

# Public Policy

HCA Public Policy No.1-2017



**TO:** HCA MEMBERS

**FROM:** HCA POLICY STAFF

**RE:** SUMMARY OF HOME HEALTH CONDITIONS OF PARTICIPATION FINAL RULE

**DATE:** JANUARY 18, 2017

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## Background

On January 9, 2017, the U.S. Centers for Medicare and Medicaid Services (CMS) posted final regulations that will provide the most substantial changes to the existing Medicare Conditions of Participation (CoPs) since 1989. **The changes will be effective July 13, 2017.**

CMS initially proposed changes to the Medicare CoPs on October 9, 2014, and HCA returned comprehensive comments at that time.

In our comments, we expressed strong concerns that the proposed changes, though laudable, would:

1. Add new and unfunded costs at the very same time that CMS is implementing dramatic cuts in home health via rebasing, and while New York home health agencies (HHAs) have been subject to negative Medicare margins for 14 straight years;
2. Be in steep conflict with CMS efforts and CMS-approved waivers to New York and other states to enroll Medicaid and dual Medicare-Medicaid patients into managed care; and
3. Pose significant feasibility challenges and resource dislocation of agency staff, particularly given the fragile and already overextended status of many New York agencies.

We will continue to make these arguments in any discussions held by the incoming President Administration, and we will seek to delay, eliminate or mitigate any adverse regulations affecting Medicare and/or Medicaid.

The lengthy final rule (<https://www.gpo.gov/fdsys/pkg/FR-2017-01-13/pdf/2017-00283.pdf>) contains an array of new requirements and changes related to: nursing, therapy and aide services; supervision assessments; patients' rights; care planning; quality improvement; clinical records; agency structural requirements; governance; management; and other CoPs that dictate the operation and function of HHAs certified by Medicare (and Medicaid). These revisions affect all levels of a home care agency's operations – from the delivery of services, to the management of staff, to recordkeeping, to the overall structure of your organization. While some of the changes are merely technical or organizational in nature, others would have a significant impact on HHA clinical and administrative functions.

Indeed, CMS estimates these changes will cost home health agencies \$293 million nationally in the first year and \$290 million in year two.

The purpose of this memorandum is to provide a preliminary summary of the most important features of the new finalized CoPs. We will update this information and notify members as needed. These summaries are organized by section number and by category so that your staff can easily cross-reference each provision in the final CoPs with the existing CoPs in order to assess the impact on your organization. Also attached to this memorandum is a chart (from the *Federal Register* notice) showing the relationship between the pre-existing CoPs and the newly finalized changes, otherwise known as the CrossWalk.

HCA encourages members to share this memorandum with all of your key management, supervisory, clinical, compliance and other staff responsible for adhering to CoPs and related federal and state regulatory requirements. While not all agencies are subject to CoPs directly, we stress that the CoPs govern the provision of services provided by Medicare-certified agencies (CHHAs and LTHHCPs) under fee-for-service, private duty and managed care, including those services that are contracted to other provider partners, such as LHCSAs. Therefore, it is recommended that agencies who contract out for services also share this information with their partners.

## General Comments

In addition to federal standards, applicable under Medicare nationwide, the CoPs also form the basis for many of New York State's regulations, which are applicable across the entire spectrum of home care service delivery, such as home health aide training and supervisory requirements and others. As such, HCA will also be consulting with state regulatory officials – including state survey officials – to determine the impact of CMS's final federal changes on existing state regulations and survey practices governing all home care providers, not just Medicare-certified agencies.

The CMS changes outlined in this memo are sweeping and will require further detailed analysis and discussion with CMS officials, especially in several areas where the CoPs outline broad principles but lack prescriptive requirements, language or instructions. These broad principles are largely intended to:

- Develop a more continuous, integrated care process across all aspects of home health services, based on a patient-centered assessment, care planning, service delivery, and quality assessment and performance improvement.
- Use a patient-centered, interdisciplinary approach that recognizes the contributions of various skilled professionals and their interactions with each other to meet the patient's needs, stressing quality improvements by incorporating an outcome-oriented, data-driven quality assessment and performance improvement program specific to each HHA.
- Eliminate the focus on administrative process requirements that lack adequate consensus or evidence that they are predictive of either achieving clinically relevant outcomes for patients or preventing harmful outcomes for patients.

In addition, these new CoPs come at a time when HCA has been working to gain clarity and explanation regarding the regulatory requirements applicable to home care providers and managed care plans in a context where providers must enter into service or care-management contractual arrangements that may further complicate the intersection of federal and state regulations. HCA will be continuing to analyze the new CoP provisions in this context and provide

guidance or clarification to providers as warranted, especially in the areas of comprehensive assessments, patient care planning, quality reporting and others.

## History & Context for CoP Revisions

Although the CoPs have not changed substantially since 1989, CMS previously proposed revisions to the CoPs in March of 1997. At that time, CMS declined to finalize those changes, citing the “significant volume of public comments and the rapidly changing nature of the industry” as its explanation. According to CMS, those comments from 1997 were considered in CMS’s process of developing these current CoP revisions.

As a rationale for its newest changes, CMS noted that its approach to quality-assurance has historically relied on a “problem-focused” approach, meaning it has focused on identifying health care providers who do not meet the minimum requirements and then requiring corrective action or pursuing termination of the provider from the Medicare or Medicaid programs.

CMS wrote in the proposed and final rules: “We have found this problem-focused approach has inherent limits. Ensuring quality through the enforcement of prescriptive health and safety standards, rather than improving the quality of care for all patients, has resulted in expending much of our resources on dealing with marginal providers, rather than on stimulating broad-based improvements in the quality of care delivered to all patients.”

For these reasons, much of the focus in these CoP revisions is to produce “a patient-centered, data-driven, outcome-oriented process,” the key features of which are new requirements proposed for patients’ rights and quality assessment.

What follows is a section-by-section summary of key provisions in the following areas:

- Definition changes (484.2)
- Reporting OASIS Information (484.45)
- Patients’ Rights (484.50)
- Comprehensive Assessment of Patients (484.55)
- Care Planning, Coordination of Services, and Quality of Care (484.60)
- Quality Assessment and Performance Improvement (QAPI) (484.65)
- Infection Prevention and Control (484.70)
- Skilled Professional Services (484.75)
- Home Health Aide Services (484.80)
- Compliance with Federal, State, and Local laws and Regulations related to Health and Safety of Patients (484.100)
- Emergency Preparedness (484.102)
- Organization and Administration of Services (484.105)
- Clinical Records (484.110)
- Personnel Qualifications (484.115)
- CMS’s Estimated Cost Burden for Implementing New CoPs

## Definitions (484.2)

### *Revisions*

At section 484.2, CMS has clarified some of the definitions for terms used in the HHA CoPs. The definition for “branch office” has been modified to add the requirement that the parent agency offer more than the sharing of services – specifically, that it provides supervision and administrative control of branches on a daily basis to the extent that the branch depends upon the parent agency’s supervision and administrative functions in order to meet the CoPs, and could not do so as an independent entity.

Though the definition would no longer require the branch office to be “sufficiently close,” the parent agency would have to be available to meet the needs of any situation and respond to issues that could arise with respect to patient care or administration of the agency. A violation of a CoP in one branch office would be considered a violation by the entire HHA.

CMS also has finalized minor changes in the language of the pre-existing definitions for “clinical note”; “parent home health agency”; “proprietary agency”; and “subdivision” to “achieve consistency with the other definitions contained in this section.”

### *Deletions*

CMS also eliminated pre-existing definitions of the terms “bylaws” and “supervision.” CMS stated that the bylaws term was eliminated because it is not included in the regulatory text and thus is not necessary to define a term that is not used. A definition for supervision was eliminated because CMS believes a single definition cannot adequately encompass the variety of ways in which the term is used in the rule.

CMS eliminated the definition for “home health agency” because its definition is set out by statute at section 1861(o) of the Social Security Act (SSA). CMS also deleted the term “progress notes” because notations in the clinical record are more typically referred to as “clinical notes,” a term that is well defined and understood in the home health industry, and eliminated “nonprofit agency” as this term is not used within the regulatory text.

CMS deleted the term “subunit” because the distinction between the requirements for parent agencies and a subunit are minor. Currently, a subunit must be able, independently, to meet the CoPs. A “subunit” is distinguished from an independent HHA in that it may share the same governing body, administrator, and group of professional personnel with its parent HHA. In practice, the requirement that a “subunit” must independently meet the CoPs renders this distinction moot, and CMS believes that an entity operating for all intents and purposes as a distinct HHA should be treated as such. Therefore, upon finalization of this rule, existing subunits, which already operate under their own provider number, will be considered distinct HHAs and will be required to independently meet all CoPs without sharing a governing body or administrator.

Based on state-specific laws and regulations, this federal regulatory change will permit a subunit to apply to become a branch of its existing parent HHA if the parent provided “direct support and administrative control” of the branch. The state survey agency and CMS Regional Office are responsible for approving an HHA’s application for a branch office, in accordance with current CMS guidance as set out in various survey and certification letters and section 2182.4B of the State Operations Manual. No new subunits will be approved upon implementation of this regulation, only “branch offices.”

## **Additions**

CMS has added definitions for the terms “in advance”; “quality indicator”; “representative”; “supervised practical training”; and “verbal order.”

In advance “means that HHA staff must complete the task prior to performing any hands-on care or any patient education.” Quality indicator is “a specific, valid, and reliable measure of access, care outcomes, or satisfaction, or a measure of a process of care.” CMS stated that it added a definition for the term “quality indicator” because the use of quality indicators is central to an HHA’s successful implementation of a quality assessment and performance improvement program.

CMS has defined the term “representative” to mean the patient’s legal representative, 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 advocate for the patient.

“Supervised practical training” is defined to provide clarity for clinical care purposes. 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.”

Lastly, CMS has added a definition for the term “verbal orders” to mean those physician orders that are spoken to “appropriate personnel” (such as a nurse or other qualified medical personnel) and later put in writing so as to document as well as establish or revise the patient’s plan-of-care.

## **Reporting OASIS Information (484.45)**

CMS has replaced the pre-existing requirement that an HHA transmit data using electronic communications software through a direct telephone connection from the HHA to the state agency or CMS contractor for the Outcome and Assessment Information Set (OASIS). This requirement did not reflect current technology; instead, CMS has added a requirement that the OASIS data be transmitted in accordance with current CMS transmission policy, which now requires HHAs to transmit data using electronic communications software that complies with the Federal Information Processing Standard (FIPS 140-2, issued May 25, 2001).

In addition, CMS changed the OASIS transmission guidelines in January 2015. Now, an HHA must successfully transmit test data to the Quality Improvement and Evaluation System, Assessment Submission and Processing (QIES ASAP) System (not to the state agency) or CMS OASIS contractor.

## **Patient Rights (484.50)**

CMS has reorganized patient rights under a new section, 484.50. The section includes the following six standards: (1) Notice of rights; (2) Exercise of rights; (3) Rights of the patient; (4) Transfer and discharge; (5) Investigation of complaints; and (6) Accessibility. Some of these standards are explained below.

## *Notice of Rights*

In section 484.50(a), CMS requires that the HHA provide the patient and patient's legal representative the following information during the initial evaluation visit, **in advance of providing care**:

1. Written notice of the patient's rights and responsibilities, as well as the HHA's transfer and discharge policies. Written notice must be "understandable" to persons with limited English proficiency and accessible to individuals with disabilities. CMS has clarified that "understandable" does not mean that it must be written in every language, but that patients "achieve a grasp of the explanation of something and not necessarily a verbatim written translation." HHAs are expected to utilize technology, such as telephonic interpreting services and any other available resources for oral communication in the patient's primary or preferred language.
2. Contact information for the HHA administrator, including name, business address and phone number in order to receive complaints.
3. An OASIS privacy notice to all patients for whom OASIS data is collected.

The HHA is required to obtain the patient's or legal representative's signature confirming receipt of the notice of rights and responsibilities.

The HHA is also required to provide written notice of the patient's rights and responsibilities and the HHA's transfer and discharge policies to a patient-selected representative (without legal health care decision making authority) within **4 business days** of the initial evaluation visit.

The HHA will now be required to provide verbal notice of the patient's rights and responsibilities in the individual's primary or preferred language and in a manner the individual understands, free of charge, with the use of a competent interpreter if necessary, no later than the completion of the **second visit** from a skilled professional. The proposed rule intended to also require verbal notice in advance of providing care. In our comments on the proposed rule, HCA had questioned the need for verbal notification.

Whether communicating with a patient or representative, HHA staff would be required to provide language assistance services or auxiliary aids and services at no cost to the individual, and provide notice of the availability of assistance, when necessary, to ensure effective communication between patients, representatives, and HHA staff.

## *Rights of the Patient*

Under section 484.50(c), which lists the rights of each home health patient, CMS has added a new patient right "to be free from verbal, mental, sexual and physical abuse, including injuries of unknown source, neglect, and misappropriation of property."

In addition, CMS has listed new areas that each patient would have the right to: participate in; be informed about; and consent or refuse care in advance of and during execution. These include: completion of **all** assessments (not only the initial one as in the proposed rule); establishing and revising the plan-of-care; expected outcomes of care, including patient-identified goals, and anticipated risks and benefits; and any factors that could impact treatment effectiveness.

Patients now have the additional rights to be: advised of the state toll-free home health telephone hot line, its contact information and purpose; advised of names, addresses and phone numbers of certain listed federal and state-funded

entities; free from any discrimination or reprisal for exercising their rights or for voicing grievances; and be informed of the right to access auxiliary aids and language services to help them understand certain information provided by agencies.

### *Transfer and Discharge*

CMS has added a new standard at 484.50(d) which mandates that all patients and representatives (if any) have the right to be informed of the HHA's policies for transfer and discharge. Under this standard, an HHA can only transfer or discharge the patient for the following reasons:

- The HHA and physician agree that the HHA can no longer meet the patient's needs, based on the patient's acuity (the HHA must arrange a safe and appropriate transfer to other entities);
- The patient or payor will no longer pay for the services provided by the HHA;
- The physician and HHA agree that the measureable outcomes and goals in the plan-of-care have been achieved and the patient no longer needs HHA services;
- The patient refuses HHA services or elects to be transferred or discharged;
- The HHA determines in accordance with certain regulatory requirements that the behavior of the patient (or other persons in the patient's home) is disruptive, abusive, or uncooperative to the extent that care delivery is seriously impaired;
- A patient dies; or
- The HHA ceases to operate.

### *Investigation of Complaints*

CMS has added a standard at section 484.50(e), "Investigation of complaints," that would expand upon the current complaint investigation requirements at section 484.10(b)(5). This section requires the HHA to investigate complaints made by patients, representatives, caregivers, and families regarding treatment or care that is (or fails to be) furnished, is furnished inconsistently, or is furnished inappropriately. In addition, HHAs would be required to investigate allegations of mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and/or misappropriation of patient property by anyone furnishing services on behalf of the HHA.

HHAs are required to document both the existence of the complaint and its resolution and to take action to prevent any further potential violation, including retaliation, while the complaint is being investigated.

The final rule requires any HHA staff, regardless of whether employed directly or obtained under arrangements with another entity, to immediately report – to the HHA or other appropriate authorities in accordance with state law – any incidences of mistreatment, neglect, or abuse, or any misappropriation of patient property that staff have noticed during the normal course of providing services to patients

## *Accessibility*

HHAs must provide information to patients in plain language and in a manner that is accessible and timely to: (1) Persons with disabilities, including accessible websites and the provision of auxiliary aids and services at no cost to the individual; and (2) Persons with limited English proficiency through the provision of language services at no cost to the individual, including oral interpretation and written translations.

## **Comprehensive Assessment of Patients (484.55)**

While retaining most of the existing CoP provisions, CMS updated new content requirements so that the comprehensive assessment accurately reflects the patient's status and must include at a minimum the following patient information:

- Current health, psychosocial, functional, and cognitive status;
- Strengths, goals, and care preferences, including information that may be used to demonstrate the patient's progress toward achievement of the goals identified by the patient and the measurable outcomes identified by the HHA;
- The continuing need for home care;
- Medical, nursing, rehabilitative, social, and discharge-planning needs;
- A review of all medications the patient is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy.
- Patient's primary caregiver(s), if any, and other available supports, including the willingness and ability to provide care, and availability and schedules;
- The patient's representative (if any);
- Incorporation of the current version of OASIS items. The OASIS data items would also include: clinical record items, demographics and patient history, living arrangements, supportive assistance, sensory status, integumentary status, respiratory status, elimination status, neuro/emotional/behavioral status, activities of daily living, medications, equipment management, emergent care, and data items collected at inpatient facility admission or discharge only.

CMS also changed the requirement that an update of the comprehensive assessment must be completed within 48 hours of a patient returning home after a hospital admission to allow for a physician to establish a (different) resumption date.

Lastly, CMS's final rule added a requirement that was not in its proposed rule requiring that the comprehensive assessment must include information about the caregiver's willingness and ability to provide care and to check on the caregiver's availability and schedules.



## Care Planning, Coordination of Services, and Quality of Care (484.60)

CMS has revised the pre-existing CoP regulations concerning the plan-of-care set forth at section 484.18, "Acceptance of patients, plan-of-care, and medical supervision" and the current section 484.14(g), "Coordination of patient services," by creating a new condition of participation, "Care planning, coordination of services, and quality of care" in section 484.60.

### *Plan-of-Care*

The new section 484.60 specifies that the HHA will have to provide the patient an "individualized" written plan-of-care that would include the care and services necessary to meet the patient-specific needs identified in the comprehensive assessment, and the outcomes that the HHA anticipates would occur as a result of developing the individualized plan-of-care and subsequently implementing its elements.

This seems to conflict with the comments section on patients' rights where CMS states that it has removed the requirement that each patient routinely be given a copy of the plan-of-care. HCA will seek clarification from CMS.

CMS believes that "an evidence and outcome-based approach to patient care that can be understood by the patient and caregivers, with specificity of orders and adherence to best practice interventions, would provide a basis for the development of the optimal plan-of-care and goals."

Some additional parts that must comprise the plan-of-care will include: patient and caregiver education and training to facilitate timely discharge; patient-specific interventions and education, measurable outcomes and goals identified by the HHA and patient; and information related to any advance directives.

With regard to patients and caregivers receiving education and training, this includes written instructions outlining medication schedule/instructions, visit schedule and any other pertinent instruction related to the patient's care and treatments that the HHA will provide, specific to the patient's care needs.

If HHA services are initiated following a patient's hospital discharge, the plan-of-care also must include a description of the patient's risk for emergency department visits and hospital re-admission; however, CMS removed the terms "low, medium, or high" that were in the proposed rule to describe the patient's risk.

CMS also affirms that a revised plan-of-care must reflect current information from the patient's updated comprehensive assessment, and contain information concerning the patient's progress toward the measurable outcomes and goals identified by the HHA and patient in the plan-of-care.

Furthermore, CMS finalized a provision making it the HHA's responsibility to notify the patient, representative (if any), caregivers, and the physician who is responsible for the HHAs plan-of-care when the individualized plan-of-care is updated due to a significant change in the patient's health status.

### *Compliance with Physician's Verbal Orders*

CMS is retaining the current requirement that only personnel authorized by applicable state laws, regulations and the HHA's internal policies may accept verbal orders from physicians.

When services are provided on the basis of a physician's verbal orders, a nurse acting in accordance with state licensure requirements, or other qualified practitioner responsible for furnishing or supervising the ordered services, in accordance with state law and the HHA's policies, must document the orders in the patient's clinical record, and sign, date, and **time** the orders. Verbal orders must be authenticated and dated by the physician in accordance with applicable state laws and regulations, as well as the HHA's internal policies.

CMS affirms in the final rule it has revised this section of the CoPs to permit any nurse acting in accordance with state licensure requirements to receive verbal orders from a physician.

CMS has also revised this section of the rule to permit drugs, services and treatment to be ordered by **any** physician, not just the one responsible for the patient's plan-of-care.

### *Review and Revisions of the Plan-of-Care*

CMS affirms in the final rule that the individualized plan-of-care must be reviewed and revised by the physician who is responsible for the home health plan-of-care and the HHA as frequently as the patient's condition or needs require, but no less frequently than once every 60 days, beginning with the start-of-care date.

The HHA must promptly alert the relevant physician(s) to any changes in the patient's condition or needs that suggest that outcomes are not being achieved and/or that the plan-of-care should be altered.

Furthermore, this section of the CoPs states that any revision to the plan-of-care, due to a change in patient health status, must be communicated to the patient, representative (if any), caregiver, and all physicians issuing orders for the HHA plan-of-care. Also, any revisions related to plans for the patient's discharge must be communicated to the patient, representative, caregiver, all physicians issuing orders for the HHA plan-of-care, and the patient's primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any).

### *Coordination of Care*

In section 484.60(d), "Coordination of care," HHAs would be required to do the following:

1. Assure communication with all physicians involved in the plan-of-care.
2. Integrate orders from all physicians involved in the plan-of-care to assure the coordination of all services and interventions provided to the patient.
3. Integrate services, whether services are provided directly or under arrangement, to assure the identification of patient needs and factors that could affect patient safety and treatment effectiveness and the coordination of care provided by all disciplines.
4. Coordinate care delivery to meet the patient's needs, and involve the patient, representative (if any), and caregiver(s), as appropriate, in the coordination of care activities.
5. Ensure that each patient, and his or her caregiver(s) where applicable, receive ongoing education and training provided by the HHA, as appropriate, regarding the care and services identified in the plan-of-care. The HHA must provide training, as necessary, to ensure a timely discharge.

CMS added in the final rule (this was not in the proposed rule) that HHAs must assure communication with **all** physicians involved in the plan-of-care, and integrate orders from all physicians involved in the plan-of-care to assure the coordination of all services and interventions provided to the patient.

### ***Written Information to the Patient***

At section 484.60(e), CMS replaced what was in the proposed rule entitled “Discharge or transfer summary,” with a new sections entitled “Written information to the patient.” In this section, CMS states the HHA must provide the patient and caregiver with a copy of written instructions outlining:

1. Visit schedule, including frequency of visits by HHA personnel and personnel acting on behalf of the HHA;
2. Patient medication schedule/instructions, including: medication name, dosage and frequency and which medications will be administered by HHA personnel and personnel acting on behalf of the HHA;
3. Any treatments to be administered by HHA personnel and personnel acting on behalf of the HHA, including therapy services;
4. Any other pertinent instruction related to the patient’s care and treatments that the HHA will provide, specific to the patient’s care needs; and
5. Name and contact information of the HHA clinical manager.

### **Quality Assessment and Performance Improvement (QAPI) (484.65)**

CMS has replaced two pre-existing HHA CoPs – sections 484.16, “Group of professional personnel,” and 484.52, “Evaluation of the agency’s program” – with a single, new CoP, at section 484.65, called “Quality Assessment and Performance Improvement” (QAPI).

CMS believes that the pre-existing CoPs rely on a problem-oriented, external, after-the-fact (occurrence) approach to resolve patient care issues. The new and finalized QAPI CoPs in section 484.65 will require proactive performance monitoring through an effective, ongoing, agency-wide, data-driven QAPI program that is under the supervision of the HHA governing body.

Specifically, CMS states that HHAs must develop, implement, evaluate, and maintain an effective, ongoing, HHA-wide, data-driven QAPI program. The HHA’s governing body must ensure that the program: reflects the complexity of its organization and services; involves all HHA services (including those services provided under contract or arrangement); focuses on indicators related to improved outcomes, including the use of **emergent care services** (this was added to the final rule), hospital admissions and re-admissions; and takes actions that address the HHA’s medical errors. The HHA must maintain documentary evidence of its QAPI program and be able to demonstrate its operation to CMS and or state surveyors.

CMS has organized this new CoP into the following five standards:

1. **Program Scope:** The data-driven QAPI program should be capable of showing measurable improvement in indicators for which there was evidence that the improvement led to improved health outcomes (i.e. reduced hospitalizations and readmissions), safety, and quality-of-care for patients. The HHA will also have to

measure, analyze, and track quality indicators, including adverse patient events, as well as other indicators of performance so that the agency can adequately assess its processes, services, and operations.

2. **Program Data:** The HHA's QAPI program should utilize quality indicator data, including measures derived from the OASIS C2 (CMS-provided reports), where applicable, and other relevant data, to monitor the effectiveness and safety of services and the quality of care provided to patients, and identify and prioritize opportunities for improvement. This second standard requires the HHA to track its performance to assure that improvements are sustained over time.
3. **Program Activities:** The HHA's QAPI program activities must focus on high-risk, high-volume, or problem-prone areas of service, and consider the incidence, prevalence, and severity of problems in those areas. CMS states that the HHA must immediately correct any identified problems that directly or potentially threaten the health and safety of patients. Additionally, the HHA's QAPI activities should track incidents and adverse patient events, as well as analyze those events, so that preventive actions and mechanisms can be implemented by the HHA.
4. **Performance Improvement Projects:** Beginning **January 13, 2018**, HHAs must conduct performance improvement projects. The number and scope of distinct improvement projects conducted annually must reflect the scope, complexity, and past performance of the HHA's services and operations. The HHA must also document the quality improvement projects undertaken, the reasons for conducting these projects, and the measurable progress achieved on these projects.

In the final rule, CMS's responds to all of the comments that were submitted to the proposed rule and in this specific area CMS states that it agrees that a phased-in implementation timeframe is appropriate for the requirement that HHAs conduct performance improvement projects because it will take additional time to collect the data necessary to identify areas that are appropriate for performance improvement. CMS has added a phase-in to allow HHAs the time necessary to collect data prior to implementing performance improvement projects. This allows for a full 12-month time period between the time that this final rule is published and the time that HHAs must begin conducting performance improvement projects. All other QAPI requirements are expected to be implemented within the standard time frame for implementation of the CoPs as a whole (by July 13, 2017).

5. **Executive Responsibilities:** The HHA's governing body must assume responsibility for the agency's QAPI program. The governing body is required to define, implement, and maintain a program for quality improvement and patient safety that is ongoing and agency-wide.

Unfortunately, in this final rule CMS did not outline the structures and methods for implementing the performance improvement projects requirement as HCA requested in our comments to CMS. Instead, CMS has focused this section of the CoPs toward the expected results of the program. While CMS believes this provides flexibility to the HHA, as it is free to develop a creative program that meets the HHA's needs and reflects the scope of its services, HCA has expressed concerns that CMS may retrospectively set some minimum standards for the new QAPI program and cite agencies that don't meet them. Lastly, CMS believes that the standards of this proposal should be such that small and mid-size HHAs are able to effectively implement this CoP as easily as larger HHAs – another area that HCA expressed concern about in our comments.

## **Infection Prevention and Control (484.70)**

The pre-existing HHA CoPs have no requirement for an HHA-wide infection-control program; however, the regulation at section 484.12(c) states that the HHA and its staff must comply with accepted professional standards and principles that apply to professionals furnishing services in an HHA.

Infection-control practices are part of accepted professional standards and principles, and thus should not be new to HHAs.

In this final rule, CMS has established a new CoP at section 484.70, "Infection prevention and control," because CMS believes that it is appropriate to address this important issue as a distinct part of the regulatory process.

Section 484.70 will require a HHA to maintain and document an infection-control program with the goal of preventing and controlling infections and communicable diseases. Specifically, section 484.70(b) states that the HHA must maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases as an integral part of the HHA's QAPI program. The infection control program must include: (1) a method for identifying infectious and communicable disease problems; and (2) a plan for action to result in improvement and disease prevention.

Section 484.70(c) also requires that each HHA provide infection-control education to staff, patients, and caregivers.

CMS has organized this new CoP under the following three standards: (1) prevention; (2) control; and (3) education.

## **Skilled Professional Services (484.75)**

In the final rule, CMS has consolidated the pre-existing CoP provisions governing skilled nursing services at section 484.30, therapy services at section 484.32, and medical social services at section 484.34, under one new CoP, section 484.75.

CMS has organized this new CoP into the following three areas: (1) provision of services by skilled professionals; (2) responsibilities of skilled professionals; and (3) supervision of skilled professional assistants.

Rather than having separate CoPs for each discipline, CMS now has a single CoP, which broadly describes the expectations for all skilled professionals who participate in the interdisciplinary approach to home health care delivery.

Section 484.75 requires skilled professionals to participate in all aspects of care when providing services to HHA patients. This includes, but is not limited to: participation in the ongoing patient assessment process; development and maintenance of the interdisciplinary plan-of-care; patient, caregiver, and family counseling; patient and caregiver education; and communication with other health care providers. Section 484.75 will also require skilled professionals to be actively involved in the HHA's QAPI program and participate in HHA in-service trainings. Furthermore, section 484.75 requires services being provided by skilled professional assistants to be supervised by the appropriate professional (eg., nurse, therapist, or social worker).

CMS made one revision in this section of the rule (from the proposed rule) which requires skilled professional to communicate with all physicians involved in the patient's plan-of-care.

## Home Health Aide Services (484.80)

Section 1891(a)(3)(D) of the SSA requires the Secretary to establish minimum standards for home health aide training and competency evaluation programs. Section 1861(m)(4) of the SSA requires Medicare-covered home health aide services to be furnished only by individuals who have successfully completed a training program approved by the Secretary.

In this final rule, CMS has retained the pre-existing requirements while making clarifying and organizational changes, as suggested in the proposed rule. CMS addresses the retained and new requirements for home health aide services at section 484.80. The home health aide requirements are now organized as the following nine standards within this section, summarized below.

### *Home health aide qualifications*

Section 484.80(a)(1) states that a qualified home health aide is an individual who has successfully completed **one** of the following: (1) a training and competency evaluation program that meets the requirements described in section 484.80(b) and section 484.80(c); *or* (2) a competency evaluation program that meets the requirements described in section 484.80(c); *or* (3) a nurse aide training and competency evaluation program that is approved by the state as meeting the requirements of section 483.151 through section 483.154 (state review and approval of nurse aide training and competency evaluation programs) and is currently listed in good standing on the state nurse aide registry; *or* (4) a state licensure program that meets the requirements described in sections 484.80(b) and 484.80(c).

Under section 484.80(a)(2), CMS specifies that a home health aide or nurse aide is not considered to have completed a program if there has been a 24-month or greater lapse in furnishing services for compensation. In such a case, the aide would need to complete another training program before the home health aide can provide services, as specified in section 484.80(a)(1).

### *Content and duration of home health aide classroom and supervised practical training*

Section 484.80(b) sets forth the requirements for training content, duration, training methods, and documentation for home health aides.

CMS clarified the pre-existing requirement that home health aide training address “communication skills.” The clarification seeks to be more specific. Now, at section 484.80(b)(3)(i), CMS requires that training programs address “Communication skills, including the ability to read, write, and verbally report clinical information to patients, representatives, and caregivers, as well as to other HHA staff.”

An additional change to this section relates to a new skill requirement. CMS now requires, at section 484.80(b)(3)(ix)(xiii), that home health aide training programs address, as an appropriate and safe technique in performing personal hygiene and grooming tasks, “recognizing and reporting changes in skin condition.” This is a slight deviation from the proposed rule, which would have also required home health aides to recognize and report changes in pressure ulcers – a provision which is outside the home health aide’s normal scope of practice and was subsequently removed.

### *Competency evaluation*

In the pre-existing CoPs, the provisions regarding in-service training and competency evaluations of home health aides were combined. CMS believes that these requirements should be separated into two standards in order to emphasize their importance: competency evaluation now at section 484.80(c), and in-service training at section 484.80(d).

In section 484.80(c)(3), CMS maintains the current requirement that an RN must perform the competency evaluation. In addition to the RN, CMS is now requiring that the competency evaluation be done in consultation with other skilled professionals, as appropriate.

Further, as specified in section 484.80(c)(4), if a home health aide is going to perform a task for which he or she was rated “unsatisfactory,” the task must be performed under the supervision of a registered nurse until the aide achieves an evaluation of “satisfactory.” This is consistent with the proposed rule, and a new change. In the pre-existing CoPs, this supervision was able to be provided by a licensed practical nurse (LPN) or RN.

### *In-service training*

CMS retained 12 as the minimum number of hours of in-service training required for a 12-month period. The training can occur while an aide is furnishing care to a patient.

CMS also kept the requirements in its proposed rule that aide in-service training can be offered by any organization, and that the training is must be supervised by an RN.

### *Qualifications for instructors conducting classroom and supervised practical training*

This standard was retained from the previous CoPs by CMS.

### *Eligible training and competency evaluation organizations*

This standard was retained from the previous CoPs by CMS.

### *Home health aide assignments and duties*

At section 484.80(g)(4), CMS now requires that home health aides be members of the interdisciplinary team, report changes in the patient’s condition to an RN or other appropriate skilled professional (regarding clinical observations within the home health aide’s scope), and must complete appropriate records in compliance with the HHA’s policies and procedures.

### *Supervision of home health aides*

Section 484.80(h) now differentiates the aide supervision requirements based on the skill level of the care required by the patient.

To that end, section 484.80(h)(1) requires that if a patient is receiving skilled care, the home health aide supervisor (RN or therapist) must make an onsite visit to the patient’s home no less frequently than every 14 days. The home health aide does **not** have to be present during this visit. If an area of concern in home health aide service is noted

by the home health aide supervisor, then the supervisor must make an on-site visit to the location where the patient is receiving care in order to observe and assess the home health aide's provision of care. This differs slightly from the language in the proposed rule, changing "potential deficiency" to "area of concern."

In addition to the regularly scheduled 14-day supervision visits and the as-needed observation visits, HHAs are required to make an annual on-site visit to a patient's home to observe and assess each home health aide while he or she is performing patient-care activities. The HHA must observe each home health aide with at least one patient, and may increase the number of home health aide-patient interaction observations as necessary to assure a full assessment of the aide's patient-care knowledge and skills.

In section 484.80(h)(2), CMS requires that if home health aide services are provided to a patient who is **not** receiving skilled care, the RN must make an on-site visit to the location where the patient is receiving care no less frequently than every 60 days in order to observe and assess each home health aide while he or she is performing care. If an area of concern in home health aide service is noted by the home health aide supervisor, then the supervisor must make an on-site visit to the location where the patient is receiving care in order to observe and assess the home health aide's provision of care.

Section 484.80(h)(4) is new and stipulates that aide supervision must ensure that aides deliver care in a safe and effective manner, including, but not limited to the following elements: following the patient's plan-of-care for completion of tasks assigned to a home health aide by the RN or other appropriate skilled professional; maintaining an open communication process with the patients, representative (if any), caregivers, and family; demonstrating competency with assigned tasks; complying with infection prevention and control policies and procedures; reporting changes in the patient's condition; and honoring patients' rights. All elements must be accounted for during every supervisory visit.

#### *Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit*

Section 484.80(i) applies to individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit. CMS retained the requirements from the pre-existing CoPs but made some clarifying revisions. Under this provision, a Medicare-certified HHA that provides personal care aide services to Medicaid patients under a State Medicaid personal care benefit is required to determine and ensure the competency of individual aides for those Medicaid-approved services performed. The aide only needs to demonstrate competency in the services the individual is required to furnish.

### **Compliance with Federal, State, and Local laws and Regulations related to Health and Safety of Patients (484.100)**

CMS has retained, with minor changes, most of the provisions concerning compliance with federal, state, and local laws that are contained in the pre-existing CoPs. This particular CoP will now be located at section 484.100.

This CoP is divided into the following standards summarized below.

#### *Disclosure of ownership and management information*

The HHA must comply with the requirements of 420(C), and also must disclose the following information:

- Names and addresses of all persons with an ownership or controlling interest



- Name and address of each officer, director, agent, or managing employee
- Name and address of the entity responsible for the management of the HHA
- Names and addresses of the CEO and chairperson of the board of that entity

Section 1126(b) stipulates that the term “**managing employee**” means an individual, including a general manager, business manager, administrator, or director, who exercises operational or managerial control over the entity, or who directly or indirectly conducts the day-to-day operations of the entity. Accordingly, for purposes of this rule, “**director**” refers to a corporate director and not a medical director or nursing director. Section 420.201 defines an “agent” as any person who has been delegated the authority to obligate or act on behalf of a provider.

In this rule, CMS defines an “**officer**” to be any person who is responsible for the overall management of the operation of the HHA; CMS requires that the HHA provide information on all individuals who are officers of the HHA under the law of the state in which the HHA is incorporated. Because the business address of an agency is self-explanatory, the additional address that CMS requests in the standard refers to a residential address for all individuals to whom the rule applies. A Post Office Box address is **not** considered a business or residential address and would **not** be satisfactory for purposes of compliance with this requirement.

### *Licensing*

The HHA, its branches, and all persons furnishing services to patients must be licensed, certified, or registered, as applicable, in accordance with the state licensing authority as meeting those requirements.

### *Laboratory services*

Section 484.100(c)(1) is new and relates to HHAs engaged in certain types of lab testing, with appliances that have been approved for such purposes by the Food and Drug Administration. Such testing must be in compliance with all applicable requirements of part 493. Additionally, this section prohibits HHAs from substituting their own self-administered testing equipment, such as glucometers, in lieu of a patient’s self-administered testing equipment when assisting a patient in administering the test.

However, as stated in the preamble to the proposed rule, “Agencies may also use their own self-administered testing equipment, such as in the days immediately following physician orders to obtain the testing equipment, when a patient may not have the time and resources immediately available to complete the process.” CMS expects the HHA to use available resources to assist the patient in obtaining his or her own testing equipment as quickly as possible.

Section 484.100(c)(2) requires that if the HHA refers specimens for laboratory testing, the referral laboratory has to be certified in accordance with the applicable requirements of part 493. The laboratory services standard is a federal requirement in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

## **Emergency Preparedness (484.102)**

This is a new Condition of Participation, based on the Emergency Preparedness (EP) federal rule issued by CMS in November 2016 for all sectors, and effective November 2017. HCA has contacted CMS to gain clarity on the true effective date of these Emergency Preparedness CoPs, considering the new CoPs are effective in July 2017, two months before the EP federal rule is scheduled to take effect. We will notify the membership when we learn more.

This CoP requires the HHA to comply with all applicable federal, state, and local emergency preparedness requirements, and establish and maintain an emergency preparedness program that meets the requirements of this section. This includes the following elements summarized below:

### *Emergency plan*

The HHA must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. The plan must: be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach; include strategies for addressing emergency events identified by the risk assessment; address patient population, the type of services the HHA could provide in an emergency, continuity of operations and delegations of authority and succession plans and more; include a process for cooperation and collaboration with all levels of emergency preparedness officials' efforts to maintain an integrated response, including documentation of HHA's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

### *Policies and procedures*

The HHA must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in section (a), the risk assessment in section (a)(1), and the communication plan in section (c). At a minimum, the policies and procedures must meet address:

- 1) Individual plans for each of the HHA's patients during a disaster, to be included as part of the comprehensive patient assessment.
- 2) The procedures to inform state and local emergency preparedness officials about HHA patients in need of evacuation from residences due to an emergency situation based on the patient's medical and psychiatric condition and home environment.
- 3) The procedures to follow up with on-duty staff and patients to determine services that are needed in the event that there is an interruption in services during or due to an emergency. The HHA must inform state and local officials of any on-duty staff or patients that they cannot contact.
- 4) A system of medical documentation that preserves patient information, protects confidentiality, and secures and maintains the availability of records.
- 5) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration or state of federally designated health care professionals to address surge needs during an emergency.

### *Communication plan*

The HHA must develop and maintain an emergency preparedness communication plan that complies with federal, state and local laws and must be reviewed and updated at least annually. The plan must include:

- 1) Names and contact information for staff, entities providing services under arrangement, patients' physicians, volunteers

- 2) Contact information for federal, state, tribal, regional, or local emergency preparedness staff, other sources of assistance.
- 3) Primary and alternate means for communicating with the HHA's staff, federal, state, tribal, regional, and local emergency management agencies.
- 4) A method for sharing information and medical documentation for patients under the HHA's care, as necessary, with other health care providers to maintain the continuity of care.
- 5) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).
- 6) A means of providing information about the HHA's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

### *Training and testing*

The HHA must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.

- **Training program:** The HHA must do all of the following: (i) conduct initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles; (ii) provide emergency preparedness training at least **annually**; (iii) maintain documentation of the training; and (iv) demonstrate staff knowledge of emergency procedures.
- **Testing:** The HHA must conduct exercises to test the emergency plan at least **annually**. The HHA must participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based exercise. If the HHA experiences an actual natural or man-made emergency that requires activation of the emergency plan, the HHA is exempt from engaging in a community-based or individual, facility-based full-scale exercise for one year following the onset of the actual event. The HHA must also conduct an additional exercise that may include, but is not limited to the following: (1) a second full-scale exercise that is community-based or individual, facility-based; (2) a tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan; (3) analyze the HHA's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the HHA's emergency plan, as needed.
- **Integrate health care systems:** If an HHA is part of a healthcare system consisting of multiple separately certified health care facilities that elects to have a unified and integrated emergency preparedness program, the HHA may choose to participate in the health care system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following: (a) demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program; (b) be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances,

patient populations, and services offered; (c) demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program; and (d) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section.

The unified and integrated emergency plan must also be based on and include all of the following: (i) documented community-based risk assessment, utilizing an all-hazards approach; (ii) documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach; and (iii) integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, as well as a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

## **Organization and Administration of Services (484.105)**

This CoP on organization and administration of services revises the previous regulations at section 484.14, and is now located at 484.105.

Section 484.105 designates the requirements of HHAs related to organization, management, and administration of resources, and highlights that the HHA must assure that these administrative and supervisory functions are not delegated to any other agency or organization, and all services that are not directly furnished must be monitored and controlled. CMS notes that the goal of these revisions is to consolidate those areas that receive the most frequent deficiency citations under the direct responsibility and authority of HHA management. Organizational structure, lines of authority, and services provided must be in writing. The specific standards of this section are summarized below.

### ***Governing Body***

The HHA must establish a governing body to assume full legal authority and responsibility for the agency's overall management and operation, the provision of all home health services, fiscal operations, review of the agency's budget and operations plans, and its quality assessment and performance improvement program. This governing body can be comprised of members of the HHA's own choosing, and these members may be (but are not required to be) individuals from the previously-required Professional Advisory Committee.

### ***Administrator***

Section 484.105(b), "Administrator," describes the role and also provisions for when the administrator is not available. CMS requires that the administrator be appointed by and report to the governing body, be responsible for all day-to-day operations of the HHA, and be responsible for ensuring that a clinical manager is available during all operating hours. [See section (c) on the next page for the definition of "clinical manager" (as opposed to the previous requirement of "skilled professional".)] The HHA must employ qualified personnel, including assuring the development of personnel qualifications and policies.

CMS also specifies that, at any time when the administrator is not available, a qualified pre-designated person, who is authorized in writing by the administrator and governing body, assumes the same responsibilities and obligations as the administrator, including the responsibility to be available during all operating hours. This pre-designated person may be the clinical manager, if the HHA so chooses, though this is not a requirement. The HHA may also pre-designate multiple individuals, so long as that is set forth in the HHA's policies and procedures.

The administrator is expected to be actively involved in daily responsibilities of running the HHA and its operations, as well as available to patients, representatives, and caregivers to receive complaints. The administrator should not be managing problems on the clinical level or conducting staff evaluations.

### *Clinical manager*

This new requirement specifies that HHAs designate a clinical manager, which can be one or more individuals who will provide oversight of all patient-care services and personnel, including: making patient and personnel assignments, coordinating patient care, coordinating referrals, assuring that patient needs are continually assessed, and assuring the development, implementation, and updates of the individualized plan-of-care. A clinical manager must be a licensed physician, physical therapist, speech-language pathologist, occupational therapist, audiologist, social worker, or a registered nurse (including a nurse practitioner or other advanced practice nurse). As mentioned in section (b) on the previous page, the clinical manager must be available during all operating hours.

CMS notes that skilled professionals may have the qualifications to fill this role. HHAs are responsible for assuring that any skilled professional filling this role has the necessary clinical, managerial, and communication skills needed to successfully fulfill his or her responsibilities as a clinical manager. The clinical manager qualification requirements are located in section 484.115.

The new clinical manager position is essential for managing the complex, interdisciplinary care of home health patients. According to CMS, six of the 20 most frequently cited survey deficiencies center on the need for patient care coordination and implementation, including the most frequently cited deficiency related to ensuring that each patient has a written and updated plan-of-care. "These frequent deficiency citations indicate that patient care is not being sufficiently planned, coordinated, and implemented to ensure the highest quality care for all HHA patients at all times," CMS states.

### *Parent-branch relationship*

In section 484.105(d), CMS sets forth a new standard, parent-branch relationship, as the former subunit organizational structure is removed. (See "Definitions" section on page 4.) Under this new structure, the parent HHA is responsible for reporting all branch locations of the HHA to the state survey agency at the time of the HHA's request for initial certification, at each survey, and at the time the parent proposes to add or delete a branch. Additionally, the parent HHA provides direct support and administrative control of its branches.

CMS says that, as it stands, subunits are already considered the equivalent of stand-alone HHAs and will be able to continue functioning as such under the revised CoPs. In other words, a current subunit may choose to be a distinct HHA (a parent) or go through the current approval process to become a branch, and guidance for this is provided in section 2182.3 of the State Operations Manual. CMS plans to issue a Survey and Certification letter to the states that will explain this change in terminology and revise the guidance accordingly.

CMS defines a branch office as a location or site from which an HHA provides services within a portion of the total geographic area served by the parent agency.

### *Services under arrangement*

Section 1861(w) of the Act [42 U.S.C. 1395x (w)] details the requirements for HHAs that furnish services under arrangement provided by other entities or individuals. CMS now requires that the HHA have a written agreement with another agency, with an organization, or with an individual when it has contracted with that entity or individual to provide services to its patients. Also, the primary HHA is responsible for patient care, and must conduct and provide, either directly or under arrangements, all services rendered to patients.

The entity or individual providing services under arrangement may not have: been denied Medicare enrollment; been excluded or terminated from any federal health care program or Medicaid; had its Medicare or Medicaid billing privileges revoked; or been debarred from participating in any government program.

### *Services furnished*

As stated in section 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 of these services is required to be provided directly by the HHA, but the second and additional services may be provided under arrangement. This is consistent with the pre-existing CoP requirement.

Additionally, CMS requires all services must be provided in accordance with current clinical practice guidelines and accepted professional standards of practice.

### *Outpatient physical therapy and speech-language pathology services*

This regulation has not changed, and has simply been relocated to this new section 484.105(g).

### *Institutional planning*

This regulation has not changed, and has simply been relocated to this new section 484.105(h).

## **Clinical Records (484.110)**

CMS has retained many of the long-standing clinical record requirements, while making some additional clarifications. The primary requirement under the revised clinical records CoP is that a clinical record containing pertinent past and current relevant information must be maintained for every patient who is accepted by the HHA to receive home health services. CMS has added the requirement that the information contained in the clinical record needs to be accurate, adhere to current clinical record documentation standards of practice, and be available to the physician(s) issuing the orders and appropriate HHA staff. The information can be maintained electronically.

### *Contents of clinical record (some of the following are new or modified requirements);*

1. Patient's current comprehensive assessment (and all assessments related to this admission), clinical notes, plans-of-care, and physician orders;
2. All interventions;

3. Goals and patient progress toward achieving them;
4. Contact information for the patient, the patient's representative (if any), and the patient's primary caregiver(s);
5. Contact information for the primary care practitioner or other health care professional responsible for post-HHA discharge care;
6. One of the following:
  - Completed discharge summary that is sent to the individual identified in item (5) within **five business days** of the patient's discharge; or
  - Completed transfer summary sent within **two business days** of a planned transfer, if the patient's care will be immediately continued in a health care facility; or
  - Completed transfer summary sent within **two business days** of becoming aware of an unplanned transfer if the patient is still receiving care in a health care facility at the time when the HHA becomes aware of the transfer

### *Authentication*

This is a new standard and requires that all entries in the record be legible, clear, complete, and appropriately authenticated, dated, and timed. CMS has clarified that "timed" means the actual time that an event occurred, which is not necessarily the time that it was documented in the record.

Authentication must include a signature and title (occupation), or a secured computer entry by a unique identifier, of a primary author who has reviewed and approved the entry.

### *Record Retention*

Pre-existing CoP language required that records be retained for five years "after the month the cost report to which the records apply is filed with the intermediary, unless state law stipulates a longer period of time." CMS now requires in the revised CoP that clinical records be retained for five years after the discharge of the patient, unless state law stipulates a longer period.

New York State regulations at Title 10 NYCRR Section 763.7 state that HHAs must maintain each patient's clinical records securely for not less than **six years** after discharge; in the case of minors, records are to be kept for not less than six years after discharge, or three years after they reach majority (18 years), whichever is the longer period.

CMS continues to require, in section 484.110(c)(2), that HHA policies provide for retention of records even if the HHA discontinues operations, but also requires that the HHA must notify the state agency as to where the agency's clinical records will be maintained.

## *Protection of records*

This section relates to the safeguarding of the clinical record and its contents against loss or unauthorized use and is consistent with pre-existing language. It requires that HHAs must be in compliance with the HIPAA Privacy and Security rules set forth in 45 CFR parts 160 and 164.

## *Retrieval of clinical records*

CMS now requires that a patient's clinical records (whether hard copy or electronic) be made readily available to a patient or appropriately authorized individuals or entities, free of charge, upon request at the next home visit or within four business days, whichever comes first.

## **Personnel Qualifications (484.115)**

While CMS has retained most of the pre-existing personnel qualifications, it has reorganized the section and added one new qualification and made several revisions.

Except as noted below, CMS has retained the pre-existing personnel qualifications for the following professions: administrator, audiologist, home health aide, licensed practical nurse, occupational therapist, occupational therapy assistant, physical therapist, physical therapist assistant, physician, registered nurse, social work assistant, and social worker.

CMS deleted the qualification category for "public health nurses" because public health nurses are RNs, and the qualifications for an RN are already included in this section. Additionally, "practical (vocational) nurses" are now referred to as "licensed practical (vocational) nurses," and the qualifications for a licensed practical (vocational) nurse would be a person who has completed a practical nursing program, and who furnishes services under the supervision of a qualified registered nurse.

### *Administrator*

CMS has expanded the qualifications for HHA administrators hired **after July 13, 2017** to include someone who is a licensed physician, registered nurse (including nurse practitioners and other advance practice nurses), or someone who has an undergraduate degree. Additionally, the administrator must have experience in health service administration, with at least one year of supervisory or administrative experience in home health care or a related health care program.

### *Speech-Language Pathologist*

CMS revised the personnel qualifications for speech-language pathologists (SLPs) so that a qualified SLP is an individual who has a master's or doctoral degree in speech-language pathology, and is either:

1. Licensed as a speech-language pathologist by the state in which he or she furnishes such services; or



2. In the case of an individual who furnishes services in a state which does not license speech-language pathologists:
  - Has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating supervised clinical experience);
  - Performed not less than nine 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
  - Successfully completed a national examination in speech-language pathology approved by the U.S. Secretary of Health and Human Services.

## **CMS's Estimated Cost Burden for Implementing New CoPs**

In its final rule, CMS estimates that, for HHAs nationwide, it will cost approximately \$293.3 million in Year 1 and \$290.1 million in Year 2 and thereafter to implement and comply with these new CoPs.

CMS estimates that this cost burden will be focused in the following four areas: (1) burden with information collection requirements; (2) updates to the patient rights sections; (3) implementing the new QAPI program; and (4) implementing the new infection prevention and control program.

In our detailed comments to CMS after the issuance of the proposed CoPs, HCA urged CMS to conduct a comprehensive reconsideration of the proposed rule to:

- Balance goals with agency feasibility and impact;
- Ensure commensurate adjustments in Medicare and Medicaid rates to home care agencies, as well as adjustments to Medicare and Medicaid managed care premiums for home care, to cover the cost of agency implementation; and
- Reconcile the jurisdictional and procedural conflicts between the proposed expanded standards and the rapid shift to the provision of Medicare and Medicaid home care through managed care.

Unfortunately, CMS has decided to implement these revised CoPs which will require HHAs to incur significant additional costs to their agencies without any compensatory adjustments to Medicare and Medicaid rates for home care services, including premium adjustments to Medicaid and Medicare managed care plans for home health agency services.

## **Next Steps**

As stated above, HCA will continue to analyze these revisions and their impact on HHAs in New York State. Additionally, we will advocate on your behalf to CMS and the state Department of Health (DOH) before, during, and after the CoPs take effect to ensure as smooth an implementation as possible and report back with concerns from members in the field.

Lastly, HCA is in the process of developing education opportunities for the membership related to these CoPs. Stay tuned for information about both webinar and in-person events in the coming weeks.

*For further information, contact HCA Policy staff.*

circumstance, we would require that a SLP has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating supervised clinical experience); 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 successfully completed a national examination in speech-language pathology approved by the Secretary.

**III. Home Health Crosswalk (Cross Reference of Former to New Requirements)**

The table below shows the relationship between the former sections to the new regulations.

Current CoPs	Revised CoPs
§ 484.1, Basis and scope .....	Revised at § 484.1
§ 484.2, Definitions .....	Revised at § 484.2
§ 484.4, Personnel qualifications .....	Revised at § 484.115
Home health aide qualifications .....	Revised at § 484.80
§ 484.10, Patient rights .....	§ 484.50, Patient rights
§ 484.10(a) .....	Revised at § 484.50(a)
§ 484.10(b) .....	Revised at §§ 484.50(b), (c), and (e)
§ 484.10(c) .....	Revised at § 484.50 (c)
§ 484.10(d) .....	Revised at § 484.50(c)
§ 484.10(e) .....	Revised at § 484.50(c)
§ 484.10(f) .....	Revised at § 484.50(c)
	New standard at § 484.50(d), Transfer and discharge.
	New standard at § 484.50(e), Investigation of complaints.
§ 484.11, Release of patient identifiable OASIS information .....	§ 484.40, Release of patient identifiable OASIS information.
§ 484.12, Compliance with Federal, State, and local laws, disclosure and ownership information, and accepted professional standards and principles.	§ 484.100, Compliance with Federal, State, and local laws and regulations related to the health and safety of patients.
§ 484.12(a) .....	Revised at § 484.100 and § 484.100(b)
§ 484.12(b) .....	Redesignated at § 484.100(a).
§ 484.12(c) .....	Revised at § 484.60, § 484.70, and § 484.105(f)
§ 484.14, Organization, services, and administration .....	§ 484.105, Organization and administration of services.
§ 484.14(a) .....	Revised at § 484.105(f).
§ 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)
§ 484.14(e) .....	Revised at § 484.75(b) and § 484.115.
§ 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).
§ 484.14(i) .....	Revised at § 484.105(h).
§ 484.14(j) .....	Revised at § 484.100(c).
§ 484.16, Group of professional personnel .....	Deleted, see § 484.65, Quality assessment and performance improvement (QAPI).
§ 484.18, Acceptance of patients, plan of care, and medical supervision.	§ 484.60, Care planning, coordination of services, and quality of care.
§ 484.18(a) .....	Revised at § 484.60(a).
§ 484.18(b) .....	Revised at § 484.60(c).
§ 484.18(c) .....	Revised at § 484.60(b).
	New standard at § 484.60(e), Written information to the patient.
§ 484.20, Reporting OASIS information .....	§ 484.45, Reporting OASIS information.
§ 484.30, Skilled nursing services .....	§ 484.75, Skilled professional services.
§ 484.32, Therapy services .....	§ 484.75, Skilled professional services.
§ 484.34, Medical social services .....	§ 484.75, Skilled professional services.
§ 484.36, Home health aide services .....	§ 484.80, Home health aide services.
§ 484.36(a)(1) .....	Revised at § 484.80(b).
§ 484.36(a)(2)(i) .....	Revised at § 484.80(f).
§ 484.36(a)(2)(ii) .....	Revised at § 484.80(e).
§ 484.36(a)(3) .....	Revised at § 484.80(b).
§ 484.36(b)(1) .....	Revised at § 484.80(c).
§ 484.36(b)(2)(i) .....	Revised at § 484.80(c).
§ 484.36(b)(2)(ii) .....	Revised at § 484.80(h).
§ 484.36(b)(2)(iii) .....	Revised at § 484.80(d).
§ 484.36(b)(3)(i) .....	Revised at § 484.80(c) and (d).
§ 484.36(b)(3)(ii) .....	Revised at § 484.80(c) and (d).
§ 484.36(b)(3)(iii) .....	Revised at § 484.80(c).
§ 484.36(b)(4) .....	Revised at § 484.80(c).
§ 484.36(b)(5) .....	Redesignated at § 484.80(c).
§ 484.36(b)(6) .....	Deleted.
§ 484.36(c) .....	Revised at § 484.80(g).
§ 484.36(d) .....	Revised at § 484.80(h).
§ 484.36(e) .....	Revised at § 484.80(i).
§ 484.38, Qualifying to furnish outpatient physical therapy or speech pathology services.	Revised at § 484.105(g).
§ 484.48, Clinical records .....	§ 484.110, Clinical records.
§ 484.48(a) .....	Revised at § 484.110(c).

Current CoPs	Revised CoPs
§ 484.48(b) .....	Revised at § 484.110(d). New standard at § 484.110(a), Contents of clinical record. New standard at § 484.110(b), Authentication. New standard at § 484.110(e), Retrieval of clinical records.
§ 484.52, Evaluation of the agency's program .....	Deleted, see § 484.65, Quality assessment and performance improvement and § 484.70, Infection prevention and control.
§ 484.55, Comprehensive assessment of patients .....	§ 484.55, Comprehensive assessment of patients.

**IV. Analysis of and Responses to Public Comments**

We received 199 letters of public comment from HHA industry associations, patient advocacy organizations, HHAs, and individuals. A summary of the major issues and our responses follow.

*Effective Date*

*Comment:* The vast majority of commenters made suggestions related to the effective date of the final rule. Commenters strongly expressed a need for a significant period of time to prepare for implementation of the new rules, noting that HHAs would need to adjust resource allocation, staffing, and potentially even infrastructure. Recommended implementation time frames ranged from 6 months to 5 years. The most frequent suggestion was to implement the final rule 1 year following its publication.

*Response:* We agree that it is appropriate to allow additional time to implement the final rule in order to allow HHAs adequate time to prepare for these changes. We believe that requiring HHAs to comply with the requirements of this rule on July 13, 2017 is sufficient to allow for appropriate HHA preparations to implement these changes. Therefore, we are finalizing an effective date of July 13, 2017.

*Definitions*

*Comment:* We received a few comments in support of the branch and parent office definition. One commenter strongly supported the change and emphasized with the automation age and web-based storage and access, the parent office can easily identify and investigate exceptions to standards of care for all patients and all employees, focusing administrative time on investigation, action and improvement. One commenter suggested CMS use the term of "Service Location" in lieu of "Branch Office." Several commenters asked that CMS clarify some concerns regarding the branch office definition. The commenters asked that CMS provide guidance on what constitutes an adequate level of supervision on a "daily basis." They specifically asked if

there is a certain amount or type of communication between the branch and parent offices. In addition, one commenter asked whether a survey citation for a violation in a branch office would apply to the entire HHA.

*Response:* We appreciate the public comments regarding this issue. We will continue to use the term "branch location" because it has been in use for more than a decade, and both HHAs and surveyors are accustomed to the term. To change the terminology without a pressing reason to do so would risk unnecessary and unwanted confusion among HHAs and surveyors. The concept of an adequate level of supervision on a daily basis is longstanding, and refers to the parent HHA's ability to demonstrate administrative control over each branch. We did not propose, nor are we finalizing, any specific requirements for communication because our primary concern relates to the evidence of control rather than the process for achieving it. As stated in the proposed rule, a violation that occurred in care and services being provided by a branch location would be considered a violation by the HHA as a whole. Therefore, it is essential for the parent to exercise adequate control, supervision, and guidance for all branches under its leadership.

*Comment:* We received several comments supporting the inclusion of the proposed definition of quality indicator. One commenter stated it is a much needed addition. Another commenter stated the addition of quality indicator as a definition would allow an HHA to take into account its patient population and unique characteristics while meeting the needs of the patients.

*Response:* We appreciate support from the public regarding this definition, and are finalizing it without change.

*Comment:* Several commenters submitted comments regarding the proposed definition of the term "representative." Commenters supported our goal of creating a patient-centered definition that acknowledges the importance of patient choice, patient involvement in his or her care, and the

role of family, friends, and caregivers. A commenter stated that this definition should facilitate more timely communication and cooperation between the HHA, patient, and representatives and family members. However, a few commenters expressed concern with the potential for confusion between legally designated representatives, such as a legal guardian, and patient-designated representatives. One commenter stated that HHAs may face questions of whom to listen to in situations where a patient has designated a representative who may not have legal status to make health care decisions. Another commenter stated that state laws regarding the rights and responsibilities of those with health care power of attorney can sometimes prevent an HHA from responding to communications and requests from a caregiver or loved one. The commenter suggested that the definition of "representative" should clearly acknowledge that legal limitations may exist that limit the HHA's ability to be responsive to communications and requests from patient-identified representatives at any given point in time. Recognition of this fact in the definition will assist agencies in managing those complex and conflicted situations that arise in the delivery of home health services. Similarly, another commenter suggested that the term "representative" be used only where the requirements include decision-making authority, while a different term, such as "caregiver" be used when the requirement is in relation to those individuals that provide support to the patient.

*Response:* We appreciate the broad-based support for this patient-centered definition of the term "representative." We acknowledge that patients may have several different representatives, each serving a different support and/or decision making role in the patient's life. Although conflicts between representatives who have legal authority and those who do not do have legal authority exist, we believe that these situations are relatively uncommon. The resolution of such conflicts would be dependent upon the exact scope of the legal representation. For example, an