ACCREDITATION UNIVERSITY

CONDITIONS OF PARTICIPATION (CoPs) INTENSIVE

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HOME HEALTH

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ACCREDITATION COMMISSION *for* HEALTH CARE

OBJECTIVES

- To gain an understanding of how the Medicare Conditions of Participation (CoPs) are organized
- Review the current CoPs and issues that cause deficiencies
- Review the new CoPs and discuss ways to avoid deficiencies

NEW MEDICARE CoPs

- CMS issued a final rule January 13, 2017 that includes the new CoPs, with an implementation date of January 13, 2018
- 2017 Final Rule in the Federal Register as of January 13, 2017
  - https://www.gpo.gov/fdsys/pkg/FR-2017-01-13/pdf/2017-00283.pdf
  - CoPs actually start on page 75 of 88 pages

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WHY THE CHANGE?

- Promote high-quality patient care at all times for all patients
- Continuous, integrated care process across all services, based on patient-centered assessment, care planning, service delivery, and Quality Assessment/Performance Improvement
- Interdisciplinary approach recognizing skills of all of the team members; very similar to the hospice IDT/IDG approach
- Outcome oriented – make quality improvements through QAPI specific to each HHA
  - This will fold into the HHVBPM

THE NEW CONDITIONS

Subpart A - General Provisions

- 484.1 Basis and scope
- 484.2 Definitions

Subpart B - Patient Care

- 484.40 Condition of Participation: Release of patient-identifiable OASIS information
- 484.45 Condition of Participation: Reporting OASIS information
- 484.50 Condition of Participation: Patient rights
- 484.55 Condition of Participation: Comprehensive assessment of patients
- 484.60 Condition of Participation: Care planning, coordination of services, and quality of care
- 484.65 Condition of Participation: Quality Assessment and Performance Improvement (QAPI)
- 484.70 Condition of Participation: Infection prevention and control
- 484.75 Condition of Participation: Skilled professional services
- 484.80 Condition of Participation: Home Health Aide services

THE NEW CONDITIONS

Subpart C - Organizational Environment

- 484.100 Condition of Participation: Compliance with federal, state, and local laws and regulations related to health and safety of patients
- 484.102 Condition of Participation: Emergency preparedness
- 484.105 Condition of Participation: Organization and administration of services
- 484.110 Condition of Participation: Clinical records
- 484.115 Condition of Participation: Personnel qualifications

DELETED REQUIREMENTS

Conditions:

- Group of Professional Personnel – PAC Committee
  - **ACHC deleted this requirement; check state requirements prior to deleting**
- Evaluation of Agency's Program – Annual Agency Evaluation
  - **ACHC deleted this requirement; check state requirements prior to deleting**

Standards:

- Quarterly Record Reviews
  - **ACHC maintained this requirement**
- 60-day summary to physicians
  - **ACHC deleted this requirement; check state requirements prior to deleting**
- Sub-units eliminated

SUBPART A

Subpart A – General Provisions

- 484.1 Basis and scope
- 484.2 Definitions

Subpart A

484.2 BRANCH OFFICE

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
- Removed "located sufficiently close"

CMS RESPONSE: "The concept of an adequate level of supervision on a DAILY BASIS is longstanding, and refers to the parent HHA's ability to demonstrate administrative control over branch. We are not giving any specific requirements for communication because our primary concern relates to the evidence of control rather than the process for achieving it. It is essential for the parent to exercise adequate control, supervision and guidance for all branches under its leadership."

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Subpart A

484.2 ELIMINATES SUB-UNITS

All current sub-units will have to be eliminated and converted to a parent or branch by the implementation date of the CoPs.

CMS RESPONSE: "Sub-units are already the equivalent of stand-alone HHAs and will be able to continue functioning as such, relieving the need to change to branches. Since there would be no threat to an HHA's ability to function and service its patients, we do not agree that it would be appropriate for CMS to allocate survey resources to those HHAs that desire to, but do not need to, convert a sub-unit to a branch. Thus, the current process and priority levels will remain the same."

Memo issued 11-17-17

SUBPART B

Subpart B – Patient Care

- 484.40 Condition of Participation: Release of patient-identifiable OASIS information
- 484.45 Condition of Participation: Reporting OASIS information
- 484.50 Condition of Participation: Patient rights
- 484.55 Condition of Participation: Comprehensive assessment of patients
- 484.60 Condition of Participation: Care planning, coordination of services, and quality of care
- 484.65 Condition of Participation: Quality Assessment and Performance Improvement (QAPI)
- 484.70 Condition of Participation: Infection prevention and control
- 484.75 Condition of Participation: Skilled professional services
- 484.80 Condition of Participation: Home Health Aide services

Subpart B

484.40 RELEASE OF OASIS INFORMATION

484.40

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.

HHAs and their agents must develop and implement policies and procedures to protect the security of electronic personal health information (ePHI) 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.

Subpart B

484.45 REPORTING OASIS INFORMATION

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

4 Standards:

a) Encoding and Transmitting OASIS Data
b) Accuracy of Encoded OASIS Data
c) Transmittal of OASIS Data
d) Data Format

Subpart B

484.45 REPORTING OASIS INFORMATION

484.45(a) Encoding and Transmitting OASIS Data

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

OASIS must be transmitted 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.

Subpart B

484.45 REPORTING OASIS INFORMATION

484.45(b) Accuracy of Encoded OASIS Data

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

"Accurate" means that the OASIS data transmitted to CMS is consistent with the current condition(s) of the patient.

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Subpart B

484.45 REPORTING OASIS INFORMATION

484.45(c) 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.

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

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.

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

Subpart B

484.45 REPORTING OASIS INFORMATION

484.45(d) Standard: Data Format.

The HHA must encode and transmit data using the software available from CMS or software that conforms to CMS standard electronic record layout, edit specifications, and data dictionary, and that includes the required OASIS data set.

OASIS data are being successfully transmitted to CMS (as verified by the presence of reports).

Subpart B

484.50 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.

6 Standards:

a) Notice of Rights
b) Exercise Rights
c) Rights of the Patient
d) Transfer and Discharge
e) Investigation of Complaints
f) Accessibility

CONDITIONS OF PARTICIPATION

Subpart B

484.50 PATIENT RIGHTS

484.50(a) Standard: Notice of rights.

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:

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.

Subpart B

484.50 PATIENT RIGHTS

484.50(a)(1)(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;

Patients and/or representative have received this information in a language they understand.

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

Language assistance should be provided through the use of competent bilingual staff, staff interpreters, contracts, formal arrangements with local organizations providing interpretation, translation services, or technology and telephonic interpretation services.

Subpart B

484.50 PATIENT RIGHTS

484.50(a)(1)(ii) Contact information for the HHA administrator, including the administrator's name, business address, and business phone number in order to receive complaints.

484.50(a)(1)(iii) An OASIS privacy notice to all patients for whom the OASIS data is collected.

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.

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Subpart B

484.50 PATIENT RIGHTS

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.

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

Subpart B

484.50 PATIENT RIGHTS

484.50(b)(1) If a patient has been adjudged to lack legal capacity to make healthcare 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 healthcare 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 healthcare 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.

Subpart B

484.50 PATIENT RIGHTS

The patient has the right to:

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

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

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;

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;

CONDITIONS OF PARTICIPATION

Subpart B

484.50 PATIENT RIGHTS

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.

Subpart B

484.50 PATIENT RIGHTS

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

484.50(c)(6) Have a confidential clinical record. Access to or release of patient information and clinical records is permitted.

Agencies need to be in compliance with:

- The Privacy Rule
- The Security Rule
- The Breach Notification Rule
- The HIPAA Rule

Subpart B

484.50 PATIENT RIGHTS

484.50(c)(7) Be advised of:

- The extent to which payment for services may be expected from Medicare, Medicaid or any other federally funded or federal aide program
- The charges for services that may not may not be covered by any of the above
- The charges the individual may have to pay before care is initiated
- 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).

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Subpart B

484.50 PATIENT RIGHTS

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.

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.

Subpart B

484.50 PATIENT RIGHTS

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

- Agency on Aging
- Center for Independent Living
- Protection and Advocacy Agency
- Aging and Disability Resource Center
- Quality Improvement Organization

Subpart B

484.50 PATIENT RIGHTS

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.

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.

Subpart B

484.50 PATIENT RIGHTS

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

Subpart B

484.50 PATIENT RIGHTS

484.50(d) (2) The patient or payer will no longer pay for the services provided by the agency.

484.50(d) (3) The transfer or discharge is appropriate because the physician responsible for the plan of care and the HHA agree that the measurable outcomes and goals in the plan of care have been achieved, 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;

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. 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 would document the communication with the physician, as well as the measures the HHA took to investigate the patient's refusal and the interventions the HHA to obtain patient participation with the plan of care.

Subpart B

484.50 PATIENT RIGHTS

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 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.

i. Advise the patient, representative (if any), the physician(s) issuing orders for the HH POC, 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;
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;
iii. Provide the patient and representative (if any), with contact information for other agencies or providers who may be able to provide care; and
iv. Document the problem(s) and efforts made to resolve the problem(s), and enter this documentation into its clinical records.

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Subpart B

484.50 PATIENT RIGHTS

484.50(d)(6) The patient dies; or

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

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.

Subpart B

484.50 PATIENT RIGHTS

484.50(e)(1) The HHA must:

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

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

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

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.

Subpart B

484.50 PATIENT RIGHTS

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.

Plain language 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.

CONDITIONS OF PARTICIPATION

Subpart B

484.55 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.

4 Standards:

a) Initial assessment of patients
b) Completion of the comprehensive assessment
c) Contents of the comprehensive assessment
d) Update of the comprehensive assessment

Subpart B

484.55(a) COMPREHENSIVE ASSESSMENT OF PATIENTS

484.55(a) 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.

For patients receiving only nursing services or both nursing and therapy services, a Registered Nurse must conduct the initial assessment visit. For therapy only patients, the initial assessment may be made by the applicable rehabilitation professional rather than the Registered Nurse.

If an HHA is unable to complete the initial assessment within the 48 hours 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.

Subpart B

484.55(a) COMPREHENSIVE ASSESSMENT OF PATIENTS

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.

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Subpart B

484.55(b) COMPREHENSIVE ASSESSMENT OF PATIENTS

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. 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.

Subpart B

484.55(b) COMPREHENSIVE ASSESSMENT OF PATIENTS

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. A qualified therapist (registered and/or licensed by the state in which they practice) must perform the comprehensive assessment for those patients receiving therapy services.

Subpart B

484.55(c) COMPREHENSIVE ASSESSMENT OF PATIENTS

484.55(c) 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;

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

Assessing a patient's psychosocial status refers to an evaluation of mental health and functional capacity within the community. This 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.

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

Assessing 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.

CONDITIONS OF PARTICIPATION

Subpart B

484.55(c) COMPREHENSIVE ASSESSMENT OF PATIENTS

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;

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.

Subpart B

484.55(c) COMPREHENSIVE ASSESSMENT OF PATIENTS

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

Each assessment must clearly demonstrate the continuing need and eligibility for skilled home health service(s).

Subpart B

484.55(c) COMPREHENSIVE ASSESSMENT OF PATIENTS

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

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.

The patient's clinical record should reflect all medications, including times 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.

In 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.

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Subpart B

484.55(c) COMPREHENSIVE ASSESSMENT OF PATIENTS

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.

Subpart B

484.55(d) COMPREHENSIVE ASSESSMENT OF PATIENTS

484.55(d) Update of the comprehensive assessment

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

484.55(d)(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.

Subpart B

484.55(d) COMPREHENSIVE ASSESSMENT OF PATIENTS

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

CONDITIONS OF PARTICIPATION

Subpart B

484.60 CARE PLANNING, COORDINATION OF SERVICES & 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.

Subpart B

484.60 CARE PLANNING, COORDINATION OF SERVICES & QUALITY OF CARE

5 Standards

a) Plan of Care
b) Conformance with physician orders
c) Review and revision of the plan of care
d) Coordination of care
e) Written information to the patient

Subpart B

484.60 CARE PLANNING, COORDINATION OF SERVICES & QUALITY OF CARE

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.

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.

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Subpart B

484.60 CARE PLANNING, COORDINATION OF SERVICES & QUALITY OF CARE

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;

Subpart B

484.60 CARE PLANNING, COORDINATION OF SERVICES & QUALITY OF CARE

(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 advance directives; and

Subpart B

484.60 CARE PLANNING, COORDINATION OF SERVICES & QUALITY OF CARE

(xvi) Any additional items the HHA or physician may choose to include:
(i) All pertinent diagnoses means all known diagnoses.
484.60(a)(3) All patient care orders, including verbal orders, must be recorded in the plan of care.

All orders must be complete and accurate and documented in the medical record.

Subpart B

484.60 CARE PLANNING, COORDINATION OF SERVICES & QUALITY OF CARE

484.60 (b) Conformance with physician's 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.

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.

Subpart B

484.60 CARE PLANNING, COORDINATION OF SERVICES & QUALITY OF CARE

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.

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 , timed, and dated with the date of receipt by the nurse or qualified therapist.

Section 5

484.60 CARE PLANNING & COORDINATION

484.60 (c) 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.

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.

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Subpart B

484.60 CARE PLANNING, COORDINATION OF SERVICES & QUALITY 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:

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

There must be evidence in the clinical record that the HHA has explained to the patient 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 or by evidence of new orders received, that all relevant physicians providing care to the patient have been notified of the change in patient health status and associated changes to the plan of care.

Subpart B

484.60 CARE PLANNING, COORDINATION OF SERVICES & QUALITY OF CARE

484.60(c)(3)(ii) Any revisions related to plans for the patient's discharge must be communicated to the patient, representative, caregiver, all physicians 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).

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, his/her representatives 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.

Subpart B

484.60 CARE PLANNING, COORDINATION OF SERVICES & QUALITY OF CARE

484.60(d) Standard: Coordination of Care.

The HHA must:

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

The physician who initiated home health care is responsible for the ongoing plan of care; however, in order to ensure the development and implementation of a coordinated plan of care, communication with all physicians involved in the patient's care is often necessary.

Subpart B

484.60 CARE PLANNING, COORDINATION OF SERVICES & QUALITY OF CARE

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

Upon admission or upon any change in patient condition, the responsible physician identifies any other relevant physicians that should be contacted for orders to be included in the HHA plan of care. 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.

Subpart B

484.60 CARE PLANNING, COORDINATION OF SERVICES & QUALITY OF CARE

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

The agency manages the scheduling of patients taking into consideration the type of services that are being provided on a given day; 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 ensures 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.

Subpart B

484.60 CARE PLANNING, COORDINATION OF SERVICES & QUALITY OF 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.

The goals of the HHA episode are established at admission and revised as indicated. 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.

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Subpart B

484.60 CARE PLANNING, COORDINATION OF SERVICES & QUALITY OF CARE

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

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

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.

Subpart B

484.60 CARE PLANNING, COORDINATION OF SERVICES & QUALITY OF CARE

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

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

484.60(e)(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.

Subpart B

484.65 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.

CONDITIONS OF PARTICIPATION

Subpart B

484.65 QAPI

5 Standards

a) Program Scope
b) Program Data
c) Program Activities
d) Performance Improvement Projects
e) Executive Responsibilities

Subpart B

484.65 QAPI

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.

Subpart B

484.65 QAPI

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--

484.65(b)(2)(i) Monitor the effectiveness and safety of services and quality of care; and

484.65(b)(2)(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.

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Subpart B

484.65 QAPI

484.65(c) Standard: Program activities.

484.65(c)(1) The HHA's Performance Improvement activities must—

484.65(c)(1)(i) Focus on high risk, high volume, or problem-prone areas;

484.65(c)(1)(ii) Consider incidence, prevalence, and severity of problems in those areas; and

484.65(c)(1)(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.

Subpart B

484.65 QAPI

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.

High-risk 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.

Problem-prone areas refer to the potential for negative outcomes that are associated with a diagnosis or condition for a particular patient group or a particular component of the HHA operation.

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.

Subpart B

484.65 QAPI

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.

Subpart B

484.65 QAPI

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

Subpart B

484.70 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.

3 Standards

a) Prevention
b) Control
c) Education

Subpart B

484.70 INFECTION PREVENTION AND CONTROL

484.70(a) Standard: Prevention

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

484.70(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:

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

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

NOTES

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Subpart B

484.70 INFECTION PREVENTION AND CONTROL

484.70(c) Standard: Education.

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

Appropriate use, transport, storage, and cleaning methods of patient care equipment according to manufacturer's guidelines and receive the following provide the following for staff education.

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.

Subpart B

484.75 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.

Subpart B

484.75 SKILLED PROFESSIONAL SERVICES

3 Standards

a) Provision of services by skilled professionals
b) Responsibilities of skilled professionals
c) Supervision of skilled professional assistants

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

CONDITIONS OF PARTICIPATION

Subpart B

484.75 SKILLED PROFESSIONAL SERVICES

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

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

Subpart B

484.75 SKILLED PROFESSIONAL SERVICES

484.75(b) Standard: Responsibilities of skilled professionals.

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

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

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;

Subpart B

484.75 SKILLED PROFESSIONAL SERVICES

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

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

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Subpart B

484.75 SKILLED PROFESSIONAL SERVICES

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

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

484.75(c)(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.

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

Subpart B

484.80 HOME HEALTH AIDE SERVICES

All Home Health Aide services must be provided by individuals who meet the personnel requirements…

9 Standards

a) Home Health Aide qualifications;
b) Content and duration of Home Health Aide classroom and supervised practical training;
c) Competency evaluation;
d) In-service training;

Subpart B

484.80 HOME HEALTH AIDE SERVICES

e) Qualifications for instructors conducting classroom and supervised practical training;
f) Eligible training and competency evaluation organizations;
g) Home Health Aide assignments and duties;
h) Supervision of Home Health Aides;
i) Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit.

Subpart B

484.80 HOME HEALTH AIDE SERVICES

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.

Subpart B

484.80 HOME HEALTH AIDE SERVICES

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.

Subpart B

484.80 HOME HEALTH AIDE SERVICES

484.80(b) Standard: Content and duration of Home Health Aide classroom and supervised practical training.

§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 16 hours of supervised practical training as part of the 75 hours.

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Subpart B

484.80 HOME HEALTH AIDE SERVICES

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.

Subpart B

484.80 HOME HEALTH AIDE SERVICES

(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;

Subpart B

484.80 HOME HEALTH AIDE SERVICES

(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, including pressure ulcers; 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.

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.

Subpart B

484.80 HOME HEALTH AIDE SERVICES

484.80(c) Standard: Competency evaluation.

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

484.80(c)(1) The competency evaluation must address each of the subjects listed in paragraph (b)(3) of this section. Subject areas specified under paragraphs (b)(3)(i), (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. The following skills must be evaluated by observing the aide's performance while carrying out the task with a patient.

Subpart B

484.80 HOME HEALTH AIDE SERVICES

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.

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.

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484.80 HOME HEALTH AIDE SERVICES

484.80(d) Standard: In-service training.

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

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

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

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Subpart B

484.80 HOME HEALTH AIDE SERVICES

484.80(e) Standard: Qualifications for instructors conducting classroom and supervised practical training.

Classroom and supervised practical training must be performed by a Registered Nurse who possesses a minimum of 2 years' nursing experience, at least 1 year of which must be in Home Health Care, or by other individuals under the general supervision of the Registered Nurse.

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484.80 HOME HEALTH AIDE SERVICES

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

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

Subpart B

484.80 HOME HEALTH AIDE SERVICES

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

Subpart B

484.80 HOME HEALTH AIDE SERVICES

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.

Subpart B

484.80 HOME HEALTH AIDE SERVICES

484.80(g) Standard: Home Health Aide assignments and duties.

484.80(g)(1) Home Health Aides are assigned to a specific patient by a Registered Nurse or other appropriate skilled professional, with written patient care instructions for a Home Health Aide prepared by that Registered Nurse or other appropriate skilled professional (that is, Physical Therapist, Speech-Language Pathologist, or Occupational Therapist).

Subpart B

484.80 HOME HEALTH AIDE SERVICES

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.

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Subpart B

484.80 HOME HEALTH AIDE SERVICES

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.

Subpart B

484.80 HOME HEALTH AIDE SERVICES

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.

Subpart B

484.80 HOME HEALTH AIDE SERVICES

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.

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484.80 HOME HEALTH AIDE SERVICES

(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.

Subpart B

484.80 HOME HEALTH AIDE SERVICES

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.

Subpart B

484.80 HOME HEALTH AIDE SERVICES

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.

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Subpart B

484.80 HOME HEALTH AIDE SERVICES

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.

Subpart B

484.80 HOME HEALTH AIDE SERVICES

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

Subpart C – Organizational Environment

- 484.100 Condition of participation: Compliance with federal, state, and local laws and regulations related to health and safety of patients
- 484.102 Condition of participation: Emergency preparedness
- 484.105 Condition of participation: Organization and administration of services
- 484.110 Condition of participation: Clinical records
- 484.115 Condition of participation: Personnel qualifications

Subpart C

484.100 FEDERAL, STATE, AND LOCAL LAWS

Compliance with federal, state, and local laws and regulations related to 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.

3 standards:

a) Disclosure

b) Licensing

c) Laboratory Services

Subpart C

484.100 FEDERAL, STATE, AND LOCAL LAWS

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 §420.201, 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.

Subpart C

484.100 FEDERAL, STATE, AND LOCAL LAWS

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.

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Subpart C

484.100 FEDERAL, STATE, AND LOCAL LAWS

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.

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.

The HHA may not substitute its equipment for a patient's equipment when assisting with self-administered tests.

Subpart C

484.102 EMERGENCY PREPAREDNESS

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:

5 standards:

a) Emergency plan
b) Policies and procedures
c) Communication plan
d) Testing
e) Integrated healthcare systems

Subpart C

484.102 EMERGENCY PREPAREDNESS

484.102(a) Emergency plan. The HHA must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually.

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.

Subpart C

484.102 EMERGENCY PREPAREDNESS

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.

Subpart C

484.102 EMERGENCY PREPAREDNESS

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.

Subpart C

484.102 EMERGENCY PREPAREDNESS

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.

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Subpart C

484.102 EMERGENCY PREPAREDNESS

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.

Subpart C

484.102 EMERGENCY PREPAREDNESS

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.

Subpart C

484.102 EMERGENCY PREPAREDNESS

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.

Subpart C

484.102 EMERGENCY PREPAREDNESS

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.

Subpart C

484.102 EMERGENCY PREPAREDNESS

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:

(A) A second full-scale exercise that is community-based or individual, facility based or

(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.

Subpart C

484.102 EMERGENCY PREPAREDNESS

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.

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Subpart C

484.102 EMERGENCY PREPAREDNESS

484.102(e) Integrated healthcare systems.

If a HHA is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the HHA may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:

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

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

Subpart C

484.102 EMERGENCY PREPAREDNESS

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include all of the following:

(i) A documented community- based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

Subpart C

484.105 ORGANIZATION & ADMINISTRATION SERVICES

The HHA must organize, manage, and administer its resources to attain and maintain the highest practicable functional capacity, including providing optimal care to achieve the goals and outcomes identified in the patient's plan of care, for each patient's medical, nursing, and rehabilitative needs.

The HHA must ensure 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.

Subpart C

484.105 ORGANIZATION & ADMINISTRATION SERVICES

8 standards:

a) Governing body
b) Administrator
c) Clinical manager
d) Parent branch relationship
e) Services under arrangement
f) Services furnished
g) Outpatient therapies
h) Institutional planning

Subpart C

484.105 ORGANIZATION & ADMINISTRATION SERVICES

484.105 (a) Standard: Governing body.

A governing body (or designated persons so functioning) must assume full legal authority and responsibility for the agency's overall management and operation, the provision of all home health services, fiscal operations, review of the agency's budget and its operational plans, and its Quality Assessment and Performance Improvement Program.

Subpart C

484.105 ORGANIZATION & ADMINISTRATION SERVICES

484.105(b) Standard: Administrator.

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;

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

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Subpart C

484.105 ORGANIZATION & ADMINISTRATION SERVICES

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

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

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.

Subpart C

484.105 ORGANIZATION & ADMINISTRATION SERVICES

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—

(1) Making patient and personnel assignments;

(2) Coordinating patient care;

(3) Coordinating referrals;

(4) Ensuring that patient needs are continually assessed; and

(5) Ensuring the development, implementation, and updates of the individualized plan of care.

Subpart C

484.105 ORGANIZATION & ADMINISTRATION SERVICES

484.105(d) Standard: Parent branch relationship.

(1) The parent HHA is responsible for reporting all branch locations of the HHA to the state survey agency at the time of the HHA's request for initial certification, at each survey, and at the time the parent proposes to add or delete a branch.

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

CONDITIONS OF PARTICIPATION

Subpart C

484.105 ORGANIZATION & ADMINISTRATION SERVICES

484.105(e) Standard: Services under arrangement.

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)).

Subpart C

484.105 ORGANIZATION & ADMINISTRATION SERVICES

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.

Subpart C

484.105 ORGANIZATION & ADMINISTRATION SERVICES

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.

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Subpart C

484.105 ORGANIZATION & ADMINISTRATION SERVICES

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.

Subpart C

484.105 ORGANIZATION & ADMINISTRATION SERVICES

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.

Subpart C

484.105 ORGANIZATION & ADMINISTRATION SERVICES

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.

Subpart C

484.105 ORGANIZATION & ADMINISTRATION SERVICES

484.105(h)(2)(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.

Subpart C

484.105 ORGANIZATION & ADMINISTRATION SERVICES

484.105(h)(2)(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:

484.105(h)(2)(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.

484.105(h)(2)(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.

Subpart C

484.105 ORGANIZATION & ADMINISTRATION SERVICES

484.105(h)(2)(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.

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Subpart C

484.110 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.

Subpart C

484.110 CLINICAL RECORDS

5 Standards

a) Contents of clinical record
b) Authentication
c) Retention of records
d) Protection of records
e) Retrieval of clinical records

Subpart C

484.110 CLINICAL RECORDS

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;

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);

Subpart C

484.110 CLINICAL RECORDS

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

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.

Subpart C

484.110 CLINICAL RECORDS

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.

Subpart C

484.110 CLINICAL RECORDS

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.

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Subpart C

484.110 CLINICAL RECORDS

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.

Subpart C

484.110 CLINICAL RECORDS

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).

Subpart C

484.115 PERSONNEL QUALIFICATIONS

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.

Subpart C

484.115 PERSONNEL QUALIFICATIONS

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(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.

Subpart C

484.115 PERSONNEL QUALIFICATIONS

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.

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