used as a part of a program to manage inappropriate client behavior.

(5) Foods proposed for use as a primary reinforcement of adaptive behavior are evaluated in light of the client's nutritional status and needs.

(6) Unless otherwise specified by medical needs, the diet must be prepared at least in accordance with the latest edition of the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences, adjusted for age, sex, disability and activity.

(b) *Standard: Meal services.* (1) Each client must receive at least three meals daily, at regular times comparable to normal mealtimes in the community with—

(i) Not more than 14 hours between a substantial evening meal and breakfast of the following day, except on weekends and holidays when a nourishing snack is provided at bedtime, 16 hours may elapse between a substantial evening meal and breakfast; and

(ii) Not less than 10 hours between breakfast and the evening meal of the same day, except as provided under paragraph (b)(1)(i) of this section.

(2) Food must be served—

(i) In appropriate quantity;

(ii) At appropriate temperature;

(iii) In a form consistent with the developmental level of the client; and

(iv) With appropriate utensils.

(3) Food served to clients individually and uneaten must be discarded.

(c) *Standard: Menus.* (1) Menus must—

(i) Be prepared in advance;

(ii) Provide a variety of foods at each meal;

(iii) Be different for the same days of each week and adjusted for seasonal changes; and

(iv) Include the average portion sizes for menu items.

(2) Menus for food actually served must be kept on file for 30 days.

(d) *Standard: Dining areas and service.* The facility must—

(1) Serve meals for all clients, including persons with ambulation deficits, in dining areas, unless otherwise specified by the interdisciplinary team or a physician;

(2) Provide table service for all clients who can and will eat at a table, including clients in wheelchairs;

(3) Equip areas with tables, chairs, eating utensils, and dishes designed to meet the developmental needs of each client;

(4) Supervise and staff dining rooms adequately to direct self-help dining procedure, to assure that each client receives enough food and to assure that each client eats in a manner consistent with his or her developmental level: and

(5) Ensure that each client eats in an upright position, unless otherwise specified by the interdisciplinary team or a physician.

PART 484—HOME HEALTH SERVICES

Subpart A—General Provisions

Sec.

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.
484.58 Condition of participation: Discharge planning.
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 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 D [Reserved]

Subpart E—Prospective Payment System for Home Health Agencies

484.200 Basis and scope.
484.202 Definitions.
484.205 Basis of payment.
484.215 Initial establishment of the calculation of the national, standardized prospective payment rates.
484.220 Calculation of the case-mix and wage area adjusted prospective payment rates.
484.225 Annual update of the unadjusted national, standardized prospective payment rates.
484.230 Low-utilization payment adjustments.
484.235 Partial payment adjustments.
484.240 Outlier payments.
484.245 Requirements under the Home Health Quality Reporting Program (HH QRP).
484.250 OASIS data.
484.260 Limitation on review.
484.265 Additional payment.

Subpart F—Home Health Value-Based Purchasing (HHVBP) Models

HHVBP MODEL COMPONENTS FOR COMPETING HOME HEALTH AGENCIES WITHIN STATE BOUNDARIES FOR THE ORIGINAL HHVBP MODEL

484.300 Basis and scope of subpart.
484.305 Definitions.
484.310 Applicability of the Home Health Value-Based Purchasing (HHVBP) Model.
484.315 Data reporting for measures and evaluation and the public reporting of model data under the Home Health Value-Based Purchasing (HHVBP) Model.
484.320 Calculation of the Total Performance Score.
484.325 Payments for home health services under Home Health Value-Based Purchasing (HHVBP) Model.
484.330 Process for determining and applying the value-based payment adjustment under the Home Health Value-Based Purchasing (HHVBP) Model.
484.335 Appeals process for the Home Health Value-Based Purchasing (HHVBP) Model.

HHVBP MODEL COMPONENTS FOR COMPETING HOME HEALTH AGENCIES (HHAS) FOR HHVBP MODEL EXPANSION—EFFECTIVE JANUARY 1, 2022

484.340 Basis and scope of this subpart.
484.345 Definitions.
484.350 Applicability of the Expanded Home Health Value-Based Purchasing (HHVBP) Model.
484.355 Data reporting for measures and evaluation and the public reporting of model data under the expanded Home Health Value-Based Purchasing (HHVBP) Model.
484.358 HHVBP Measure removal factors.
484.360 Calculation of the Total Performance Score.
484.365 Payments for home health services under the Expanded Home Health Value-Based Purchasing (HHVBP) Model.
484.370 Process for determining and applying the value-based payment adjustment under the Expanded Home Health Value-Based Purchasing (HHVBP) Model.
484.375 Appeals process for the Expanded Home Health Value-Based Purchasing (HHVBP) Model.

AUTHORITY: 42 U.S.C. 1302 and 1395hh.

SOURCE: 54 FR 33367, Aug. 14, 1989, unless otherwise noted.

Subpart A—General Provisions

SOURCE: 82 FR 4578, Jan. 13, 2017, unless otherwise noted.

§ 484.1 Basis and scope.

(a) *Basis.* This part is based on:

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

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

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

§ 484.2 Definitions.

As used in subparts A, B, and C, of this part—

Allowed practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as defined at this part.

Branch office means an approved location or site from which a home health agency provides services within a portion of the total geographic area served by the parent agency. The parent home health agency must provide supervision and administrative control of any branch office. It is unnecessary for the branch office to independently

meet the conditions of participation as a home health agency.

Clinical note means a notation of a contact with a patient that is written, timed, and dated, and which describes signs and symptoms, treatment, drugs administered and the patient's reaction or response, and any changes in physical or emotional condition during a given period of time.

Clinical nurse specialist means an individual as defined at § 410.76(a) and (b) of this chapter, and who is working in collaboration with the physician as defined at § 410.76(c)(3) of this chapter.

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

Nurse practitioner means an individual as defined at § 410.75(a) and (b) of this chapter, and who is working in collaboration with the physician as defined at § 410.75(c)(3) of this chapter.

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

Physician is a doctor of medicine, osteopathy, or podiatric medicine, and who is not precluded from performing this function under paragraph (d) of this section. (A doctor of podiatric medicine may perform only plan of treatment functions that are consistent with the functions he or she is authorized to perform under State law.)

Physician assistant means an individual as defined at § 410.74(a) and (c) of this chapter.

Primary home health agency means the HHA which accepts the initial referral of a patient, and which provides services directly to the patient or via another health care provider under arrangements (as applicable).

Proprietary agency means a private, for-profit agency.

Pseudo-patient means a person trained to participate in a role-play situation, or a computer-based mannequin device. A pseudo-patient must be capable of responding to and interacting with the home health aide trainee, and must demonstrate the general characteristics of the primary patient population served by the HHA in key areas such as age, frailty, functional status, and cognitive status.

Public agency means an agency operated by a state or local government.

Quality indicator means a specific, valid, and reliable measure of access, care outcomes, or satisfaction, or a measure of a process of care.

Representative means the patient's legal representative, such as a guardian, who makes health-care decisions on the patient's behalf, or a patient-selected representative who participates in making decisions related to the patient's care or well-being, including but not limited to, a family member or an advocate for the patient. The patient determines the role of the representative, to the extent possible.

Simulation means a training and assessment technique that mimics the reality of the homecare environment, including environmental distractions and constraints that evoke or replicate substantial aspects of the real world in a fully interactive fashion, in order to teach and assess proficiency in performing skills, and to promote decision making and critical thinking.

Subdivision means a component of a multi-function health agency, such as the home care department of a hospital or the nursing division of a health department, which independently meets the conditions of participation for HHAs. A subdivision that has branch offices is considered a parent agency.

Summary report means the compilation of the pertinent factors of a patient's clinical notes that is submitted to the patient's physician, physician assistant, nurse practitioner, or clinical nurse specialist.

Supervised practical training means training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while providing covered services to an individual under the direct supervision of either a registered nurse or a licensed practical nurse who is under the supervision of a registered nurse.

Verbal order means a physician, physician assistant, nurse practitioner, or clinical nurse specialist order that is spoken to appropriate personnel and later put in writing for the purposes of

documenting as well as establishing or revising the patient's plan of care.

[82 FR 4578, Jan. 13, 2017, as amended at 84 FR 51825, Sept. 30, 2019; 85 FR 27627, May 8, 2020]

Subpart B—Patient Care

SOURCE: 82 FR 4578, Jan. 13, 2017, unless otherwise noted.

§ 484.40 Condition of participation: Release of patient identifiable OASIS information.

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

§ 484.45 Condition of participation: Reporting OASIS information.

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

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

(b) *Standard: Accuracy of encoded OASIS data.* The encoded OASIS data must accurately reflect the patient's status at the time of assessment.

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

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

(2) Transmit data using electronic communications software that complies with the Federal Information Processing Standard (FIPS 140–2, issued May 25, 2001) from the HHA or the HHA contractor to the CMS collection site.

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

(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.

[82 FR 4578, Jan. 13, 2017, as amended at 85 FR 70356, Nov. 4, 2020]

§ 484.50 Condition of participation: Patient rights.

The patient and representative (if any), have the right to be informed of the patient's rights in a language and manner the individual understands. The HHA must protect and promote the exercise of these rights.

(a) *Standard: Notice of rights.* The HHA must—

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

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

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

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

(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.

(3) [Reserved]

(4) Provide written notice of the patient's rights and responsibilities under this rule and the HHA's transfer and discharge policies as set forth in paragraph (d) of this section to a patient-selected representative within 4 business days of the initial evaluation visit.

(b) *Standard: Exercise of rights.* (1) If a patient has been adjudged to lack legal capacity to make health care decisions as established by state law by a court

of proper jurisdiction, the rights of the patient may be exercised by the person appointed by the state court to act on the patient's behalf.

(2) If a state court has not adjudged a patient to lack legal capacity to make health care decisions as defined by state law, the patient's representative may exercise the patient's rights.

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

(c) *Standard: Rights of the patient.* The patient has the right to—

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

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

(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;

(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.

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

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

(7) Be advised, orally and in writing, of—

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

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

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

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

(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.

(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.

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

(i) Agency on Aging,

(ii) Center for Independent Living,

(iii) Protection and Advocacy Agency,

(iv) Aging and Disability Resource Center; and

(v) Quality Improvement Organization.

(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.

(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.

(d) *Standard: Transfer and discharge.* The patient and representative (if any), have a right to be informed of the

HHA's policies for transfer and discharge. The HHA may only transfer or discharge the patient from the HHA if:

(1) The transfer or discharge is necessary for the patient's welfare because the HHA and the physician or allowed practitioner who is responsible for the home health plan of care agree that the HHA can no longer meet the patient's needs, based on the patient's acuity. The HHA must arrange a safe and appropriate transfer to other care entities when the needs of the patient exceed the HHA's capabilities;

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

(3) The transfer or discharge is appropriate because the physician or allowed practitioner who is responsible for the home health plan of care and the HHA agree that the measurable outcomes and goals set forth in the plan of care in accordance with § 484.60(a)(2)(xiv) have been achieved, and the HHA and the physician or allowed practitioner who is responsible for the home health plan of care agree that the patient no longer needs the HHA's services;

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

(5) The HHA determines, under a policy set by the HHA for the purpose of addressing discharge for cause that meets the requirements of paragraphs (d)(5)(i) through (d)(5)(iii) of this section, that the patient's (or other persons in the patient's home) behavior is disruptive, abusive, or uncooperative to the extent that delivery of care to the patient or the ability of the HHA to operate effectively is seriously impaired. The HHA must do the following before it discharges a patient for cause:

(i) Advise the patient, the representative (if any), the physician(s) or allowed practitioner(s) issuing orders for the home health plan of care, and the patient's primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any) that a discharge for cause is being considered;

(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;

(6) The patient dies; or

(7) The HHA ceases to operate.

(e) *Standard: Investigation of complaints.* (1) The HHA must—

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

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

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

(ii) Document both the existence of the complaint and the resolution of the complaint; and

(iii) Take action to prevent further potential violations, including retaliation, while the complaint is being investigated.

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

(f) *Standard: Accessibility.* Information must be provided to patients in plain language and in a manner that is accessible and timely to—

(1) Persons with disabilities, including accessible Web sites and the provision of auxiliary aids and services at no cost to the individual in accordance with the Americans with Disabilities Act and Section 504 of the Rehabilitation Act.

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

[82 FR 4578, Jan. 13, 2017, as amended at 84 FR 51825, Sept. 30, 2019; 85 FR 27628, May 8, 2020; 86 FR 62421, Nov. 9, 2021]

§ 484.55 Condition of participation: Comprehensive assessment of patients.

Each patient must receive, and an HHA must provide, a patient-specific, comprehensive assessment. For Medicare beneficiaries, the HHA must verify the patient's eligibility for the Medicare home health benefit including homebound status, both at the time of the initial assessment visit and at the time of the comprehensive assessment.

(a) *Standard: Initial assessment visit.* (1) A registered nurse must conduct an initial assessment visit to determine the immediate care and support needs of the patient; and, for Medicare patients, to determine eligibility for the Medicare home health benefit, including homebound status. The initial assessment visit must be held either within 48 hours of referral, or within 48 hours of the patient's return home, or on the physician or allowed practitioner-ordered start of care date.

(2) When rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician or allowed practitioner who is responsible for the home health plan of care, the initial assessment visit may be made by the appropriate rehabilitation skilled professional. For Medicare patients, an occupational therapist may complete the initial assessment when occupational therapy is ordered with another qualifying rehabilitation therapy service (speech-language pathology or physical therapy) that establishes program eligibility.

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

(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.

(3) When physical therapy, speech-language pathology, or occupational therapy is the only service ordered by the physician or allowed practitioner, a physical therapist, speech-language pathologist, or occupational therapist may complete the comprehensive assessment, and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status. For Medicare patients, the occupational therapist may complete the comprehensive assessment when occupational therapy is ordered with another qualifying rehabilitation therapy service (speech-language pathology or physical therapy) that establishes program eligibility.

(c) *Standard: Content of the comprehensive assessment.* The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:

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

(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;

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

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

(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.

(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;

(7) The patient's representative (if any);

(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.

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

(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.

(2) Within 48 hours of the patient's return to the home from a hospital admission of 24 hours or more for any reason other than diagnostic tests, or on physician or allowed practitioner-ordered resumption date;

(3) At discharge.

[82 FR 4578, Jan. 13, 2017, as amended at 85 FR 27628, May 8, 2020; 86 FR 62421, Nov. 9, 2021]

§ 484.58 Condition of participation: Discharge planning.

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

(b) *Standard: Discharge or transfer summary content.* (1) The HHA must send all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, to the receiving facility or health care practitioner to ensure the safe and effective transition of care.

(2) The HHA must comply with requests for additional clinical information as may be necessary for treatment of the patient made by the receiving facility or health care practitioner.

[84 FR 51883, Sept. 30, 2019]

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

Patients are accepted for treatment on the reasonable expectation that an HHA can meet the patient's medical, nursing, rehabilitative, and social needs in his or her place of residence. Each patient must receive an individualized written plan of care, including any revisions or additions. The individualized plan of care must specify the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, including identification of the responsible discipline(s), and the measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care. The individualized plan of care must also specify the patient and caregiver education and training. Services must be furnished in accordance with accepted standards of practice.

(a) *Standard: Plan of care.* (1) Each patient must receive the home health services that are written in an individualized plan of care that identifies patient-specific measurable outcomes and goals, and which is established, periodically reviewed, and signed by a doctor of medicine, osteopathy, or podiatry or allowed practitioner acting within the

scope of his or her state license, certification, or registration. If a physician or allowed practitioner refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician or allowed practitioner is consulted to approve additions or modifications to the original plan.

(2) The individualized plan of care must include the following:

(i) All pertinent diagnoses;

(ii) The patient's mental, psychosocial, and cognitive status;

(iii) The types of services, supplies, and equipment required;

(iv) The frequency and duration of visits to be made;

(v) Prognosis;

(vi) Rehabilitation potential;

(vii) Functional limitations;

(viii) Activities permitted;

(ix) Nutritional requirements;

(x) All medications and treatments;

(xi) Safety measures to protect against injury;

(xii) A description of the patient's risk for emergency department visits and hospital re-admission, and all necessary interventions to address the underlying risk factors.

(xiii) Patient and caregiver education and training to facilitate timely discharge;

(xiv) Patient-specific interventions and education; measurable outcomes and goals identified by the HHA and the patient;

(xv) Information related to any advanced directives; and

(xvi) Any additional items the HHA or physician or allowed practitioner may choose to include.

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

(b) *Standard: Conformance with physician or allowed practitioner orders.* (1) Drugs, services, and treatments are administered only as ordered by a physician or allowed practitioner.

(2) Influenza and pneumococcal vaccines may be administered per agency policy developed in consultation with a physician, physician assistant, nurse practitioner, or clinical nurse specialist, and after an assessment of the patient to determine for contraindications.

(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.

(4) When services are provided on the basis of a physician or allowed practitioner's verbal orders, a nurse acting in accordance with state licensure requirements, or other qualified practitioner responsible for furnishing or supervising the ordered services, in accordance with state law and the HHA's policies, must document the orders in the patient's clinical record, and sign, date, and time the orders. Verbal orders must be authenticated and dated by the physician or allowed practitioner in accordance with applicable state laws and regulations, as well as the HHA's internal policies.

(c) *Standard: Review and revision of the plan of care.* (1) The individualized plan of care must be reviewed and revised by the physician or allowed practitioner who is responsible for the home health plan of care and the HHA as frequently as the patient's condition or needs require, but no less frequently than once every 60 days, beginning with the start of care date. The HHA must promptly alert the relevant physician(s) or allowed practitioner(s) to any changes in the patient's condition or needs that suggest that outcomes are not being achieved and/or that the plan of care should be altered.

(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.

(3) Revisions to the plan of care must be communicated as follows:

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

(ii) Any revisions related to plans for the patient's discharge must be communicated to the patient, representative, caregiver, all physicians or allowed practitioners issuing orders for

the HHA plan of care, and the patient's primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any).

(d) *Standard: Coordination of care.* The HHA must:

(1) Assure communication with all physicians or allowed practitioners involved in the plan of care.

(2) Integrate orders from all physicians or allowed practitioners involved in the plan of care to assure the coordination of all services and interventions provided to the patient.

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

(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.

(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.

(e) *Standard: Written information to the patient.* The HHA must provide the patient and caregiver with a copy of written instructions outlining:

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

(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.

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

(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.

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

[82 FR 4578, Jan. 13, 2017, as amended at 85 FR 27628, May 8, 2020]

§ 484.65 Condition of participation: Quality assessment and performance improvement (QAPI).

The HHA must develop, implement, evaluate, and maintain an effective, ongoing, HHA-wide, data-driven QAPI program. The HHA's governing body must ensure that the program reflects the complexity of its organization and services; involves all HHA services (including those services provided under contract or arrangement); focuses on indicators related to improved outcomes, including the use of emergent care services, hospital admissions and re-admissions; and takes actions that address the HHA's performance across the spectrum of care, including the prevention and reduction of medical errors. The HHA must maintain documentary evidence of its QAPI program and be able to demonstrate its operation to CMS.

(a) *Standard: Program scope.* (1) The program must at least be capable of showing measurable improvement in indicators for which there is evidence that improvement in those indicators will improve health outcomes, patient safety, and quality of care.

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

(b) *Standard: Program data.* (1) The program must utilize quality indicator data, including measures derived from OASIS, where applicable, and other relevant data, in the design of its program.

(2) The HHA must use the data collected to—

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

(ii) Identify opportunities for improvement.

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

(c) *Standard: Program activities.* (1) The HHA's performance improvement activities must—

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

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

(iii) Lead to an immediate correction of any identified problem that directly or potentially threaten the health and safety of patients.

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

(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.

(d) *Standard: Performance improvement projects.* Beginning July 13, 2018 HHAs must conduct performance improvement projects.

(1) The number and scope of distinct improvement projects conducted annually must reflect the scope, complexity, and past performance of the HHA's services and operations.

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

(e) *Standard: Executive responsibilities.* The HHA's governing body is responsible for ensuring the following:

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

(2) That the HHA-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety, and that all improvement actions are evaluated for effectiveness;

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

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

[82 FR 4578, Jan. 13, 2017, as amended at 82 FR 31732, July 10, 2017]

§ 484.70 Condition of participation: Infection prevention and control.

The HHA must maintain and document an infection control program which has as its goal the prevention and control of infections and communicable diseases.

(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.

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

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

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

(c) *Standard: Education.* The HHA must provide infection control education to staff, patients, and caregiver(s).

[82 FR 4578, Jan. 13, 2017, as amended at 86 FR 61621, Nov. 5, 2021; 88 FR 36510, June 5, 2023]

§ 484.75 Condition of participation: Skilled professional services.

Skilled professional services include skilled nursing services, physical therapy, speech-language pathology services, and occupational therapy, as specified in § 409.44 of this chapter, and physician or allowed practitioner and medical social work services as specified in § 409.45 of this chapter. Skilled professionals who provide services to HHA patients directly or under arrangement must participate in the coordination of care.

(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.

(b) *Standard: Responsibilities of skilled professionals.* Skilled professionals must assume responsibility for, but not be restricted to, the following:

(1) Ongoing interdisciplinary assessment of the patient;

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

(3) Providing services that are ordered by the physician or allowed practitioner as indicated in the plan of care;

(4) Patient, caregiver, and family counseling;

(5) Patient and caregiver education;

(6) Preparing clinical notes;

(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;

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

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

(c) *Supervision of skilled professional assistants.* (1) Nursing services are provided under the supervision of a registered nurse that meets the requirements of § 484.115(k).

(2) Rehabilitative therapy services are provided under the supervision of an occupational therapist or physical therapist that meets the requirements of § 484.115(f) or (h), respectively.

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

[82 FR 4578, Jan. 13, 2017, as amended at 85 FR 27628, May 8, 2020]

§ 484.80 Condition of participation: Home health aide services.

All home health aide services must be provided by individuals who meet the personnel requirements specified in paragraph (a) of this section.

(a) *Standard: Home health aide qualifications.* (1) A qualified home health aide is a person who has successfully completed:

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

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

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

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

(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.

(b) *Standard: Content and duration of home health aide classroom and supervised practical training.* (1) Home health aide training must include classroom and supervised practical training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while providing services to an individual under the direct supervision of a registered nurse, or a licensed practical nurse who is under the supervision of a registered nurse. Classroom and supervised practical training must total at least 75 hours.

(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.

(3) A home health aide training program must address each of the following subject areas:

(i) Communication skills, including the ability to read, write, and verbally report clinical information to patients, representatives, and caregivers, as well as to other HHA staff.

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

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

(iv) Basic infection prevention and control procedures.

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

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

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

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

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

(A) Bed bath;

(B) Sponge, tub, and shower bath;

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

(D) Nail and skin care;

(E) Oral hygiene;

(F) Toileting and elimination;

(x) Safe transfer techniques and ambulation;

(xi) Normal range of motion and positioning;

(xii) Adequate nutrition and fluid intake;

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

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

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

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

(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.

(1) The competency evaluation must address each of the subjects listed in paragraph (b)(3) of this section. Subject areas specified under paragraphs (b)(3)(i), (iii), (ix), (x), and (xi) of this section must be evaluated by observing an aide's performance of the task with a patient or pseudo-patient. The remaining subject areas may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient, or with a pseudo-patient as part of a simulation.

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

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

(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.

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

(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.

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

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

(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.

(f) *Standard: Eligible training and competency evaluation organizations.* A home health aide training program and competency evaluation program may be offered by any organization except by an HHA that, within the previous 2 years:

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

(2) Permitted an individual who does not meet the definition of a ''qualified home health aide'' as specified in paragraph (a) of this section to furnish home health aide services (with the exception of licensed health professionals and volunteers); or

(3) Was subjected to an extended (or partially extended) survey as a result of having been found to have furnished substandard care (or for other reasons as determined by CMS or the state); or

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

(5) Was found to have compliance deficiencies that endangered the health and safety of the HHA's patients, and had temporary management appointed to oversee the management of the HHA; or

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

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

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

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

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

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

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

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

(g) *Standard: Home health aide assignments and duties.* (1) Home health aides are assigned to a specific patient by a registered nurse or other appropriate skilled professional, with written patient care instructions for a home health aide prepared by that registered nurse or other appropriate skilled professional (that is, physical therapist, speech-language pathologist, or occupational therapist).

(2) A home health aide provides services that are:

(i) Ordered by the physician or allowed practitioner;

(ii) Included in the plan of care;

(iii) Permitted to be performed under state law; and

(iv) Consistent with the home health aide training.

(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.

(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.

(h) *Standard: Supervision of home health aides.* (1)(i) If home health aide services are provided to a patient who is receiving skilled nursing, physical or occupational therapy, or speech language pathology services—

(A) A registered nurse or other appropriate skilled professional who is familiar with the patient, the patient's plan of care, and the written patient care instructions described in paragraph (g) of this section, must complete a supervisory assessment of the aide services being provided no less frequently than every 14 days; and

(B) The home health aide does not need to be present during the supervisory assessment described in paragraph (h)(1)(i)(A) of this section.

(ii) The supervisory assessment must be completed onsite (that is, an in person visit), or on the rare occasion by

using two-way audio-video telecommunications technology that allows for real-time interaction between the registered nurse (or other appropriate skilled professional) and the patient, not to exceed 1 virtual supervisory assessment per patient in a 60-day episode.

(iii) If an area of concern in aide services is noted by the supervising registered nurse or other appropriate skilled professional, then the supervising individual must make an on-site visit to the location where the patient is receiving care in order to observe and assess the aide while he or she is performing care.

(iv) A registered nurse or other appropriate skilled professional must make an annual on-site visit to the location where a patient is receiving care in order to observe and assess each aide while he or she is performing care.

(2)(i) If home health aide services are provided to a patient who is not receiving skilled nursing care, physical or occupational therapy, or speech language pathology services—

(A) The registered nurse must make an onsite, in person visit every 60 days to assess the quality of care and services provided by the home health aide and to ensure that services meet the patient's needs; and

(B) The home health aide does not need to be present during this visit.

(ii) Semi-annually the registered nurse must make an on-site visit to the location where each patient is receiving care in order to observe and assess each home health aide while he or she is performing non-skilled care.

(3) If a deficiency in aide services is verified by the registered nurse or other appropriate skilled professional during an on-site visit, then the agency must conduct, and the home health aide must complete, retraining and a competency evaluation for the deficient and all related skills.

(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.

(5) If the home health agency chooses to provide home health aide services under arrangements, as defined in section 1861(w)(1) of the Act, the HHA's responsibilities also include, but are not limited to:

(i) Ensuring the overall quality of care provided by an aide;

(ii) Supervising aide services as described in paragraphs (h)(1) 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.

(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.

[82 FR 4578, Jan. 13, 2017, as amended at 84 FR 51825, Sept. 30, 2019; 85 FR 27628, May 8, 2020; 86 FR 62421, Nov. 9, 2021]

Subpart C—Organizational Environment

SOURCE: 82 FR 4578, Jan. 13, 2017, unless otherwise noted.

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

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

(a) *Standard: Disclosure of ownership and management information.* The HHA must comply with the requirements of part 420 subpart C, of this chapter. The HHA also must disclose the following information to the state survey agency at the time of the HHA's initial request for certification, for each survey, and at the time of any change in ownership or management:

(1) The names and addresses of all persons with an ownership or controlling interest in the HHA as defined in § 420.201, § 420.202, and § 420.206 of this chapter.

(2) The name and address of each person who is an officer, a director, an agent, or a managing employee of the HHA as defined in § 420.201, § 420.202, and § 420.206 of this chapter.

(3) The name and business address of the corporation, association, or other company that is responsible for the management of the HHA, and the names and addresses of the chief executive officer and the chairperson of the board of directors of that corporation, association, or other company responsible for the management of the HHA.

(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.

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

(2) If the HHA refers specimens for laboratory testing, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of part 493 of this chapter.

§ 484.102 Condition of participation: Emergency preparedness.

The Home Health Agency (HHA) must comply with all applicable Federal, State, and local emergency preparedness requirements. The HHA must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The HHA must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do all of the following:

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

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

(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.

(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.

(b) *Policies and procedures.* The HHA must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2

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

(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.

(2) The procedures to inform State and local emergency preparedness officials about HHA patients in need of evacuation from their residences at any time due to an emergency situation based on the patient's medical and psychiatric condition and home environment.

(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.

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

(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.

(c) *Communication plan.* The HHA must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Volunteers.

(2) Contact information for the following:

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

(ii) Other sources of assistance.

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

(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.

(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).

(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.

(d) *Training and testing.* The HHA must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) *Training program.* The HHA must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least every 2 years.

(iii) Maintain documentation of the training.

(iv) Demonstrate staff knowledge of emergency procedures.

(v) If the emergency preparedness policies and procedures are significantly updated, the HHA must conduct training on the updated policies and procedures.

(2) *Testing.* The HHA must conduct exercises to test the emergency plan at least annually. The HHA must do the following:

(i) Participate in a full-scale exercise that is community-based; or

(A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise every 2 years; or.

(B) If the HHA experiences an actual natural or man-made emergency that requires activation of the emergency plan, the HHA is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event.

(ii) Conduct an additional exercise every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:

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

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the HHA's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the HHA's emergency plan, as needed.

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

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

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

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

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

(i) A documented community-based risk assessment, 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.

[82 FR 4578, Jan. 13, 2017, as amended at 84 FR 51825, Sept. 30, 2019]

§ 484.105 Condition of participation: Organization and administration of services.

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

(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.

(b) *Standard: Administrator.* (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 assuring the development of personnel qualifications and policies.

(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.

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

(c) *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) Assuring that patient needs are continually assessed, and

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

(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.

(e) *Standard: Services under arrangement.* (1) The HHA must ensure that all services furnished under arrangement provided by other entities or individuals meet the requirements of this part and the requirements of section 1861(w) of the Act (42 U.S.C. 1395x (w)).

(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.

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

(f) *Standard: Services furnished.* (1) Skilled nursing services and at least one other therapeutic service (physical therapy, speech-language pathology, or occupational therapy; medical social services; or home health aide services) are made available on a visiting basis, in a place of residence used as a patient's home. An HHA must provide at least one of the services described in this subsection directly, but may provide the second service and additional services under arrangement with another agency or organization.

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

(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.

(h) *Standard: Institutional planning.* The HHA, under the direction of the governing body, prepares an overall

plan and a budget that includes an annual operating budget and capital expenditure plan.

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

(2) *Capital expenditure plan.* (i) There is a capital expenditure plan for at least a 3-year period, including the operating budget year. The plan includes and identifies in detail the anticipated sources of financing for, and the objectives of, each anticipated expenditure of more than $600,000 for items that would under generally accepted accounting principles, be considered capital items. In determining if a single capital expenditure exceeds $600,000, the cost of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition, improvement, modernization, expansion, or replacement of land, plant, building, and equipment are included. Expenditures directly or indirectly related to capital expenditures, such as grading, paving, broker commissions, taxes assessed during the construction period, and costs involved in demolishing or razing structures on land are also included. Transactions that are separated in time, but are components of an overall plan or patient care objective, are viewed in their entirety without regard to their timing. Other costs related to capital expenditures include title fees, permit and license fees, broker commissions, architect, legal, accounting, and appraisal fees; interest, finance, or carrying charges on bonds, notes and other costs incurred for borrowing funds.

(ii) If the anticipated source of financing is, in any part, the anticipated payment from title V (Maternal and Child Health Services Block Grant) or title XVIII (Medicare) or title XIX (Medicaid) of the Social Security Act, the plan specifies the following:

(A) Whether the proposed capital expenditure is required to conform, or is likely to be required to conform, to current standards, criteria, or plans developed in accordance with the Public Health Service Act or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963.

(B) Whether a capital expenditure proposal has been submitted to the designated planning agency for approval in accordance with section 1122 of the Act (42 U.S.C. 1320a–1) and implementing regulations.

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

(3) *Preparation of plan and budget.* The overall plan and budget is prepared under the direction of the governing body of the HHA by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff (if any) of the HHA.

(4) *Annual review of plan and budget.* The overall plan and budget is reviewed and updated at least annually by the committee referred to in paragraph (i)(3) of this section under the direction of the governing body of the HHA.

§ 484.110 Condition of participation: Clinical records.

The HHA must maintain a clinical record containing past and current information for every patient accepted by the HHA and receiving home health services. Information contained in the clinical record must be accurate, adhere to current clinical record documentation standards of practice, and be available to the physician(s) or allowed practitioner(s) issuing orders for the home health plan of care, and appropriate HHA staff. This information may be maintained electronically.

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

(1) The patient's current comprehensive assessment, including all of the assessments from the most recent home health admission, clinical notes, plans of care, and physician or allowed practitioner orders;

(2) All interventions, including medication administration, treatments, and

services, and responses to those interventions;

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

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

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

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

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

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

(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.

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

(2) The HHA's policies must provide for retention of clinical records even if it discontinues operation. When an HHA discontinues operation, it must inform the state agency where clinical records will be maintained.

(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 protected health information set out at 45 CFR parts 160 and 164.

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

[82 FR 4578, Jan. 13, 2017, as amended at 85 FR 70356, Nov. 4, 2020]

§ 484.115 Condition of participation: Personnel qualifications.

HHA staff are required to meet the following standards:

(a) *Standard: Administrator, home health agency.* (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.

(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.

(b) *Standard: Audiologist.* A person who:

(1) Meets the education and experience requirements for a Certificate of Clinical Competence in audiology granted by the American Speech-Language-Hearing Association; or

(2) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

(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.

(d) *Standard: Home health aide.* A person who meets the qualifications for

home health aides specified in section 1891(a)(3) of the Act and implemented at §484.80.

(e) *Standard: Licensed practical (vocational) nurse.* A person who has completed a practical (vocational) nursing program, is licensed in the state where practicing, and who furnishes services under the supervision of a qualified registered nurse.

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

(1)(i) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the state in which practicing, unless licensure does not apply;

(ii) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA), or successor organizations of ACOTE; and

(iii) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(2) On or before December 31, 2009—

(i) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the state in which practicing; or

(ii) When licensure or other regulation does not apply—

(A) Graduated after successful completion of an occupational therapist education program accredited by the accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or successor organizations of ACOTE; and

(B) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc., (NBCOT).

(3) On or before January 1, 2008—

(i) Graduated after successful completion of an occupational therapy program accredited jointly by the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or

(ii) Is eligible for the National Registration Examination of the American Occupational Therapy Association or the National Board for Certification in Occupational Therapy.

(4) On or before December 31, 1977—

(i) Had 2 years of appropriate experience as an occupational therapist; and

(ii) Had achieved a satisfactory grade on an occupational therapist proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(5) If educated outside the United States, must meet both of the following:

(i) Graduated after successful completion of an occupational therapist education program accredited as substantially equivalent to occupational therapist entry level education in the United States by one of the following:

(A) The Accreditation Council for Occupational Therapy Education (ACOTE).

(B) Successor organizations of ACOTE.

(C) The World Federation of Occupational Therapists.

(D) A credentialing body approved by the American Occupational Therapy Association.

(E) Successfully completed the entry level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(ii) On or before December 31, 2009, is licensed or otherwise regulated, if applicable, as an occupational therapist by the state in which practicing.

(g) *Standard: Occupational therapy assistant.* A person who—

(1) Meets all of the following:

(i) Is licensed or otherwise regulated, if applicable, as an occupational therapy assistant by the state in which practicing, unless licensure does apply.

(ii) Graduated after successful completion of an occupational therapy assistant education program accredited by the Accreditation Council for Occupational Therapy Education, (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or its successor organizations.

(iii) Is eligible to take or successfully completed the entry-level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(2) On or before December 31, 2009—

(i) Is licensed or otherwise regulated as an occupational therapy assistant, if applicable, by the state in which practicing; or any qualifications defined by the state in which practicing, unless licensure does not apply; or

(ii) Must meet both of the following:

(A) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association.

(B) After January 1, 2010, meets the requirements in paragraph (f)(1) of this section.

(3) After December 31, 1977 and on or before December 31, 2007—

(i) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association; or

(ii) Completed the requirements to practice as an occupational therapy assistant applicable in the state in which practicing.

(4) On or before December 31, 1977—

(i) Had 2 years of appropriate experience as an occupational therapy assistant; and

(ii) Had achieved a satisfactory grade on an occupational therapy assistant proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(5) If educated outside the United States, on or after January 1, 2008—

(i) Graduated after successful completion of an occupational therapy assistant education program that is accredited as substantially equivalent to occupational therapist assistant entry level education in the United States by—

(A) The Accreditation Council for Occupational Therapy Education (ACOTE).

(B) Its successor organizations.

(C) The World Federation of Occupational Therapists.

(D) By a credentialing body approved by the American Occupational Therapy Association; and

(E) Successfully completed the entry level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(ii) [Reserved]

(h) *Standard: Physical therapist.* A person who is licensed, if applicable, by the state in which practicing, unless licensure does not apply and meets one of the following requirements:

(1)(i) Graduated after successful completion of a physical therapist education program approved by one of the following:

(A) The Commission on Accreditation in Physical Therapy Education (CAPTE).

(B) Successor organizations of CAPTE.

(C) An education program outside the United States determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or an organization identified in 8 CFR 212.15(e) as it relates to physical therapists.

(ii) Passed an examination for physical therapists approved by the state in which physical therapy services are provided.

(2) On or before December 31, 2009—

(i) Graduated after successful completion of a physical therapy curriculum approved by the Commission on Accreditation in Physical Therapy Education (CAPTE); or

(ii) Meets both of the following:

(A) Graduated after successful completion of an education program determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified in 8 CFR 212.15(e) as it relates to physical therapists.

(B) Passed an examination for physical therapists approved by the state in

which physical therapy services are provided.

(3) Before January 1, 2008 graduated from a physical therapy curriculum approved by one of the following:

(i) The American Physical Therapy Association.

(ii) The Committee on Allied Health Education and Accreditation of the American Medical Association.

(iii) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association.

(4) On or before December 31, 1977 was licensed or qualified as a physical therapist and meets both of the following:

(i) Has 2 years of appropriate experience as a physical therapist.

(ii) Has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(5) Before January 1, 1966—

(i) Was admitted to membership by the American Physical Therapy Association;

(ii) Was admitted to registration by the American Registry of Physical Therapists; or

(iii) Graduated from a physical therapy curriculum in a 4-year college or university approved by a state department of education.

(6) Before January 1, 1966 was licensed or registered, and before January 1, 1970, had 15 years of fulltime experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy.

(7) If trained outside the United States before January 1, 2008, meets the following requirements:

(i) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy.

(ii) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.

(i) *Standard: Physical therapist assistant.* A person who is licensed, registered or certified as a physical therapist assistant, if applicable, by the state in which practicing, unless licensure does not apply and meets one of the following requirements:

(1)(i) Graduated from a physical therapist assistant curriculum approved by the Commission on Accreditation in Physical Therapy Education of the American Physical Therapy Association; or if educated outside the United States or trained in the United States military, graduated from an education program determined to be substantially equivalent to physical therapist assistant entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified at 8 CFR 212.15(e); and

(ii) Passed a national examination for physical therapist assistants.

(2) On or before December 31, 2009, meets one of the following:

(i) Is licensed, or otherwise regulated in the state in which practicing.

(ii) In states where licensure or other regulations do not apply, graduated before December 31, 2009, from a 2-year college-level program approved by the American Physical Therapy Association and after January 1, 2010, meets the requirements of paragraph (h)(1) of this section.

(3) Before January 1, 2008, where licensure or other regulation does not apply, graduated from a 2-year college level program approved by the American Physical Therapy Association.

(4) On or before December 31, 1977, was licensed or qualified as a physical therapist assistant and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(j) *Standard: Physician.* A person who meets the qualifications and conditions specified in section 1861(r) of the Act and implemented at §410.20(b) of this chapter.

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

(l) *Standard: Social Work Assistant.* A person who provides services under the supervision of a qualified social worker and:

(1) Has a baccalaureate degree in social work, psychology, sociology, or other field related to social work, and has had at least 1 year of social work experience in a health care setting; or

(2) Has 2 years of appropriate experience as a social work assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that the determinations of proficiency do not apply with respect to persons initially licensed by a state or seeking initial qualification as a social work assistant after December 31, 1977.

(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.

(n) *Standard: Speech-language pathologist*. A person who has a master's or doctoral degree in speech-language pathology, and who meets either of the following requirements:

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

(2) In the case of an individual who furnishes services in a state which does not license speech-language pathologists:

(i) Has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating supervised clinical experience);

(ii) Performed not less than 9 months of supervised full-time speech-language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field; and

(iii) Successfully completed a national examination in speech-language pathology approved by the Secretary.

[82 FR 4578, Jan. 13, 2017, as amended at 82 FR 31732, July 10, 2017]

Subpart D [Reserved]

Subpart E—Prospective Payment System for Home Health Agencies

SOURCE: 65 FR 41212, July 3, 2000, unless otherwise noted.

§ 484.200 Basis and scope.

(a) *Basis*. This subpart implements section 1895 of the Act, which provides for the implementation of a prospective payment system (PPS) for HHAs for portions of cost reporting periods occurring on or after October 1, 2000.

(b) *Scope*. This subpart sets forth the framework for the HHA PPS, including the methodology used for the development of the payment rates, associated adjustments, and related rules.

§ 484.202 Definitions.

As used in this subpart—

Case-mix index means a scale that measures the relative difference in resource intensity among different groups in the clinical model.

Discipline means one of the six home health disciplines covered under the Medicare home health benefit (skilled nursing services, home health aide services, physical therapy services, occupational therapy services, speech-language pathology services, and medical social services).

Furnishing Negative Pressure Wound Therapy (NPWT) using a disposable device means the device is paid separately (specified by the assigned CPT® code) and does not include payment for the professional services. The nursing and therapy services are to be included as part of the payment under the home health prospective payment system.

HHCAHPS stands for Home Health Care Consumer Assessment of Healthcare Providers and Systems.

HH QRP stands for Home Health Quality Reporting Program.

Home health market basket index means an index that reflects changes over time in the prices of an appropriate mix of goods and services included in home health services.

Rural area means an area defined in § 412.64(b)(1)(ii)(C) of this chapter.

Urban area means an area defined in § 412.64(b)(1)(ii)(A) and (B) of this chapter.

[70 FR 68142, Nov. 9, 2005, as amended at 81 FR 76796, Nov. 3, 2016; 83 FR 56628, Nov. 13, 2018; 84 FR 60644, Nov. 8, 2019; 88 FR 77878, Nov. 13, 2023]

§ 484.205 Basis of payment.

(a) *Method of payment.* An HHA receives a national, standardized prospective payment amount for home health services previously paid on a reasonable cost basis (except the osteoporosis drug defined in section 1861(kk) of the Act) as of August 5, 1997. The national, standardized prospective payment is determined in accordance with § 484.215.

(b) *Unit of payment*—(1) *Episodes before December 31, 2019.* For episodes beginning on or before December 31, 2019, an HHA receives a unit of payment equal to a national, standardized prospective 60-day episode payment amount.

(2) *Periods on or after January 1, 2020.* For periods beginning on or after January 1, 2020, a HHA receives a unit of payment equal to a national, standardized prospective 30-day payment amount.

(c) *OASIS data.* A HHA must submit to CMS the OASIS data described at § 484.55(b) and (d) in order for CMS to administer the payment rate methodologies described in §§ 484.215, 484.220, 484. 230, 484.235, and 484.240.

(d) *Payment adjustments.* The national, standardized prospective payment amount represents payment in full for all costs associated with furnishing home health services and is subject to the following adjustments and additional payments:

(1) A low-utilization payment adjustment (LUPA) of a predetermined per-visit rate as specified in § 484.230.

(2) A partial payment adjustment as specified in § 484.235.

(3) An outlier payment as specified in § 484.240.

(e) *Medical review.* All payments under this system may be subject to a medical review adjustment reflecting the following:

(1) Beneficiary eligibility.

(2) Medical necessity determinations.

(3) Case-mix group assignment.

(f) *Durable medical equipment (DME) and disposable devices.* DME provided as a home health service as defined in section 1861(m) of the Act is paid the fee schedule amount. Separate payment is made for ''furnishing NPWT using a disposable device,'' as that term is defined in § 484.202, and is not included in the national, standardized prospective payment.

(g) *Split percentage payments.* Normally, there are two payments (initial and final) paid for an HH PPS unit of payment. The initial payment is made in response to a request for anticipated payment (RAP) as described in paragraph (h) of this section, and the residual final payment is made in response to the submission of a final claim. Split percentage payments are made in accordance with requirements at § 409.43(c) of this chapter.

(1) *Split percentage payments for episodes beginning on or before December 31, 2019*—(i) *Initial and residual final payments for initial episodes on or before December 31, 2019.* (A) The initial payment for initial episodes is paid to an HHA at 60 percent of the case-mix and wage-adjusted 60-day episode rate.

(B) The residual final payment for initial episodes is paid at 40 percent of the case-mix and wage-adjusted 60-day episode rate.

(ii) *Initial and residual final payments for subsequent episodes before December 31, 2019.* (A) The initial payment for subsequent episodes is paid to an HHA at 50 percent of the case-mix and wage-adjusted 60-day episode rate.

(B) The residual final payment for subsequent episodes is paid at 50 percent of the case-mix and wage-adjusted 60-day episode rate.

(2) *Split percentage payments for periods beginning on or after January 1, 2020 through December 31, 2020*—(i) *HHAs certified for participation on or before December 31, 2018.* (A) The initial payment for all 30-day periods is paid to an HHA at 20 percent of the case-mix and wage-adjusted 30-day payment rate.

(B) The residual final payment for all 30-day periods is paid at 80 percent of the case-mix and wage-adjusted 30-day payment rate.

(ii) *HHAs certified for participation in Medicare on or after January 1, 2019.* Split percentage payments are not made to HHAs that are certified for participation in Medicare effective on or after January 1, 2019. Newly enrolled HHAs must submit a request for anticipated payment, which is set at 0 percent, at the beginning of every 30-day period. An HHA that is certified for participation in Medicare effective on

or after January 1, 2019 receives a single payment for a 30-day period of care after the final claim is submitted.

(3) *Split percentage payments for periods beginning on or after January 1, 2021 through December 31, 2021.* All HHAs must submit a request for anticipated payment within 5 calendar days after the start of care date for initial 30-day periods and within 5 calendar days after the ''from date'' for each subsequent 30-day period of care, which is set at 0 percent at the beginning of every 30-day period. HHAs receive a single payment for a 30-day period of care after the final claim is submitted.

(4) *Payments for periods beginning on or after January 1, 2022.* All HHAs must submit a Notice of Admission (NOA) at the beginning of the initial 30-day period of care as described in paragraph (j) of this section. HHAs receive a single payment for a 30-day period of care after the final claim is submitted.

(h) *Requests for anticipated payment (RAP) for 30-day periods of care starting on January 1, 2020 through December 31, 2020.* (1) HHAs that are certified for participation in Medicare effective by December 31, 2018 submit requests for anticipated payment (RAPs) to request the initial split percentage payment as specified in paragraph (g) of this section. HHAs that are certified for participation in Medicare effective on or after January 1, 2019 are still required to submit RAPs although no split percentage payments are made in response to these RAP submissions. The HHA can submit a RAP when all of the following conditions are met:

(i) After the OASIS assessment required at § 484.55(b)(1) and (d) is complete, locked or export ready, or there is an agency-wide internal policy establishing the OASIS data is finalized for transmission to the national assessment system.

(ii) Once a physician or allowed practitioner's verbal orders for home care have been received and documented as required at §§ 484.60(b) and 409.43(d) of this chapter.

(iii) A plan of care has been established and sent to the physician or allowed practitioner as required at § 409.43(c) of this chapter.

(iv) The first service visit under that plan has been delivered.

(2) A RAP is based on the physician or allowed practitioner signature requirements in § 409.43(c) of this chapter and is not a Medicare claim for purposes of the Act (although it is a ''claim'' for purposes of Federal, civil, criminal, and administrative law enforcement authorities, including but not limited to the following:

(i) Civil Monetary Penalties Law (as defined in 42 U.S.C. 1320a–7a(i)(2)).

(ii) The Civil False Claims Act (as defined in 31 U.S.C. 3729(c)).

(iii) The Criminal False Claims Act (18 U.S.C. 287)).

(iv) The RAP is canceled and recovered unless the claim is submitted within the greater of 60 days from the end date of the appropriate unit of payment, as defined in paragraph (b) of this section, or 60 days from the issuance of the RAP.

(3) CMS has the authority to reduce, disprove, or cancel a RAP in situations when protecting Medicare program integrity warrants this action.

(i) *Submission of RAPs for CY 2021*—(1) *General.* All HHAs must submit a RAP, which is to be paid at 0 percent, within 5 calendar days after the start of care and within 5 calendar days after the ''from date'' for each subsequent 30-day period of care.

(2) *Criteria for RAP submission for CY 2021.* The HHA shall submit RAPs only when all of the following conditions are met:

(i) Once physician or allowed practitioner's written or verbal orders that contain the services required for the initial visit have been received and documented as required at §§ 484.60(b) and 409.43(d) of this chapter.

(ii) The initial visit within the 60-day certification period must have been made and the individual admitted to home health care.

(3) *Consequences of failure to submit a timely RAP.* When a home health agency does not file the required RAP for its Medicare patients within 5 calendar days after the start of each 30-day period of care—

(i) Medicare does not pay for those days of home health services based on the ''from date'' on the claim to the date of filing of the RAP;

(ii) The wage and case-mix adjusted 30-day period payment amount is reduced by 1/30th for each day from the home health based on the ''from date'' on the claim until the date of filing of the RAP;

(iii) No LUPA payments are made that fall within the late period;

(iv) The payment reduction cannot exceed the total payment of the claim; and

(v)(A) The non-covered days are a provider liability; and

(B) The provider must not bill the beneficiary for the non-covered days.

(4) *Exception to the consequences for filing the RAP late.* (i) CMS may waive the consequences of failure to submit a timely-filed RAP specified in paragraph (i)(3) of this section.

(ii) CMS determines if a circumstance encountered by a home health agency is exceptional and qualifies for waiver of the consequence specified in paragraph (i)(3) of this section.

(iii) A home health agency must fully document and furnish any requested documentation to CMS for a determination of exception. An exceptional circumstance may be due to, but is not limited to the following:

(A) Fires, floods, earthquakes, or similar unusual events that inflict extensive damage to the home health agency's ability to operate.

(B) A CMS or Medicare contractor systems issue that is beyond the control of the home health agency.

(C) A newly Medicare-certified home health agency that is notified of that certification after the Medicare certification date, or which is awaiting its user ID from its Medicare contractor.

(D) Other situations determined by CMS to be beyond the control of the home health agency.

(j) *Submission of Notice of Admission (NOA)*—(1) *For periods of care that begin on and after January 1, 2022.* For all 30-day periods of care after January 1, 2022, all HHAs must submit a Notice of Admission (NOA) to their Medicare contractor within 5 calendar days after the start of care date. The NOA is a one-time submission to establish the home health period of care and covers contiguous 30-day periods of care until the individual is discharged from Medicare home health services.

(2) *Criteria for NOA submission.* In order to submit the NOA, the following criteria must be met:

(i) Once a physician or allowed practitioner's written or verbal orders that contains the services required for the initial visit have been received and documented as required at §§ 484.60(b) and 409.43(d) of this chapter.

(ii) The initial visit must have been made and the individual admitted to home health care.

(3) *Consequences of failure to submit a timely Notice of Admission.* When a home health agency does not file the required NOA for its Medicare patients within 5 calendar days after the start of care—

(i) Medicare does not pay for those days of home health services from the start date to the date of filing of the notice of admission;

(ii) The wage and case-mix adjusted 30-day period payment amount is reduced by 1/30th for each day from the home health start of care date until the date of filing of the NOA;

(iii) No LUPA payments are made that fall within the late NOA period;

(iv) The payment reduction cannot exceed the total payment of the claim; and

(v)(A) The non-covered days are a provider liability; and

(B) The provider must not bill the beneficiary for the non-covered days.

(4) *Exception to the consequences for filing the NOA late.* (i) CMS may waive the consequences of failure to submit a timely-filed NOA specified in paragraph (j)(3) of this section.

(ii) CMS determines if a circumstance encountered by a home health agency is exceptional and qualifies for waiver of the consequence specified in paragraph (j)(3) of this section.

(iii) A home health agency must fully document and furnish any requested documentation to CMS for a determination of exception. An exceptional circumstance may be due to, but is not limited to the following:

(A) Fires, floods, earthquakes, or similar unusual events that inflict extensive damage to the home health agency's ability to operate.

(B) A CMS or Medicare contractor systems issue that is beyond the control of the home health agency.

(C) A newly Medicare-certified home health agency that is notified of that certification after the Medicare certification date, or which is awaiting its user ID from its Medicare contractor.

(D) Other situations determined by CMS to be beyond the control of the home health agency.

[83 FR 56628, Nov. 13, 2018, as amended at 84 FR 60644, Nov. 8, 2019; 85 FR 27628, May 8, 2020]

§ 484.215 Initial establishment of the calculation of the national, standardized prospective payment rates.

(a) *Determining an HHA's costs.* In calculating the initial unadjusted national 60-day episode payment applicable for a service furnished by an HHA using data on the most recent available audited cost reports, CMS determines each HHA's costs by summing its allowable costs for the period. CMS determines the national mean cost per visit.

(b) *Determining HHA utilization.* In calculating the initial unadjusted national 60-day episode payment, CMS determines the national mean utilization for each of the six disciplines using home health claims data.

(c) *Use of the market basket index.* CMS uses the HHA market basket index to adjust the HHA cost data to reflect cost increases occurring between October 1, 1996 through September 30, 2001.

(d) *Calculation of the unadjusted national average prospective payment amount for the 60-day episode.* For episodes beginning on or before December 31, 2019, CMS calculates the unadjusted national 60-day episode payment in the following manner:

(1) By computing the mean national cost per visit.

(2) By computing the national mean utilization for each discipline.

(3) By multiplying the mean national cost per visit by the national mean utilization summed in the aggregate for the six disciplines.

(4) By adding to the amount derived in paragraph (d)(3) of this section, amounts for nonroutine medical supplies, an OASIS adjustment for estimated ongoing reporting costs, an OASIS adjustment for the one time implementation costs associated with assessment scheduling form changes and amounts for Part B therapies that could have been unbundled to Part B prior to October 1, 2000. The resulting amount is the unadjusted national 60-day episode rate.

(e) *Standardization of the data for variation in area wage levels and case-mix.* CMS standardizes—

(1) The cost data described in paragraph (a) of this section to remove the effects of geographic variation in wage levels and variation in case-mix;

(2) The cost data for geographic variation in wage levels using the hospital wage index; and

(3) The cost data for HHA variation in case-mix using the case-mix indices and other data that indicate HHA case-mix.

(f) For periods beginning on or after January 1, 2020, a national, standardized prospective 30-day payment rate applies. The national, standardized prospective 30-day payment rate is an amount determined by the Secretary, as subsequently adjusted in accordance with § 484.225.

[65 FR 41212, July 3, 2000, as amended at 83 FR 56629, Nov. 13, 2018]

§ 484.220 Calculation of the case-mix and wage area adjusted prospective payment rates.

CMS adjusts the national, standardized prospective payment rates as referenced in § 484.215 to account for the following:

(a) HHA case-mix using a case-mix index to explain the relative resource utilization of different patients. To address changes to the case-mix that are a result of changes in the coding or classification of different units of service that do not reflect real changes in case-mix, the national, standardized prospective payment rate will be adjusted downward as follows:

(1) For CY 2008, the adjustment is 2.75 percent.

(2) For CY 2009 and CY 2010, the adjustment is 2.75 percent in each year.

(3) For CY 2011, the adjustment is 3.79 percent.

(4) For CY 2012, the adjustment is 3.79 percent.

(5) For CY 2013, the adjustment is 1.32 percent.

(6) For CY 2016, CY 2017, and CY 2018, the adjustment is 0.97 percent in each year.

(b) Geographic differences in wage levels using an appropriate wage index based on the site of service of the beneficiary.

(c) Beginning on January 1, 2023, CMS applies a cap on decreases to the home health wage index such that the wage index applied to a geographic area is not less than 95 percent of the wage index applied to that geographic area in the prior calendar year. The 5-percent cap on negative wage index changes is implemented in a budget neutral manner through the use of wage index budget neutrality factors.

[72 FR 49879, Aug. 29, 2007, as amended at 80 FR 68717, Nov. 5, 2015; 83 FR 56629, Nov. 13, 2018; 87 FR 66886, Nov. 4, 2022]

§ 484.225 Annual update of the unadjusted national, standardized prospective payment rates.

(a) CMS annually updates the unadjusted national, standardized prospective payment rate on a calendar year basis (in accordance with section 1895(b)(1)(B) of the Act).

(b) For 2007 and subsequent calendar years, in accordance with section 1895(b)(3)(B)(v) of the Act, in the case of a home health agency that does not submit home health quality data, as specified by the Secretary, the unadjusted national, standardized prospective rate is equal to the rate for the previous calendar year increased by the applicable home health market basket index amount minus 2 percentage points. Any reduction of the percentage change will apply only to the calendar year involved and will not be taken into account in computing the prospective payment amount for a subsequent calendar year.

(c) For CY 2020, the national, standardized prospective 30-day payment amount is an amount determined by the Secretary. CMS annually updates this amount on a calendar year basis in accordance with paragraphs (a) and (b) of this section.

[80 FR 68717, Nov. 5, 2015, as amended at 83 FR 56629, Nov. 13, 2018; 84 FR 60645, Nov. 8, 2019]

§ 484.230 Low-utilization payment adjustments.

(a) For episodes beginning on or before December 31, 2019, an episode with four or fewer visits is paid the national per-visit amount by discipline determined in accordance with § 484.215(a) and updated annually by the applicable market basket for each visit type, in accordance with § 484.225.

(1) The national per-visit amount is adjusted by the appropriate wage index based on the site of service of the beneficiary.

(2) An amount is added to the low-utilization payment adjustments for low-utilization episodes that occur as the beneficiary's only episode or initial episode in a sequence of adjacent episodes.

(3) For purposes of the home health PPS, a sequence of adjacent episodes for a beneficiary is a series of claims with no more than 60 days without home care between the end of one episode, which is the 60th day (except for episodes that have been PEP-adjusted), and the beginning of the next episode.

(b) For periods beginning on or after January 1, 2020, an HHA receives a national 30-day payment of a predetermined rate for home health services, unless CMS determines at the end of the 30-day period that the HHA furnished minimal services to a patient during the 30-day period.

(1) For each payment group used to case-mix adjust the 30-day payment rate, the 10th percentile value of total visits during a 30-day period of care is used to create payment group specific thresholds with a minimum threshold of at least 2 visits for each case-mix group.

(2) A 30-day period with a total number of visits less than the threshold is paid the national per-visit amount by discipline determined in accordance with § 484.215(a) and updated annually by the applicable market basket for each visit type, in accordance with § 484.225.

(3) The national per-visit amount is adjusted by the appropriate wage index based on the site of service for the beneficiary.

(c) An amount is added to low-utilization payment adjustments for low-utilization periods that occur as the

beneficiary's only 30-day period or initial 30-day period in a sequence of adjacent periods of care. For purposes of the home health PPS, a sequence of adjacent periods of care for a beneficiary is a series of claims with no more than 60 days without home care between the end of one period, which is the 30th day (except for episodes that have been partial payment adjusted), and the beginning of the next episode.

[83 FR 56629, Nov. 13, 2018]

§ 484.235 Partial payment adjustments.

(a) *Partial episode payments (PEPs) for episodes beginning on or before December 31, 2019.* (1) An HHA receives a national, standardized 60-day payment of a predetermined rate for home health services unless CMS determines an intervening event, defined as a beneficiary elected transfer or discharge with goals met or no expectation of return to home health and the beneficiary returned to home health during the 60-day episode, warrants a new 60-day episode for purposes of payment. A start of care OASIS assessment and physician or allowed practitioner certification of the new plan of care are required.

(2) The PEP adjustment does not apply in situations of transfers among HHAs of common ownership.

(i) Those situations are considered services provided under arrangement on behalf of the originating HHA by the receiving HHA with the common ownership interest for the balance of the 60-day episode.

(ii) The common ownership exception to the transfer PEP adjustment does not apply if the beneficiary moves to a different MSA or Non-MSA during the 60-day episode before the transfer to the receiving HHA.

(iii) The transferring HHA in situations of common ownership not only serves as a billing agent, but must also exercise professional responsibility over the arranged-for services in order for services provided under arrangements to be paid.

(3) If the intervening event warrants a new 60-day payment and a new physician or allowed practitioner certification and a new plan of care, the initial HHA receives a partial episode payment adjustment reflecting the length of time the patient remained under its care based on the first billable visit date through and including the last billable visit date. The PEP is calculated by determining the actual days served as a proportion of 60 multiplied by the initial 60-day payment amount.

(b) *Partial payment adjustments for periods beginning on or after January 1, 2020.* (1) An HHA receives a national, standardized 30-day payment of a predetermined rate for home health services unless CMS determines an intervening event, defined as a beneficiary elected transfer or discharge with goals met or no expectation of return to home health and the beneficiary returned to home health during the 30-day period, warrants a new 30-day period for purposes of payment. A start of care OASIS assessment and certification of the new plan of care are required.

(2) The partial payment adjustment does not apply in situations of transfers among HHAs of common ownership.

(i) Those situations are considered services provided under arrangement on behalf of the originating HHA by the receiving HHA with the common ownership interest for the balance of the 30-day period.

(ii) The common ownership exception to the transfer partial payment adjustment does not apply if the beneficiary moves to a different MSA or Non-MSA during the 30-day period before the transfer to the receiving HHA.

(iii) The transferring HHA in situations of common ownership not only serves as a billing agent, but must also exercise professional responsibility over the arranged-for services in order for services provided under arrangements to be paid.

(3) If the intervening event warrants a new 30-day payment and a new physician or allowed practitioner certification and a new plan of care, the initial HHA receives a partial payment adjustment reflecting the length of time the patient remained under its care based on the first billable visit date through and including the last billable visit date. The partial payment is calculated by determining the actual

days served as a proportion of 30 multiplied by the initial 30-day payment amount.

[83 FR 56629, Nov. 13, 2018, as amended at 85 FR 27628, May 8, 2020]

§ 484.240 Outlier payments.

(a) For episodes beginning on or before December 31, 2019, an HHA receives an outlier payment for an episode whose estimated costs exceeds a threshold amount for each case-mix group. The outlier threshold for each case-mix group is the episode payment amount for that group, or the PEP adjustment amount for the episode, plus a fixed dollar loss amount that is the same for all case-mix groups.

(b) For periods beginning on or after January 1, 2020, an HHA receives an outlier payment for a 30-day period whose estimated cost exceeds a threshold amount for each case-mix group. The outlier threshold for each case-mix group is the 30-day payment amount for that group, or the partial payment adjustment amount for the 30-day period, plus a fixed dollar loss amount that is the same for all case-mix groups.

(c) The outlier payment is a proportion of the amount of imputed cost beyond the threshold.

(d) CMS imputes the cost for each claim by multiplying the national per-15 minute unit amount of each discipline by the number of 15 minute units in the discipline and computing the total imputed cost for all disciplines.

[83 FR 56630, Nov. 13, 2018]

§ 484.245 Requirements under the Home Health Quality Reporting Program (HH QRP).

(a) *Participation.* Beginning January 1, 2007, an HHA must report Home Health Quality Reporting Program (HH QRP) data in accordance with the requirements of this section.

(b) *Data submission.* (1) Except as provided in paragraph (d) of this section, and for a program year, an HHA must submit all of the following to CMS:

(i) Data—

(A) Required under section 1895(b)(3)(B)(v)(II) of the Act, including HHCAHPS survey data; and

(B) On measures specified under sections 1899B(c)(1) and 1899B(d)(1) of the Act.

(ii) Standardized patient assessment data required under section 1899B(b)(1) of the Act.

(iii) For purposes of HHCAHPS survey data submission, the following additional requirements apply:

(A) *Patient count.* An HHA that has less than 60 eligible unique HHCAHPS patients must annually submit to CMS their total HHCAHPS patient count to CMS to be exempt from the HHCAHPS reporting requirements for a calendar year.

(B) *Survey requirements.* An HHA must contract with an approved, independent HHCAHPS survey vendor to administer the HHCAHPS on its behalf.

(C) *CMS approval.* CMS approves an HHCAHPS survey vendor if the applicant has been in business for a minimum of 3 years and has conducted surveys of individuals and samples for at least 2 years.

(*1*) For HHCAHPS, a ''survey of individuals'' is defined as the collection of data from at least 600 individuals selected by statistical sampling methods and the data collected are used for statistical purposes.

(*2*) All applicants that meet the requirements in this paragraph (b)(1)(iii)(C) are approved by CMS.

(D) *Disapproval by CMS.* No organization, firm, or business that owns, operates, or provides staffing for an HHA is permitted to administer its own HHCAHPS Survey or administer the survey on behalf of any other HHA in the capacity as an HHCAHPS survey vendor. Such organizations are not be approved by CMS as HHCAHPS survey vendors.

(E) *Compliance with oversight activities.* Approved HHCAHPS survey vendors must fully comply with all HHCAHPS oversight activities, including allowing CMS and its HHCAHPS program team to perform site visits at the vendors' company locations.

(2)(i) *Data submission requirements.* The data submitted under paragraph (b) of this section must be submitted in the form and manner, and at a time, specified by CMS.

(ii) *Data completion thresholds.* (A) A home health agency must meet or exceed the data submission threshold for each submission year (July 1 through June 30) set at 90 percent of all required OASIS or successor instrument records submitted through the CMS designated data submission systems.

(B) A home health agency must meet or exceed the data submission compliance threshold described in paragraph (b)(2)(ii)(A) of this section to avoid receiving a 2-percentage point reduction to its annual payment update for a given fiscal year described under § 484.225(b).

(3) *Measure removal factors.* CMS may remove a quality measure from the HH QRP based on one or more of the following factors:

(i) Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

(ii) Performance or improvement on a measure does not result in better patient outcomes.

(iii) A measure does not align with current clinical guidelines or practice.

(iv) The availability of a more broadly applicable (across settings, populations, or conditions) measure for the particular topic.

(v) The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.

(vi) The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.

(vii) Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

(viii) The costs associated with a measure outweigh the benefit of its continued use in the program.

(c) *Exceptions and extension requirements.* (1) An HHA may request and CMS may grant exceptions or extensions to the reporting requirements under paragraph (b) of this section for one or more quarters, when there are certain extraordinary circumstances beyond the control of the HHA.

(2) An HHA may request an exception or extension within 90 days of the date that the extraordinary circumstances occurred by sending an email to CMS HHAPU reconsiderations at *HHAPUReconsiderations@cms.hhs.gov* that contains all of the following information:

(i) HHA CMS Certification Number (CCN).

(ii) HHA Business Name.

(iii) HHA Business Address.

(iv) CEO or CEO-designated personnel contact information including name, title, telephone number, email address, and mailing address (the address must be a physical address, not a post office box).

(v) HHA's reason for requesting the exception or extension.

(vi) Evidence of the impact of extraordinary circumstances, including, but not limited to, photographs, newspaper, and other media articles.

(vii) Date when the HHA believes it will be able to again submit data under paragraph (b) of this section and a justification for the proposed date.

(3) Except as provided in paragraph (c)(4) of this section, CMS does not consider an exception or extension request unless the HHA requesting such exception or extension has complied fully with the requirements in this paragraph (c).

(4) CMS may grant exceptions or extensions to HHAs without a request if it determines that one or more of the following has occurred:

(i) An extraordinary circumstance, such as an act of nature, affects an entire region or locale.

(ii) A systemic problem with one of CMS's data collection systems directly affects the ability of an HHA to submit data under paragraph (b) of this section.

(d) *Reconsiderations.* (1)(i) HHAs that do not meet the quality reporting requirements under this section for a program year will receive a letter of noncompliance via the United States Postal Service and the CMS-designated data submission system.

(ii) An HHA may request reconsideration no later than 30 calendar days after the date identified on the letter of non-compliance.

(2) Reconsideration requests may be submitted to CMS by sending an email to CMS HHAPU reconsiderations at *HHAPureConsiderations@cms.hhs.gov*

containing all of the following information:

(i) HHA CCN.

(ii) HHA Business Name.

(iii) HHA Business Address.

(iv) CEO or CEO-designated personnel contact information including name, title, telephone number, email address, and mailing address (the address must be a physical address, not a post office box).

(v) CMS identified reason(s) for noncompliance as stated in the non-compliance letter.

(vi) Reason(s) for requesting reconsideration, including all supporting documentation.

(3) CMS does not consider a reconsideration request unless the HHA has complied fully with the submission requirements in paragraphs (d)(1) and (2) of this section.

(4) CMS makes a decision on the request for reconsideration and provide notice of the decision to the HHA via letter sent via the United States Postal Service.

(e) *Appeals.* An HHA that is dissatisfied with CMS' decision on a request for reconsideration submitted under paragraph (d) of this section may file an appeal with the Provider Reimbursement Review Board (PRRB) under 42 CFR part 405, subpart R.

[84 FR 60645, Nov. 8, 2019, as amended at 87 FR 66886, Nov. 4, 2022; 88 FR 77878, Nov. 13, 2023]

§ 484.250 OASIS data.

An HHA must submit to CMS the OASIS data described at § 484.55(b) and (d) as is necessary for CMS to administer the payment rate methodologies described in §§ 484.215, 484.220, 484.230, 484.235, and 484.240.

[84 FR 60646, Nov. 8, 2019]

§ 484.260 Limitation on review.

An HHA is not entitled to judicial or administrative review under sections 1869 or 1878 of the Act, or otherwise, with regard to the establishment of the payment unit, including the national 60-day prospective episode payment rate, adjustments and outlier payments. An HHA is not entitled to the review regarding the establishment of the transition period, definition and application of the unit of payments, the computation of initial standard prospective payment amounts, the establishment of the adjustment for outliers, and the establishment of case-mix and area wage adjustment factors.

§ 484.265 Additional payment.

An additional payment is made to a home health agency in accordance with § 476.78 of this chapter for the costs of sending requested patient records to the QIO in electronic format, by facsimile, or by photocopying and mailing.

[85 FR 59026, Sept. 18, 2020]

Subpart F—Home Health Value-Based Purchasing (HHVBP) Models

SOURCE: 80 FR 68718, Nov. 5, 2015, unless otherwise noted.

HHVBP MODEL COMPONENTS FOR COMPETING HOME HEALTH AGENCIES WITHIN STATE BOUNDARIES FOR THE ORIGINAL HHVBP MODEL

§ 484.300 Basis and scope of subpart.

This subpart is established under sections 1102, 1115A, and 1871 of the Act (42 U.S.C. 1315a), which authorizes the Secretary to issue regulations to operate the Medicare program and test innovative payment and service delivery models to improve coordination, quality, and efficiency of health care services furnished under Title XVIII.

§ 484.305 Definitions.

As used in this subpart—

Applicable measure means a measure for which a competing HHA has provided a minimum of—

(1) Twenty home health episodes of care per year for the OASIS-based measures;

(2) Twenty home health episodes of care per year for the claims-based measures; or

(3) Forty completed surveys for the HHCAHPS measures.

Applicable percent means a maximum upward or downward adjustment for a given performance year, not to exceed the following:

(1) For CY 2018, 3-percent.

(2) For CY 2019, 5-percent.

(3) For CY 2020, 6-percent.

(4) For CY 2021, 7-percent.

Benchmark refers to the mean of the top decile of Medicare-certified HHA performance on the specified quality measure during the baseline period, calculated for each state.

Competing home health agency or agencies means an agency or agencies:

(1) That has or have a current Medicare certification; and,

(2) Is or are being paid by CMS for home health care delivered within any of the states specified in § 484.310.

Home health prospective payment system (HH PPS) refers to the basis of payment for home health agencies as set forth in §§ 484.200 through 484.245.

Larger-volume cohort means the group of competing home health agencies within the boundaries of selected states that are participating in HHCAHPs in accordance with § 484.250.

Linear exchange function is the means to translate a competing HHA's Total Performance Score into a value-based payment adjustment percentage.

New measures means those measures to be reported by competing HHAs under the HHVBP Model that are not otherwise reported by Medicare-certified HHAs to CMS and were identified to fill gaps to cover National Quality Strategy Domains not completely covered by existing measures in the home health setting.

Payment adjustment means the amount by which a competing HHA's final claim payment amount under the HH PPS is changed in accordance with the methodology described in § 484.325.

Performance period means the time period during which data are collected for the purpose of calculating a competing HHA's performance on measures.

Selected state(s) means those nine states that were randomly selected to compete/participate in the HHVBP Model via a computer algorithm designed for random selection and identified at § 484.310(b).

Smaller-volume cohort means the group of competing home health agencies within the boundaries of selected states that are exempt from participation in HHCAHPs in accordance with § 484.250.

Total Performance Score means the numeric score ranging from 0 to 100 awarded to each competing HHA based on its performance under the HHVBP Model.

Value-based purchasing means measuring, reporting, and rewarding excellence in health care delivery that takes into consideration quality, efficiency, and alignment of incentives. Effective health care services and high performing health care providers may be rewarded with improved reputations through public reporting, enhanced payments through differential reimbursements, and increased market share through purchaser, payer, and/or consumer selection.

[80 FR 68718, Nov. 5, 2015, as amended at 81 FR 76796, Nov. 3, 2016; 82 FR 51752, Nov. 7, 2017; 86 FR 62422, Nov. 9, 2021]

§ 484.310 Applicability of the Home Health Value-Based Purchasing (HHVBP) Model.

(a) *General rule.* The HHVBP Model applies to all Medicare-certified home health agencies (HHAs) in selected states.

(b) *Selected states.* Nine states have been selected in accordance with CMS's selection methodology. All Medicare-certified HHAs that provide services in Massachusetts, Maryland, North Carolina, Florida, Washington, Arizona, Iowa, Nebraska, and Tennessee will be required to compete in this model.

§ 484.315 Data reporting for measures and evaluation and the public reporting of model data under the Home Health Value-Based Purchasing (HHVBP) Model.

(a) Competing home health agencies will be evaluated using a set of quality measures.

(b) Competing home health agencies in selected states will be required to report information on New Measures, as determined appropriate by the Secretary, to CMS in the form, manner, and at a time specified by the Secretary, and subject to any exceptions or extensions CMS may grant to home health agencies for the Public Health Emergency as defined in § 400.200 of this chapter.

(c) Competing home health agencies in selected states will be required to

collect and report such information as the Secretary determines is necessary for purposes of monitoring and evaluating the HHVBP Model under section 1115A(b)(4) of the Act (42 U.S.C. 1315a).

[80 FR 68718, Nov. 5, 2015, as amended at 81 FR 76796, Nov. 3, 2016; 84 FR 60646, Nov. 8, 2019; 85 FR 27628, May 8, 2020; 86 FR 62422, Nov. 9, 2021]

§ 484.320 Calculation of the Total Performance Score.

A competing home health agency's Total Performance Score for a model year is calculated as follows:

(a) CMS will award points to the competing home health agency for performance on each of the applicable measures excluding the New Measures.

(b) CMS will award points to the competing home health agency for reporting on each of the New Measures worth up to ten percent of the Total Performance Score.

(c)(1) For performance years 1 through 3, CMS will sum all points awarded for each applicable measure excluding the New Measures, weighted equally at the individual measure level to calculate a value worth 90 percent of the Total Performance Score.

(2) For performance years 4 and 5, CMS will sum all points awarded for each applicable measure within each category of measures (OASIS-based, claims-based and HHCAHPS) excluding the New Measures, weighted at 35 percent for the OASIS-based measure category, 35 percent for the claims-based measure category, and 30 percent for the HHCAHPS measure category when all three measure categories are reported, to calculate a value worth 90 percent of the Total Performance Score.

(d) The sum of the points awarded to a competing HHA for each applicable measure and the points awarded to a competing HHA for reporting data on each New Measure is the competing HHA's Total Performance Score for the calendar year.

[80 FR 68718, Nov. 5, 2015, as amended at 81 FR 76796, Nov. 3, 2016; 83 FR 56630, Nov. 13, 2018]

§ 484.325 Payments for home health services under Home Health Value-Based Purchasing (HHVBP) Model.

CMS will determine a payment adjustment up to the maximum applicable percentage, upward or downward, under the HHVBP Model for each competing home health agency based on the agency's Total Performance Score using a linear exchange function. Payment adjustments made under the HHVBP Model will be calculated as a percentage of otherwise-applicable payments for home health services provided under section 1895 of the Act (42 U.S.C. 1395fff).

§ 484.330 Process for determining and applying the value-based payment adjustment under the Home Health Value-Based Purchasing (HHVBP) Model.

(a) *General.* Competing home health agencies will be ranked within the larger-volume and smaller-volume cohorts in selected states based on the performance standards that apply to the HHVBP Model for the baseline year, and CMS will make value-based payment adjustments to the competing HHAs as specified in this section.

(b) *Calculation of the value-based payment adjustment amount.* The value-based payment adjustment amount is calculated by multiplying the Home Health Prospective Payment final claim payment amount as calculated in accordance with § 484.205 by the payment adjustment percentage.

(c) *Calculation of the payment adjustment percentage.* The payment adjustment percentage is calculated as the product of: The applicable percent as defined in § 484.320, the competing HHA's Total Performance Score divided by 100, and the linear exchange function slope.

§ 484.335 Appeals process for the Home Health Value-Based Purchasing (HHVBP) Model.

(a) *Requests for recalculation*—(1) *Matters for recalculation.* Subject to the limitations on review under section 1115A of the Act, a HHA may submit a request for recalculation under this section if it wishes to dispute the calculation of the following:

(i) Interim performance scores.

(ii) Annual total performance scores.

(iii) Application of the formula to calculate annual payment adjustment percentages.

(2) *Time for filing a request for recalculation.* A recalculation request must be submitted in writing within 15 calendar days after CMS posts the HHA-specific information on the HHVBP Secure Portal, in a time and manner specified by CMS.

(3) *Content of request.* (i) The provider's name, address associated with the services delivered, and CMS Certification Number (CCN).

(ii) The basis for requesting recalculation to include the specific quality measure data that the HHA believes is inaccurate or the calculation the HHA believes is incorrect.

(iii) Contact information for a person at the HHA with whom CMS or its agent can communicate about this request, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box).

(iv) The HHA may include in the request for recalculation additional documentary evidence that CMS should consider. Such documents may not include data that was to have been filed by the applicable data submission deadline, but may include evidence of timely submission.

(4) *Scope of review for recalculation.* In conducting the recalculation, CMS will review the applicable measures and performance scores, the evidence and findings upon which the determination was based, and any additional documentary evidence submitted by the home health agency. CMS may also review any other evidence it believes to be relevant to the recalculation.

(5) *Recalculation decision.* CMS will issue a written notification of findings. A recalculation decision is subject to the request for reconsideration process in accordance with paragraph (b) of this section.

(b) *Requests for reconsideration*—(1) *Matters for reconsideration.* A home health agency may request reconsideration of the recalculation of its annual total performance score and payment adjustment percentage following a decision on the home health agency's recalculation request submitted under paragraph (a) of this section, or the decision to deny the recalculation request submitted under paragraph (a) of this section.

(2) *Time for filing a request for reconsideration.* The request for reconsideration must be submitted via the HHVBP Secure Portal within 15 calendar days from CMS' notification to the HHA contact of the outcome of the recalculation process.

(3) *Content of request.* (i) The name of the HHA, address associated with the services delivered, and CMS Certification Number (CCN).

(ii) The basis for requesting reconsideration to include the specific quality measure data that the HHA believes is inaccurate or the calculation the HHA believes is incorrect.

(iii) Contact information for a person at the HHA with whom CMS or its agent can communicate about this request, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box).

(iv) The HHA may include in the request for reconsideration additional documentary evidence that CMS should consider. Such documents may not include data that was to have been filed by the applicable data submission deadline, but may include evidence of timely submission.

(4) *Scope of review for reconsideration.* In conducting the reconsideration review, CMS will review the applicable measures and performance scores, the evidence and findings upon which the determination was based, and any additional documentary evidence submitted by the HHA. CMS may also review any other evidence it believes to be relevant to the reconsideration. The HHA must prove its case by a preponderance of the evidence with respect to issues of fact.

(5) *Reconsideration decision.* CMS reconsideration officials will issue a written determination.

[81 FR 76796, Nov. 3, 2016]

HHVBP MODEL COMPONENTS FOR COMPETING HOME HEALTH AGENCIES (HHAS) FOR HHVBP MODEL EXPANSION—EFFECTIVE JANUARY 1, 2022

SOURCE: 86 FR 62422, Nov. 9, 2021, unless otherwise noted.

§ 484.340 Basis and scope of this subpart.

This subpart is established under sections 1102, 1115A, and 1871 of the Act (42 U.S.C. 1315a), which authorizes the Secretary to issue regulations to operate the Medicare program and test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to individuals under Titles XVIII and XIX of the Act.

§ 484.345 Definitions.

As used in this subpart—

Achievement threshold means the median (50th percentile) of home health agency performance on a measure during a Model baseline year, calculated separately for the larger- and smaller-volume cohorts.

Applicable measure means a measure (OASIS- and claims-based measures) or a measure component (HHCAHPS survey measure) for which a competing HHA has provided a minimum of one of the following:

(1) Twenty home health episodes of care per year for each of the OASIS-based measures.

(2) Twenty home health episodes of care per year for each of the claims-based measures.

(3) Forty completed surveys for each component included in the HHCAHPS survey measure.

Applicable percent means a maximum upward or downward adjustment for a given payment year based on the applicable performance year, not to exceed 5 percent.

Benchmark refers to the mean of the top decile of Medicare-certified HHA performance on the specified quality measure during the Model baseline year, calculated separately for the larger- and smaller-volume cohorts.

Competing home health agency or agencies (HHA or HHAs) means an agency or agencies that meet the following:

(1) Has or have a current Medicare certification; and

(2) Is or are being paid by CMS for home health care services.

HHA baseline year means the calendar year used to determine the improvement threshold for each measure for each individual competing HHA.

Home health prospective payment system (HH PPS) refers to the basis of payment for HHAs as set forth in §§ 484.200 through 484.245.

Improvement threshold means an individual competing HHA's performance level on a measure during the HHA baseline year.

Larger-volume cohort means the group of competing HHAs that are participating in the HHCAHPS survey in accordance with § 484.245.

Linear exchange function is the means to translate a competing HHA's Total Performance Score into a value-based payment adjustment percentage.

Model baseline year means the calendar year used to determine the benchmark and achievement threshold for each measure for all competing HHAs.

Nationwide means the 50 States and the U.S. territories, including the District of Columbia.

Payment adjustment means the amount by which a competing HHA's final claim payment amount under the HH PPS is changed in accordance with the methodology described in § 484.370.

Payment year means the calendar year in which the applicable percent, a maximum upward or downward adjustment, applies.

Performance year means the calendar year during which data are collected for the purpose of calculating a competing HHA's performance on measures.

Pre-Implementation year means CY 2022.

Smaller-volume cohort means the group of competing HHAs that are exempt from participation in the HHCAHPS survey in accordance with § 484.245.

Total Performance Score (TPS) means the numeric score ranging from 0 to 100 awarded to each competing HHA based

on its performance under the expanded HHVBP Model.

[86 FR 62422, Nov. 9, 2021, as amended at 87 FR 66887, Nov. 4, 2022]

§ 484.350 Applicability of the Expanded Home Health Value-Based Purchasing (HHVBP) Model.

(a) *General rule.* The expanded HHVBP Model applies to all Medicare-certified HHAs nationwide.

(b) *New HHAs.* A new HHA is certified by Medicare on or after January 1, 2022. For new HHAs, the following apply:

(1) The HHA baseline year is the first full calendar year of services beginning after the date of Medicare certification.

(2) The first performance year is the first full calendar year following the HHA baseline year.

(c) *Existing HHAs.* An existing HHA is certified by Medicare before January 1, 2022 and the HHA baseline year is CY 2022.

[86 FR 62422, Nov. 9, 2021, as amended at 87 FR 66887, Nov. 4, 2022]

§ 484.355 Data reporting for measures and evaluation and the public reporting of model data under the expanded Home Health Value-Based Purchasing (HHVBP) Model.

(a) Competing home health agencies will be evaluated using a set of quality measures.

(1) *Data submission.* Except as provided in paragraph (d) of this section, for the pre-implementation year and each performance year, an HHA must submit all of the following to CMS in the form and manner, and at a time, specified by CMS:

(i) Data on measures specified under the expanded HHVBP model.

(ii) HHCAHPS survey data. For purposes of HHCAHPS Survey data submission, the following additional requirements apply:

(A) *Survey requirements.* An HHA must contract with an approved, independent HHCAHPS survey vendor to administer the HHCAHPS survey on its behalf.

(B) *CMS approval.* CMS approves an HHCAHPS survey vendor if the applicant has been in business for a minimum of 3 years and has conducted surveys of individuals and samples for at least 2 years.

(C) *Definition of survey of individuals.* For the HHCAHPS survey, a ''survey of individuals'' is defined as the collection of data from at least 600 individuals selected by statistical sampling methods and the data collected are used for statistical purposes.

(D) *Administration of the HHCAHPS survey.* No organization, firm, or business that owns, operates, or provides staffing for an HHA is permitted to administer its own HHCAHPS survey or administer the survey on behalf of any other HHA in the capacity as an HHCAHPS survey vendor. Such organizations are not approved by CMS as HHCAHPS survey vendors.

(E) *Compliance by HHCAHPS survey vendors.* Approved HHCAHPS survey vendors must fully comply with all HHCAHPS survey oversight activities, including allowing CMS and its HHCAHPS survey team to perform site visits at the vendors' company locations.

(F) *Patient count exemption.* An HHA that has less than 60 eligible unique HHCAHPS survey patients must annually submit to CMS its total HHCAHPS survey patient count to be exempt from the HHCAHPS survey reporting requirements for a calendar year.

(2) [Reserved]

(b) Competing home health agencies are required to collect and report such information as the Secretary determines is necessary for purposes of monitoring and evaluating the expanded HHVBP Model under section 1115A(b)(4) of the Act (42 U.S.C. 1315a).

(c) For each performance year of the expanded HHVBP Model, CMS publicly reports applicable measure benchmarks and achievement thresholds for each cohort as well as all of the following for each competing HHA that qualified for a payment adjustment for the applicable performance year on a CMS website:

(1) The Total Performance Score.

(2) The percentile ranking of the Total Performance Score.

(3) The payment adjustment percentage.

(4) Applicable measure results and improvement thresholds.

(d) CMS may grant an exception with respect to quality data reporting requirements in the event of extraordinary circumstances beyond the control of the HHA. CMS may grant an exception as follows:

(1) A competing HHA that wishes to request an exception with respect to quality data reporting requirements must submit its request to CMS within 90 days of the date that the extraordinary circumstances occurred. Specific requirements for submission of a request for an exception are available on the CMS website.

(2) CMS may grant an exception to one or more HHAs that have not requested an exception if CMS determines either of the following:

(i) That a systemic problem with CMS data collection systems directly affected the ability of the HHA to submit data.

(ii) That an extraordinary circumstance has affected an entire region or locale.

§ 484.358 HHVBP Measure removal factors.

CMS may remove a quality measure from the expanded HHVBP Model based on one or more of the following factors:

(a) Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made (that is, topped out).

(b) Performance or improvement on a measure does not result in better patient outcomes.

(c) A measure does not align with current clinical guidelines or practice.

(d) A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available.

(e) A measure that is more proximal in time to desired patient outcomes for the particular topic is available.

(f) A measure that is more strongly associated with desired patient outcomes for the particular topic is available.

(g) Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

(h) The costs associated with a measure outweigh the benefit of its continued use in the program.

[88 FR 77878, Nov. 13, 2023]

§ 484.360 Calculation of the Total Performance Score.

A competing HHA's Total Performance Score for a performance year is calculated as follows:

(a) CMS awards points to the competing home health agency for performance on each of the applicable measures.

(1) CMS awards greater than or equal to 0 points and less than 10 points for achievement to each competing home health agency whose performance on a measure during the applicable performance year meets or exceeds the applicable cohort's achievement threshold but is less than the applicable cohort's benchmark for that measure.

(2) CMS awards greater than 0 but less than 9 points for improvement to each competing home health agency whose performance on a measure during the applicable performance year exceeds the improvement threshold but is less than the applicable cohort's benchmark for that measure.

(3) CMS awards 10 points to a competing home health agency whose performance on a measure during the applicable performance year meets or exceeds the applicable cohort's benchmark for that measure.

(b) For all performance years, CMS calculates the weighted sum of points awarded for each applicable measure within each category of measures (OASIS-based, claims-based, and HHCAHPS Survey-based) weighted at 35 percent for the OASIS-based measure category, 35 percent for the claims-based measure category, and 30 percent for the HHCAHPS survey measure category when all three measure categories are reported, to calculate a value worth 100 percent of the Total Performance Score.

(1) Where a single measure category is not included in the calculation of the Total Performance Score for an individual HHA, due to insufficient volume for all of the measures in the category, the remaining measure categories are reweighted such that the proportional

contribution of each remaining measure category is consistent with the weights assigned when all three measure categories are available. Where two measure categories are not included in the calculation of the Total Performance Score for an individual HHA, due to insufficient volume for all measures in those measure categories, the remaining measure category is weighted at 100 percent of the Total Performance Score.

(2) When one or more, but not all, of the measures in a measure category are not included in the calculation of the Total Performance Score for an individual HHA, due to insufficient volume for at least one measure in the category, the remaining measures in the category are reweighted such that the proportional contribution of each remaining measure is consistent with the weights assigned when all measures within the category are available.

(c) The sum of the weight-adjusted points awarded to a competing HHA for each applicable measure is the competing HHA's Total Performance Score for the calendar year. A competing HHA must have a minimum of five applicable measures to receive a Total Performance Score.

§ 484.365 Payments for home health services under the Expanded Home Health Value–Based Purchasing (HHVBP) Model.

CMS determines a payment adjustment up to the applicable percent, upward or downward, under the expanded HHVBP Model for each competing HHA based on the agency's Total Performance Score using a linear exchange function that includes all other HHAs in its cohort that received a Total Performance Score for the applicable performance year. Payment adjustments made under the expanded HHVBP Model are calculated as a percentage of otherwise-applicable payments for home health services provided under section 1895 of the Act (42 U.S.C. 1395fff).

§ 484.370 Process for determining and applying the value-based payment adjustment under the Expanded Home Health Value-Based Purchasing (HHVBP) Model.

(a) *General.* Competing home health agencies are ranked within the larger-volume and smaller-volume cohorts nationwide based on the performance standards in this part that apply to the expanded HHVBP Model, and CMS makes value-based payment adjustments to the competing HHAs as specified in this section.

(b) *Calculation of the value-based payment adjustment amount.* The value-based payment adjustment amount is calculated by multiplying the home health prospective payment final claim payment amount as calculated in accordance with § 484.205 by the payment adjustment percentage.

(c) *Calculation of the payment adjustment percentage.* The payment adjustment percentage is calculated as the product of all of the following:

(1) The applicable percent as defined in § 484.345.

(2) The competing HHA's Total Performance Score divided by 100.

(3) The linear exchange function slope.

[86 FR 62422, Nov. 9, 2021, as amended at 87 FR 66887, Nov. 4, 2022]

§ 484.375 Appeals process for the Expanded Home Health Value-Based Purchasing (HHVBP) Model.

(a) *Requests for recalculation*—(1) *Matters for recalculation.* Subject to the limitations on judicial and administrative review under section 1115A of the Act, a HHA may submit a request for recalculation under this section if it wishes to dispute the calculation of the following:

(i) Interim performance scores.

(ii) Annual total performance scores.

(iii) Application of the formula to calculate annual payment adjustment percentages.

(2) *Time for filing a request for recalculation.* A recalculation request must be submitted in writing within 15 calendar days after CMS posts the HHA-specific information on the CMS website, in a time and manner specified by CMS.

(3) *Content of request.* (i) The provider's name, address associated with the services delivered, and CMS Certification Number (CCN).

(ii) The basis for requesting recalculation to include the specific data that the HHA believes is inaccurate or the calculation the HHA believes is incorrect.

(iii) Contact information for a person at the HHA with whom CMS or its agent can communicate about this request, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box).

(iv) The HHA may include in the request for recalculation additional documentary evidence that CMS should consider. Such documents may not include data that was to have been filed by the applicable data submission deadline, but may include evidence of timely submission.

(4) *Scope of review for recalculation.* In conducting the recalculation, CMS reviews the applicable measures and performance scores, the evidence and findings upon which the determination was based, and any additional documentary evidence submitted by the HHA. CMS may also review any other evidence it believes to be relevant to the recalculation.

(5) *Recalculation decision.* CMS issues a written notification of findings. A recalculation decision is subject to the request for reconsideration process in accordance with paragraph (b) of this section.

(b) *Requests for reconsideration*—(1) *Matters for reconsideration.* A home health agency may request reconsideration of the recalculation of its annual total performance score and payment adjustment percentage following a decision on the HHA's recalculation request submitted under paragraph (a) of this section, or the decision to deny the recalculation request submitted under paragraph (a) of this section.

(2) *Time for filing a request for reconsideration.* The request for reconsideration must be submitted via the CMS website within 15 calendar days from CMS' notification to the HHA contact of the outcome of the recalculation process.

(3) *Content of request.* (i) The name of the HHA, address associated with the services delivered, and CMS Certification Number (CCN).

(ii) The basis for requesting reconsideration to include the specific data that the HHA believes is inaccurate or the calculation the HHA believes is incorrect.

(iii) Contact information for a person at the HHA with whom CMS or its agent can communicate about this request, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box).

(iv) The HHA may include in the request for reconsideration additional documentary evidence that CMS should consider. The documents may not include data that was to have been filed by the applicable data submission deadline, but may include evidence of timely submission.

(4) *Scope of review for reconsideration.* In conducting the reconsideration review, CMS reviews the applicable measures and performance scores, the evidence and findings upon which the determination was based, and any additional documentary evidence submitted by the HHA. CMS may also review any other evidence it believes to be relevant to the reconsideration. The HHA must prove its case by a preponderance of the evidence with respect to issues of fact.

(5) *Reconsideration decision.* (i) CMS reconsideration officials issue a written decision that is final and binding upon issuance unless the CMS Administrator—

(A) Renders a final determination reversing or modifying the reconsideration decision; or

(B) Does not review the reconsideration decision within 14 days of the request.

(ii) An HHA may request that the CMS Administrator review the reconsideration decision within 7 calendar days of the decision.

(iii) If the CMS Administrator receives a request to review, the CMS Administrator must do one of the following:

(A) Render a final determination based on his or her review of the reconsideration decision.

(B) Decline to review a reconsideration decision made by CMS.

(C) Choose to take no action.

(iv) If the CMS Administrator does not review an HHA's request within 14 days (as described in paragraph (b)(5)(iii)(B) or (C) of this section), the reconsideration official's written reconsideration decision is final.

[86 FR 62422, Nov. 9, 2021, as amended at 88 FR 77879, Nov. 13, 2023]

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

Subpart A [Reserved]

Subpart B—Conditions of Participation: Comprehensive Outpatient Rehabilitation Facilities

Sec.
485.50 Basis and scope.
485.51 Definition.
485.54 Condition of participation: Compliance with State and local laws.
485.56 Condition of participation: Governing body and administration.
485.58 Condition of participation: Comprehensive rehabilitation program.
485.60 Condition of participation: Clinical records.
485.62 Condition of participation: Physical environment.
485.64 [Reserved]
485.66 Condition of participation: Utilization review plan.
485.68 Condition of participation: Emergency preparedness.
485.70 Personnel qualifications.
485.74 Appeal rights.

Subparts C–D [Reserved]

Subpart E—Conditions of Participation: Rural Emergency Hospitals (REHs)

485.500 Basis and scope.
485.502 Definitions.
485.504 Basic requirements.
485.506 Designation and certification of REHs.
485.508 Condition of participation: Compliance with Federal, state, and local laws and regulations.
485.510 Condition of participation: Governing body and organizational structure of the REH.
485.512 Condition of participation: Medical staff.
485.514 Condition of participation: Provision of services.
485.516 Condition of participation: Emergency services.
485.518 Condition of participation: Laboratory services.
485.520 Condition of participation: Radiologic services.
485.522 Condition of participation: Pharmaceutical services.
485.524 Condition of participation: Additional outpatient medical and health services.
485.526 Condition of participation: Infection prevention and control and antibiotic stewardship programs.
485.528 Condition of participation: Staffing and staff responsibilities.
485.530 Condition of participation: Nursing services.
485.532 Condition of participation: Discharge planning.
485.534 Condition of participation: Patient's rights.
485.536 Condition of participation: Quality assessment and performance improvement program.
485.538 Condition of participation: Agreements.
485.540 Condition of participation: Medical records.
485.542 Condition of participation: Emergency preparedness.
485.544 Condition of participation: Physical environment.
485.546 Condition of participation: Skilled nursing facility distinct part unit.

Subpart F—Conditions of Participation: Critical Access Hospitals (CAHs)

485.601 Basis and scope.
485.603 Rural health network.
485.604 Personnel qualifications.
485.606 Designation and certification of CAHs.
485.608 Condition of participation: Compliance with Federal, State, and local laws and regulations.
485.610 Condition of participation: Status and location.
485.612 Condition of participation: Compliance with hospital requirements at the time of application.
485.614 Condition of participation: Patient's rights.
485.616 Condition of participation: Agreements.
485.618 Condition of participation: Emergency services.
485.620 Condition of participation: Number of beds and length of stay.
485.623 Condition of participation: Physical plant and environment.
485.625 Condition of participation: Emergency preparedness.
485.627 Condition of participation: Organizational structure.