

§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.

Interpretive Guidelines §484.1

To qualify for a provider agreement as a home health agency under Medicare and Medicaid, an entity must meet and continue to meet all the statutory provisions of §1861(o), 1891 and 1861(z) of the Act, including the Condition of Participation (CoP) requirements.

This, in part, means the HHA:

- *is primarily engaged in providing skilled nursing services and other therapeutic services [§1861(o)(1) of the Act; 42 CFR 484.105, Organization and administration of services];*
- *has policies to govern the services which it provides and provides for supervision of such services [§1861(o)(2) of the Act; 42 CFR 484.75, Skilled professional services and § 484.65 Quality assessment and performance improvement (QAPI). See also 82 FR 4542];*
- *maintains clinical records on all patients [§1861(o)(3) of the Act; 42 CFR 484.110, Clinical records];*
- *for any HHA in a state or local jurisdiction with a law that requires agencies or organizations like HHAs to be licensed, is licensed pursuant to such law, or is approved, by the State or local agency responsible for licensing agencies or organizations of this nature, as meeting the standards established for such licensing [§1861(o)(4) of the Act; 42 CFR 484.100, Compliance with Federal, State and local laws and regulations related to health and safety of patients];*
- *has in effect an overall plan and budget [§1861(o)(5) of the Act; 42 CFR 484.105, Organization and administration of services];*
- *meets the conditions of participation specified in section 1891(a) and such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such agency or organization [§1861(o)(6) of the Act; 42 CFR 484.1, Basis and Scope, et seq.];*
- *provides the Secretary with a surety bond [§1861(o)(7) of the Act; 42 CFR Part 489, Subpart F];*
- *meets such additional requirements (including conditions relating to bonding or establishing of escrow accounts as the Secretary finds necessary for the financial security of the program) as the Secretary finds necessary for the effective and efficient operation of the program [§1861(o)(8) of the Act; 42 CFR 484.1, Basis and Scope, et seq.];*
- *except that for purposes of part A “home health agency” shall not include any agency or organization which is primarily for the care and treatment of mental diseases. The Secretary may waive the requirement of a surety bond under paragraph (7) in the case of an agency or organization that provides a comparable surety bond under State law [§1861(o) of the Act; 42 CFR 484.1, Basis and Scope, et seq.].*

CMS is required to determine whether an HHA is complying substantially with the Medicare participation requirements established by the Act and regulations. Section 1866(b)(2)(B) of the Act states in part that a provider's participation agreement may be terminated if CMS determines that "the provider fails substantially to meet the applicable provisions of section 1861." To remain a Medicare participating HHA, the HHA must remain in substantial compliance with all conditions of participation.

No Tag

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§484.2 Definitions.

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

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

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

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

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

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

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

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

***Physician** is a doctor of medicine, osteopathy, or podiatric medicine, and who is not precluded from performing this function under paragraph (d) of this section. (A doctor of*

podiatric medicine may perform only plan of treatment functions that are consistent with the functions he or she is authorized to perform under State law.)

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

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

Proprietary agency means a private, for-profit agency.

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

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

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

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

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

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

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

Supervised practical training means training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while providing covered services to an

individual under the direct supervision of either a registered nurse or a licensed practical nurse who is under the supervision of a registered nurse.

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

Subpart B--Patient Care