Subpart A--General Provisions

§484.1 Basis and scope.

§484.1 (a) Basis. This part is based on:

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

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

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

§484.2 Definitions.
As used in subparts A, B, and C, of 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.**

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

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

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.**

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.**

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.**

Subpart B--Patient Care

§484.40 Condition of participation: Release of patient identifiable OASIS information.
The HHA and agent acting on behalf of the HHA in accordance with a written contract must ensure the confidentiality of all patient identifiable information contained in the clinical record, including OASIS data, and may not release patient identifiable OASIS information to the public.

Interpretive Guidelines §484.40

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

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

- Ensure the confidentiality, integrity, and availability of such 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;
- 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)

§484.45 Condition of participation: Reporting OASIS information.

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

Interpretive Guidelines §484.45

The 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)(1)(i-iii), (d)(2), (d)(3).

§484.45(a) <u>Standard: Encoding and transmitting OASIS data.</u>

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

Interpretive Guidelines §484.45(a)

"CMS system" means the national Quality Improvement Evaluation System, Assessment Submission and Processing (QIES ASAP) system.

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

"Transmit" means electronically send OASIS information, from the agency directly to CMS via the national Quality Improvement Evaluation System, Assessment Submission and Processing (QIES ASAP) 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). OASIS must also be transmitted 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 until further notice; and
- Patients for whom Medicare or Medicaid insurance is not billed.

As long as the 30 day submission time frame is met, HHAs are free to develop schedules for transmitting the data that best suit their needs.

§484.45(b) Standard: Accuracy of encoded OASIS data.

The encoded OASIS data must accurately reflect the patient's status at the time of assessment.

Interpretive Guidelines §484.45(b)

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

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

§484.45(c)(1) For all completed assessments, transmit OASIS data in a format that meets the requirements of paragraph (d) of this section.

Interpretive Guidelines §484.45(c)(1)

If OASIS data are being successfully transmitted to CMS (as verified by the presence of OASIS data reports), §484.45(c)(1) is presumed to be met.

§484.45(c)(2) Successfully transmit test data to the QIES ASAP System or CMS OASIS contractor.

Interpretive Guidelines §484.45(c)(2)

The purpose of making a test transmission to the QIES ASAP system or CMS OASIS contractor is to establish connectivity. Prior to the initial certification survey, HHAs must demonstrate connectivity to the OASIS QIES ASAP system by--

1. Making a test transmission of start of care or resumption of care OASIS data that passes CMS edit checks; and

2. Receiving validation reports back from the QIES ASAP system confirming successful transmission of data.

§484.45(c)(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.

Interpretive Guidelines §484.45(c)(3)

HHAs may directly transmit OASIS data (to the national data repository) via jHAVEN (Home Assessment Validation and Entry System), which is an application that allows providers to collect and maintain agency, patient and OASIS assessment data or other software that conforms to the FIPS 140-2.

§484.45(c)(4)Transmit data that includes the CMS-assigned branch identification number, as applicable.

§484.45(d) <u>Standard: Data Format.</u>
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.

§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.

§484.50(a) <u>Standard: Notice of rights.</u>
The HHA must-

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

Interpretive Guidelines §484.50(a)(1)

The term representative is defined at §484.2. Representative means the patient's legal representative, such as a guardian, who makes health-care decisions on the patient's behalf, 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. In a case where a legal representative cannot be present for the initial evaluation, the HHA may communicate the information to the patient directly and electronically with the legal representative to prevent any delay in the initiation of services.

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 of 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 should be provided directly to the patient.

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.

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

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

Interpretive Guidelines §484.50(a)(1)(i)
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 in 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 through the use of competent bilingual staff, staff interpreters, contracts or formal arrangements with local organizations providing interpretation, translation services, or technology and telephonic interpretation services.
- All agency staff should be trained to identify patients with any language barriers which may prevent effective communication of the rights and responsibilities. Staff that have on-going contact with patients who have language barriers, should be trained in effective communication techniques, including the effective use of an interpreter.

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

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

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

Interpretive Guidelines §484.50(a)(1)(iii)
Use of the OASIS Privacy Notice is required as per 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.

This Standard references all patients for whom OASIS data is transmitted to CMS, although OASIS data may be collected on all HHA patients served by the agency regardless of payer source.

§484.50(a)(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.

§484.50(a)(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.

Interpretive Guidelines §484.50(a)(3)
If an HHA patient speaks a language which the HHA has not translated into written material, the HHA may delay the verbal notification of rights and responsibilities until an interpreter is present (either physically, electronically or telephonically) to verbally translate. However, this may be delayed until no later than the second visit.

HHAs should document that verbal discussion of rights took place and that the patient and/or representative was able to confirm her/his understanding of rights.

§484.50(a)(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.

§484.50(b) Standard: Exercise of rights.

§484.50(b)(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.

§484.50(b)(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.

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

Interpretive Guidelines §484.50(b)
The HHA should include official documentation of any adjudication by the courts which indicate that a patient lacks the legal capacity to make his/her own health care decisions and the names of any person identified by the courts who may exercise the patient's rights.

§484.50(c) Standard: Rights of the patient.

The patient has the right to—
§484.50(c)(1)Have his or her property and person treated with respect;

Interpretive Guidelines §484.50(c)(1)
Respect for Property: The patient has the right to expect the HHA staff will respect his/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 agency staff.

Respect for Person: The HHA must consider and accommodates any patient requests within the parameters of the assessment and plan of care, and the patient must be treated as an active partner in the delivery of care. The HHA must keep the patient informed of the visit schedule and timely and promptly notifies the patient when scheduled services are changed.

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 should be developed taking into account the convenience of the patient rather than of the agency personnel.

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

Interpretive Guidelines §484.50(c)(2)
The patient has a right to be free from abuse from the HHA staff and others in his/her home environment. The HHA addresses any allegations of or evidence of 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 must be knowledgeable of these laws and comply with the reporting requirements.

The HHA must intervene immediately as indicated by the circumstances if an injury is the result of an HHA staff member actions. HHAs must immediately remove staff from patient care if there are allegations of misconduct related to abuse or misappropriation of property.

Abuse means the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish including the use of abuse through 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 includes any incident where a beneficiary is coerced, manipulated, or forced to participate in any form of sexual activity for which they did not give affirmative permission (or gave affirmative permission without the understanding or mental capacity required to give permission) or sexual assault against a beneficiary who is unable to defend him/herself.

Physical abuse refers to 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.

An 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.

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

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

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

Interpretive Guidelines §484.50(c)(3)
The HHA should have written policies and procedures on the acceptance, processing, review, and resolution of patient complaints. These policies include complaint intake procedures, time frames for investigations, documentation, and outcomes and actions that may be taken by the HHA to resolve patient complaints. See also §484.50(e) Investigation of complaints.

The clinical record and the patient's home folder should confirm that the patient was provided with information regarding their right to lodge a complaint to the HHA and the procedures to be followed to submit a complaint.

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

(i) Completion of all assessments;

(ii) The care to be furnished, based on the comprehensive assessment;

(iii) Establishing and revising the plan of care;

(iv) The disciplines that will furnish the care;

(v) The frequency of visits;

(vi) Expected outcomes of care, including patient-identified goals, and anticipated risks and benefits;

(vii) Any factors that could impact treatment effectiveness; and

(viii) Any changes in the care to be furnished.

Interpretive Guidelines §484.50(c)(4)

The patient's informed consent on the items (i-viii) is not intended to be a single signed form. This informed consent and patient participation takes place on an ongoing basis as the patient's care changes and evolves during the episodes of care. Both at the initial start of care and as changes occur in the care, there is evidence in the medical record (may be in clinical notes by the HHA) that the patient was consulted as to preference and the patient consented to the new services and care.

Participation means that the patient is given options when there are changes being made to the patient's plan of care. For example, patient preferences should be solicited when a bath or shower is being added to the plan. The patient's preferences should be honored unless contraindicated by the physical restrictions or medical contraindications that limit patient choice.

Informed means that all aspects of the planned care and services, and the manner in which the care and services will be delivered, are reviewed with the patient by HHA staff soliciting their 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.

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

Interpretive Guidelines §484.50(c)(5)
If a planned visit or planned service is not provided to the patient as described in the plan of care on an occasional basis due to unavoidable circumstances or patient preference, the HHA must document the justification for the missed visit or service in the clinical record. Also see §484.60 (a)(1)

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

Interpretive Guidelines §484.50(c)(6)
45 CFR Part 160 and 164 pertain to requirements of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). The HIPAA Privacy Rule (45 CFR Part 160 and Subparts A and E of Part 164), Security Rule (45 CFR Part 160 and Subparts A and C of Part 164), and Breach Notification 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.

• The HIPAA 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 when protected health information (PHI) may be used and 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 (PHI)

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

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

HHAs have unique concerns and risks regarding staff and contractors who transport documents and/or electronic devices containing PHI such as during their visits to patient's homes. HHA should be periodically trained on the security of these documents and data.

§484.50(c)(7) Be advised of –

(i) The extent to which payment for HHA services may be expected from Medicare, Medicaid, or any other Federally-funded or Federal aid program known to the HHA,

(ii) The charges for services that may not be covered by Medicare, Medicaid, or any other Federally-funded or Federal aid program known to the HHA,

(iii) The charges the individual may have to pay before care is initiated; and

(iv) Any changes in the information provided in accordance with paragraph (c)(7) of this section when they occur. The HHA must advise the patient and representative (if any), of these changes as soon as possible, in advance of the next home health visit. The HHA must comply with the patient notice requirements at 42 CFR 411.408(d)(2) and 42 CFR 411.408(f).

Interpretive Guidelines §484.50(c)(7)
The patient's medical record must include evidence that the patient was advised, prior to services beginning, of the extent any planned services may not be covered by Medicare; documentation that the patient was informed of such and informed; before the services are provided, what the patient would be expected to pay if he/she decides to receive the services anyway. This provides the patient with an opportunity to make an informed decision regarding the provision of services by the HHA for which he/she may have partial or total liability.

If, after the services begin, a change occurs in the patient charges because new services are being added or existing services are no longer covered, the same notification must occur regarding extent of payment and patient liability, prior to the beginning of the new services.

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

Interpretive Guidelines §484.50(c)(8)
§405.1200 through §405.1204 describe the expedited determination process which is a right that Medicare beneficiaries may exercise to dispute the termination of their Medicare covered services in certain settings including home health. These notifications apply only to Medicare beneficiaries.

§484.50(c)(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.

§484.50(c)(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.

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

Interpretive Guidelines §484.50(c)(11)
Discrimination against a patient as reprisal for exercising the right to complain is defined as treating a patient differently from other patients subsequent to a complaint and without justification for the difference.

Examples of reprisal may include but not be limited to a reduction of current services, a complete discontinuation of services, or discharge from the HHA subsequent to a complaint and without medical justification for the change of service.

§484.50(c)(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.

§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:

§484.50(d)(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;

Interpretive Guidelines §484.50(d)(1)
When a patient's care needs change to require more than intermittent services or require specialized services not provided by the agency, the HHA informs the patient/representative and the physician that 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. The HHA should assist the patient/family or representative if any to choose an alternative entity by identifying those entities in the area that may be able to meet the patient's needs based on the patient's acuity. Once the patient chooses an alternate entity, the HHA must contact that entity to facilitate a safe transfer through communication and transfer of information. The HHA must ensure timely transfer of patient information to the alternate entity to facilitate continuity of care. The HHA ensures that patient information is provided to the receiving entity prior to or simultaneously with the patient services at the new entity.

Also see §484.110(a)(6)(ii) regarding time frame requirement for the transfer summary.

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

§484.50(d)(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;

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

Interpretive Guidelines §484.50(d)(4)
A patient who occasionally declines a service is distinguished from a patient who refuses service altogether, or whom 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 from refusing services. In the case of patient refusals of skilled care, the HHA documents the communication with the physician(s), as well as the measures the HHA took to investigate the patient's refusal and the interventions the HHA took to obtain patient participation with the plan of care.

The HHA may consider discharge if the patient's decline of 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.

§484.50(d)(5) The HHA determines, under a policy set by the HHA for the purpose of addressing discharge for cause that meets the requirements of paragraphs (d)(5)(i) through (d)(5)(iii) of this

section, that the patient's (or other persons in the patient's home) behavior is disruptive, abusive, or uncooperative to the extent that delivery of care to the patient or the ability of the HHA to operate effectively is seriously impaired. The HHA must do the following before it discharges a patient for cause:

Interpretive Guidelines §484.50(d)(5)
Disruptive, abusive behavior includes verbal, non-verbal or physical threats, sexual harassment, or any incident in which agency staff feel threatened or unsafe resulting in a serious impediment to the agency's ability to operate safely and effectively in the delivery of care.

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

Documentation in the clinical record describes the behaviors, circumstances and the agency attempted interventions to resolve the problems.

(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;

Interpretive Guidelines §484.50(d)(5)(i)
The patient and/or their representative and the physician issuing orders for the home health care must be notified that a discharge for cause is being considered as soon as the discharge is considered.

As a component of the discharge process the HHA should attempt to identify a health care professional (other than the physician issuing home health orders) who may be providing care to the patient and notify them of the pending discharge.

(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;

Interpretive Guidelines §484.50(d)(5)(ii)
The clinical record must 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.

In extreme situations when staff are threatened or endangered during a visit, the HHA may be required to take immediate actions to discharge or transfer the patient without taking measures to resolve the issue.

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

Interpretive Guidelines §484.50(d)(5)(iii)
Evidence in the record should document that the HHA provided the patient/representative with information including contact numbers for other community resources and/or names of other agencies which may be able to provide services.

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

§484.50(d)(6) The patient dies; or

§484.50(d)(7) The HHA ceases to operate.

Interpretive Guidelines §484.50(d)(7)
The agency must provide sufficient notice of planned cessation of business to enable patients to select an alternative service provider and for the HHA to facilitate the safe transfer of the patients to the other agencies.

§484.50(e) <u>Standard: Investigation of complaints.</u>

§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:

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

(i)(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.

Interpretive Guidelines §484.50(e)(1)(i-iii)

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, time frames for investigations, documentation, and outcomes and actions the HHA may resolve patient complaints. Complaint investigations should be incorporated into the agency's Quality Assurance Performance Improvement program.

The agency should be able to produce documentation for each complaint received to confirm that investigations were conducted and detail the findings and resolution of each complaint received. The documentation should describe any actions taken by the HHA to remove any risks to the patient while the complaint was being investigated. Resolution of the complaint should include a report back to the complainant describing agency findings and corrective actions taken if applicable.

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

Interpretive Guidelines: §484.50(e)(2)
Immediately is defined as reporting without delay. The interim between discovery and reporting may be influenced by the individual situation. However, the reporting must be accomplished as soon as possible following the discovery.

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

§484.50(f)(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.

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

Interpretive Guidelines §484.50(f)(1), (2)
Plain language (also referred to as Plain English) is communication the patient/representative 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.

"Auxiliary Aids and Services" who are hearing impaired may include services and devices such as qualified interpreters on-site or through video remote interpreting (VRI) services; note takers; real-time computer-aided transcription services; written materials; exchange of written notes; telephone handset amplifiers; assistive listening devices; assistive listening systems; telephones compatible with hearing aids; closed caption decoders; open and closed captioning, including real-time captioning; voice, text, and video-based telecommunications products and systems, including text telephones (TTYs), videophones, and captioned telephones, or equally effective telecommunications devices; videotext displays; accessible electronic and information technology. Auxiliary aids and services for individuals who are blind or have low vision may include services and devices such as qualified readers; taped texts; audio recordings; Brailed materials and displays; screen reader software; magnification software; optical readers; secondary auditory programs (SAP); large print materials; accessible electronic and information technology; or other effective methods of making visually delivered materials available to individuals who are blind or have low vision.

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

§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.

§484.55(a) Standard: Initial assessment visit.

§484.55(a)(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.

Interpretive Guidelines §484.55(a)(1)
For patients with orders for only nursing services or both nursing and rehabilitation therapy services, a registered nurse must conduct the initial assessment visit. For patients receiving only rehabilitation therapy, the initial assessment may be made by the applicable rehabilitation professional rather than the registered nurse. See §484.55(a)(2)

The initial assessment bridges the gap between the first patient encounter and the completion of the comprehensive assessment. Immediate care and support needs are those items and services that will

maintain the patient's health and safety through the interim period until the HHA can complete the comprehensive assessment and implement the plan of care. These care and support needs may include items such as the availability of medication, mobility aids for safety, skilled treatments, fall risks measures, and nutritional needs.

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

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

§484.55(a)(2) When rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician who is 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.

Interpretive Guidelines §484.55(a)(2)
Occupational therapy alone cannot establish initial eligibility for the Medicare home health benefit. The patient needs skilled nursing (SN), physical therapy (PT) and/or speech-language pathology (SLP) to initially qualify for the benefit. Once the patient has initially qualified for the Medicare home health benefit, a continued need for OT (after the need for SN, PT, and/or SLP have ceased) can be used to qualify the patient for subsequent episodes of care. See 42 CFR 409.42(c)(4).

§484.55(b) Standard: Completion of the comprehensive assessment.

§484.55(b)(1) The comprehensive assessment must be completed in a timely manner, consistent with the patient's immediate needs, but no later than 5 calendar days after the start of care.

Interpretive Guidelines §484.55(b)(1)
The start of care date is the date of the initial assessment and the comprehensive assessment must be completed within 5 calendar days of that date.

§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.

§484.55(b)(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.

Interpretive Guidelines: 484.55(b)(3)
A qualified therapist (registered and/or licensed by the State in which they practice) should perform the comprehensive assessment for therapy services ordered.

§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:

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

Interpretive Guidelines §484.55(c)(1)
Completion of the comprehensive assessment should provide the HHA with a complete picture of the patient's status in order to develop the 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 their functional capacity within the community is intended to be a screening of the patient's relationships and living environment and their impact on the delivery of services and the patient's ability to participate in his or her own care.

Assessment the patient's functional status includes the patient's level of ability to function independently in the home such as activities of daily living.

Assessment 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.

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

Interpretive Guidelines §484.55(c)(2)
Consistent with the principles of patient centered care, the intent in identifying patient strengths is to empower the patient to take an active role in their care. The HHA asks the patient to recognize her/his own strengths while the HHA also identifies patient strengths to inform the plan of care and to set goals with associated outcomes. Examples of patient strengths assessed by HHAs through observation and patient self-identification may include factors such as patient's awareness of disease status, knowledge of medications, 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 informing the patient what will be done for them and when (i.e. the patient as passive recipient of services).

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

A 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.

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

Interpretive Guidelines §484.55(c)(3)
Medicare does not limit the number of continuous 60-day episode recertifications for beneficiaries who continue to be eligible for the home health benefit. Therefore, the assessment must clearly demonstrate the continuing need and patient eligibility for the home health benefit.

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

Interpretive Guidelines §484.55(c)(4)
The HHA identifies those social needs of the patient that may impact the success of the plan of care. These may include a wide range of needs including but not limited to support services such as meals on wheels; information regarding personal resources, transportation and interpersonal relationships.

§484.55(c)(5) A review of all medications the patient is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy.

Interpretive Guidelines §484.55(c)(5)
The patient's clinical record should identify all medications the patient is taking, including frequency of administration and route, that the patient is taking both prescription and non-prescription. The documentation in the clinical record should confirm that the HHA nurse considered each medication the patient is currently taking for possible side effects and the list of medications in its entirety for possible drug interactions. The HHA should have policies that guide the clinical staff in the event there is a concern identified with a medication that should be reported to the physician.

In rehabilitation therapy only cases, the therapist submits a list of the medications, which he/she collects during the comprehensive assessment, to a HHA nurse for review. The HHA should contact the physician if indicated.

§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;

§484.55(c)(7) The patient's representative (if any);

§484.55(c)(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.

§484.55(d) <u>Standard: Update of the comprehensive assessment.</u>

The comprehensive assessment must be updated and revised (including the administration of the OASIS) as frequently as the patient's condition warrants due to a major decline or improvement in the patient's health status, but not less frequently than--

Interpretive Guidelines §484.55(d)
A marked improvement or worsening of a patient's condition, which changes the plan of care needed and was not anticipated in the plan of care, would be considered a major change.

§484.55(d)(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.

Interpretive Guidelines §484.55(d)(1)

The update of the comprehensive assessment may be performed any time up to and including the 60th day from the previous comprehensive assessment.

§484.55(d)(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;

§484.55(d)(3) At discharge.

Interpretive Guidelines § 484.55(d)(3)
The update of the comprehensive assessment at discharge would include a summary of the patient's progress in meeting the care plan goals.

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

Patients are accepted for treatment on the reasonable expectation that an HHA can meet the patient's medical, nursing, rehabilitative, and social needs in his or her place of residence.

Each patient must receive an individualized written plan of care, including any revisions or additions.

The individualized plan of care must specify the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, including identification of the responsible discipline(s), and the measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care.

The individualized plan of care must also specify the patient and caregiver education and training.

Services must be furnished in accordance with accepted standards of practice.

Interpretive Guidelines §484.60
A reasonable expectation that the HHA can provide care means that the skilled services which the HHA will provide may be provided effectively and safely within the home in consideration of the patient's level of acuity.

"Accepted standards of practice" include guidelines and/or 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.

§484.60 (a) <u>Standard: Plan of care.</u>

§484.60(a)(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.

Interpretive Guidelines §484.60(a)(1)
Patient measurable outcomes may include such measurements as end-result functional and physical health improvement/stabilization, health care utilization measures (hospitalization and emergency department use), and potentially avoidable events.

Patient specific goals are individualized to the patient based on the medical diagnosis, physician's orders, comprehensive assessment and patient input. Progress/non-progress toward achieving the goals is evaluated through measurable outcomes, which may be described as a patient's response to a health care intervention.

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

The patient's physician(s) provide orders for treatments and services. These orders may be obtained from more than one physician and are the foundation of the plan of care. These are the "relevant" physicians. The HHA includes goals for the patients, patient preferences and service schedules as a part of the plan of care (See §484.60(a)(2) below).

If the HHA misses visits or services and the visit cannot be rescheduled within the week as required by the plan of care, it must notify the responsible physician of the missed visit if there is any potential for clinical impact upon the patient. The physician decides whether the patient visit may be skipped or additional intervention is required by the HHA due to the impact on the patient.

If the patient or the patient's representative refuses care (such as dressing changes, essential medication or other services that could impact the patient's clinical wellbeing) on more than one occasion the HHA attempts to identify the cause of the refusal. If the HHA is unable to identify and address the cause, the HHA must communicate with the patient's responsible physician to discuss the options.

The physician should not be approached to delay or 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 that requests HHA services but does not provide the actual plan of care components (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.

§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 may choose to include.

Interpretive Guidelines §484.60(a)(2)(i-xvi)

(i) All pertinent diagnoses means all known diagnoses.

(ii) Mental status is most generally screened by asking questions on orientation to time place and person.

(ii) Psychosocial status may include, as relevant to the plan of care, interpersonal relationships in the immediate family, financial status, homemaker/household needs, vocational rehabilitation needs, family social problems and transportation needs.

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

Interpretive Guidelines: §484.60(a)(3)

All patient care orders, including verbal orders are part of the plan of care. The plan 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 to resign 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.

§484.60(b) Standard: Conformance with physician orders.

§484.60(b)(1) Drugs, services, and treatments are administered only as ordered by a physician. Drugs, services and treatments are ordered by the physician that establishes and periodically reviews the plan of care.

§484.60(b)(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 the screening contraindications.

Interpretive Guidelines §484.60(b)(2)
The HHA, in consultation with a physician, develops a written policy that addresses vaccination screening for safety exclusions and assessing contraindications prior to administration of the vaccine, as well as vaccine administration policies and procedures, including managing adverse reactions. No individual physician order is required for the vaccine unless required by State law. The administration of these vaccines is an exception to §484.60(b)(1).

§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'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 HHA's internal policies.

Interpretive Guidelines §484.60(b)(4)
When services are furnished based on a physician's oral order, the order must be put into writing by personnel authorized to do so by applicable State laws and regulations as well as by the HHA's internal policies. The orders must be signed and include the date and time 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. LPNs, LVNs and therapy assistants may receive verbal orders as permitted by State law.

In the absence of a state requirement, the HHA should establish a timeframe for physician authentication, (i.e. method of obtaining the physician signature of verbal/telephone orders received). The signature may

be written or in electronic form following the requirements of the particular system. A method must be established to identify the signer.

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

§484.60(c)(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.

Interpretive Guidelines §484.60(c)(1)
For responsible physician see §484.60(a)(1).

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

The plan of care may include orders for treatment or services incorporated from physicians other than the responsible physician. These orders are approved by the responsible physician as an updated plan of care. With a change in patient condition, the HHA should notify the responsible physician and the physician(s) associated with the relevant aspect of care.

Interim changes in physician orders and the plan of care do not automatically restart the timeframe for physician review of the plan of care.

§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.

§484.60(c)(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.

Interpretive Guidelines §484.60(c)(3)(i)
There must be evidence in the clinical record that the HHA has explained to the patient or their legal representative that a change to the plan of care has occurred and how this change will impact the care delivered by the HHA. The clinical record also documents, through notation, that the revised plan of care was shared with or by evidence of new orders received by 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).

Interpretive Guidelines §484.60(c)(3)(ii)
Discharge planning begins early in the provision of care and must be revised as the patient's medical condition or life circumstances change. As these changes are identified there must be evidence in the clinical record that the HHA discussed these changes with the patient, any representatives, caregivers and the responsible physician.

Other health care professionals who may need to be notified of discharge plan changes are those relevant physicians who are also contributing orders to the care plan.

§484.60(d) Standard: Coordination of Care.

The HHA must:

§484.60(d)(1) Assure communication with all physicians involved in the plan of care.

Interpretive Guidelines §484.60(d)(1)
The physician who initiated home health care is responsible for the ongoing plan of care; however, in order to assure the development and implementation of a coordinated plan of care, communication with all physicians involved in the patient's care is often necessary. While a patient may see several physicians for various medical problems, not all of the physicians would necessarily be involved in the skilled services defined in the home health plan of care. For this requirement physicians involved in the plan of care are those physicians who give orders that are directly related to home health skilled services.

§484.60(d)(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.

Interpretive Guidelines §484.60(d)(2)
The clinical manager or other staff designated by the HHA is responsible for integrating orders from all relevant physicians involved into the HHA plan of care and ensuring the orders are approved by the responsible physician.

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

Interpretive Guidelines §484.60(d)(3)
The HHA schedules/provides care by various disciplines in a manner that:

- The agency manages the scheduling of patients taking into consideration patient preferences and the type of services that are being provided; a patient may become fatigued after a HH aide visit assisting with a bath just before a physical therapy visit, thus making the therapy session less effective.

- The agency manages 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.

- The agency works with the patient to recommend and make safety modifications in the home.

- The agency assures that staff who provide care are communicating any patient concerns and patient progress toward the goals of the plan of care with others involved in the patient's care.

§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.

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

Interpretive Guidelines §484.60(d)(5)
The comprehensive assessment, patient-centered plan of care and the goals identified therein inform the training and education objectives for each patient. The goals of the HHA episode are established at admission and revised as indicated by the patient's condition. With the discharge plan clearly identified, patient education and documentation of the patient response to the education begins upon admission and continues throughout the HHA services. The patient/caregiver responses to and comprehension of the training is monitored.

§484.60(e) <u>Standard: Written information to the patient.</u>

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

Interpretive Guidelines §484.60(e)
Once the comprehensive assessment is completed (within 5 days of the initial visit) and the plan of care is approved by the responsible physician, the documents listed in (e) (1-5) must be provided to the patient and/or their representative.

Clear written communication between the HHA and the patient and/or representative ensures that patients and families understand what services to expect from the HHA, the purpose of each service and when to expect the services.

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

Interpretive Guidelines §484.60(e)(1)
The most current written visit schedule provided to the patient is consistent with the most current plan of care.

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

Interpretive Guidelines §484.60(e)(2)
The written information regarding the patient's medication regimen is provided to the patient and/or caregiver and is based on the results of the medication review conducted at §484.55 (c) (5). The medication administration instructions must be written in plain language avoiding the use of medical abbreviations.

This information is also provided in rehabilitation therapy only cases. See §484.55 (c) (5) for communication between the therapist and the HHA nurse regarding medications.

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

§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.

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

Interpretive Guidelines §484.60(e)(5)
The name and contact information of the clinical manager (telephone number must be provided and e-mail may be provided as well if the patient prefers electronic communication) must be provided to the patient. The HHA explains to the patient that the clinical manager may be contacted to discuss any concerns about their services.

§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(a) Standard: Program scope.

§484.65(a)(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.

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

Interpretive Guidelines §484.65(a)(2)
The indicators utilized in the HHA QAPI program are selected by the HHA and are 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 includes procedures for and frequency of measurement and analysis of indicators.

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

§484.65(b) Standard: Program data.

§484.65(b)(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.

§484.65(b)(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.

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

Interpretive Guidelines §484.65(b)

The governing body ensures that the HHA systematically collects data to measure various aspects of quality of care; the frequency of data collection; how the data will be collected and analyzed; the HHA uses the data that is collected to assess quality and stimulate performance improvement.

§484.65(c) Standard: Program activities.

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

§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.

Interpretive Guidelines §484.65(c)(1)-(3)
High risk areas may include global concerns such as a type of service such as pediatrics, geographic concerns such as the safety of a neighborhood served or specific patient care services such as 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 and service 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.

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

§484.65(d) Standard: Performance improvement projects.

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

§484.65(d)(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.

§484.65(d)(2) The HHA must document the quality improvement projects undertaken, the reasons for conducting these projects, and the measurable progress achieved on these projects.

Interpretive Guidelines §484.65(d)(1), (2)
The HHA should have at a minimum 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.

§484.65(e) Standard: Executive Responsibilities.

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

§484.65(e)(1) That an ongoing program for quality improvement and patient safety is defined, implemented, and maintained;

§484.65(e)(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;

§484.65(e)(3) That clear expectations for patient safety are established, implemented, and maintained; and

§484.65(e)(4) That any findings of fraud or waste are appropriately addressed.

Interpretive Guidelines §484.65(e)(1)-(4)
In the event that the HHA identifies or otherwise learns of a possibly illegal action by its employees, contractors or responsible/relevant physicians, it is the responsibility of the HHA to report the actions to the appropriate authorities according to the individual State laws and the nature of the action(s).

§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(a) Standard: Prevention

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

Interpretive Guidelines §484.70(a)

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 when health care is delivered. Standard precautions are based on the principle that all blood, body fluids, secretions, excretions, may contain transmissible infectious agents.

The following are six (6) elements, identified by the Center for Disease Control and Prevention (CDC) which apply during any episodes of patient care;

Hand Hygiene;

Environmental Cleaning and Disinfection;

Injection and Medication Safety;

Appropriate Use of Personal Protective Equipment;

Minimizing Potential Exposures; and

Reprocessing of reusable medical equipment between each patient and when soiled.

1. Hand Hygiene

Hand Hygiene should be performed at a minimum:

Before contact with a patient;

Before performing an aseptic task (e.g., insertion of IV, preparing an injection, performing wound care);

After contact with the patient or objects in the immediate vicinity of the patient;

After contact with blood, body fluids or contaminated surfaces;

Moving from a contaminated-body site to a clean body site during patient care; and

After removal of personal protective equipment (PPE);

Alcohol based hand sanitizers are the most effective products for reducing the number of germs on the hands of health care providers. Antiseptic soaps and detergents are the next most effective and non-antimicrobial soaps are the least effective. When hands are not visibly dirty, alcohol based hand sanitizers are the preferred method for hand hygiene. The agency 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 maintain their equipment and supplies clean,

during the home visit, during transport of reusable patient care items in a carrying case in the staff vehicle and use in multiple patients' homes.

3. Injection and Medication Safety

Safe injection practices include but are not limited to:

Use aseptic technique when preparing and administering medications;

Do not reuse needles, lancets, or syringes for more than one use on one patient; Use single-dose vials for parenteral medications whenever possible;

Do not administer medications from a single-dose vial or ampule to multiple patients;

Use fluid infusion and administration sets (i.e intravenous bags, tubing and connectors) for one patient only and dispose appropriately after use;

Consider a syringe or needle/cannula contaminated once it has been used to enter or connect to patient's intravenous infusion bag or administration set;

Enter medication containers with a new needle and a new syringe even when obtaining additional doses for the same patient;

Insulin pens must be dedicated for a single patient and never shared even if the needle is changed;

Sharps disposal should be in compliance with applicable state and local laws and regulations.

4. Appropriate Use of Personal Protective Equipment

Appropriate Use of Personal Protective Equipment (PPE) refers to use of specialized clothing or equipment worn for protection and as a barrier against infectious materials or any potential infectious disease exposure. PPE protects the caregiver's skin, hands, face, respiratory tract, and clothing from exposure. Examples of PPE includes: gloves, gowns, face masks, eye protections if there is the potential for exposure to blood or body fluids of any patient. The selection of PPE is determined by the expected amount of exposure to the infectious materials, durability of the PPE, and suitability of the PPE for the task.

5. Minimizing Potential Exposures

Minimizing Potential Exposures focuses in the home health setting on prevention of exposure for other family members and visitors and the prevention of transmission by the HHA staff while transporting medical specimens and medical waste, such as sharps.

6. Reprocessing of Reusable Medical Equipment Between Each Patient and When Soiled

Reprocessing (cleaning and disinfecting) of reusable medical equipment is essential. Reusable medical equipment (e.g., blood glucose meters and other devices such as, blood pressure cuffs, oximeter probes) must be cleaned/disinfected prior to use on another patient and when soiled. The HHA must ensure that its staff are trained to:

- Maintain separation between clean and soiled equipment to prevent cross contamination; and

- To follow the manufacturer's instructions for use and current standards of practice for patient care equipment transport, storage, and cleaning/disinfecting.

§484.70(b) Standard: Control.

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

Interpretive Guidelines §484.70(b)

The HHA should have a surveillance program to identify, investigate and control infections or transmission of communicable disease specific to care/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."

The HHA infection control program should use observation and evaluation of services from all disciplines to identify sources or causative factors of infection, track patterns and trends of infections, establish a corrective plan, and monitor effectiveness of the corrective plan.

Cross Reference to §484.65(a), QAPI Program Scope.

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

Interpretive Guidelines §484.70(b)(1)

The HHA should develop a procedure for the identification of infections or risk for infections among patients. It is the prerogative of the HHA to determine the methodology to be used for identification. Examples of methodologies might include:

- Clinical record review;
- Staff reporting procedures;
- Review of laboratory results;
- Data analysis for physician 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.

The issues identified through the analysis of surveillance data should be used as a basis to improve care practices and control infections and transmission of communicable diseases.

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

Interpretive Guidelines §484.70(b)(2)
The plan developed to address or prevent infections or transmission of communicable disease should be based on the surveillance findings, any root cause identification, tracking data and analysis of findings.

Actions to facilitate improvements and disease prevention may include the following:

- Policy, procedure or practice changes to improve care;
- Education for patients, caregivers, and HHA personnel to prevent infections and transmission of communicable diseases; and/or
- 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 should evaluate and revises the plan as needed.

§484.70(c) Standard: Education.

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

Interpretive Guidelines §484.70(c)
HHA staff education should include as a minimum:

- Information on appropriate use, transport, storage, and cleaning methods of patient care equipment according to manufacturer's guidelines:
- Job-specific, infection prevention education and training to all healthcare personnel for all of their respective tasks;
- Processes to ensure that all healthcare 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);
- In-service infection control education for staff at periodic intervals (minimally annually) consistent with accepted standards of practice, such as: at orientation, annually, and as needed to meet the staffs 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 the patient's care, medical waste disposal, including instructions on how to implement current infection prevention/treatment practices in the home setting.

The education provided to patients and caregivers should be specific to the patient's plan of care, health conditions, and individual learning needs. The HHA should review training information with the

patient/caregiver, such as how to clean and care for equipment (for example: blood glucose meters, reusable catheters etc…) at sufficient intervals to re-enforce the comprehension an application of the training.

§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 and medical social work services as specified in §409.45 of this chapter.

Skilled professionals who provide services to HHA patients directly or under arrangement must participate in the coordination of care.

Interpretive Guidelines §484.75

§409.44 defines skilled nursing care as, "Skilled nursing care consists of those services that must, under State law, be performed by a registered nurse, or practical (vocational) nurse….."

§409.44 defines skilled therapy services as, "Physical therapy, speech-language pathology services, and occupational therapy: Speech-language pathology services and physical or occupational therapy services must relate directly and specifically to a treatment regimen (established by the physician, after any needed consultation with the qualified therapist) that is designed to treat the beneficiary's illness or injury."

§409.45 defines medical social services as: "The services are ordered by a physician and included in the plan of care; the services are necessary to resolve social or emotional problems that are expected to be an impediment to the effective treatment of the beneficiary's medical condition or to his or her rate of recovery; if these services are furnished to a beneficiary's family member or caregiver, they are furnished on a short-term basis and it can be demonstrated that the service is necessary to resolve a clear and direct impediment to the effective treatment of the beneficiary's medical condition or to his or her rate of recovery."

§484.75(a) <u>Standard: Provision of services by skilled professionals.</u>

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.

§484.75(b) <u>Standard: Responsibilities of skilled professionals.</u>

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

§484.75(b)(1) Ongoing interdisciplinary assessment of the patient;

Interpretive Guidelines §484.75(b)(1)

The term "interdisciplinary" is a term for an approach to healthcare that includes a range of health service personnel, both professionals and non-professionals, with the majority being from professional groups. Ongoing interdisciplinary assessment is the continual involvement of all HHA professional staff involved in the plan of care from the initial assessment through discharge and periodic interactive, discussions regarding the status and recommendations for the plan of care. An interdisciplinary approach recognizes the contributions of various health care disciplines (MDs, RNs, LPN/LVN, PT, OT, SLP, MSW, HH aides) and their interactions with each other to meet the patient's needs.

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

§484.75(b)(3) Providing services that are ordered by the physician as indicated in the plan of care;

§484.75(b)(4) Patient, caregiver, and family counseling;

§484.75(b)(5) Patient and caregiver education;

§484.75(b)(6) Preparing clinical notes;

§484.75(b)(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;

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

Interpretive Guidelines §484.75(b)(8)
An effective QAPI program should involve the contribution of all skilled professional staff for their input and personal investment in the implementation of the program. Skilled professional staff, regardless of whether the staff is a direct employee of the agency or under arrangement, are 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 or participation in performance improvement projects.

§484.75(b)(9) Participation in HHA-sponsored in-service training.

Interpretive Guidelines §484.75(b)(9)
Skilled professional staff, regardless of whether the staff is a direct employee of the agency or under arrangement, are expected to participate in all in-service training sessions and programs required by the HHA.

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

Interpretive Guidelines §484.75(c)
Documentation in the clinical record should show how communication and oversight exist between the skilled professional and assistant regarding the patient's status, the patient's response to services furnished by the assistant, and the effectiveness of the written instructions provided to the assistants.

Specific written instructions to assistants must be based on treatments prescribed in the 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.

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

Interpretive Guidelines §484.75(c)(1)
The HHA identifies a RN to supervise the care provided by Licensed Practical/Vocational Nurses. The RN monitors and evaluates LPN/LVN performance in the provision of services, provision of treatments, patient education, communication with the RN, and data collection regarding the patient's status and health needs as delegated by the RN. Only a registered nurse may perform comprehensive assessment, evaluations, care planning and discharge planning.

§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(e-f) or (g-h), respectively.

Interpretive Guidelines §484.75(c)(2)
An assistant must be supervised by a skilled therapy professional for the applicable therapy type. Only physical therapists may supervise physical therapist assistants and only occupational therapists may supervise occupational therapy assistants. The applicable therapist monitors and evaluates therapy assistant performance in the, 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 assessment, patient evaluations, care planning and discharge planning.

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

Interpretive Guidelines §484.75(c)(3)
Any social service provided by a social work assistant must be supervised by a Medical 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. Only the medical social worker may perform comprehensive assessment, patient evaluations, care planning and discharge planning.

§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(a) Standard: Home health aide qualifications.

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

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

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

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

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

Interpretive Guidelines §484.80(a)(1)
The regulation describes four methods by which a home health aide may become qualified.

1. The candidate may successfully complete a training program that an HHA provides (unless prohibited by non-compliance) and successfully complete competency testing by that HHA.

2. The candidate may qualify by completing a competency 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. Per Part 42 CFR 483 Subpart D Requirements for States and State Agencies on Nurse Aide Training and Competency Evaluation, a nurse aide who has completed an approved course, passed the written exam, 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.

4. The candidate may qualify by successfully completing a State administered program that licenses or certifies HH aides and meets or exceeds the requirements under paragraphs (b) and (c) of this section.

The HHA is responsible for ensuring that any home health aide, employed by the HHA directly or under arrangement, who provides aide services for the HHA meets the provisions of this regulation. The HHA must ensure that all its aides are competent to carry out the patient care they are assigned, in a safe, effective, and efficient manner. This includes home health aides trained and evaluated by other HHA's or other organizations, and those hired by the HHA under an arrangement as well as those who are employed by the HHA.

In situations where a state has more stringent requirements for aide education, training, competency evaluations, certification and supervision, those state requirements take precedence over Federal requirements. Likewise, in situations where the federal requirements are more stringent, those Federal requirements would take precedence over the more lenient state requirements.

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

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

§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. Classroom and supervised practical training must total at least 75 hours.

§484.80(b)(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.

§484.80(b)(3) A home health aide training program must address each of the following subject areas:
(i) Communication skills, including the ability to read, write, and verbally report clinical information to patients, representatives, and caregivers, as well as to other HHA staff.

(ii) Observation, reporting, and documentation of patient status and the care or service furnished.

(iii) Reading and recording temperature, pulse, and respiration.

(iv) Basic infection prevention and control procedures.

(v) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor.

(vi) Maintenance of a clean, safe, and healthy environment.

(vii) Recognizing emergencies and the knowledge of instituting emergency procedures and their application.

(viii) The physical, emotional, and developmental needs of and ways to work with the populations served by the HHA, including the need for respect for the patient, his or her privacy, and his or her property.

(ix) Appropriate and safe techniques in performing personal hygiene and grooming tasks that include

(A) Bed bath;

(B) Sponge, tub, and shower bath;

(C) Hair shampooing in sink, tub, and bed;

(D) Nail and skin care;

(E) Oral hygiene;

(F) Toileting and elimination;

(x) Safe transfer techniques and ambulation;

(xi) Normal range of motion and positioning;

(xii) Adequate nutrition and fluid intake;

(xiii) Recognizing and reporting changes in skin condition; and

(xiv) Any other task that the HHA may choose to have an aide perform as permitted under state law.

(xv) The HHA is responsible for training home health aides, as needed, for skills not covered in the basic checklist, as described in paragraph (b)(3)(ix) of this section.

Interpretive Guidelines §484.80(b)(3)(i)-(xv)
These requirements have added two additional areas that must be included in HHA training. 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. New training content added in the January 13, 2018 requirements include:

1. Communication skills in regards 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.

The HHA ensures that HH aides determined as competent prior to January 13, 2018 complete new training modules for the above.

§484.80(b)(4) The HHA must maintain documentation that demonstrates that the requirements of this standard have been met.

§484.80(c) Standard: Competency evaluation.

An individual may furnish home health services on behalf of an HHA only after that individual has successfully completed a competency evaluation program as described in this section.

Interpretive Guidelines §484.80(c)
The HHA may not allow an aide to provide services to patients independently until they have successfully completed competency testing either at that HHA or at another training facility and successful completion is verified through documentation provided by the applicant or the training facility.

§484.80(c)(1) The competency evaluation must address each of the subjects listed in paragraph (b)(3) of this section. Subject areas specified under paragraphs (b)(3)(i), (b)(3)(iii), (b)(3)(ix), (b)(3)(x), and (b)(3)(xi) of this section must be evaluated by observing an aide's 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.

Interpretive Guidelines §484.80(c)(1)
The following skills must be evaluated by observing the aide's performance while carrying out the task with a patient.

(b)(3)(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;

(b)(3)(iii) Reading and recording temperature, pulse, and respiration;

(b)(3)(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;

(b)(3)(x) Safe transfer techniques and ambulation;

(b)(3)(xi) Normal range of motion and positioning.

Each of the tasks above must be observed in its entirety to confirm the competence of the HHA aide. The tasks must not be simulated in any manner and the use of a mannequin or pseudo-patient is not an acceptable substitute.

§484.80(c)(2) A home health aide competency evaluation program may be offered by any organization, except as specified in paragraph (f) of this section.

§484.80(c)(3) The competency evaluation must be performed by a registered nurse in consultation with other skilled professionals, as appropriate.

Interpretive Guidelines §484.80(c)(3)
Other skilled professionals may provide input into the components of the competency evaluation, for example a physical therapist may contribute to the competency evaluation/ observation for assessing transfer techniques or ambulation. However, a RN is ultimately responsible for the competency assessment of the HHA aide. The competency evaluation may be completed by more than one RN.

§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.

§484.80(c)(5) The HHA must maintain documentation which demonstrates that the requirements of this standard have been met.

Interpretive Guidelines §484.80(c)(5)
Documentation of competency must include:

- A description of the competency evaluation program, including the qualifications of the instructors;
- Documentation that confirms that competency was determined by direct observation and the results of those observations.
- Documentation that distinguishes between skills evaluated during patient care, and those taught in a laboratory, i.e. using a volunteer or combination of evaluation techniques including direct observation of patient care, skills lab demonstration, written and oral examinations.
- How additional skills (beyond the basic skills listed in the regulation) are taught and tested if the admission policies and case-mix of HHA patients require aides to assist medically complex patients.

If an aide is unable to provide the above evidence they will need to complete competency testing before providing care to patients.

§484.80(d) <u>Standard: In-service training.</u>

A home health aide must receive at least l2 hours of in-service training during each 12-month period. In service training may occur while an aide is furnishing care to a patient.

Interpretive Guidelines §484.80(d)
For the 12 months following the successful completion of the HHA aide training/competency evaluation, the annual 12 hours of in service is considered to be met unless the HHA is introducing a new procedure which would indicate the need for the HHA aide to also attend.

When in service training is conducted during patient care, the HHA staff must respect the patient's right to be informed of and consent to the training and be informed how the training will be conducted.

§484.80(d)(1) In-service training may be offered by any organization and must be supervised by a registered nurse.

Interpretive Guidelines §484.80(d)(1)
RN supervision means that the RN approves the content of and attends the inservice training to ensure the content is consistent with the HHA's policies and procedure and to respond to interactive questions from participants.

§484.80(d)(2) The HHA must maintain documentation that demonstrates the requirements of this standard have been met.

§**484.80(e) <u>Standard: Qualifications for instructors conducting classroom and supervised practical training.</u>**

Classroom and supervised practical training must be performed by a registered nurse who possesses a minimum of 2 years nursing experience, at least 1 year of which must be in home health care, or by other individuals under the general supervision of the registered nurse.

Interpretive Guidelines §484.80(e)
"Other individuals" refers to:

- Physical therapists;
- Occupational therapists;
- Speech and language pathologists;
- Medical social workers,
- LPN/LVNs; and
- Nutritionists.

§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:

§484.80(f)(1) Was out of compliance with the requirements of paragraphs (b), (c), (d), or (e) of this section; or

§484.80(f)(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

Interpretive Guidelines §484.80(f)(2)
If a HHA chooses to use volunteers for patient care services, the volunteer must either be capable of providing the service secondary to a State license (RN/LPN/LVN/physical therapist, occupational therapist or speech therapist) or have successfully completed any training/competency requirements applicable to the service performed.

§484.80(f)(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

Interpretive Guidelines §484.80(f)(3)
Sub-standard care is defined as non-compliance with the HHA regulations at a Condition level.

If a partially extended survey is conducted, but no Condition of Participation is found to be out of compliance, the HHA would not be precluded from offering its own aide training and/or competency evaluation program. If a Condition of Participation is found to be out of compliance during a partially extended survey the HHA may complete any training course and competency evaluation program in progress. However, the HHA may not accept new candidates into the program or begin a new program for 2 years after receiving written notice from the CMS Regional Office that the HHA was found to be out of compliance with one or more Conditions of Participation.

Correction of the Condition level deficiency does not remove the 2-year restriction identified in this standard.

§484.80(f)(4) Was assessed a civil monetary penalty of $5,000 or more as an intermediate sanction; or

§484.80(f)(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

§484.80(f)(6) Had all or part of its Medicare payments suspended; or

§484.80(f)(7) Was found under any federal or state law to have:

(i) Had its participation in the Medicare program terminated; or

(ii) Been assessed a penalty of $5,000 or more for deficiencies in federal or state standards for HHAs; or

(iii) Been subjected to a suspension of Medicare payments to which it otherwise would have been entitled; or

(iv) Operated under temporary management that was appointed to oversee the operation of the HHA and to ensure the health and safety of the HHA's patients; or

(v) Been closed, or had its patients transferred by the state; or

(vi) Been excluded from participating in federal health care programs or debarred from participating in any government program.

Interpretive Guidelines §484.80(f)(7)(i)-(vi)
The most reliable source of information to assure that an HHA has not been excluded from participating in federal health programs is the List of Excluded Individuals and Entities on the HHS Office of Inspector General (OIG) website: https://oig.hhs.gov/exclusions/

To confirm whether an entity providing services under arrangement has been debarred in accordance with the debarment regulations at 2 CFR 180.300, a HHA may check the System for Award Management (SAM), an official website of the U.S. government: https://www.sam.gov/portal/SAM/##11#1

§484.80(g) Standard: Home health aide assignments and duties.

§484.80(g)(l) Home health aides are assigned to a specific patient by a registered nurse or other appropriate skilled professional, with written patient care instructions for a home health aide prepared by that registered nurse or other appropriate skilled professional (that is, physical therapist, speech-language pathologist, or occupational therapist).

Interpretive Guidelines §484.80(g)(l)
The act of assigning a "specific patient" to an home health aide should be an intentional & deliberate decision that takes into consideration the skills of the aide, the availability of the aide for patient care continuity, patient preference whenever possible, and other considerations as determined by the patient's care needs.

Most generally, home health aide services are provided in conjunction with and as an adjunct to a skilled nursing service. However, it is possible that a skilled therapist may identify the need for home health aide

services as discussed in §484.80(b)(3) in association with a skilled therapy service only. In these cases the skilled therapist may develop the plan for the aide and may perform the supervisory visit. Any concerns identified by the therapist during the supervisory visits must be communicated to the HHA clinical manager or HHA supervising nurse.

§484.80(g)(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.

§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.

Interpretive Guidelines §484.80(g)(3)(iv)
Self-administration of medications means that the patient (or the patient's caregiver) is able to 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 in this requirement means that the HH Aide may take only a passive role in this activity. This assistance is limited to getting water or fluids for the patient to take their medication.

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

Interpretive Guidelines §484.80(g)(4)
The term "interdisciplinary" is used as a generic term for an approach to healthcare that includes a range of health service workers, both professionals and non-professionals, with the majority being from

professional groups. The home health interdisciplinary team, which meets together, is composed of the disciplines including MDs, RNs, LPN/LVN, PT& PTA, OT & OTA, SLP, MSW, and HH aides.

During interdisciplinary team discussions the HHA aide must participate as a member either in person or remotely.

§484.80(h) Standard: Supervision of home health aides.

§484.80(h)(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 §484.80(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.

Interpretive Guidelines §484.80(h)(1)(i-iii)
If, during the supervisory visit, a concern is identified at a patient's home without the aide being present, the skilled professional must go on site with the aide at the next scheduled aide visit to address the concern.

An annual on-site supervisory visit must be made while the aide is providing care to a single patient.

§484.80(h)(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.

§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 a competency evaluation in accordance with paragraph (c) of this section.

§484.80(h)(4) Home health aide supervision must ensure that aides furnish care in a safe and effective manner, including, but not limited to, the following elements:

(i) Following the patient's plan of care for completion of tasks assigned to a home health aide by the registered nurse or other appropriate skilled professional;

(ii) Maintaining an open communication process with the patient, representative (if any), caregivers, and family;

(iii) Demonstrating competency with assigned tasks;

(iv) Complying with infection prevention and control policies and procedures;

(v) Reporting changes in the patient's condition; and

(vi) Honoring patient rights.

Interpretive Guidelines §484.80(h)(4)(i)-(vi)
Each supervisory visit would need to document how home health aide supervision evaluated the elements of this standard. Documentation of the on-site supervisory visit addresses at a minimum the elements in (i) through (vi).

§484.80(h)(4)(ii) - Maintaining an open communication process with the patient and/or representative, means that the aide is able to explain what he/she is 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.

§484.80(h)(5) If the home health agency chooses to provide home health aide services under arrangements, as defined in §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.

§484.80(i) Standard: Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit.

An individual may furnish personal care services, as defined in §440.167 of this chapter, on behalf of an HHA. Before the individual may furnish personal care services, the individual must meet all

qualification standards established by the state. The individual only needs to demonstrate competency in the services the individual is required to furnish.

Subpart C--Organizational Environment

§484.100 Condition of participation: Compliance with Federal, State, and local laws and regulations related to the health and safety of patients.

The HHA and its staff must operate and furnish services in compliance with all applicable federal, state, and local laws and regulations related to the health and safety of patients. If state or local law provides licensing of HHAs, the HHA must be licensed.

Interpretive Guidelines §484.100
Non-compliance with this condition means: 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. 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.

§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:

§484.100(a)(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.

§484.100(a)(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.

§484.100(a)(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.

§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.

§484.100(c) Standard: Laboratory services.

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

Interpretive Guidelines §484.100(c)
This standard addresses the relevant requirements of 42 CFR Part 493—Laboratory Requirements that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

If HHAs perform any testing as defined by CLIA, then the HHA is regarded as a laboratory. The CLIA definition of a laboratory is a facility that performs testing on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings.

An HHA may request a Certificate of Waiver (COW) if it performs only waived laboratory tests. Waived tests are those tests that have been determined to be so simple that if performed incorrectly will pose no risk of harm. A list of waived tests may be viewed at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Categorization_of_Tests.html.

A parent HHA may apply for one COW as long as all of its sites are under one HHA Medicare provider number.

Interpretive Guidelines §484.100(c)(1)
If the HHA nurse or HHA employee provides only assistance to a patient who has her/his own glucose meter, a COW is not required. If the HHA nurse or HHA employee conducts the test, whether the patient's equipment or the agency equipment is used, a COW is required.

Agencies may allow patients to use the HHA testing equipment for a short, defined period of time until the patient has obtained his or her own testing equipment or the laboratory test is needed for a short period of time. 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.

§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.

§484.102 Condition of participation: Emergency preparedness.

*****Refer to State Operations Manual Appendix Z, Emergency Preparedness for All Provider and Certified Supplier Types for guidance*****

The 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:

§484.102(a) 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:

§484.102(a)(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

§484.102(a)(2) Include strategies for addressing emergency events identified by the risk assessment.

§484.102(a)(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.

§484.102(a)(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.

§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 annually. At a minimum, the policies and procedures must address the following:

§484.102(b)(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 provisions at §484.55.

§484.102(b)(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.

§484.102(b)(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.

§484.102(b)(4) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.

§484.102(b)(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.

§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 annually. The communication plan must include all of the following:

§484.102(c)(1) Names and contact information for the following:

(i) Staff

(ii) Entities providing services under arrangement. (iii) Patients' physicians

(iv) Volunteers.

§484.102(c)(2) Contact information for the following:

(i)Federal, State, tribal, regional, or local emergency preparedness staff

(ii) Other sources of assistance.

§484.102(c)(3) Primary and alternate means for communicating with the HHA's staff, Federal, State, tribal, regional, and local emergency management agencies.

§484.102(c)(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.

§484.102(c)(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).

§484.102(c)(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.

§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 annually.
§484.102(d)(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 annually.

iii. Maintain documentation of the training.

iv. Demonstrate staff knowledge of emergency procedures.

§484.102(d)(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 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.
ii. Conduct an additional exercise that may include, but is not limited to the following:
ii(A) A second full-scale exercise that is community-based or individual, facility based.
ii(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.
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.

§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:

§484.102(e)(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

§484.102(e)(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

§484.102(e)(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.

§484.102(e)(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, 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.

§484.102(e)(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.

§484.105 Condition of Participation: The HHA must organize, manage, and administer its resources to attain and maintain the highest practicable functional capacity, including providing optimal care to achieve the goals and outcomes identified in the patient's plan of care, for each patient's medical, nursing, and rehabilitative needs. The HHA must assure that administrative and supervisory functions are not delegated to another agency or organization, and all services not furnished directly are monitored and controlled. The HHA must set forth, in writing, its organizational structure, including lines of authority, and services furnished.

Interpretive Guidelines §484.105
The roles of the governing body, administrator and clinical manager may not be delegated.

Delegated means relinquishing the day to day responsibility for the operation of the HHA to another person or organization on an on-going basis (does not include periodic "acting" employees in the absence of the administrator or clinical manger.)

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.

§484.105 (a) <u>Standard: Governing body.</u>
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(b) <u>Standard: Administrator.</u>

§484.105(b)(1) The administrator must:

(i) Be appointed by and report to the governing body;

(ii) Be responsible for all day to day operations of the HHA;

(iii) Ensure that a clinical manager as described in paragraph (c) of this section is available during all operating hours;

Interpretive Guidelines §484.105 (b)(1)(iii)
"Operating hours" include all hours which open and providing care to patients.

(iv) Ensure that the HHA employs qualified personnel, including assuring the development of personnel qualifications and policies.

§484.105(b)(2) When the administrator is not available, a qualified, pre-designated person, who is authorized in writing by the administrator and the governing body, assumes the same responsibilities and obligations as the administrator. The pre-designated person may be the clinical manager as described in paragraph (c) of this section.

Interpretive Guidelines §484.105(b)(2)
Pre-designation means that the individual who is responsible for fulfilling the role of the administrator in his/her absence is established in advance and approved by the governing body.

The HHA administrator names, in advance, the person or persons who will assume the administrator responsibilities in his/her absence. The appointments must also be pre-approved by the governing body.

§484.105(b)(3)The administrator or a pre-designated person is available during all operating hours.

Interpretive Guidelines §484.105(b)(3)
Available means physically present at the agency or able to be contacted via telephone or other electronic means.

§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)(1) Making patient and personnel assignments,

§484.105(c)(2) Coordinating patient care,

§484.105(c)(3) Coordinating referrals,

§484.105(c)(4) Assuring that patient needs are continually assessed, and

§484.105(c)(5) Assuring the development, implementation, and updates of the individualized plan of care.

Interpretive Guidelines §484.105(c)
§484.115 defines the qualifications of a clinical manager to be a licensed physician, physical therapist, speech-language pathologist, occupational therapist, audiologist, social worker, or a registered nurse.

§484.105(d) Standard: Parent branch relationship.

§484.105(d)(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)(2) The parent HHA provides direct support and administrative control of its branches.

Interpretive Guidelines §484.105(d)(1), (2)
A branch office is a location, physically separate from the parent location, from which an HHA provides services under the same certification number as the parent agency. The parent location provides supervision and administrative control of branch offices on a daily basis to the extent that the branch depends upon the parent's supervision and administrative functions in order to meet the CoPs, and could not do so as an independent entity.

A citation of non-compliance at either a standard or Condition level, whether identified at the parent or a branch, is applicable to the both parent and branches.

Administrative control and direct support of a branch requires that the parent agency maintains responsibility for:

- The governing body oversight of the branch;
- Any branch contracts for services provided under arrangement;
- The branch 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;
- Assuming responsibility for branch human resource management;
- Assuring the appropriate disposition of closed clinical records from the branch; and
- Ensuring branch personnel training requirements are met.

If a branch provides a service which the parent does not provide, the parent retains overall responsibility for the quality of all such services provided.

484.105(e) <u>Standard: Services under arrangement.</u>

484.105(e)(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)).

484.105(e)(2) An HHA must have a written agreement with another agency, with an organization, or with an individual when that entity or individual furnishes services under arrangement to the HHA's patients. The HHA must maintain overall responsibility for the services provided under arrangement, as well as the manner in which they are furnished. The agency, organization, or individual providing services under arrangement may not have been:

(i) Denied Medicare or Medicaid enrollment;

(ii) Been excluded or terminated from any federal health care program or Medicaid;

(iii) Had its Medicare or Medicaid billing privileges revoked; or

(iv) Been debarred from participating in any government program.

484.105(e)(3) The primary HHA is responsible for patient care, and must conduct and provide, either directly or under arrangements, all services rendered to patients.

Interpretive Guidelines §484.105(e)(3)
The HHA retains overall responsibility for all services provided, whether directly or through arrangement. For example, an HHA may, in arranging or contracting for a service such as physical therapy, require the other party to do the day-by-day professional evaluation of the therapy service. However, the HHA may not delegate its overall administrative and supervisory responsibilities. All contracts for services should specify how the HHA supervision will occur.

§484.105(f) Standard: Services furnished.

484.105(f)(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)(2) All HHA services must be provided in accordance with current clinical practice guidelines and accepted professional standards of practice.

Interpretive Guidelines §484.105(f)(2)
The HHA must offer skilled nursing services and at least one other therapeutic service. However, only one service has to 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 his/her behalf with no intermediaries.

Contract services may be used as an adjunct to staffing for a direct service but may not be used in lieu of HHA staff if the service is considered to be provided directly. The use of contract staff in a direct service must be on a temporary basis to provide coverage for an unexpected staffing shortage or to provide a specialized service that the direct employees cannot provide.

If an HHA staff member is employed by more than one certified provider, each provider must maintain separate records regarding the employee's work schedule and issue a separate W-2 form to the employee.

§484.105(g) Standard: Outpatient physical therapy or speech language pathology services.

An HHA that furnishes outpatient physical therapy or speech-language pathology services must meet all of the applicable conditions of this part and the additional health and safety requirements set forth in §485.711, §485.713, §485.715, §485.719, §485.723, and §485.727 of this chapter to implement section 1861(p) of the Act.

Interpretive Guidelines §484.105(g)
If an HHA provides outpatient physical therapy services or outpatient speech pathology services it must also meet the following requirements:

§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

[§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: Disaster preparedness The organization has a written plan, periodically rehearsed, with procedures to be followed in the event of an internal or external disaster and for the care of casualties (patients and personnel) arising from a disaster.

§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.

§484.105(h)(1) Annual operating budget. There is an annual operating budget that includes all anticipated income and expenses related to items that would, under generally accepted accounting principles, be considered income and expense items. However, it is not required that there be prepared, in connection with any budget, an item by item identification of the components of each type of anticipated income or expense.

§484.105(h)(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:

(ii)(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.

(ii)(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.

(ii)(C) Whether the designated planning agency has approved or disapproved the proposed capital expenditure if it was presented to that agency.

§484.105(h)(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.

§484.105(h)(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.

§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) issuing orders for the home health plan of care, and appropriate HHA staff. This information may be maintained electronically.

§484.110(a) Standard: Contents of clinical record.
The record must include:

§484.110(a)(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;

§484.110(a)(2) All interventions, including medication administration, treatments, and services, and responses to those interventions;

Interpretive Guidelines §484.110(a)(2)
All interventions refers to those interventions performed by the HHA.

§484.110(a)(3) Goals in the patient's plans of care and the patient's progress toward achieving them;

§484.110(a)(4) Contact information for the patient, the patient's representative (if any), and the patient's primary caregiver(s);

§484.110 (a)(5) Contact information for the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA; and

Interpretive Guidelines §484.110(a)(5)
If the patient identifies an attending physician (whether it is the responsible HHA physician or another physician) who will resume their care after the HHA episode, the contact information of the physician should be included in the clinical record.

§484.110(a)(6)

(i) A completed discharge summary that is sent to the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any) within 5 business days of the patient's discharge; or

(ii) A completed transfer summary that is sent within 2 business days of a planned transfer, if the patient's care will be immediately continued in a health care facility; or

(iii) A completed transfer summary that is sent within 2 business days of becoming aware of an unplanned transfer, if the patient is still receiving care in a health care facility at the time when the HHA becomes aware of the transfer.

Interpretive Guidelines §484.110(a)(6)(i)-(iii)
Discharge summaries may contain the following items:

- Admission and discharge dates;
- Physician responsible for the home health plan of care;
- Reason for admission to home health;
- Disciplines, intervention provided and number of visits by each;
- Laboratory data;
- Medications the patient is on at the time of discharge;
- Patient's discharge condition/needs;
- Patient outcomes in meeting the goals in the plan of care; and
- Patient and family post-discharge instructions;

A discharge summary is sent to the primary care physician or primary care practitioner within 5 business from the date of the final visit.

The contents of a transfer summary typically contains the same components as a discharge summary.

§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.

§484.110(c) Standard: Retention of records.

§484.110(c)(1) Clinical records must be retained for 5 years after the discharge of the patient, unless state law stipulates a longer period of time.

§484.110(c)(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.

§484.110(d) Standard: Protection of records.

The clinical record, its contents, and the information contained therein must be safeguarded against loss or unauthorized use. The HHA must be in compliance with the rules regarding personal health information set out at 45 CFR parts 160 and 164.

Interpretive Guidelines §484.110(d)
HHA staff, whether employed directly or under arrangement, who carry documents and/or electronic devices containing Protected Health Information from patient's homes to the HHA office, or to and from the HHA staff member's home creates additional confidentiality/protection concerns with patient records.

All HHA staff must receive periodic training on the protection of patient clinical records. HHAs must establish policies and procedures to ensure the security of clinical records at all times and the privacy of information contained within such records to prevent loss or unauthorized use in the patient's home, in transit and in the office setting.

§484.110(e) Standard: Retrieval of clinical records.
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).

§484.115 Condition of participation: Personnel qualifications.
HHA staff are required to meet the following standards:

§484.115 (a) Standard: Administrator, home health agency.
§484.115(a)(1) For individuals that began employment with the HHA prior to January 13, 2018, a person who:
(i) Is a licensed physician;
(ii) Is a registered nurse; or
(iii) Has training and experience in health service administration and at least 1 year of supervisory administrative experience in home health care or a related health care program.

§484.115(a)(2) For individuals that begin employment with an HHA on or after January 13, 2018, a person who:
(i) Is a licensed physician, a registered nurse, or holds an undergraduate degree; and
(ii) Has experience in health service administration, with at least 1 year of supervisory or administrative experience in home health care or a related health care program.

Interpretive Guidelines §484.115(a)(2)
An "undergraduate degree" means a bachelor's degree or an associate's degree.

§484.115 (b) Standard: Audiologist.

A person who:
§484.115 (b)(1) Meets the education and experience requirements for a Certificate of Clinical Competence in audiology granted by the American Speech-Language-Hearing Association; or
§484.115 (b)(2) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

§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.

§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.

§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.

§484.115(f) Standard: Occupational therapist.
A person who—
§484.115(f)(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).

§484.115(f)(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).

§484.115(f)(3) On or before January 1, 2008—

(i) Graduated after successful completion of an occupational therapy program accredited jointly by the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or
(ii) Is eligible for the National Registration Examination of the American Occupational Therapy Association or the National Board for Certification in Occupational Therapy.

§484.115(f)(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.

§484.115(f)(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.

§484.115(g) <u>Standard: Occupational therapy assistant.</u>
A person who—
§484.115(g)(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.
(ii) Graduated after successful completion of an occupational therapy assistant education program accredited by the Accreditation Council for Occupational Therapy Education, (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or its successor organizations.
(iii) Is eligible to take or successfully completed the entry-level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

§484.115(g)(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.

§484.115(g)(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.

§484.115(g)(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.

§484.115(g)(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.
(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).

§484.115(h) <u>Standard: Physical therapist.</u>
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:

§484.115(h)(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.

§484.115(h)(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.

§484.115(h)(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.

§484.115(h)(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.

§484.115(h)(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.

§484.115(h)(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.

§484.115(h)(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.

§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:

§484.115(i)(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.

§484.115(i)(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.

§484.115(i)(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.

§484.115(i)(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.

§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.

§484.115(k) Standard: Registered nurse.
A graduate of an approved school of professional nursing who is licensed in the state where practicing.

§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.

§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.

§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:

§484.115(n)(1) Is licensed as a speech-language pathologist by the state in which the individual furnishes such services; or

§484.115(n)(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.