§ 483.480 Condition of participation: Dietetic services.

(a) Standard: Food and nutrition services. (1) Each client must receive a nourishing, well-balanced diet including modified and specially-prescribed diets.

(2) A qualified dietitian must be employed either full-time, part-time, or on a consultant basis at the facility’s discretion.

(3) If a qualified dietitian is not employed full-time, the facility must designate a person to serve as the director of food services.

(4) The client’s interdisciplinary team, including a qualified dietitian and physician, must prescribe all modified and special diets including those 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 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.
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§ 484.1  Subpart B—Administration
484.10 Condition of participation: Patient rights.
484.12 Condition of participation: Compliance with Federal, State, and local laws, disclosure and ownership information, and accepted professional standards and principles.
484.14 Condition of participation: Organization, services, and administration.
484.16 Condition of participation: Group of professional personnel.
484.18 Condition of participation: Acceptance of patients, plan of care, and medical supervision.

Subpart C—Furnishing of Services
484.30 Condition of participation: Skilled nursing services.
484.32 Condition of participation: Therapy services.
484.34 Condition of participation: Medical social services.
484.36 Condition of participation: Home health aide services.
484.38 Condition of participation: Qualifying to furnish outpatient physical therapy or speech pathology services.
484.43 Condition of participation: Clinical records.
484.52 Condition of participation: Evaluation of the agency’s program.

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)) unless otherwise indicated.

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

Editorial Note: Nomenclature changes affecting part 484 appear at 56 FR 32973, July 18, 1991.

Subpart A—General Provisions

§ 484.1  Basis and scope.
(a) Basis and scope. This part is based on the indicated provisions of the following sections of the Act:
(1) Sections 1861(o) and 1891 establish the conditions that an HHA must meet in order to participate in Medicare.
(2) Section 1861(z) specifies the Institutional planning standards that HHAs must meet.
(b) 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]
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.

§ 484.4 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
(b) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

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). 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 after December 31, 1977.

Occupational therapy assistant. A person who:
(a) Meets the requirements for certification as an occupational therapy assistant established by the American Occupational Therapy Association; or
(b) Has 2 years of appropriate experience as an occupational 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 such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapy 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

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(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 initial qualification as a physical therapy assistant 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, osteopath 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 (RN). 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:
§ 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 by anyone who is furnishing services on behalf of the HHA and must not be subjected to discrimination or reprisal for doing so.

(b) The HHA must investigate complaints made by a patient or the patient’s family or guardian regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for the patient’s property by anyone furnishing services on behalf of the HHA, and must document both the existence of the complaint and the resolution of the complaint.

(c) Standard: Right to be informed and to participate in planning care and treatment. (1) The patient has the right to be informed, in advance about the care to be furnished, and of any changes in the care to be furnished.

(i) The HHA must advise the patient in advance of the disciplines that will furnish care, and the frequency of visits proposed to be furnished.

(ii) The HHA must advise the patient in advance of any change in the plan of care before the change is made.

(2) The patient has the right to participate in the planning of the care.

(i) The HHA must advise the patient in advance of the right to participate in planning the care or treatment and in planning changes in the care or treatment.

(ii) The HHA complies with the requirements of subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. The HHA must inform and distribute written information to the patient, in advance, concerning its policies on advance directives, including a description of applicable State law. The HHA may furnish advance directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided.

(d) Standard: Confidentiality of medical records. The patient has the right to confidentiality of the clinical records maintained by the HHA. The HHA must advise the patient of the agency’s policies and procedures regarding disclosure of clinical records.

(e) Standard: Patient liability for payment. (1) The patient has the right to be advised, before care is initiated, of the extent to which payment for the services may be expected from Medicare or other sources, and the extent to which payment may be required from the patient. Before care is initiated, the HHA must inform the patient, orally and in writing, of—

(i) The extent to which payment may be expected from Medicare, Medicaid, or any other Federally funded or aided program known to the HHA;

(ii) The charges for services that will not be covered by Medicare; and
(iii) The charges that the individual may have to pay.

(2) The patient has the right to be advised orally and in writing of any changes in the information provided in accordance with paragraph (e)(1) of this section when they occur. The HHA must advise the patient of these changes orally and in writing as soon as possible, but no later than 30 calendar days from the date that the HHA becomes aware of a change.

(f) Standard: Home health hotline. The patient has the right to be advised of the availability of the toll-free HHA hotline in the State. When the agency accepts the patient for treatment or care, the HHA must advise the patient in writing of the telephone number of the home health hotline established by the State, the hours of its operation, and that the purpose of the hotline is to receive complaints or questions about local HHAs. The patient also has the right to use this hotline to lodge complaints concerning the implementation of the advance directives requirements.

§ 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 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: Compliance with accepted professional standards and principles. The HHA and its staff must comply with accepted professional standards and principles that apply to professionals furnishing services in an HHA.

§ 484.14 Condition of participation: Organization, services, and administration.

Organization, services furnished, administrative control, and lines of authority for the delegation of responsibility down to the patient care level are clearly set forth in writing and are readily identifiable. Administrative and supervisory functions are not delegated to another agency or organization and all services not furnished directly, including services provided through subunits, are monitored and controlled by the parent agency. If an agency has subunits, appropriate administrative records are maintained for each subunit.

(a) Standard: Services furnished. Part-time or intermittent skilled nursing services and at least one other therapeutic service (physical, speech, 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 qualifying services directly through agency employees, but may provide the second qualifying service and additional services under arrangements with another agency or organization.
(b) Standard: Governing body. A governing body (or designated persons so functioning) assumes full legal authority and responsibility for the operation of the agency. The governing body appoints a qualified administrator, arranges for professional advice as required under §484.16, adopts and periodically reviews written bylaws or an acceptable equivalent, and oversees the management and fiscal affairs of the agency.

(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 62 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. 1395x(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. 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 and Crippled Children’s Services) 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.

(j) 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 FDA, such testing must be in compliance with applicable requirements of part 493 of this chapter.

(2) If the HHA chooses to refer specimens for laboratory testing to another laboratory, 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.

§ 484.30 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, coordinates services, informs 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]

§ 484.34 Condition of participation: Medical social services.

If the agency furnishes medical social services, those services are given by a qualified social worker or by a qualified social work assistant under the supervision of a qualified social worker, and in accordance with the plan of care. The social worker assists the physician and other team members in understanding the significant social and emotional factors related to the health problems, participates in the development of the plan of care, prepares clinical and progress notes, works with the family, uses appropriate community resources, participates in discharge planning and in-service programs, and acts as a consultant to other agency personnel.

§ 484.36 Condition of participation: Home health aide services.

Home health aides are selected on the basis of such factors as a sympathetic attitude toward the care of the sick, ability to read, write, and carry out directions, and maturity and ability to deal effectively with the demands of the job. They are closely supervised to ensure their competence in providing care. For home health services furnished (either directly or through arrangements with other organizations) after August 14, 1990, the HHA must use individuals who meet the personnel qualifications specified in §484.4 for “home health aide”.

(a) Standard: Home health aide training—(1) Content and duration of training. The aide training program must address each of the following subject areas through classroom and supervised practical training totalling at least 75 hours, with at least 16 hours devoted to supervised practical training. The individual being trained must complete at least 16 hours of classroom training before beginning the supervised practical training.

(i) Communications skills.

(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 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 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.
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.

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 HCFA or the State);
(D) Has been 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, 1988—
(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 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 not 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 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.

(3) If home health aide services are provided to a patient who is not receiving skilled nursing care, physical or occupational therapy or speech-language pathology services, the registered nurse must make a supervisory visit to the patient’s home no less frequently than every 62 days. In these cases, to ensure that the aide is properly caring for the patient, each supervisory visit must occur while the home health aide is providing patient care.

(4) If home health aide services are provided by an individual who is not
§ 484.52 Condition of participation: Evaluation of the agency’s program.

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 1863(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.

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 62-day period that a patient receives home health services to determine adequacy of the plan of care and appropriateness of continuation of care.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

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Subpart G—[Reserved]

Subpart H—Conditions of Participation for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services

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485.707 Condition of participation: Compliance with Federal, State, and local laws.
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485.715 Condition of participation: Speech pathology services.