professional.</p>	
	<p><b>484.55(b) Standard: Completion of the comprehensive assessment</b></p> <ol style="list-style-type: none"> <li>(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.</li> <li>(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.</li> <li>(3) When physical therapy, speech-language pathology, or occupational therapy is the only service ordered by the physician, a physical therapist, speech-language pathologist or occupational therapist may complete the comprehensive assessment, and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status. The occupational therapist may complete the comprehensive assessment if the need for occupational therapy establishes program eligibility.</li> </ol>	
	<p><b>484.55(c) Standard: Content of the comprehensive assessment</b></p> <p>The comprehensive assessment must accurately reflect the patient’s status, and must include, at a minimum, the following information:</p> <ol style="list-style-type: none"> <li>(1) The patient’s current health, psychosocial, functional, and cognitive status;</li> <li>(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</li> </ol>	

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	<p>identified by the patient and the measurable outcomes identified by the HHA;</p> <ul style="list-style-type: none"><li>(3) The patient’s continuing need for home care;</li><li>(4) The patient’s medical, nursing, rehabilitative, social, and discharge planning needs;</li><li>(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,</li><li>(6) The patient’s primary caregiver(s), if any, and other available supports, including their:<ul style="list-style-type: none"><li>(i) Willingness and ability to provide care, and</li><li>(ii) Availability and schedules;</li></ul></li><li>(7) The patient’s representative (if any);</li><li>(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.</li></ul>	
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<p><b>484.55(d) Standard: Update of the comprehensive assessment</b></p> <p>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—</p> <ol style="list-style-type: none"><li>(1) The last 5 days of every 60 days beginning with the start-of-care date, unless there is a<ol style="list-style-type: none"><li>(i) Beneficiary elected transfer;</li><li>(ii) Significant change in condition; or</li><li>(iii) Discharge and return to the same HHA during the 60-day episode.</li></ol></li><li>(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-ordered resumption date;</li><li>(3) At discharge.</li></ol>	
<p><b><u>§484.60 Condition of Participation: Care Planning, coordination of services, and quality of care</u></b></p> <p>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 measureable 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 patient and caregiver education and training. Services must be furnished in accordance with accepted standards of practice.</p>	

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**484.60(a) Standard: Plan of care**

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

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	<ul style="list-style-type: none"> <li>(xv) Information related to any advanced directives; and</li> <li>(xvi) Any additional items the HHA or physician may choose to include.</li> </ul> <p>(3) All patient care orders, including verbal orders, must be recorded in the plan of care</p>	
	<p><b>484.60(b) Standard: Conformance with physician orders</b></p> <ul style="list-style-type: none"> <li>(1) Drugs, services, and treatments are administered only as ordered by a physician.</li> <li>(2) Influenza and pneumococcal vaccines may be administered per agency policy developed in consultation with a physician, and after an assessment of the patient to determine for contraindications.</li> <li>(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.</li> <li>(4) When services are provided on the basis of a physician’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 in accordance with applicable state laws and regulations, as well as the HHAs’ internal policies.</li> </ul>	

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**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 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. The HHA must promptly alert the relevant physician(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.
- (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 measureable outcomes and goals identified by the HHA and patient in the plan of care.
- (3) Revisions to the plan of care must be communicated as follows:
  - (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 issuing orders for the HHA plan of care.
  - (ii) Any revisions related to plans for the patient’s discharge must be communicated to the patient, representative, caregiver, all physicians 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).

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	<p><b>484.60(d) Standard: Coordination of care</b></p> <p>The HHA must:</p> <ol style="list-style-type: none"><li>(1) Assure communication with all physicians involved in the plan of care.</li><li>(2) Integrate orders from all physicians involved in the plan of care to assure the coordination of all services and interventions provided to the patient.</li><li>(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.</li><li>(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.</li><li>(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.</li></ol>	
	<p><b>484.60(e) Standard: Written information to the patient</b></p> <p>The HHA must provide the patient and caregiver with a copy of written instructions outlining:</p> <ol style="list-style-type: none"><li>(1) Visit schedule, including frequency of visits by HHA personnel and personnel acting on behalf of the HHA.</li><li>(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.</li><li>(3) Any treatments to be administered by HHA personnel and personnel acting on behalf of the HHA, including therapy services.</li></ol>	



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	<p>(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.</p> <p>(5) Name and contact information of the HHA clinical manager</p>	
	<p><b><u>§484.65 Condition of Participation: Quality assessment and performance improvement (QAPI)</u></b></p> <p>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.</p>	
	<p><b>484.65(a) Standard: Program scope</b></p> <p>(1) The program must at least be capable of showing measureable improvement in indicators for which there is evidence that improvement in those indicators will improve health outcomes, patient safety, and quality of care.</p> <p>(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.</p>	

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	<p><b>484.65(b) Standard: Program data</b></p> <ul style="list-style-type: none"><li>(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.</li><li>(2) The HHA must use the data collected to—<ul style="list-style-type: none"><li>(i) Monitor the effectiveness and safety of services and quality of care; and</li><li>(ii) Identify opportunities for improvement</li></ul></li><li>(3) The frequency and detail of the data collection must be approved by the HHA’s governing body.</li></ul>	
	<p><b>484.65(c) Program activities</b></p> <ul style="list-style-type: none"><li>(1) The HHA’s performance improvement activities must—<ul style="list-style-type: none"><li>(i) Focus on high risk, high volume, or problem-prone areas;</li><li>(ii) Consider incidence, prevalence, and severity of problems in those areas; and</li><li>(iii) Lead to an immediate correction of any identified problem that directly or potentially threaten the health and safety of patients.</li></ul></li><li>(2) Performance improvement activities must track adverse patient events, analyze their causes, and implement preventive actions.</li><li>(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.</li></ul>	

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	<p><b>484.65(d) Standard: Performance improvement projects</b></p> <p>Beginning January 13, 2018, HHAs must conduct performance improvement projects.</p> <ol style="list-style-type: none"><li>(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.</li><li>(2) The HHA must document the quality improvement projects undertaken, the reasons for conducting these projects, and the measurable progress achieved on these projects.</li></ol>	
	<p><b>484.65(e) Standard: Executive responsibilities</b></p> <p>The HHA’s governing body is responsible for ensuring the following:</p> <ol style="list-style-type: none"><li>(1) That an ongoing program for quality improvement and patient safety is defined, implemented, and maintained;</li><li>(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;</li><li>(3) That clear expectations for patient safety are established, implemented, and maintained; and</li><li>(4) That any findings of fraud or waste are appropriately addressed.</li></ol>	

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<p><b><u>§484.70 Condition of Participation: Infection prevention and control</u></b></p> <p>The HHA must maintain and document an infection control program which has as its goal the prevention and control of infections and communicable diseases.</p>	
<p><b>484.70(a) Standard: Prevention</b></p> <p>The HHA must follow accepted standards of practice, including the use of standard precautions, to prevent the transmission of infections and communicable diseases.</p>	
<p><b>484.70(b) Standard: Control</b></p> <p>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;</p> <ul style="list-style-type: none"> <li>(1) A method for identifying infectious and communicable disease problems; and</li> <li>(2) A plan for the appropriate actions that are expected to result in improvement and disease prevention.</li> </ul>	
<p><b>484.70(c) Standard: Education</b></p> <p>The HHA must provide infection control education to staff, patients, and caregiver(s).</p>	

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<p><b><u>§484.75 Condition of Participation: Skilled professional services</u></b></p> <p>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 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.</p>	
<p><b>484.75(a) Standard: Provision of services by skilled professionals</b></p> <p>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.</p>	
<p><b>484.75(b) Standard: Responsibilities of skilled professions</b></p> <p>Skilled professionals must assume responsibility for, but not be restricted to, the following:</p> <ol style="list-style-type: none"> <li>(1) Ongoing interdisciplinary assessment of the patient;</li> <li>(2) Development and evaluation of the plan of care in partnership with the patient, representative (if any), and caregivers(s)</li> <li>(3) Providing services that are ordered by the physician as indicated in the plan of care;</li> <li>(4) Patient, caregiver, and family counseling;</li> <li>(5) Patient and caregiver education;</li> <li>(6) Preparing clinical notes;</li> <li>(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;</li> <li>(8) Participation in the HHA’s QAPI program; and</li> <li>(9) Participation in HHA-sponsored in-service training.</li> </ol>	

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	<p><b>484.75(c) Standard; Supervision of skilled professional assistants</b></p> <p>(1) Nursing services are provided under the supervision of a registered nurse that meets the requirements of § 484.115(k).</p> <p>(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</p> <p>(3) Medical social services are provided under the supervision of a social worker that meets the requirements of §484.115(m).</p>	
	<p><b><u>§484.80 Condition of Participation: Home health aide services</u></b></p> <p>All home health aide services must be provided by individuals who meet the personnel requirements specified in paragraph (a) of this section.</p>	
	<p><b>484.80 Standard: Home health aide qualification</b></p> <p>(1) A qualified home health aide is a person who has successfully completed:</p> <p>(i) A training and competency evaluation program as specified in paragraphs (b) and (c) respectively of this section; or</p> <p>(ii) A competency evaluation program that meets the requirements of paragraph (c) of this section or</p> <p>(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;</p>	

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	<p style="text-align: center;">or</p> <p>(iv) The requirements of a state licensure program that meets the provisions of paragraphs (b) and (c) of this section.</p> <p>(2) A home health aide or nurse aide is not considered to have completed a program, as specified in paragraph (a) (1) of this section, if, since the individual’s most recent completion of the program(s), there has been a continuous period of 24 consecutive months during which none of the services furnished by the individual as described in §409.40 of this chapter were for compensation. If there has been a 24-month lapse in furnishing services for compensation, the individual must complete another program, as specified in paragraph (a) (1) of this section , before providing services.</p>	
	<p><b>484.80(b) Standard: Content and duration of home health aide classroom and supervised practical training</b></p> <p>(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.</p> <p>(2) A minimum of 16 hours of classroom training must precede a minimum of 16 hours of supervised practical training as part of the 75 hours.</p> <p>(3) A home health aide training program must address each of the following subject areas;</p> <p style="padding-left: 20px;">(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;</p> <p style="padding-left: 20px;">(ii) Observation, reporting, and documentation of patient status and the care or service</p>	

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	<p>furnished;</p> <ul style="list-style-type: none"> <li>(iii) Reading and recording temperature, pulse, and respiration;</li> <li>(iv) Basic infection prevention and control procedures;</li> <li>(v) Basic elements of body functioning and changes in body function that must be reported to an aide’s supervisor;</li> <li>(vi) Maintenance of a clean, safe, and healthy environment;</li> <li>(vii) Recognizing emergencies and the knowledge of instituting emergency procedures and their application;</li> <li>(viii) The physical, emotional, and developmental needs of and ways to work with the populations served by the HHA, including the need for respect for the patient, his or her privacy, and his or her property;</li> <li>(ix) Appropriate and safe techniques in performing personal hygiene and grooming tasks that include— <ul style="list-style-type: none"> <li>(A) Bed bath</li> <li>(B) Sponge, tub, and shower bath;</li> <li>(C) Hair shampooing in sink, tub, and bed;</li> <li>(D) Nail and skin care;</li> <li>(E) Oral hygiene;</li> <li>(F) Toileting and elimination;</li> </ul> </li> <li>(x) Safe transfer techniques and ambulation;</li> <li>(xi) Normal range of motion and positioning;</li> <li>(xii) Adequate nutrition and fluid intake;</li> <li>(xiii) Recognizing and reporting changes in skin condition; and</li> <li>(xiv) Any other task that the HHA may choose to have an aide perform as permitted under state law.</li> <li>(xv) The HHA is responsible for training home health aides, as needed, for skills not covered in the basic checklist, as described in</li> </ul>	
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	<p>paragraph (b)(3)(ix) of this section.</p> <p>(4) The HHA must maintain documentation that demonstrates that the requirements of this standard have been met.</p>	
	<p><b>484.80(c) Standard: Competency evaluation</b></p> <p>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.</p> <p>(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 aides’ performance of the task with a patient. The remaining subject areas may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient.</p> <p>(2) A home health aide competency evaluation program may be offered by any organization, except as specified in paragraph (f) of this section.</p> <p>(3) The competency evaluation must be performed by a registered nurse in consultation with other skilled professionals, as appropriate.</p> <p>(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.</p>	

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	<p>(5) The HHA must maintain documentation which demonstrates that the requirements of this standard have been met.</p>	
	<p><b>484.80(d) Standard: In-Service Training</b></p> <p>A home health aide must receive at least 12 hours of in-service training during each 12-month period. In-service training may occur while an aide is furnishing care to a patient.</p> <p>(1) In-service training may be offered by any organization and must be supervised by a registered nurse.</p> <p>(2) The HHA must maintain documentation that demonstrates the requirements of this standard have been met.</p>	
	<p><b>484.80(e) Standard: Qualifications for instructors conducting classroom and supervised practical training</b></p> <p>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.</p>	
	<p><b>484.80(f) Standard: Eligible training and competency evaluation organization</b></p> <p>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:</p> <p>(1) Was out of compliance with the requirements of paragraphs (b), (c), (d), or (e) of this section ; or</p> <p>(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</p> <p>(3) Was subjected to an extended (or partially extended)</p>	

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	<p>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</p> <p>(4) Was assessed a civil monetary penalty of \$5000 or more as an intermediate sanction; or</p> <p>(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</p> <p>(6) Had all or part of its Medicare payments suspended; or</p> <p>(7) Was found under any federal or state law to have:</p> <ul style="list-style-type: none"><li>(i) Had its participation in the Medicare program terminated; or</li><li>(ii) Been assessed a penalty of \$5000 or more for deficiencies in federal or state standards for HHAs; or</li><li>(iii) Been subjected to a suspension of Medicare payments to which it otherwise would have been entitled; or</li><li>(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</li><li>(v) Been closed, or had its patients transferred by the state; or</li><li>(vi) Been excluded from participating in federal health care programs or debarred from participating in any government program.</li></ul>	
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**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).
- (2) A home health aide provides services that are:
  - (i) Ordered by the physician;
  - (ii) Included in the plan of care;
  - (iii) Permitted to be performed under state law; and
  - (iv) Consistent with the home health aide training.
- (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 medication ordinarily self-administered.
- (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.

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**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 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 §484.40(g), must make an onsite visit to the patient’s home no less frequently than every 14 days. The home health aide does not have to be present during this visit.
  - (ii) 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.
  - (iii) 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.
- (2) If home health aide services are provided to a patient who is not receiving skilled nursing care, physical or occupational therapy, or speech-language pathology services, the registered nurse must make an on-site visit to the location where the patient is receiving care no less frequently than every 60 days in order to observe and assess each aide while he or she is performing care.
- (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

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	<p>must conduct, and the home health aide must complete a competency evaluation in accordance with paragraph (c) of this section.</p> <p>(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:</p> <ul style="list-style-type: none"><li>(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;</li><li>(ii) Maintaining an open communication process with the patient, representative (if any), caregivers, and family;</li><li>(iii) Demonstrating competency with assigned tasks;</li><li>(iv) Complying with infection prevention and control policies and procedures;</li><li>(v) Reporting changes in the patient’s condition; and</li><li>(vi) Honoring patient rights.</li></ul> <p>(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:</p> <ul style="list-style-type: none"><li>(i) Ensuring the overall quality of care provided by an aide;</li><li>(ii) Supervising aide services as described in paragraphs (h)(1) and (2) of this section; and</li><li>(iii) Ensuring that home health aides who provide services under arrangement have met the training or competency evaluation requirements, or both, of this part.</li></ul>	
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<p><b>484.80(i) Standard: Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit.</b></p> <p>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.</p>	
<p><b><u>§484.100 Condition of Participation: Compliance with Federal, State, and local laws and regulations related to the health and safety of patients</u></b></p> <p>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.</p>	
<p><b>484.100(a) Standard: Disclosure of ownership and management information</b></p> <p>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:</p> <ol style="list-style-type: none"> <li>(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.</li> <li>(2) The name and address of each person who is an officer, a director, an agent, or a managing employee of the HHA as defined in §420.201, §420.202, and §420.206 of this chapter.</li> </ol>	

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	<p>(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.</p>	
	<p><b>484.100 (b) Standard: Licensing</b></p> <p>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.</p>	
	<p><b>484.100 (c) Standard: Laboratory services</b></p> <p>(1) If the HHA engages in laboratory testing outside of the context of assisting an individual in self-administering a test with an appliance that has been cleared for that purpose by the Food and Drug Administration, the testing must be in compliance with all applicable requirements of part 493 of this chapter. The HHA may not substitute its equipment for a patient’s equipment when assisting with self-administered tests.</p> <p>(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.</p>	



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<p><b><u>§484.102 Condition of Participation: Emergency preparedness</u></b></p> <p>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:</p>	
<p>(a) <i>Emergency plan.</i> The HHA must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. The plan must do all of the following:</p> <ul style="list-style-type: none"> <li>(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.</li> <li>(2) Include strategies for addressing emergency events identified by the risk assessment</li> <li>(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 delegations of authority and succession plans.</li> <li>(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, including documentation of the HHA’s efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.</li> </ul>	
<p>(b) <i>Policies and procedures.</i> 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,</p>	

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	<p>and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:</p> <ul style="list-style-type: none"> <li>(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.</li> <li>(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.</li> <li>(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.</li> <li>(4) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.</li> <li>(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.</li> </ul>	
	<p>(c) <i>Communication plan.</i> 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 annually. The communication plan must include all of the following:</p> <ul style="list-style-type: none"> <li>(1) Names and contact information for the following: <ul style="list-style-type: none"> <li>(i) Staff</li> </ul> </li> </ul>	

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	<ul style="list-style-type: none"> <li>(ii) Entities providing services under arrangement</li> <li>(iii) Patients’ physicians</li> <li>(iv) Volunteers</li> <li>(2) Contact information for the following:             <ul style="list-style-type: none"> <li>(i) Federal, State, tribal, regional or local emergency preparedness staff</li> <li>(ii) Other sources of assistance</li> </ul> </li> <li>(3) Primary and alternate means for communicating with the HHA’s staff, Federal, State, tribal, regional, and local emergency management agencies.</li> <li>(4) A method for sharing information and medical documentation for patients under the HHA’s care, as necessary, with other health care providers to maintain the continuity of care.</li> <li>(5) A means of providing information about the general condition and location of patients under the facility’s care as permitted under 45 CFR 164.510(b)(4).</li> <li>(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.</li> </ul>	
	<p>(d) <i>Training and testing.</i> 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 annually.</p> <p>(1) Training program. The HHA must do all of the following:</p> <ul style="list-style-type: none"> <li>(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.</li> </ul>	

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<ul style="list-style-type: none"> <li>(ii) Provide emergency preparedness training at least annually.</li> <li>(iii) Maintain documentation of the training.</li> <li>(iv) Demonstrate staff knowledge of emergency procedures</li> </ul> <p>(2)Testing. The HHA must conduct exercises to test the emergency plan at least annually. The HHA must do the following:</p> <ul style="list-style-type: none"> <li>(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the HHA experiences an actual natural or man-made emergency that requires activation of the emergency plan, the HHA is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.</li> <li>(ii) Conduct an additional exercise that may include, but is not limited to the following: <ul style="list-style-type: none"> <li>(A) A second full-scale exercise that is community-based or individual, facility-based.</li> <li>(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.</li> </ul> </li> <li>(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.</li> </ul>	
<p>(e) <i>Integrated healthcare systems.</i> 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</p>	

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	<p>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:</p> <ol style="list-style-type: none"><li>(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.</li><li>(2) Be developed and maintained in a manner that takes into account each separately certified facility’s unique circumstances, patient populations, and services offered.</li><li>(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.</li><li>(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:<ol style="list-style-type: none"><li>(i) A documented community-based risk assessment, utilizing an all-hazards approach.</li><li>(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.</li></ol></li><li>(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 meet the requirements of paragraphs (c) and (d) of this section, respectively.</li></ol>	
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<p><b><u>§484.105 Condition of Participation: Organization and administration of Services</u></b></p> <p>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.</p>	
<p><b>484.105 (a) Standard: Governing body</b></p> <p>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.</p>	
<p><b>484.105 (b) Standard: Administrator</b></p> <p>(1) The administrator must:</p> <ul style="list-style-type: none"> <li>(i) Be appointed by and report to the governing body;</li> <li>(ii) Be responsible for all day-to-day operations of the HHA;</li> <li>(iii) Ensure that a clinical manager as described in paragraph (c) of this section is available during all operating hours;</li> <li>(iv) Ensure that the HHA employs qualified personnel, including assuring the development of personnel qualifications and policies.</li> </ul> <p>(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</p>	

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	<p>same responsibilities and obligations as the administrator. The pre-designated person may be the clinical manager as described in paragraph (c) of this section.</p> <p>(3) The administrator or a pre-designated person is available during all operating hours.</p>	
	<p><b>484.105 (c) Standard: Clinical manager</b></p> <p>One or more qualified individuals must provide oversight of all patient care services and personnel. Oversight must include the following—</p> <ol style="list-style-type: none"> <li>(1) Making patient and personnel assignment,</li> <li>(2) Coordinating patient care,</li> <li>(3) Coordinating referrals,</li> <li>(4) Assuring that patient needs are continually assessed, and</li> <li>(5) Assuring the development, implementation, and updates of the individualized plan of care.</li> </ol>	
	<p><b>484.105 (d) Standard: Parent-branch relationship</b></p> <ol style="list-style-type: none"> <li>(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.</li> <li>(2) The parent HHA provides direct support and administrative control of its branches.</li> </ol>	

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	<p><b>484.105 (e) Standard: Services under arrangement</b></p> <p>(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)).</p> <p>(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:</p> <ul style="list-style-type: none"><li>(i) Denied Medicare or Medicaid enrollment;</li><li>(ii) Been excluded or terminated from any federal health care program or Medicaid;</li><li>(iii) Had its Medicare or Medicaid billing privileges revoked; or</li><li>(iv) Been debarred from participating in any government program.</li></ul> <p>(3) The primary HHA is responsible for patient care, and must conduct and provide, either directly or under arrangements, all services rendered to patients.</p>	
	<p><b>484.105 (f) Standard: Services furnished</b></p> <p>(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.</p>	



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	<p>(2) All HHA services must be provided in accordance with current clinical practice guidelines and accepted professional standards of practice.</p>	
	<p><b>484.105 (g) Standard: Outpatient physical therapy or speech-language pathology services.</b></p> <p>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, §485.727 of this chapter to implement section 1861(p) of the Act.</p>	
	<p><b>484.105 (h) Standard: Institutional planning.</b></p> <p>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.</p> <p>(1)<i>Annual operating budget.</i> There is an annual operating budget that includes all anticipated income and expenses related to items that would, under generally accepted accounting principles, be considered income and expense items. However, it is not required that there be prepared, in connection with any budget, an item by item identification of the components of each type of anticipated income or expense.</p> <p>(2)<i>Capital expenditure plan.</i></p> <p>(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</p>	

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	<p>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 separate 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.</p> <p>(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:</p> <p>(A) Whether the proposed capital expenditure is required to conform, or is likely to be required</p>	
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	<p>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.</p> <p>(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.</p> <p>(C) Whether the designated planning agency has approved or disapproved the proposed capital expenditure if it was present to that agency.</p> <p>(3) <i>Preparation of plan and budget.</i> 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.</p> <p>(4) <i>Annual review of plan and budget.</i> The overall plan and budget is reviewed and updated at least annually by the committee referred to in paragraph (i)(3) of this section and under the direction of the governing body of the HHA.</p>	
	<p><b><u>§484.110 Condition of Participation: Clinical records.</u></b></p> <p>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) issuing orders for the home health plan of care, and appropriate HHA staff. This information may be maintained electronically.</p>	

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**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 orders;
- (2) All interventions, including medication administration, treatments, and services, and responses to those interventions;
- (3) Goals in the patient’s plans of care and the patient’s progress toward achieving them;
- (4) Contact information for the patient, the patient’s representative (if any), and the patient’s primary caregiver(s);
- (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
- (6)
  - (i) A completed discharge summary that is sent to the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any) within 5 business days of the patient’s discharge; or
  - (ii) A completed transfer summary that is sent within 2 business days of a planned transfer, if the patient’s care will be immediately continued in a health care facility; or
  - (iii) A completed transfer summary that is sent within 2 business days of becoming aware of an unplanned transfer, if the patient is still receiving care in a health care facility at the time when the HHA becomes aware of the transfer.

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	<p><b>484.110 (b) Standard: Authentication.</b></p> <p>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.</p>	
	<p><b>484.110 (c) Standard: Retention of records.</b></p> <ol style="list-style-type: none"><li>(1) Clinical records must be retained for 5 years after the discharge of the patient, unless state law stipulates a longer period of time.</li><li>(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.</li></ol>	
	<p><b>484.110 (d) Standard: Protection of records.</b></p> <p>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 protected health information set out at 45 CFR parts 160 and 164.</p>	
	<p><b>484.110 (e) Standard: Retrieval of clinical records.</b></p> <p>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).</p>	

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<p><b><u>§484.115 Condition of Participation: Personnel qualifications</u></b></p> <p>HHA staff are required to meet the following standards:</p>	
<p><b>484.115 (a) Standard: Administrator, home health agency</b></p> <p>(1) For individuals that began employment with the HHA prior to July 13, 2017, a person who:</p> <ul style="list-style-type: none"> <li>(i) Is a licensed physician;</li> <li>(ii) Is a registered nurse; or</li> <li>(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.</li> </ul> <p>(2) For individuals that begin employment with an HHA on or after July 13, 2017, a person who:</p> <ul style="list-style-type: none"> <li>(i) Is a licensed physician, a registered nurse, or holds an undergraduate degree; and</li> <li>(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.</li> </ul>	
<p><b>484.115 (b) Standard: Audiologist</b></p> <p>A person who:</p> <ul style="list-style-type: none"> <li>(1) Meets the education and experience requirements for a Certificate of Clinical Competence in audiology granted by the American Speech-Language-Hearing Association; or</li> <li>(2) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.</li> </ul>	

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<p><b>484.115 (c) Standard: Clinical manager</b></p> <p>A person who is a licensed physician, physical therapist, speech-language pathologist, occupational therapist, audiologist, social worker, or a registered nurse.</p>	
<p><b>484.115 (d) Standard: Home health aide</b></p> <p>A person who meets the qualifications for home health aides specified in section 1891(a) (3) of the Act and implemented at §484.80.</p>	
<p><b>484.115 (e) Standard: Licensed practical (vocational) nurse.</b></p> <p>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.</p>	
<p><b>484.115 (f) Standard: Occupational therapist.</b></p> <p>A person who—</p> <ul style="list-style-type: none"> <li>(1)</li> <li>(i) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the state in which practicing, unless licensure does not apply;</li> <li>(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</li> <li>(iii) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and</li> </ul>	

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	<p>administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).</p> <p>(2) On or before December 31, 2009—</p> <p>(i) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the state in which practicing; or</p> <p>(ii) When licensure or other regulation does not apply—</p> <p>(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</p> <p>(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)</p> <p>(3) On or before January 1, 2008—</p> <p>(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</p> <p>(ii) Is eligible for the National Registration Examination of the American Occupational Therapy Association or the National Board for Certification in Occupational Therapy.</p> <p>(4) On or before December 31, 1977—</p> <p>(i) Had 2 years of appropriate experience as an occupational therapist, and</p> <p>(ii) Had achieved a satisfactory grade on an occupational therapist proficiency examination</p>	
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	<p>conducted, approved, or sponsored by the U.S. Public Health Service.</p> <p>(5) If educated outside the United States, must meet both of the following:</p> <p>(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:</p> <p>(A) The Accreditation Council for Occupational Therapy Education (ACOTE).</p> <p>(B) Successor organizations of ACOTE.</p> <p>(C) The World Federation of Occupational Therapists</p> <p>(D) A credentialing body approved by the American Occupational Therapy Association.</p> <p>(E) Successfully completed the entry level certification examination for occupational therapists developed and administered by the national Board of Certification in Occupational Therapy, Inc. (NBCOT).</p> <p>(ii) On or before December 31, 2009, is licensed or otherwise regulated, if applicable, as an occupational therapist by the state in which practicing.</p>	
	<p><b>484.115 (g) Standard: Occupational therapist assistant</b></p> <p>A person who—</p> <p>(1) Meets all of the following:</p> <p>(i) Is licensed or otherwise regulated, if applicable, as an occupational therapy assistant by the state in which practicing, unless licensure does apply.</p> <p>(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.</p>	

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	<ul style="list-style-type: none"><li>(iii) Is eligible to take or successfully completed the entry-level certification examination for occupational therapy assistants developed and administered by the national Board for Certification in Occupational Therapy, Inc. (NBCOT).</li><li>(2) On or before December 31, 2009—<ul style="list-style-type: none"><li>(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</li><li>(ii) Must meet both of the following:<ul style="list-style-type: none"><li>(A) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association.</li><li>(B) After January 1, 2010, meets the requirements in paragraph (f) (1) of this section.</li></ul></li></ul></li><li>(3) After December 31, 1977 and on or before December 31, 2007—<ul style="list-style-type: none"><li>(i) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association; or</li><li>(ii) Completed the requirements to practice as an occupational therapy assistant applicable in the state in which practicing.</li></ul></li><li>(4) On or before December 31, 1977—<ul style="list-style-type: none"><li>(i) Had 2 years of appropriate experience as an occupational therapy assistant; and</li><li>(ii) Had achieved a satisfactory grade on an occupational therapy assistant proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.</li></ul></li><li>(5) If educated outside the United States, on or after January 1, 2008—</li></ul>	
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	<p>(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—</p> <ul style="list-style-type: none"> <li>(A) The Accreditation Council for Occupational Therapy Education (ACOTE)</li> <li>(B) Its successor organizations</li> <li>(C) The World Federation of Occupational Therapists</li> <li>(D) By a credentialing body approved by the American Occupational Therapy Association; and</li> <li>(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).</li> </ul>	
	<p><b>484.115 (h) Standard: Physical therapist</b></p> <p>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:</p> <ul style="list-style-type: none"> <li>(1) <ul style="list-style-type: none"> <li>(i) Graduated after successful completion of a physical therapist education program approved by one of the following: <ul style="list-style-type: none"> <li>(A) The Commission on Accreditation in Physical Therapy Education (CAPTE)</li> <li>(B) Successor organizations of CAPTE</li> <li>(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</li> </ul> </li> </ul> </li> </ul>	

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	<p>organization identified in 8 CFR 212.15(e) as it relates to physical therapists.</p> <ul style="list-style-type: none"><li>(ii) Passed an examination for physical therapists approved by the state in which physical therapy services are provided.</li></ul> <p>(2) On or before December 31, 2009—</p> <ul style="list-style-type: none"><li>(i) Graduated after successful completion of a physical therapy curriculum approved by the Commission on Accreditation in Physical Therapy Education (CAPTE); or</li><li>(ii) Meets both of the following:<ul style="list-style-type: none"><li>(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.</li><li>(B) Passed an examination for physical therapists approved by the state in which physical therapy services are provided.</li></ul></li></ul> <p>(3) Before January 1, 2008 graduated from a physical therapy curriculum approved by one of the following:</p> <ul style="list-style-type: none"><li>(i) The American Physical Therapy Association</li><li>(ii) The committee on Allied Health Education and Accreditation of the American Medical Association</li><li>(iii) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association.</li></ul> <p>(4) On or before December 31, 1977 was licensed or qualified as a physical therapist and meets both of the following:</p> <ul style="list-style-type: none"><li>(i) Has 2 years of appropriate experience as a physical therapist.</li><li>(ii) Has achieved a satisfactory grade on a proficiency examination conducted, approved,</li></ul>	
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	<p style="text-align: center;">or sponsored by the U.S. Public Health Service.</p> <p>(5) Before January 1, 1966—</p> <ul style="list-style-type: none"> <li>(i) Was admitted to membership by the American Physical Therapy Association;</li> <li>(ii) Was admitted to registration by the American Registry of Physical Therapists; or</li> <li>(iii) Graduated from a physical therapy curriculum in a 4-year college or university approved by a state department of education.</li> </ul> <p>(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.</p> <p>(7) If trained outside the United States before January 1, 2009, meets the following requirements:</p> <ul style="list-style-type: none"> <li>(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,</li> <li>(ii) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.</li> </ul>	
	<p><b>484.115 (i) Standard: Physical therapist assistant</b></p> <p>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;</p> <ul style="list-style-type: none"> <li>(1) <ul style="list-style-type: none"> <li>(i) Graduated from a physical therapist assistant curriculum approved by the Commission on Accreditation in Physical Therapy Education of</li> </ul> </li> </ul>	

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	<p>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</p> <p>(ii) Passed a national examination for physical therapist assistants.</p> <p>(2) On or before December 31, 2009, meets one of the following:</p> <p>(i) Is licensed, or otherwise regulated in the state in which practicing.</p> <p>(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.</p> <p>(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.</p> <p>(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.</p>	
	<p><b>484.115 (j) Standard: Physician</b></p> <p>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.</p>	

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	<p><b>484.115 (k) Standard: Registered Nurse</b></p> <p>A graduate of an approved school of professional nursing who is licensed in the state where practicing.</p>	
	<p><b>484.115 (l) Standard: Social Work Assistant</b></p> <p>A person who provides services under the supervision of a qualified social worker and:</p> <ul style="list-style-type: none"><li>(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</li><li>(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.</li></ul>	
	<p><b>484.115 (m) Standard: Social Worker</b></p> <p>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.</p>	

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	<p><b>484.115 (n) Standard: Speech-language pathologist</b></p> <p>A person who has a master’s or doctoral degree in speech-language pathology, and who meets either of the following requirements;</p> <ul style="list-style-type: none"><li>(1) Is licensed as a speech-language pathologist by the state in which the individual furnishes such services; or</li><li>(2) In the case of an individual who furnishes services in a state which does not license speech-language pathologists:<ul style="list-style-type: none"><li>(i) Has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating supervised clinical experience);</li><li>(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</li><li>(iii) Successfully completed a national examination in speech-language pathology approved by the Secretary.</li></ul></li></ul>	
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