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CMS FINALIZES NEW CONDITIONS OF PARTICIPATION FOR HOME HEALTH: PART 6

Review of the New Home Health Conditions of Participation - Emergency Preparedness, Organization and Administration of Services, Personnel Qualifications and Clinical Records.

This is the sixth article in a series discussing CMS's Final Revised Home Health Conditions of Participation ("Final CoPs"). With the release of the Final CoPs, CMS is finalizing the significant changes they proposed to make to the home health Conditions of Participation in October 2014. Although these major revisions are mostly adopted as proposed, CMS has introduced a number of "clarifying changes" in the final rule that are substantive.

Since the Final CoPs impose numerous requirements, Hall Render will issue a series of articles summarizing various components. Recently, Hall Render published an article that contained a brief analysis of the Final CoPs, as well as Parts 1, 2, 3, 4 and 5 in the series: CMS Finalizes New Conditions of Participation for Home Health: Part 1; CMS Finalizes New Conditions of Participation for Home Health: Part 2; CMS Finalizes New Conditions of Participation for Home Health: Part 3; CMS Finalizes New Conditions of Participation for Home Health: Part 4; and CMS Finalizes New Conditions of Participation for Home Health: Part 5.

Hall Render's New Home Health Conditions of Participation homepage with summaries and links to each article in the series is located here.

EMERGENCY PREPAREDNESS - SEC. 484.102

Executive Summary. The CoP for Emergency Preparedness was formerly located at 484.22. This CoP mirrors the Emergency Preparedness regulations for most Medicare certified providers, which were effective on November 16, 2016. This CoP requires HHAs to comply with all applicable federal, state and local emergency preparedness requirements. Standards of this CoP include: an Emergency Plan; Emergency Preparedness Policies and Procedures; a Communication Plan; Training and Testing; and HHAs that are part of an integrated health system.

Detailed Summary.

Emergency Plan, Sec. 484.102(a): The CoPs require the HHA to have an Emergency Plan ("Plan") that must be reviewed and updated at least annually. The Plan must be based on a facility- and community-based risk assessment utilizing an all-hazards approach. The Plan must include strategies for addressing emergency events as indicated in the risk assessment. It also must address patient populations that include what services the HHA can provide in an emergency and continuity of operations during an emergency. The Plan must include a process for cooperation and collaboration with all emergency preparedness officials in order to maintain an integrated response during an emergency situation.

Policies and Procedures, Sec. 484.102(b): The CoPs require the HHA to develop and implement policies and procedures based on the Plan. These policies and procedures must be reviewed and updated at least annually. The policies and procedures must address how the HHA handles patients during a disaster that must be addressed in the comprehensive patient assessment for each patient. The HHA must have a procedure for informing state and local officials who would need to be evacuated from their homes due to an emergency. The HHA must have a procedure for determining how services will be provided when there is an interruption in services due to an emergency. This includes a requirement that the HHA notify state and local officials of any on-duty staff or patients they are unable to contact. The HHA must have a system for protecting patient information and the confidentiality of such information in the event of an emergency. The HHA is required to have a process on the use of volunteers or other staffing to address surge needs during an emergency.

Communication Plan, Sec. 484.102(c): The HHA must develop and maintain an emergency preparedness communication plan that must be reviewed and updated at least annually. The communication plan must have contact information for staff, contracted entities providing services to the HHA, patients' physicians, volunteers, emergency preparedness staff at all levels of government and other sources of assistance. The HHA must have a primary and alternative means of communication for contacting staff and emergency preparedness agencies. The HHA must implement a method for sharing patient information with other health care providers to ensure continuity of care.

Training and Testing, Sec. 484.102(d): HHAs are required to develop and maintain an emergency training and testing program taking into account the Emergency Plan, Risk Assessment, Policies and Procedures and Communication Plan described above. The training and testing

program must be updated at least annually. The training program must provide training on emergency preparedness policies and procedures. This training must be to staff, individuals providing services under arrangement and volunteers at least annually. The HHA must maintain documentation of the training. With regard to testing, the HHA must conduct exercises to test the emergency preparedness plan at least annually. The HHA must participate in a full-scale and community-based exercise on the emergency preparedness plan. If a community-based exercise is not accessible, the testing may be facility-based. A second community or facility-based exercise must also be conducted. This exercise must include a tabletop exercise, which includes a group discussion led by a facilitator.

Integrated Health Care Systems, Sec. 484.102(e): If an HHA is part of an integrated health care system that includes other certified providers, the HHA has the option of choosing to be part of the health care system's emergency preparedness plan. If the HHA participates in the system-wide emergency preparedness plan, it must ensure the HHA's patient population and services offered are taken into account.

ORGANIZATION AND ADMINISTRATION OF SERVICES - SEC. 484.105

Executive Summary. The CoP for Organization and Administration of Services was formerly located at Sec. 484.14. This CoP requires an HHA to organize, manage and administer its services in such a fashion that it maintains "the highest practicable functional capacity" and provide "optimal care" in accordance with the patient's plan of care.

The CoP prohibits HHAs from delegating administrative and supervisory functions to another HHA or organization.

The CoP requires HHAs to put in writing their organizational structure that includes lines of authority and services furnished. The operating and capital budgets required by this CoP must be prepared under the direction of the HHA's governing body. There must be a planning and budget committee that includes representatives of the HHA's governing body, administrative staff and medical staff (if the HHA has a medical staff). This same committee must review the overall plan and budget at least annually under the direction of the governing body.

Detailed Summary.

Governing Body, Sec. 484.105(a): The HHA's governing body has full legal authority for the HHA's operation and management. This assumption of operation and management includes provision of all home health services, fiscal operations, budget, operational plans and the HHA's Quality Assessment and Performance Improvement program. It should be noted that CMS did not agree with a comment in the Final CoPs that there be specific disciplines and requirements of when the governing body should meet. In response, CMS stated HHAs should be able to "establish a governing body composed of individuals of its choosing."

Administrator, Sec. 484.105(b): The HHA's administrator must be appointed by the governing body and be responsible for running the HHA's daily operations.

When the administrator is not available, he/she must pre-designate a qualified individual to assume the responsibilities of the administrator. CMS emphasized in commentary to the Final CoP that pre-designation should be by both the administrator and governing body. CMS also emphasized the time necessary to obtain governing body approval should be established in the HHA's policies and procedures. This final regulation specifically states the designee may be the clinical manager and that an HHA may have more than one designee. CMS stated in the Final CoP commentary that it did believe one individual could serve as both the administrator and clinical manager.

CMS stated in commentary to the Final CoPs it was not requiring the administrator to be a full-time employee of the HHA or that an administrator would be prohibited from working part-time for more than one HHA. Despite saying these practices are not prohibited under the Final CoPs, CMS highly discouraged such practices.

Clinical Manager, Sec. 484.105(c): HHAs must have one or more qualified clinical manager(s) who provide oversight of all patient care and personnel. This oversight includes patient and personnel assignments, coordination of care, coordination of referrals, assessment of patient needs and ensuring the plan of care is developed, implemented and updated. As a result of a comment in the Final CoPs, HHAs should take note that a clinical manager must be "available during all operating hours." Operating hours are defined in the State Operations Manual Interpretive Guidelines as "all hours that staff from the agency are providing services to patients."

The role of the clinical manager generated several comments in the Final CoP. The essence of these comments revolved around whether a specific title or management position should be attributed to the clinical manager. CMS was firm in its belief that HHAs should have a specific individual identified as the clinical manager. CMS believes the clinical manager "is essential for managing the complex, interdisciplinary care of home health patients," citing data that six of the twenty most cited deficiencies were for poor patient care

coordination and ensuring patients have written and updated plans of care.

Parent-Branch Relationship, Sec. 484.105(d): 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.

There was significant discussion in the commentary to the Final CoP with regard to the elimination of subunits. Most commenters supported eliminating subunits but felt there were many logistical issues to be considered when converting a subunit to a branch. There was also concern that CMS currently has no guidance on converting a subunit to a branch or freestanding HHA. There were also numerous and valid questions pertaining to how CMS proposed to handle provider enrollment, claims processing, patient care coordination, data submission, patient admission and discharge in the conversion process.

In its response to these comments, CMS provided little guidance. 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.

CMS had little sympathy for commenters asking for additional time (6 to 12 months) for HHAs choosing to convert a subunit to an independent HHA. These commenters posed valid questions about being able to complete the logistics of a conversion prior to the July 13, 2017 effective date of the Final CoPs. In response to these comments, CMS merely stated HHAs converting subunits to independent HHAs have ample time to implement this conversion and no additional time would be given to facilitate such a conversion.

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, has 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 still highly 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.

CLINICAL RECORDS - SEC. 484.110

Executive Summary. The CoP for Clinical Records was formerly located at Sec. 484.48. This Final CoP requires HHAs to maintain a clinical record of "past and current information" of all patients receiving home health services. The clinical record must contain accurate information and adhere to standards of practice for accurate documentation. The clinical record must be available to physicians and other home health staff issuing orders for home health plans of care. The clinical record may be maintained electronically.

Detailed Summary.

Contents of Clinical Record, Sec. 484.110(a): The clinical record must include the "current" comprehensive assessment and all assessments from the most recent home health admission. With regard to the "current" assessment, CMS simply stated this assessment "would be the assessment with the most recent date." CMS also stated that HHAs should not stop with the "current" assessment. The clinical record must contain "all assessments ever related to the patient's current admission." For purposes of clarity, CMS stated HHAs could choose to keep the most "current" assessment in a different part of the clinical record "if that would improve clarity for users of the clinical record." In reality, this statement by CMS is likely suggesting HHAs should consider placing the "current" assessment in a different part of the record so it will be more easily identified by surveyors when conducting HHA surveys.

The clinical record must also contain clinical notes, plans of care and physician orders. The clinical record must contain all interventions including medication administration, treatments and services and responses to those interventions. Patient goals in plans of care and progress toward achieving those goals must be in the clinical record. Contact information for the patient, the patient's representative, primary caregiver(s), primary care practitioner or other health care professionals providing care to the patient after discharge must be included in the clinical record. Providing contact information for primary caregiver(s) was added to the Final CoP in response to commentary to the Final CoPs. There were many comments addressing the time required (or lack thereof) to complete the transfer and discharge summary with commenters offering a wide array of alternative time requirements for completing these summaries.

A discharge summary must be sent to the primary care practitioner or other health care professionals providing services to the patient within five days of discharge from the HHA. The discharge summary is not to be confused with the transfer summary, which must be sent within two business days of the planned or unplanned transfer if the patient is receiving care in a health care facility at the time when the HHA becomes aware of the transfer.

There were many comments addressing the time required (or lack thereof) to complete the transfer and discharge summary with commenters offering a wide array of alternative time requirements for completing these summaries. CMS appreciated the "wide array of comments" on completion of the transfer and discharge summaries. CMS suggested that ideally the transfer summary should be prepared and sent on the day of transfer and the discharge summary prepared and sent within two days of discharge but understood this "may not be feasible in all transfer and discharge situations and that the Final CoP were to establish maximum timeframes." Therefore, CMS found the two-business day requirement for the transfer summary and five business days for the discharge summary are "appropriate maximum standards." In response to other comments regarding unplanned transfers, CMS amended the Final CoP to state the transfer summary should be completed "within two business days of becoming aware of the unplanned transfer, only if the patient is still receiving care in the receiving health care facility at the time the HHA becomes aware of the unplanned transfer."

Authentication, Sec. 484.110(b): Entries in the clinical record must be legible, clear, complete, appropriately authenticated, dated and timed. The authentication must include a signature and title. A secured computer entry utilizing a unique identifier is also allowed if the primary author has reviewed and approved the entry.

There were a few comments in the Final CoPs regarding the authentication standard, mostly with regard to the timing of the authentication in the clinical record. In response to these comments, CMS clarified the meaning of "timed" stating it "means the actual time that an event occurred, which is not necessarily the time when the documentation was entered into the record." More importantly, CMS states "[t]he date and time requirement applies to all entries in the record" even if the entry is not time sensitive with regard to patient care. It is also important to note that while CMS allows electronic signatures, it believes "that maintaining the original, signed paper documents is essential

for purpose of authentication of documents."

Retention of Records, Sec. 484.110(c): Clinical records must be retained for at least five years unless state law requires a longer retention time. The HHA must have a policy for retaining clinical records if it discontinues operation and must inform the state agency where the clinical records will be stored. HHAs should be aware that the five-year retention requirement is what CMS believes is "sufficient for health and safety purposes." Therefore, HHAs should be cognizant of other record retention requirements under federal and state law and regulations and develop policies accordingly.

Protection of Records, Sec. 484.110(d): The clinical record must be safeguarded from loss or unauthorized use. The HHA must also comply with HIPAA with regard to protected health information.

Retrieval of Clinical Records, Sec. 484.110(e): The HHA must make the clinical record available to the patient free of charge and available at the next home visit or within four business days, whichever comes first. Again, HHAs should be cognizant of other federal and state laws and regulations that may pose more strict requirements for the retrieval of clinical records and develop policies accordingly.

PERSONNEL QUALIFICATIONS - SEC. 484.115

Executive Summary. The CoP for Personnel Services was formerly located at Sec. 484.4. This Final CoP addresses Personnel Qualifications for various HHA personnel. While this is technically a new CoP, many of the current personnel qualifications have been retained. CMS did revise the current personnel qualifications for Administrator and Speech-Language Pathologist. These revisions are set forth below.

Detailed Summary.

Administrator, Home Health Agency, Sec. 484.115(a): If the administrator was employed by the HHA prior to July 13, 2017, the administrator was properly qualified if he/she is a licensed physician, registered nurse or has training in health service administration and at least one year of administrative experience in home health or a related health care program. This provision was not in the proposed CoPs. CMS added this provision for administrators employed prior the effective date of the Final CoP stating it was not its "intent to disqualify currently any currently employed administrator."

If the administrator is employed after July 13, 2017, the administrator is properly qualified if he/she is a licensed physician, registered nurse or has an undergraduate degree and has at least one year of administrative experience in home health or a related health care program. Any new administrator employed after the effective date of the Final CoPs must meet these new requirements even if he/she "was previously employed as an administrator for a different HHA." Therefore, any administrator qualified under the previous requirements should be aware of these new personnel requirements prior to seeking employment with another HHA. CMS also believes the new administrator qualifications "will serve as a disincentive to the creation of HHAs that are operated with fraudulent intent, as many of these entities are opened by individuals who would not meet these minimum qualifications."

Audiologist, Sec. 484.115(b): An audiologist must meet the education and experience requirements for a Certificate of Clinical Competence issued by the American Speech-Language-Hearing Association. If the audiologist meets the educational requirements, he/she may still serve as the audiologist provided he/she is in the process of accumulating the supervisory experience required for certification.

Clinical Manager, Sec. 484.115(c): The clinical manager may be a licensed physician, physical therapist, speech-language pathologist, occupational therapist, social worker or registered nurse. The proposed CoP did not include a physical therapist, speech-language pathologist, occupational therapist or social worker to function as the clinical manager. These health professionals were added in response to a comment made in response to the Proposed CoPs.

Home Health Aide, Sec. 484.115(d): A home health aide must meet the Final CoP implemented at 484.80. Please refer to a more detailed discussion in this article pertaining to the Home Health Aide CoP requirements found at 484.80.

Licensed Practical (Vocational) Nurse, Sec. 484.115(e): A licensed practical (vocational) nurse must have completed the requisite nursing program or be licensed in the state where the HHA is located. The licensed practical (vocational) nurse must furnish services under the supervision of a registered nurse.

Occupational Therapist, Sec. 484.115(f): The occupational therapist ("OT") must be licensed where the HHA is located if licensure is required. If licensure is not required, the OT must have graduated from an OT program accredited by the Accreditation Council for Occupational

Therapy Education ("ACOTE") of the American Occupational Therapy Association ("AOTA") or any successor organization of the ACOTE. After completion of the requisite educational requirements, the OT must be eligible for or have taken the OT certification examination administered by the National Board for Certification in Occupational Therapy ("NBCOT"). There are additional requirements for OTs practicing on or before December 31, 1977, January 1, 2008 and December 31, 2009 that HHAs should note as they include varying educational and board certification requirements. There are also additional education and board certification requirements for OTs educated outside of the United States.

Occupational Therapy Assistant, Sec. 484.115(g): The OT assistant must be licensed where the HHA is located if licensure is required. If licensure is not required, the OT assistant must have graduated from an OT assistant program accredited by the ACOTE of the AOTA or any successor organization of the of the ACOTE. After completion of the requisite educational requirements, the OT assistant must be eligible for or have taken the OT assistant certification examination administered by the NBCOT. There are additional requirements for OT assistants practicing after December 31, 1977 and on or before December 31, 2007, on or before December 31, 2009 and after January 1, 2010. There are also additional education and board certification requirements for OT assistants educated outside of the United States.

Physical Therapist, Sec. 484.115(h): A physical therapist ("PT") must be licensed where the HHA is located if licensure is required. If licensure is not required, the PT must have graduated from a PT program approved by The Commission on Accreditation in Physical Therapy Education ("CAPTE") or any successor organization of the CAPTE. There are additional requirements for PTs practicing before January 1, 1966, on or before December 31, 1977, before January 1, 2008 and on or before December 31, 2009. There are also additional education and board certification requirements for PTs educated outside of the United States.

Physical Therapist Assistant, Sec. 484.115(i): A PT assistant must be licensed where the HHA is located if licensure is required. If licensure is not required, the PT assistant must have graduated from a PT assistant program approved by CAPTE and have passed a national examination for PT assistants. There are additional requirements for PT assistants practicing on or before December 31, 1977, before January 1, 2008 and on or before December 31, 2009.

Physician, Sec. Sec. 484.115(j): A physician must meet the Final CoP implemented at Sec. 410.20(b). Please refer to a more detailed discussion in this article pertaining to the physician CoP requirements found at Sec. 410.20.

Registered Nurse, Sec. 484.115(k): A registered nurse must have graduated from an approved school of nursing and be licensed in the state where practicing.

Social Work Assistant, Sec. 484.115(l): A social work assistant must have a baccalaureate degree in social work, psychology, sociology or another field related to social work and at least one year of social work experience in a health care setting. A social work assistant may also qualify if he/she has two years of appropriate experience and has a satisfactory grade on a proficiency examination conducted, approved or sponsored by the U.S. Public Health Service. These proficiency determinations do not apply to persons licensed or seeking initial qualifications as a social work assistant after December 31, 1977.

Social Worker, Sec. 484.115(m): A social worker must have a master's or doctoral degree from a school of social work accredited by the Council on Social Work Education and one year of social work experience in a health care setting.

Speech-Language Pathologist, Sec. 484.115(m): A speech-language pathologist must have a master's or doctoral degree in speech-language pathology and be licensed in the state where practicing. If licensure is not required, the speech-language pathologist must have completed or be in the process of completing 350 clock hours of supervised clinical practice experience. It is also permissible for the speech-language pathologist to have performed not less than nine months of supervised speech-language pathologist services after obtaining a master's or doctoral degree in speech-language pathology or a related field. Successful completion of a national examination in speech-language pathology is also allowed in states where licensure is not required.

PRACTICAL TAKEAWAYS

The CoPs require the HHA to have an Emergency Plan that must be reviewed and updated at least annually. Also, the training and testing program must be updated at least annually.

The CoP requires HHAs to put in writing their organizational structure that includes lines of authority and services furnished. The operating and capital budgets required must be prepared under the direction of the HHA's governing body. CMS stated it was not requiring the

administrator to be a full-time employee of the HHA or that an administrator would be prohibited from working part-time for more than one HHA. Despite saying these practices are not prohibited under the Final CoPs, CMS highly discourages such practices. Entries in the clinical record must be legible, clear, complete, appropriately authenticated, dated and timed. Clinical records must be retained for at least five years unless state law requires a longer retention time.

If the administrator was employed by the HHA prior to July 13, 2017, the administrator was properly qualified if he/she is a licensed physician, registered nurse or has training in health service administration and at least one year of administrative experience in home health or a related health care program.

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