

§ 484.2

42 CFR Ch. IV (10–1–17 Edition)

(2) Section 1861(z) specifies the Institutional planning standards that HHAs must meet.

(3) Section 1895 provides for the establishment of a prospective payment system for home health services covered under Medicare.

(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, as amended at 65 FR 41211, July 3, 2000]

§ 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.

Nonprofit agency means an agency exempt from Federal income taxation under section 501 of the Internal Revenue Code of 1954.

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.

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.

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

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

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

(b) On or before December 31, 2009—

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

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

(i) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the

American Occupational Therapy Association, Inc. (AOTA) or successor organizations of ACOTE; and

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

(c) On or before January 1, 2008—

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

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

(d) On or before December 31, 1977—

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

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

(e) If educated outside the United States, must meet all of the following:

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

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

(ii) Successor organizations of ACOTE.

(iii) The World Federation of Occupational Therapists.

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

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

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

§ 484.4

42 CFR Ch. IV (10–1–17 Edition)

Occupational therapy assistant. A person who—

(a) Meets all of the following:

(1) Is licensed, unless licensure does not apply, or otherwise regulated, if applicable, as an occupational therapy assistant by the State in which practicing.

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

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

(b) On or before December 31, 2009—

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

(2) Must meet both of the following:

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

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

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

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

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

(d) On or before December 31, 1977—

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

(2) Had achieved a satisfactory grade on an occupational therapy assistant proficiency examination conducted, ap-

proved, or sponsored by the U.S. Public Health Service.

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

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

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

(ii) Its successor organizations.

(iii) The World Federation of Occupational Therapists.

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

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

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

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

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

(ii) Successor organizations of CAPTE.

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

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

(b) On or before December 31, 2009—

(1) Graduated after successful completion of a physical therapy curriculum approved by the Commission

on Accreditation in Physical Therapy Education (CAPTE); or

(2) Meets both of the following:

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

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

(c) Before January 1, 2008—

(1) Graduated from a physical therapy curriculum approved by one of the following:

(i) The American Physical Therapy Association.

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

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

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

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

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

(e) Before 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 Therapists; or

(3) Has graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education.

(f) Before January 1, 1966 was licensed or registered, and before 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.

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

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

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

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

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

(1) Is licensed, or otherwise regulated in the State in which practicing.

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

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

(d) On or before December 31, 1977, was licensed or qualified as a physical

Subpart A, Nf.

therapist assistant and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

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 (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 has a master's or doctoral degree in speech-language pathology, and who meets either of the following requirements:

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

42 CFR Ch. IV (10–1–17 Edition)

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

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

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

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

[54 FR 33367, Aug. 14, 1989, as amended at 56 FR 32973, July 18, 1991; 69 FR 66426, Nov. 15, 2004; 72 FR 66406, Nov. 27, 2007; 73 FR 2433, Jan. 15, 2008; 79 FR 66118, Nov. 6, 2014]

EFFECTIVE DATE NOTE: At 82 FR 4578, Jan. 13, 2017, subpart A was revised, effective July 13, 2017. At 82 FR 31729, July 10, 2017, this amendment was delayed until Jan. 13, 2018. For the convenience of the user, the revised text is set forth as follows:

Subpart A—General Provisions

§ 484.1 Basis and scope.

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

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

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

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

§ 484.2 Definitions.

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

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

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

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

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

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

Proprietary agency means a private, for-profit agency.

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

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

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

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

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

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

Verbal order means a physician order that is spoken to appropriate personnel and later put in writing for the purposes of documenting as well as establishing or revising the patient's plan of care.

Subpart B—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 by anyone who is furnishing services on behalf of the HHA and must not be subjected to discrimination or reprisal for doing so.

(5) 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.