(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

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§ 484.4 Personnel qualifications.

Staff required to meet the conditions set forth in this part are staff who meet the qualifications specified in this section.

Administrator, home health agency. A person who:

(a) Is a licensed physician; or

(b) Is a registered nurse; or

(c) Has training and experience in health service administration and at least 1 year of supervisory or administrative experience in home health care or related health programs.

Audiologist. A person who:

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

Proprietary agency means a private profit-making agency licensed by the State.

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

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 subunits or branch offices is considered a parent agency.

Subunit means a semi-autonomous organization that—

(1) Serves patients in a geographic area different from that of the parent agency; and

(2) Must independently meet the conditions of participation for HHAs because it is too far from the parent agency to share administration, supervision, and services on a daily basis.

Summary report means the compilation of the pertinent factors of a patient's clinical notes and progress notes that is submitted to the patient's physician.

Supervision means authoritative procedural guidance by a qualified person for the accomplishment of a function or activity. Unless otherwise specified in this part, the supervisor must be on the premises to supervise an individual who does not meet the qualifications specified in §484.4.

§ 484.2 Definitions.

As used in this part, unless the context indicates otherwise—

Bylaws or equivalent means a set of rules adopted by an HHA for governing the agency's operation.

Branch office means a 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 branch office is part of the home health agency and is located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the branch independently to meet the conditions of participation as a home health agency.

Clinical note means a notation of a contact with a patient that is written and dated by a member of the health team, and that describes signs and symptoms, treatment and drugs administered and the patient's reaction, and any changes in physical or emotional condition.

HHA stands for home health agency.


Parent home health agency means the agency that develops and maintains administrative controls of subunits and/or branch offices.

Primary home health agency means the agency that is responsible for the services furnished to patients and for implementation of the plan of care.

Progress note means a written notation, dated and signed by a member of the health team, that summarizes facts about care furnished and the patient's response during a given period of time.

§ 484.3 Additional requirements.

This part also sets forth additional requirements that are considered necessary to ensure the health and safety of patients.

[60 FR 50443, Sept. 29, 1995, as amended at 65 FR 41211, July 3, 2000]
§ 484.4 Home health aide. Effective for services furnished after August 14, 1990, a person who has successfully completed a State-established or other training program that meets the requirements of §484.36(a) and a competency evaluation program or State licensure program that meets the requirements of §484.36(b) or (e), or a competency evaluation program or State licensure program that meets the requirements of §484.36(b) or (e). An individual is not considered to have completed a training and competency evaluation program, or a competency evaluation program if, since the individual’s most recent completion of this program(s), there has been a continuous period of 24 consecutive months during none of which the individual furnished services described in §409.40 of this chapter for compensation.

Occupational therapist. A person who:
(a) Is a graduate of an occupational therapy curriculum accredited jointly by the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or
(b) Is eligible for the National Registration Examination of the American Occupational Therapy Association; or
(c) Has 2 years of appropriate experience as an occupational therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapist assistant after December 31, 1977.

Physical therapist. A person who is licensed as a physical therapist by the State in which practicing, and
(a) Has graduated from a physical therapy curriculum approved by:
(1) The American Physical Therapy Association, or
(2) The Committee on Allied Health Education and Accreditation of the American Medical Association, or
(3) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association; or
(b) Prior to January 1, 1966,
(1) Was admitted to membership by the American Physical Therapy Association, or
(2) Was admitted to registration by the American Registry of Physical Therapist, or
(3) Has graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education; or
(c) Has 2 years of appropriate experience as a physical therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking qualification as a physical therapist after December 31, 1977; or
(d) Was licensed or registered prior to January 1, 1966, and prior to January 1, 1970, had 15 years of full-time 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; or
(e) If trained outside the United States,
(1) 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.

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

Physical therapy assistant. A person who is licensed as a physical therapy assistant, if applicable, by the State in which practicing, and

(1) Has graduated from a 2-year college-level program approved by the American Physical Therapy Association; or

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

Physician. A doctor of medicine, osteopathy or podiatry legally authorized to practice medicine and surgery by the State in which such function or action is performed.

Practical (vocational) nurse. A person who is licensed as a practical (vocational) nurse by the State in which practicing.

Public health nurse. A registered nurse who has completed a baccalaureate degree program approved by the National League for Nursing for public health nursing preparation or postregistered nurse study that includes content approved by the National League for Nursing for public health nursing preparation.

Registered nurse (R.N.). A graduate of an approved school of professional nursing, who is licensed as a registered nurse by the State in which practicing.

Social work assistant. A person who:

(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 these 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.

Social worker. A person who has a master's 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.

Speech–language pathologist. A person who:

(1) Meets the education and experience requirements for a Certificate of Clinical Competence in (speech pathology or 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.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32973, July 18, 1991]

Subpart B—Administration

§ 484.10 Condition of participation: Patient rights.

The patient has the right to be informed of his or her rights. The HHA must protect and promote the exercise of these rights.

(a) Standard: Notice of rights. (1) The HHA must provide the patient with a written notice of the patient's rights in advance of furnishing care to the patient or during the initial evaluation visit before the initiation of treatment.

(2) The HHA must maintain documentation showing that it has complied with the requirements of this section.

(b) Standard: Exercise of rights and respect for property and person. (1) The patient has the right to exercise his or her rights as a patient of the HHA.

(2) The patient's family or guardian may exercise the patient's rights when the patient has been judged incompetent.

(3) The patient has the right to have his or her property treated with respect.

(4) The patient has the right to voice grievances regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for property
§ 484.11 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.

[64 FR 3763, Jan. 25, 1999]
§ 484.12 Condition of participation: Compliance with Federal, State, and local laws, disclosure and ownership information, and accepted professional standards and principles.

(a) Standard: Compliance with Federal, State, and local laws and regulations. The HHA and its staff must operate and furnish services in compliance with all applicable Federal, State, and local laws and regulations. If State or applicable local law provides for the licensure of HHAs, an agency not subject to licensure is approved by the licensing authority as meeting the standards established for licensure.

(b) 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 name and address of all persons with an ownership or control 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 address of the corporation, association, or other company that is responsible for the management of the HHA, and the name and address of the chief executive officer and the chairman of the board of directors of that corporation, association, or other company responsible for the management of the HHA.

(c) Standard: Administrator. The administrator, who may also be the supervising physician or registered nurse required under paragraph (d) of this section, organizes and directs the agency’s ongoing functions; maintains ongoing liaison among the governing body, the group of professional personnel, and the staff; employs qualified personnel and ensures adequate staff education and evaluations; ensures the accuracy of public information materials and activities; and implements an effective budgeting and accounting system. A qualified person is authorized in writing to act in the absence of the administrator.

(d) Standard: Supervising physician or registered nurse. The skilled nursing and other therapeutic services furnished
are under the supervision and direction of a physician or a registered nurse (who preferably has at least 1 year of nursing experience and is a public health nurse). This person, or similarly qualified alternate, is available at all times during operating hours and participates in all activities relevant to the professional services furnished, including the development of qualifications and the assignment of personnel.

(e) Standard: Personnel policies. Personnel practices and patient care are supported by appropriate, written personnel policies. Personnel records include qualifications and licensure that are kept current.

(f) Standard: Personnel under hourly or per visit contracts. If personnel under hourly or per visit contracts are used by the HHA, there is a written contract between those personnel and the agency that specifies the following:

1. Patients are accepted for care only by the primary HHA.
2. The services to be furnished.
3. The necessity to conform to all applicable agency policies, including personnel qualifications.
4. The responsibility for participating in developing plans of care.
5. The manner in which services will be controlled, coordinated, and evaluated by the primary HHA.
6. The procedures for submitting clinical and progress notes, scheduling of visits, periodic patient evaluation.
7. The procedures for payment for services furnished under the contract.

(g) Standard: Coordination of patient services. All personnel furnishing services maintain liaison to ensure that their efforts are coordinated effectively and support the objectives outlined in the plan of care. The clinical record or minutes of case conferences establish that effective interchange, reporting, and coordination of patient care does occur. A written summary report for each patient is sent to the attending physician at least every 60 days.

(h) Standard: Services under arrangements. Services furnished under arrangements are subject to a written contract conforming with the requirements specified in paragraph (f) of this section and with the requirements of section 1861(w) of the Act (42 U.S.C. 1495x(w)).

(i) 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.

11. If the anticipated source of financing is, in any part, the anticipated payment from title V (Maternal and Child Health and Crippled Children's
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§ 484.16 Condition of participation: Group of professional personnel.

A group of professional personnel, which includes at least one physician and one registered nurse (preferably a public health nurse), and with appropriate representation from other professional disciplines, establishes and annually reviews the agency's policies governing scope of services offered, admission and discharge policies, medical supervision and plans of care, emergency care, clinical records, personnel qualifications, and program evaluation. At least one member of the group is neither an owner nor an employee of the agency.

(a) Standard: Advisory and evaluation function. The group of professional personnel meets frequently to advise the agency on professional issues, to participate in the evaluation of the agency's program, and to assist the agency in maintaining liaison with other health care providers in the community and in the agency's community information program. The meetings are documented by dated minutes.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32974, July 18, 1991]

§ 484.18 Condition of participation: Acceptance of patients, plan of care, and medical supervision.

Patients are accepted for treatment on the basis of a reasonable expectation that the patient's medical, nursing, and social needs can be met adequately by the agency in the patient's place of residence. Care follows a written plan of care established and periodically reviewed by a doctor of medicine, osteopathy, or podiatric medicine.

(a) Standard: Plan of care. The plan of care developed in consultation with the agency staff covers all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items. If a physician refers a
§ 484.20 Condition of participation: Reporting OASIS information.

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

(a) Standard: Encoding OASIS data. The HHA must encode and be capable of transmitting OASIS data for each agency patient within 7 days of completing an OASIS data set.

(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. The HHA must:

1. Electronically transmit accurate, completed, encoded and locked OASIS data for each patient to the State agency or CMS OASIS contractor at least monthly;
2. For all assessments completed in the previous month, transmit OASIS data in a format that meets the requirements of paragraph (d) of this section;
3. Successfully transmit test data to the State agency or CMS OASIS contractor beginning March 26, 1999, and no later than April 26, 1999; and
4. Transmit data using electronic communications software that provides a direct telephone connection from the HHA to the State agency or CMS OASIS contractor.

(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.

§ 484.30 Condition of participation: Skilled nursing services.

The HHA furnishes skilled nursing services by or under the supervision of a registered nurse and in accordance with the plan of care.

(a) Standard: Duties of the registered nurse. The registered nurse makes the initial evaluation visit, regularly re-evaluates the patient’s nursing needs, initiates the plan of care and necessary revisions, furnishes those services requiring substantial and specialized nursing skill, initiates appropriate preventive and rehabilitative nursing procedures, prepares clinical and progress notes, coordinates services, informs the physician and other personnel of changes in the patient’s condition and needs, counsels the patient and family in meeting nursing and related needs,
participates in in-service programs, and supervises and teaches other nursing personnel.

(b) Standard: Duties of the licensed practical nurse. The licensed practical nurse furnishes services in accordance with agency policies, prepares clinical and progress notes, assists the physician and registered nurse in performing specialized procedures, prepares equipment and materials for treatments observing aseptic technique as required, and assists the patient in learning appropriate self-care techniques.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32974, July 18, 1991]

§ 484.32 Condition of participation: Therapy services.

Any therapy services offered by the HHA directly or under arrangement are given by a qualified therapist or by a qualified therapy assistant under the supervision of a qualified therapist and in accordance with the plan of care. The qualified therapist assists the physician in evaluating level of function, helps develop the plan of care (revising it as necessary), prepares clinical and progress notes, advises and consults with the family and other agency personnel, and participates in in-service programs.

(a) Standard: Supervision of physical therapy assistant and occupational therapy assistant. Services furnished by a qualified physical therapy assistant or qualified occupational therapy assistant may be furnished under the supervision of a qualified physical or occupational therapist. A physical therapy assistant or occupational therapy assistant performs services planned, delegated, and supervised by the therapist, assists in preparing clinical notes and progress reports, and participates in educating the patient and family, and in in-service programs.

(b) Standard: Supervision of speech therapy services. Speech therapy services are furnished only by or under supervision of a qualified speech pathologist or audiologist.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32974, July 18, 1991]
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(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 knowledge of emergency procedures.

(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 personal hygiene and grooming that include—

(A) Bed bath.

(B) Sponge, tub, or shower bath.

(C) Shampoo, sink, tub, or 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) Any other task that the HHA may choose to have the home health aide perform.

“Supervised practical training” means training in a laboratory or other setting in which the trainee demonstrates knowledge while performing tasks on an individual under the direct supervision of a registered nurse or licensed practical nurse.

(2) Conduct of training—(i) Organizations. A home health aide training program may be offered by any organization except an HHA that, within the previous 2 years has been found—

(A) Out of compliance with requirements of this paragraph (a) or paragraph (b) of this section;

(B) To permit an individual that does not meet the definition of “home health aide” as specified in §484.4 to furnish home health aide services (with the exception of licensed health professionals and volunteers);

(C) Has been subject to an extended (or partial extended) survey as a result of having been found to have furnished substandard care (or for other reasons at the discretion of the CMS or the State);

(D) Has assessed a civil monetary penalty of not less than $5,000 as an intermediate sanction;

(E) Has been found to have compliance deficiencies that endanger the health and safety of the HHA's patients and has had a temporary management appointed to oversee the management of the HHA;

(F) Has had all or part of its Medicare payments suspended; or

(G) Under any Federal or State law within the 2-year period beginning on October 1, 1996—

(1) Has had its participation in the Medicare program terminated;

(2) Has been assessed a penalty of not less than $5,000 for deficiencies in Federal or State standards for HHAs;

(3) Was subject to a suspension of Medicare payments to which it otherwise would have been entitled;

(4) Had operated under a 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

(5) Was closed or had its residents transferred by the State.

(ii) Qualifications for instructors. The training of home health aides and the supervision of home health aides during the supervised practical portion of the training must be performed by or under the general supervision of a registered nurse who possesses a minimum of 2 years of nursing experience, at least 1 year of which must be in the provision of home health care. Other individuals may be used to provide instruction under the supervision of a qualified registered nurse.

(3) Documentation of training. The HHA must maintain sufficient documentation to demonstrate that the requirements of this standard are met.

(b) Standard: Competency evaluation and in-service training—(1) Applicability. An individual may furnish home health aide services on behalf of an HHA only after that individual has successfully completed a competency evaluation program as described in this paragraph. The HHA is responsible for ensuring that the individuals who furnish home health aide services on its behalf meet the competency evaluation requirements of this section.
(2) Content and frequency of evaluations and amount of in-service training.
   (i) The competency evaluation must address each of the subjects listed in paragraph (a)(1)(ii) through (xiii) of this section.
   (ii) The HHA must complete a performance review of each home health aide no less frequently than every 12 months.
   (iii) The home health aide must receive at least 12 hours of in-service training during each 12-month period. The in-service training may be furnished while the aide is furnishing care to the patient.
(3) Conduct of evaluation and training—(i) Organizations. A home health aide competency evaluation program may be offered by any organization except as specified in paragraph (a)(2)(i) of this section.
   The in-service training may be offered by any organization.
   (ii) Evaluators and instructors. The competency evaluation must be performed by a registered nurse. The in-service training generally must be supervised by a registered nurse who possesses a minimum of 2 years of nursing experience at least 1 year of which must be in the provision of home health care.
   (iii) Subject areas. The subject areas listed at paragraphs (a)(1)(iii), (ix), (x), and (xi) of this section must be evaluated after observation of the aide’s performance of the tasks associated with a patient. The other subject areas in paragraph (a)(1) of this section may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient.
(4) Competency determination. (i) A home health aide is not considered competent in any task for which he or she is evaluated as “unsatisfactory.” The aide must perform that task without direct supervision by a licensed nurse until after he or she receives training in the task for which he or she was evaluated as “unsatisfactory” and passes a subsequent evaluation with “satisfactory”.
   (ii) 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) Documentation of competency evaluation. The HHA must maintain documentation which demonstrates that the requirements of this standard are met.
(6) Effective date. The HHA must implement a competency evaluation program that meets the requirements of this paragraph before February 14, 1990. The HHA must provide the preparation necessary for the individual to successfully complete the competency evaluation program. After August 14, 1990, the HHA may use only those aides that have been found to be competent in accordance with §484.36(b).
(c) Standard: Assignment and duties of the home health aide—(1) Assignment. The home health aide is assigned to a specific patient by the registered nurse. Written patient care instructions for the home health aide must be prepared by the registered nurse or other appropriate professional who is responsible for the supervision of the home health aide under paragraph (d) of this section.
(2) Duties. The home health aide provides services that are ordered by the physician in the plan of care and that the aide is permitted to perform under State law. The duties of a home health aide include the provision of hands-on personal care, performance of simple procedures as an extension of therapy or nursing services, assistance in ambulation or exercises, and assistance in administering medications that are ordinarily self-administered. Any home health aide services offered by an HHA must be provided by a qualified home health aide.
(d) Standard: Supervision. (1) If the patient receives skilled nursing care, the registered nurse must perform the supervisory visit required by paragraph (d)(2) of this section. If the patient is not receiving skilled nursing care, but is receiving another skilled service (that is, physical therapy, occupational therapy, or speech-language pathology services), supervision may be provided by the appropriate therapist.
   (2) The registered nurse (or another professional described in paragraph (d)(1) of this section) must make an on-site visit to the patient’s home no less frequently than every 2 weeks.
§ 484.38 Condition of participation: Qualifying to furnish outpatient physical therapy or speech pathology services.

An HHA that wishes to furnish outpatient physical therapy or speech pathology services must meet all the pertinent conditions of this part and also meet 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.

[54 FR 33367, Aug. 14, 1989, as amended at 60 FR 2329, Jan. 9, 1995; 60 FR 11632, Mar. 2, 1995]

§ 484.48 Condition of participation: Clinical records.

A clinical record containing pertinent past and current findings in accordance with accepted professional standards is maintained for every patient receiving home health services. In addition to the plan of care, the record contains appropriate identifying information; name of physician; drug, dietary, treatment, and activity orders; signed and dated clinical and progress notes; copies of summary reports sent to the attending physician; and a discharge summary. The HHA must inform the attending physician of the availability of a discharge summary. The discharge summary must be sent to the attending physician upon request and must include the patient's medical and health status at discharge.

(a) Standards: Retention of records. Clinical records are retained for 5 years after the month the cost report to which the records apply is filed with the intermediary, unless State law stipulates a longer period of time. Policies provide for retention even if the HHA discontinues operations. If a patient is transferred to another health facility, a copy of the record or abstract is sent with the patient.

(b) Standards: Protection of records. Clinical record information is safeguarded against loss or unauthorized use. Written procedures govern use and removal of records and the conditions for release of information. Patient's written consent is required for release of information not authorized by law.

§ 484.52 Condition of participation: Evaluation of the agency’s program.

The HHA has written policies requiring an overall evaluation of the agency’s total program at least once a year by the group of professional personnel (or a committee of this group), HHA staff, and consumers, or by professional people outside the agency working in conjunction with consumers. The evaluation consists of an overall policy and administrative review and a clinical record review. The evaluation assesses the extent to which the agency’s program is appropriate, adequate, effective, and efficient. Results of the evaluation are reported to and acted upon by those responsible for the operation of the agency and are maintained separately as administrative records.

(a) Standard: Policy and administrative review. As a part of the evaluation process the policies and administrative practices of the agency are reviewed to determine the extent to which they promote patient care that is appropriate, adequate, effective, and efficient. Mechanisms are established in writing for the collection of pertinent data to assist in evaluation.

(b) Standard: Clinical record review. At least quarterly, appropriate health professionals, representing at least the scope of the program, review a sample of both active and closed clinical records to determine whether established policies are followed in furnishing services directly or under arrangement. There is a continuing review of clinical records for each 60-day period that a patient receives home health services to determine adequacy of the plan of care and appropriateness of continuation of care.


§ 484.55 Condition of participation: Comprehensive assessment of patients.

Each patient must receive, and an HHA must provide, a patient-specific, comprehensive assessment that accurately reflects the patient’s current health status and includes information that may be used to demonstrate the patient’s progress toward achievement of desired outcomes. The comprehensive assessment must identify the patient’s continuing need for home care and meet the patient’s medical, nursing, rehabilitative, social, and discharge planning needs. 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. The comprehensive assessment must also incorporate the use 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.

(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-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, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate rehabilitation skilled professional.

(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, a physical therapist, speech-language pathologist or occupational therapist may complete the
comprehensive assessment, and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status. The occupational therapist may complete the comprehensive assessment if the need for occupational therapy establishes program eligibility.

(c) Standard: Drug regimen review. The comprehensive assessment must include 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.

(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 five 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 resulting in a new case-mix assignment; 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;

(3) At discharge.

(e) Standard: Incorporation of OASIS data items. The OASIS data items determined by the Secretary must be incorporated into the HHA’s own assessment and 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.

[64 FR 3784, Jan. 25, 1999, as amended at 65 FR 41211, July 3, 2000]
A partial episode payment (PEP) adjustment due to an intervening event defined as a beneficiary elected transfer or a discharge and return to the same HHA during the 60-day episode, that warrants a new 60-day episode payment during an existing 60-day episode, that initiates the start of a new 60-day episode payment and a new physician certification of the new plan of care. The PEP adjustment is determined in accordance with § 484.235.

(3) A significant change in condition (SCIC) payment adjustment due to the intervening event defined as a significant change in the patient's condition during an existing 60-day episode. The SCIC adjustment occurs when a beneficiary experiences a significant change in condition during a 60-day episode that was not envisioned in the original plan of care. The SCIC adjustment is determined in accordance with § 484.237.

(4) An outlier payment is determined in accordance with § 484.240.

(b) Episode payment. The national prospective 60-day episode payment represents payment in full for all costs associated with furnishing home health services previously paid on a reasonable cost basis (except the osteoporosis drug listed in section 1861(m) of the Act as defined in section 1861(kk) of the Act) as of August 5, 1997 unless the national 60-day episode payment is subject to a low-utilization payment adjustment set forth in § 484.230, a partial episode payment adjustment set forth at § 484.235, a significant change in condition payment set forth at § 484.237, or an additional outlier payment set forth in § 484.240. All payments under this system may be subject to a medical review adjustment reflecting beneficiary eligibility, medical necessity determinations, and HHRG assignment.

DME provided as a home health service as defined in section 1861(m) of the Act continues to be paid the fee schedule amount.

(1) Split percentage payment for initial episodes. The initial percentage payment for initial episodes is paid to an HHA at 60 percent of the case-mix and wage adjusted 60-day episode rate. The residual final payment for initial episodes is paid at 40 percent of the case-mix and wage adjusted 60-day episode rate. Split percentage payments are made in accordance with requirements at § 409.43(c) of this chapter.

(2) Split percentage payment for subsequent episodes. The initial percentage payment for subsequent episodes is paid to an HHA at 50 percent of the case-mix and wage adjusted 60-day episode rate. The residual final payment for subsequent episodes is paid at 50 percent of the case-mix and wage adjusted 60-day episode rate. Split percentage payments are made in accordance with requirements at § 409.43(c) of this chapter.

(c) Low-utilization payment. An HHA receives a national 60-day episode payment of a predetermined rate for home health services previously paid on a reasonable cost basis as of August 5, 1997, unless CMS determines at the end of the 60-day episode that the HHA furnished minimal services to a patient during the 60-day episode. A low-utilization payment adjustment is determined in accordance with § 484.230.

(d) Partial episode payment adjustment. An HHA receives a national 60-day episode payment of a predetermined rate for home health services previously paid on a reasonable cost basis as of August 5, 1997, unless CMS determines an intervening event, defined as a beneficiary elected transfer, or discharge and return to the same HHA during a 60-day episode, warrants a new 60-day episode payment. The PEP adjustment would not apply in situations of transfers among HHAs of common ownership as defined in § 424.22 of this chapter. Those situations would be 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. 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. 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. The discharge and return to the same HHA during the 60-day episode is only recognized in those circumstances
when a beneficiary reached the goals in
the original plan of care. The original
plan of care must have been terminated
with no anticipated need for additional
home health services for the balance of
the 60-day episode. If the intervening
event warrants a new 60-day episode
payment and the new physician certifi-
cation of a new plan of care, the initial
HHA receives a partial episode pay-
ment adjustment reflecting the length
of time the patient remained under its
care. A partial episode payment adjust-
ment is determined in accordance with
§ 484.235.
(e) Significant change in condition ad-
justment. The HHA receives a national
60-day episode payment of a pre deter-
mined rate for home health services
paid on a reasonable cost basis as of
August 5, 1997, unless CMS determines
an intervening event defined as a bene-
ficiary experiencing a significant
change in condition during a 60-day
episode that was not envisioned in the
original plan of care occurred. In order
to receive a new case-mix assignment
for purposes of payment during the 60-
day episode, the HHA must complete
an OASIS assessment and obtain the
necessary physician change orders re-
fecting the significant change in the
treatment approach in the patient’s
plan of care. The total significant
change in condition payment adjust-
ment is a proportional payment adjust-
ment reflecting the time both prior and
after the patient experienced a signifi-
cant change in condition during the 60-
day episode. A SCIC adjustment is de-
termined in accordance with § 484.237.
(f) Outlier payment. An HHA receives
a national 60-day episode payment of a
predetermined rate for a home health
service paid on a reasonable cost basis
as of August 5, 1997, unless the imputed
cost of the 60-day episode exceeds a
threshold amount. The outlier pay-
ment is defined to be a proportion of
the imputed costs beyond the thresh-
old. An outlier payment is a payment
in addition to the national 60-day epi-
sode payment. The total of all outlier
payments is limited to 5 percent of
total outlays under the HHA PPS. An
outlier payment is determined in ac-
cordance with § 484.240.

§ 484.210 Data used for the calculation
of the national prospective 60-day
episode payment.
To calculate the national prospective
60-day episode payment, CMS uses the
following:
(a) Medicare cost data on the most
recent audited cost report data avail-
able.
(b) Utilization data based on Medi-
care claims.
(c) An appropriate wage index to ad-
just for area wage differences.
(d) The most recent projections of in-
creases in costs from the HHA market
basket index.
(e) OASIS assessment data and other
data that account for the relative re-
source utilization for different HHA
Medicare patient case-mix.

§ 484.215 Initial establishment of the
calculation of the national 60-day
episode payment.
(a) Determining an HHA’s costs. In cal-
culating the initial unadjusted na-
tional 60-day episode payment applica-
ble 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 al-
lowable costs for the period. CMS de-
termines the national mean cost per
visit.
(b) Determining HHA utilization. In
calculating the initial unadjusted na-
tional 60-day episode payment, CMS de-
termines 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 Octo-
(d) Calculation of the unadjusted na-
tional average prospective payment
amount for the 60-day episode. CMS cal-
culates the unadjusted national 60-day
episode payment in the following man-
ner:
(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 uti-
lization 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.

§ 484.220 Calculation of the adjusted national prospective 60-day episode payment rate for case-mix and area wage levels.

CMS adjusts the national prospective 60-day episode payment rate to account for—

(a) HHA case-mix using a case-mix index to explain the relative resource utilization of different patients; and

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

§ 484.225 Annual update of the unadjusted national prospective 60-day episode payment rate.

(a) CMS updates the unadjusted national 60-day episode payment rate on a fiscal year basis.

(b) For fiscal year 2001, the unadjusted national 60-day episode payment rate is adjusted using the latest available home health market basket index factors.

(c) For fiscal years 2002 and 2003, the unadjusted national prospective 60-day episode payment rate is updated by a factor equal to the applicable home health market basket minus 1.1 percentage points.

(d) For subsequent fiscal years, the unadjusted national rate is equal to the rate for the previous fiscal year increased by the applicable home health market basket index amount.

§ 484.230 Methodology used for the calculation of the low-utilization payment adjustment.

An episode with four or fewer visits is paid the national per-visit amount by discipline updated annually by the applicable market basket for each visit type. The national per-visit amount is determined by using cost data set forth in §484.210(a) and adjusting by the appropriate wage index based on the site of service for the beneficiary.

§ 484.235 Methodology used for the calculation of the partial episode payment adjustment.

(a) CMS makes a PEP adjustment to the original 60-day episode payment that is interrupted by an intervening event described in §484.205(d).

(b) The original 60-day episode payment is adjusted to reflect the length of time the beneficiary remained under the care of the original HHA based on the first billable visit date through and including the last billable visit date.

(c) The partial episode payment is calculated by determining the actual days served by the original HHA as a proportion of 60 multiplied by the original 60-day episode payment.

§ 484.237 Methodology used for the calculation of the significant change in condition payment adjustment.

(a) CMS makes a SCIC payment adjustment to the original 60-day episode payment that is interrupted by the intervening event defined in §484.205(e).

(b) The SCIC payment adjustment is calculated in two parts.

(1) The first part of the SCIC payment adjustment reflects the adjustment to the level of payment prior to the significant change in the patient's condition during the 60-day episode. The first part of the SCIC adjustment is determined by taking the span of days (the first billable visit date through and including the last billable visit date) prior to the patient's significant change in condition as a proportion of 60 multiplied by the original episode amount.
§ 484.240 Methodology used for the calculation of the outlier payment.

(a) CMS makes an outlier payment for an episode whose estimated cost exceeds a threshold amount for each case-mix group.

(b) The outlier threshold for each case-mix group is the episode payment amount for that group, the PEP adjustment amount for the episode or the total significant change in condition adjustment amount for the episode 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 estimated cost beyond the threshold.

(d) CMS imputes the cost for each episode by multiplying the national per-visit amount of each discipline by the number of visits in the discipline and computing the total imputed cost for all disciplines.

(e) The fixed dollar loss amount and the loss sharing proportion are chosen so that the estimated total outlier payment is no more than 5 percent of total payment under home health PPS.

§ 484.245 Accelerated payments for home health agencies.

(a) General rule. Upon request, an accelerated payment may be made to an HHA that is receiving payment under the home health prospective payment system if the HHA is experiencing financial difficulties because there is a delay by the intermediary in making payment to the HHA.

(b) Approval of payment. An HHA’s request for an accelerated payment must be approved by the intermediary and CMS.

(c) Amount of payment. The amount of the accelerated payment is computed as a percentage of the net payment for unbilled or unpaid covered services.

(d) Recovery of payment. Recovery of the accelerated payment is made by recoupment as HHA bills are processed or by direct payment by the HHA.

§ 484.250 Patient assessment data.

An HHA must submit to CMS the OASIS data described at §484.55(b)(1) and (d)(1) in order for CMS to administer the payment rate methodologies described in §§484.215, 484.230, 484.235, and 484.237.

§ 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.

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.