

Series: Part 6 of 6 CLIMB THE LADDER OF SUCCESS WITH CoPs

Key Changes to Standards for the Organization, Services and Administration and Clinical Records

This is the sixth of six updates in a Simione series on the NEW Centers for Medicare & Medicaid Services (CMS) Conditions of Participation (CoPs) for Home Health. These regulations take effect on July 13, 2017.

Organization, Services and Administration CFR 484.105

The final rule has these revisions to the existing Organization, Services and Administration standards:

- Expands governing body responsibilities to include full legal authority and responsibility for the agency's overall management and operation, the provision of all home health services, fiscal operations, review of agency's budget, operational plans, and QAPI program
- Requires the administrator to be responsible for all day-to-day operations and to be available during all operating hours
- Defines the parent-branch relationship and eliminates the sub-unit designation
- Identifies individuals/entities that are not eligible to contract with to provide services to agency patients
- Eliminates Professional Advisory Committee and incorporated quality and performance improvement into a structured QAPI program as discussed in Part 3 of this Simione series

This CoP is focused on the agency's responsibility to attain and maintain the highest practicable functional capacity, including providing optimal care to achieve the goals and outcomes identified in the plan of care for each patient's needs.

The new standards on the parent-branch relationship focus on the ability of the parent to demonstrate that it can monitor all services provided in its entire service area, furnished by any branch offices, to ensure compliance with the CoPs. (494.105(d)) and (e). The new definition for a branch is "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 CoPs as a home health agency." The distance from the parent to the branch is not defined; however, the parent must be able to demonstrate day-to-day control and direct supervision of the branch, including, but not limited to:

- Contracts
- Personnel oversight
- Plans of care
- Services provided
- Quality control

The designation of a sub-unit is eliminated with the effective date of the CoPs. Currently, Sub-units are semi-autonomous, serve patients in a different geographical area, and must meet the CoPs separately from the parent. Therefore, agencies currently designated as sub-units will need to transition to either a parent agency or become a branch of the parent. Both options will require action steps and may be impacted by state licensing regulations. Management of existing sub-units should consider the following:

- Decision to become a parent agency or a branch of the existing parent agency
- Patient transition process
- Application and/or approval from the state/CMS, including need for 855A
- State licensure and survey implications
- Billing and cash flow implications

The responses to comments in the Federal Register do not shed any light on these issues; however, agencies should be on the lookout for:

- CMS Survey and Certification letter to the states to explain change in terminology and revise guidance
- Revision to sections of Chapter 2 of the State Operations Manual

The change to the standard for services provided under arrangement (484.105(f)) requires that individuals or organizations providing services under arrangement may not have:

- Been denied Medicare or Medicaid enrollment
- Been excluded or terminated from any federal health care program or Medicaid
- Had its Medicare or Medicaid billing privileges revoked
- Been debarred from participating in any government program

Home health agencies can consider the following actions to prepare for the changes related to Organization, Services and Administration:

- Review and revised the policies related to the responsibilities of the governing body
 - Ensure that all members of the governing body acknowledge and understand these responsibilities
 - Develop processes and meaningful metrics for timely reporting to the governing body
- Sub-unit transition to parent agency or branch
 - Determine whether to be a stand-alone parent agency or a branch of the current parent
 - Stay current on CMS and state communications regarding required transition
 - Reach out to state associations for state-specific guidance and instructions
 - Revise organizational structure and policies to fit the evolved entity
- Steps to ensure that services under arrangements are with qualified individuals and organizations:
 - Develop policies and procedures to validate that contractors are not excluded from providing services
 - Revise contracts to include a required self-certification statement
 - Routinely check:
 - OIG's List of Excluded Individuals and entities (<https://oig.hhs.gov/exclusions>)
 - Special Advisory Bulletin (<https://oig.hhs.gov/exclusions/advisories.asp>)
 - System for Award Management (<https://www.sam.gov>)

Clinical Records CFR 484.110

The final rule has revisions to the existing Clinical Records standards, as well as the addition of two new standards. Some key changes include the following:

- Requirement that information contained in the clinical record:
 - Is accurate
 - Adheres to current clinical record documentation standards of practice
 - Be available to the physician who is responsible for the home health plan of care
 - Be available to home health agency staff
 - Demonstrate consistency between diagnosed condition, plan of care, and actual care provided
- Inclusion in the clinical record of:
 - Comprehensive assessments, clinical visit notes and individualized plan of care
 - All interventions documented with date and time which they occurred
 - Goals in the plan of care and progress toward achieving goals
 - Contact information for patient/representative/caregiver
 - Contact information for primary care practitioner who will follow the patient after discharge from home health
 - Discharge or transfer summary
- Discharge or transfer summary sent to the physician within required timeframe
 - Discharge – within five business days of discharge
 - Transfer to facility – within 2 business days of patient’s transfer or knowledge of transfer if patient is still in facility
- Record retention changed to five years from the discharge of the patient from home health, unless state law requires a longer period. This is a change from the previous requirement of 5 years after the filed cost report.
- Required policies to provide for the retention of records if the agency discontinues operations
 - If the agency discontinues operation, it must inform the state agency as to where the clinical records will be maintained
- Records must be safeguarded against loss or unauthorized use of PHI, and must follow HIPAA Privacy and Security regulations

Additionally, two new standards now apply to the Clinical Records CoP related to authentication of and patient/representative access to the clinical record. They specify as follows:

- Authentication of clinical records (484.110(b)) – all entries are legible, clear, complete and appropriately authenticated, dated and timed
 - Must include signature and title or secured computer entry by unique identifier
 - In response to a comment requesting CMS “allow providers that maintain clinical records electronically to scan the ‘signature’ documents and then destroy the paper copies,” CMS responded with the following statement, “While we understand that HHAs may desire to destroy paper copies of signature documents to reduce physical paper storage space, we believe that maintaining the original, signed paper documents is essential for purposes of authentication of the documents.”
- Patient access to clinical record (484.110(e)) – Clinical record be provided to patient/authorized representative within 4 business days or the next visit whichever comes first

Home health agencies can consider the following actions to prepare for the changes related to Clinical Records:

- Evaluate current documentation processes and EMR guides to ensure accurate, consistent and complete documentation, specifically related to adherence to standards of clinical documentation and consistency between diagnosed condition, plan of care and care provided
- Develop procedures for timely provision of clinical record documentation to the physician or patient/patient representative upon request
- Develop procedures for the creation and distribution transfer and discharge summaries, including documentation that these requirements have been met:
 - Discharge summary sent to the physician within 5 business days of discharge
 - Transfer summary sent to facility within 2 business days of transfer or 2 business days of the agency's knowledge of transfer if patient is still in facility
- Develop procedures for the retention of records should the agency discontinue operations, including storage location and notification to state agency
- Perform an assessment of the current items included in the clinical record to ensure that it will encompass all required items, including contact information for the patient/patient representative, caregiver and physician who will follow patient after discharge from home health
- Perform an assessment of current processes to ensure authentication of clinical documentation
 - For electronic records - electronic signatures or secured computer entry by unique identifier of a primary author who reviewed and approved the entry
 - For paper records – entries must be legible and clear, and include signature, date and time
 - Process for retaining paper-signed documents that have been scanned into an EMR
- Develop and provide training to agency personnel related to:
 - Clinical record documentation standards of practice
 - Processing request for clinical record documentation by patient/representative or physician within required timeframes
 - Correlate with PHI privacy practices and patient notices
 - Ensure field staff will recognize a verbal request in the home
 - New discharge and transfer summary requirements, timeframes and agency procedures