

Tool: Home Health Conditions of Participation Governance/Administration Policy and Procedure Checklist

Definitions



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Governance /Administration Policy and Procedure Checklist**

Definitions

Parent-Branch Relationship

Services Under Arrangement

Services Furnished

Outpatient Physical Therapy or Speech-Language Pathology Services

Institutional Planning

Organization, services and administration

Compliance with Federal, State, and local laws, disclosure and ownership information, and accepted professional standards and principles

Quality assessment performance improvement (QAPI).

Regulation	Recommended Action
<p>§484.1 Basis and Scope – revised</p> <ul style="list-style-type: none"> • Added a requirement at §484.105(b)(1)(i) that the administrator must report to the governing body. • Added a requirement at §484.105(b)(1)(iv) that the administrator must ensure that the HHA employs qualified personnel, including assuring the development of personnel qualifications and policies. • Revised §484.105(b)(2) to clarify that an individual that is pre-designated to fill the administrator role in the absence of the administrator (including the clinical manager) must be qualified to do so. • At §484.105(c), CMS also proposes a new clinical manager role, who “would be a qualified licensed physician or registered nurse, identified by the HHA, who is responsible for the oversight of all 	<p><i>The following are the requirements which need to be in your Policy and Procedures for this section of the Conditions of Participation and included in staff training as applicable:</i></p> <ul style="list-style-type: none"> • The administrator must report to the governing body. • The administrator must ensure that the HHA employs qualified personnel, including assuring the development of personnel qualifications and policies. • Must include in writing, the organizational structure, including lines of authority, and services furnished <p>Ensure your job descriptions, staff qualification requirements are aligned with the staff qualifications and job responsibilities listed in the HH CoP for the following positions:</p>

<p>personnel and all patient care services provided by the HHA, whether directly or under arrangement, to meet patient care needs.”</p> <ul style="list-style-type: none"> • Revised §484.105(b)(1)(iii) to require that the administrator assures that a clinical manager is available during all operating hours. • CMS stated that assuring the development of personnel qualifications, and policies and procedures, is a task more appropriately assigned to the administrator, rather than the clinical manager. CMS have revised the regulatory requirement at §484.105(b)(1)(iv) accordingly. The administrator may choose to delegate these tasks to others, including the clinical manager, as appropriate, while retaining the responsibility for assuring that tasks are completed and duties performed. <ul style="list-style-type: none"> • Revised §484.105(c) to specify that one or more qualified individuals must provide oversight of all patient care services and personnel. • Revised §484.105(c) Clinical manager by retaining a description of the clinical manager’s duties while relocating the personnel specifications for this role to new §484.115(c), which sets for the specific personnel requirements for the clinical manager. • The role of the clinical manager at §484.105(c). In particular, the clinical manager is responsible for assuring the development, implementation, and updates of the individualized plan of care. CMS believe that, in order to 	<ul style="list-style-type: none"> • Administrator • Clinical manager • The development of personnel qualifications, and policies and procedures, is a task more appropriately assigned to the administrator, rather than the clinical manager. • A clinical manager is available during all operating hours. • The clinical manager is responsible for assuring the development, implementation, and updates of the individualized plan of care, which would entail communication with all physicians involved in the plan of care and integration of orders from all physicians involved in the plan of care including those orders related to medications.
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effectively assure the development, implementation, and updates of the individualized plan of care, there would have to be communication with all physicians involved in the plan of care and integration of orders from all physicians involved in the plan of care to assure the coordination of all services and interventions provided to the patient. The requirement to integrate orders from all physicians would include those orders related to medications. Medication orders may be for long-term maintenance issues (for example, cholesterol management medications) as well as shorter-term medications for temporary issues that may or may not be directly related to the reason that home health care was initiated (for example, pain management medications that may be used in the process of surgical recovery or may be used as part of a treatment plan for a strained back that the patient just happened to experience during the time that he or she receives HHA care). CMS would continue to expect that all services or interventions that are ordered are medically necessary, as supported by documentation in the patient's record, in accordance with the requirements of 42 CFR 409.44 and 409.45.

- Removed §484.105(c)(6).
- Also in §484.105, CMS requires that an "HHA must organize, manage, and administer its resources to attain and maintain the highest practicable functional capacity, including providing optimal care to achieve the goals and

<p>outcomes identified in the patient’s plan of care, for each patient’s medical, nursing, and rehabilitative needs,” to which end the HHA</p> <p>(1) “must assure that administrative and supervisory functions are not delegated to another agency or organization,”</p> <p>(2) must assure that “all services not furnished directly are monitored and controlled,” and</p> <p>(3) “must set forth, in writing, its organizational structure, including lines of authority, and services furnished.”</p>	
<p>Parent-Branch Relationship, Sec. 484.105(d):</p> <ul style="list-style-type: none"> • HHAs are required to report all branch locations to the state survey agency when the HHA is initially certified, when it is surveyed and anytime the parent HHA seeks to add or delete a branch location. • The parent HHA is also required to provide administrative support and control over its branch locations. Distance between the parent and branch locations is no longer a consideration, provided the parent can show administrative control over the branch. • CMS stated HHAs should refer to the State Operations Manual guidance on converting a branch to a subunit and stated they will issue a Survey and Certification letter after publication of the Final CoP to provide guidance on the change in terminology. 	<p><i>The following are the requirements which need to be in your Policy and Procedures for this section of the Conditions of Participation and included in staff training as applicable:</i></p> <ul style="list-style-type: none"> ○ Parent-Branch Relationship ○ Services Under Arrangement ○ Services Furnished ○ Outpatient Physical Therapy or Speech-Language Pathology Services ○ Institutional Planning- Annual Operating Budget and Capital Expenditure Budget

Services Under Arrangement, Sec. 484.105(e):

- HHAs are required to have a written agreement with any entity or individual that provides services under arrangement to HHA patients. Even for services provided under arrangement, the HHA is responsible for the service provided including the manner in which the services are furnished.
- HHAs are required to make sure the entity or individual providing services under arrangement has not been denied enrollment in Medicare or Medicaid, excluded from any federal health care program including Medicaid, had its Medicare or Medicaid billing privileges revoked or has been debarred from any government program. CMS stated this may be accomplished via a “written and signed self-certification,” which meets the requirement that the contracted entity or individual has not been excluded from a federal health care program.
- CMS recommended that HHAs “routinely” check the OIG List of Excluded Individuals and institute policies that contracted entities are in good standing.

Services Furnished, Sec. 484.105(f):

- HHAs must provide skilled nursing services and at least one other therapeutic service in a place of residence used as the patient’s home.
- The HHA must provide at least one of these required services directly but may obtain other required services under arrangement from another HHA or organization.

Outpatient Physical Therapy or Speech-Language Pathology Services, Sec. 484.105(g):

- HHAs that provide outpatient physical therapy or speech-language pathology services must meet certain CoPs for Clinics, Rehabilitation Agencies and Public Health Agencies as Providers of Outpatient Therapy and Speech-Language Pathology Services found at 42 C.F.R. 485.

Institutional Planning, Sec. 484.105(h):

- HHAs, under the direction of the governing body, are responsible for creating an overall plan and annual operating budget including a capital expenditure plan.
- **Annual Operating Budget:** The annual operating budget must include all anticipated income and expenses utilizing generally accepted accounting principles. Item-by-item identification of components of anticipated income or expense is not required. HHAs must have a capital expenditure plan for at least a three-year period.
- **Capital Expenditure Budget:** The capital expenditure plan must identify in "detail" source of financing for a capital expenditure of \$600,000 or more. This final regulation has a wide array of things that must be considered when determining if a capital expenditure exceeds \$600,000. The HHA must take into account such things as cost studies, surveys, designs, plans, legal and accounting fees, broker commissions and other activities that are essential to the capital expenditure being proposed. It should be noted this is not an all-inclusive list, so HHAs should pay close attention to what must be included in the capital expenditure plan per this new

final regulation. If the source of capital financing is from Medicare, Medicaid or a Maternal and Child Health Block Grant, there are other requirements the HHA must satisfy.

- The capital expenditure plan must specify whether the proposed capital expenditure requires or is likely to require it conform with the Public Health Service Act or Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963.
- The capital expenditure plan must also specify whether the proposal has been submitted to and approved by the designated planning agency in accordance of Section 1122 of the Social Security Act, which addresses limitation on federal participation for capital expenditures.

<ul style="list-style-type: none"> Revised the definition of “representative” at §484.2 for additional clarity. CMS wanted a more person-centered definition of representative, but acknowledged that it is necessary to distinguish between those representatives that are chosen by a patient, but who may not have legal standing, and those representatives who are acting on legal authority to make health care decisions for a patient. CMS uses the term “patient-selected representative” to express this concept. Likewise, when referring to those representatives who are acting on legal authority to make health care decisions for a patient, CMS uses the term “legal representative.” Change the current definitions for “clinical note” Change the current definitions for “parent home health agency,” Change the current definitions for “proprietary agency,” Change the current definitions for “subdivision.” Subunits: On the effective date of this rule, any existing subunits, which already operate under their own provider number, will be considered distinct HHAs and will be required to independently meet all CoPs, including having an independent governing body and administrator. Subject to state-specific laws and regulations, this federal regulatory change will permit a subunit to apply to become a branch of its existing parent HHA. Revised the definition of “representative” at §484.2 for additional clarity. 	<p><i>The following are the requirements which need to be in your Policy and Procedures for this section of the Conditions of Participation and included in staff training as applicable:</i></p> <p>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.</p> <p>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.</p> <p>In advance means that HHA staff must complete the task prior to performing any hands-on care or any patient education.</p> <p>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).</p> <p>Proprietary agency means a private, for-profit agency. Public agency means an agency operated by a state or local government.</p>
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<ul style="list-style-type: none"> • Revised §484.50(a)(1) to clarify that it is the patient’s legal representative that must be informed of the patient rights information prior to the start of care. • Revised §484.50(a)(1)(i) to require that an HHA must provide each patient with written notice regarding the HHA’s transfer and discharge policies. This requirement was originally proposed at 484.50(d). • Redesignated proposed §484.50(a)(2) as §484.50(a)(1)(ii) and removed the requirement that HHA administrators are expected to receive patient questions. • Redesignated proposed §484.50(a)(4) as §484.50(a)(2), and clarified that a signature confirming receipt of the notice of patient rights is only required from a patient or a patient’s legal representative. • Redesignated §484.22--Emergency Preparedness under subpart B as §484.102 under subpart C to align with CoP’s related to “Organizational Environment.” Section 484.22 was implemented as part of the Emergency Preparedness final rule published on September 16, 2016 (81 FR 63859). 	<p>Quality indicator means a specific, valid, and reliable measure of access, care outcomes, or satisfaction, or a measure of a process of care.</p> <p>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.</p> <p>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.</p> <p>Summary report means the compilation of the pertinent factors of a patient’s clinical notes that is submitted to the patient’s physician.</p> <p>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.</p> <p>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.</p>
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<p>§484.12 Compliance with Federal, State, and local laws, disclosure and ownership information, and accepted professional standards and principles revised at §484.100 Regulations related to the health and safety of patients.</p>	
<p>§484.12(a) revised at §484.100</p>	
<p>§484.12(b) revised at §484.100</p>	
<p>§484.12(c) revised at §484. 60, §484.70 and §484.105(f).</p> <ul style="list-style-type: none"> • Moved proposed §484.60(a)(3) to §484.60(a)(2)(xii), making it applicable to all patients, and removed the terms “low,” “medium,” and “high.” • Added a requirement at §484.60(e), Written information to the patient. 	
<p>§484.14 Organization, services and administration revised at §484.105 Revised the requirement at §484.105 to clarify that an HHA must organize, manage, and administer its resources to attain and maintain the highest practicable functional capacity, including providing optimal care to achieve the goals and outcomes identified in the patient’s plan of care, for each patient’s medical, nursing, and rehabilitative needs.</p>	
<p>§484.14(a) revised at §484.105(f) As stated in proposed § 484.105(f)(1), skilled nursing and one of the therapeutic services must be made available on a visiting basis in the patient’s home. At least one service would be required to be provided directly by the HHA. CMS proposed a requirement for compliance with accepted professional standards and principles at § 484.105(f)(2). CMS would require that HHAs furnish all</p>	

services in accordance with accepted professional standards of practice. CMS also proposed to require that all HHA services be provided in accordance with current clinical practice guidelines.	
§484.14(b) revised at §484.105(a)	
§484.14(c) revised at §484.105(b).	
§484.14(d) revised at §484.105(b) and §484.105(c)	
<p>§484.14(e) revised at §484.75(b) and §484.115.</p> <ul style="list-style-type: none"> Revised §484.75(b)(7) to require skilled professionals to communicate with all physicians involved in the plan of care. 	
§484.14(f) revised at §484.105(e)	
§484.14(g) revised at §484.60(d) and §484.105(c)	
§484.14(h) revised at §484.105(e)	
<p>§484.14(i) revised at §484.105(h) CMS proposed to retain the ‘‘Institutional planning’’ standard as required for HHAs under section 1861(z) of the Act at § 484.105(h). CMS did not propose any revisions to this content.</p>	
§484.14(j) revised at §484.100(c)	
<p>§484.16 Group of professional personnel. Deleted, see §484.65, Quality assessment performance improvement (QAPI).</p> <ul style="list-style-type: none"> Revised §484.65 to require that QAPI program indicators include the use of emergent care services. CMS does not want to see cookie cutter QAPI domains and measures. They want you to build a program that reflects the patients that you serve in home health. In the final rule, CMS also proposes the replacement of two current HHA CoPs 	<p><i>The following are the requirements which need to be in your Policy and Procedures for this section of the Conditions of Participation and included in staff training as applicable:</i></p> <ul style="list-style-type: none"> Require that QAPI program indicators include the use of emergent care services. QAPI domains and measures must be formulated to address the patients being served by the HHA

<p>(§484.16, “Group of professional personnel,” and §484.52, “Evaluation of the agency’s program”) with a single new data-driven, Agency-wide quality assessment and performance improvement (QAPI) program aimed at “reduc[ing] medical errors, and improv[ing] the quality of health care in all settings” [§484.65].</p>	
<p>§484.30 Skilled Nursing services, revised at §484.75 Skilled Professional Services.</p> <ul style="list-style-type: none"> • Revised §484.75(b)(7) to require skilled professionals to communicate with all physicians involved in the plan of care. • Revised requirement specifically related to physician orders to allow HHAs to accept orders directly from multiple physicians who are involved in a patient’s care at that point in time, regardless of whether those physicians are part of the same group practice or not. 	<p><i>The following are the requirements which need to be in your Policy and Procedures for this section of the Conditions of Participation and included in staff training as applicable:</i></p> <ul style="list-style-type: none"> • Require skilled professionals to communicate with all physicians involved in the plan of care. • Allow HHAs to accept orders directly from multiple physicians who are involved in a patient’s care at that point in time, regardless of whether those physicians are part of the same group practice or not.