



January 6, 2015

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3819-P
Box 8016
Baltimore, MD 21244-8016

Dear Sir/Madam:

The Home Care Association of New York State (HCA) appreciates the opportunity to provide comments on the current conditions of participation (CoPs) that home health agencies (HHAs) must meet in order to participate in Medicare and Medicaid.

HCA is a statewide association representing nearly 400 health care providers, organizations and individuals involved in the delivery of home care services to over 300,000 Medicare and Medicaid patients in New York State. HCA's members include Certified Home Health Agencies (CHHAs), Long Term Home Health Care Program (LTHHCP) providers, Licensed Home Care Services Agencies (LHCSAs), providers of various waiver programs, Managed Long Term Care plans, hospices and others. HCA's home care providers are sponsored by hospitals, nursing homes and free-standing nonprofit, public and proprietary agencies.

While we support efforts by the U.S. Centers for Medicare and Medicaid Services (CMS) to revise the CoPs to focus on a patient-centered, data-driven, outcome-oriented process that promotes high quality patient care, we have strong concerns that the proposed changes:

- 1) Not only add new and unfunded costs, but are being applied at the very same time that CMS is implementing some of the most dramatic cuts in home health via rebasing, while New York home health agencies have been subject to negative Medicare margins for 12 straight years;
- 2) Are 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;
- 3) While in many cases laudable, pose significant feasibility challenges and resource dislocation of agency staff, particularly given the fragile and already over-stretched status of many New York agencies.

HCA urges a comprehensive reconsideration of the proposed rule to: balance goals with agency feasibility and impact; to 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 to 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.

Cost Estimates

HHAs currently face major reductions in Medicare reimbursement, pressures to restructure their agencies due to health systems integration, continued unfunded mandates related to face-to-face

documentation and general compliance requirements, and other pressures. While CMS's goals with the CoP changes are well intentioned, we believe that CMS greatly underestimates the new practices and systems that HHAs will have to implement and their capacity to absorb those resultant costs.

We believe that CMS understates the costs attributable to these numerous new mandates in the proposed rule. These include expenses for: satisfying new multilingual communications requirements involving verbal notifications, language assistance services, auxiliary aids and written notices of patients' rights; the time needed to explain newly proposed rights; providing each patient an individualized plan of care that would include additional items; developing the discharge or transfer summary that includes many new details; an expanded quality assessment and performance improvement program; expanded training requirements and responsibilities for home health aides; a new annual on-site home health aide supervision visit by the nurse or other skilled professional; a new clinical manager position; new requirements for clinical records; and others.

Revisions to the CoPs which add to agency costs should not be implemented without 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.

Adequate Implementation Time

As described above, the proposed CoP changes are very comprehensive and necessitate HHAs to make major changes in their operations. HCA requests that CMS provide adequate time to develop and implement these practice changes and we recommend that the new CoPs not be made effective until January 1, 2016 or such later time as necessary to allow for provider readiness and feasibility, including the dissemination of training and guidance to HHAs, the development of internal compliance protocols, staff education, and other preparatory efforts.

Components of the Proposed CoPs

What follows are several major components of CMS's proposed home health CoPs that HCA has identified for detailed comment due to the significant impact of these proposals on HHAs. HCA provides some background summarizing key issues, and then offers recommendations or comments on ways that CMS can change the proposed requirements to achieve the intended goals in a more manageable manner.

Patient Rights (§484.50)

Background

CMS would require that the HHA provide the patient and patient's representative with verbal notice of the patient's rights in the primary or preferred language of the patient or representative, and in a manner that the individual can understand, during the initial evaluation visit, and in advance of care being furnished by the HHA. The verbal notice of patient rights is in addition to the current and continued requirement for a written copy of the patient rights information.

CMS would require the HHA to provide each patient with specific business contact information for the HHA's administrator so that patients and caregivers could report complaints and specific

patient rights violations to the HHA administrator, and so that patients and caregivers can ask questions about the care being provided.

CMS proposes 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, each patient would have the right in advance of care to participate in and be informed about the patient-specific comprehensive assessment, including an assessment of the patient’s goals and care preferences, expected outcomes, any factors that could impact treatment effectiveness, and of revisions to the plan of care during treatment. Patients would also have the right to receive all of the services outlined in the plan of care.

CMS proposes to mandate that all patients and representatives (if any) have the right to be informed of the HHA’s policies governing admission, transfer, and discharge.

Patients would have the additional rights to be: advised of the names, addresses and phone numbers of pertinent, federal, state and local consumer advocacy organizations.

Issues

HCA questions whether the new rights and provision of additional care information are needed and what value they will add to patient care. While HCA recognizes the importance of patients being informed of their rights in a language and manner that is understandable, we point out that this is another unfunded expense that HHAs must incur. We don’t think it is necessary for a separate verbal notice of patient rights to be provided and seek clarification on whether it will be permissible to review the written notice of patient rights to meet this requirement.

While we support patients being informed about their treatment, some of the requirements – such as discussing with the patient factors that could impact treatment effectiveness – are not a reasonable expectation in all cases. Providing patients with revised plans of care is logistically impractical and financially burdensome in an environment where the care planning process is dynamic and requires flexibility.

We seek clarification on whether notification of the agency’s admission, transfer and discharge policy can be done verbally and we support such an option. In addition, we note that there may be additional reasons – beyond those outlined in the proposed regulations – for a patient transfer or discharge, such as an unsafe home environment, a physician’s refusal to sign the plan of care, and a lack of compliance with agreed upon care plan. Thus we request that the regulations include a reference to “other acceptable reasons” for transfer or discharge and not limit the reasons to behavior that is “disruptive, abusive or uncooperative.”

In addition, we seek clarification on the list of government and consumer organizations that must be given to patients. It would be helpful for HHAs to know how extensive the list must be and how often it must be updated since entities and their contact information change frequently.

Recommendations

HCA recommends that a separate verbal notification of a patient’s rights not be required and that agencies be allowed to review the written patient rights document with patients and family members to inform them of their rights. As mentioned above, we support eliminating some of the treatment discussion items that CMS would require, including the discussion of anticipated risks

and benefits and factors that could impact treatment effectiveness. These may not be relevant to a patient's care and should not be specifically listed in the regulations.

In addition, we support that HHAs be allowed to verbally inform their patients about the HHA's policies for admission, transfer and discharge.

Also, HHAs should be permitted to transfer or discharge a patient for any reason related to cause that affects the agency's ability to provide adequate care and/or threatens the safety of the staff. The agency would still be required to comply with sections i-iv of the standard. That section ensures that the agency has made every effort to resolve the problem, provide information on other resources for care, and notify the patient and representative and all health care professionals responsible for the patient's care of the anticipated transfer or discharge.

Lastly, we recommend that agencies should have the flexibility to determine, based on the patient population, which organizations are appropriate to be included under the requirement related to a list of government and consumer organizations.

Comprehensive Assessment of Patients (§484.55)

Background

CMS proposes some new requirements for the comprehensive assessment by a registered nurse that include an assessment of the patient's: psychosocial and cognitive status; strengths, goals, and care preferences, including the patient's progress toward achievement of the goals identified by the patient and the measurable outcomes identified by the HHA; primary caregiver(s), if any, and other available supports; and the patient's representative. CMS also outlines when the comprehensive assessment must be updated.

Another provision would change 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.

Issues

CMS maintains the requirement for the registered nurse to conduct the initial and comprehensive assessment, except in therapy only cases. However, this seems contrary to CMS's overarching goal of promoting an integrated model of care delivery, as evidenced throughout the proposed rule.

HCA requests clarification on the criteria HHAs should use to determine when a change in the patient's condition warrants an update to the comprehensive assessment. In addition, HCA seeks clarification on what is meant by "data items collected at inpatient facility admission or discharge only" under OASIS items [section (c)(8)].

Recommendations

CMS should allow either the registered nurse or the therapist to conduct the initial and comprehensive assessment when both disciplines are ordered at the initiation of care.

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

Background

Under this section, CMS specifies that:

- HHAs would have to provide patients with an individualized plan of care and revises what is included in the plan of care;
- HHA would be responsible to notify the patient, representative (if any), caregivers, and the physician who is responsible for the HHA plan of care, when the individualized plan of care is updated due to a significant change in the patient's health status;
- Revised plans 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;
- Verbal orders would have to be authenticated, dated and timed by the physician;
- HHAs would have to notify patients and doctors of updates to the patient's discharge;
- HHAs would be required to 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, the coordination of care provided by all disciplines, and communication with the physician; and
- HHAs would have to compile a discharge or transfer summary for each discharged or transferred patient.

Issues

It is not clear if patients must be given a written plan of care and any revisions to the plan of care under this new requirement. HCA would not support such a requirement as it would be cumbersome and time consuming to produce, especially when there is a change in the plan of care, and would be duplicative of information already discussed with the patient during the assessment process. This requirement will be in addition to the requirement that agencies provide a written notice when services are to be reduced or terminated, and prior to discharge. The interference of these multiple, overlapping or duplicative written notices can be overwhelming to patients, losing its intended purpose of keeping the patient informed.

The requirement that a revised plan of care must reflect current information from the patient's updated comprehensive assessment is contrary to current practice since, in many cases, a new assessment is not needed when there is a revised plan of care, and this would be a tremendous burden on HHAs and their patients.

Requiring that verbal orders be timed is very problematic as it would add another obstacle to the process of obtaining signed physician orders which already requires extensive staff resources. We question the relevance or usefulness of stamping the exact time when orders are signed and advocate that the date of the verbal order should be sufficient.

CMS's proposal that agencies develop a discharge or transfer summary for each patient and provide it to post-discharge providers will be very costly in terms of staff time and resources and duplicative of some information already in a patient's record.

The standard requires that the agency provide a summary which contains very prescriptive elements. These go beyond what would typically be included in, or needed, for an effective discharge or transfer summary. To require that the agency include the amount of information as proposed on a summary report, whether at discharge or transfer, creates an unnecessary burden for the agency. In addition, not all the information proposed for the summary report may be needed for every patient in order to facilitate an effective transfer of care. However, if any element is missing (be it necessary or not), this omission could be the basis for a deficiency citation that may have no bearing on the quality of care.

It is unclear whether CMS proposes to require a summary report be provided whenever a patient is transferred from the agency to an inpatient setting, including transfers where the patient will not be discharged from the agency.

Also, it is not clear if the summary report must also be provided to the patient and/or the patient's current providers, and this needs to be clarified.

Recommendations

CMS should provide funding to HHAs so that they can develop the computer and related systems needed to share data with physicians, hospitals and other providers. Such financial assistance is necessary for HHAs to ensure robust care planning, care coordination and quality care. While such funding has been provided to hospitals and doctors, it has not been allocated to home care providers.

We also recommend that HHAs not be required to give their patients a written plan of care nor develop another comprehensive assessment when there is a revised plan of care unless the patient's condition has changed so much as to render the current assessment obsolete. In addition, we do not support the requirement that verbal orders be time-stamped.

In addition, we question the value of a separate discharge summary and recommend that a streamlined version of this information be incorporated into the patient's record. If this is not agreeable, then we suggest that professional standards of practice dictate what should be communicated in a discharge/transfer summary to health care professionals assuming care of the patient. Any additional information will be provided as requested by the receiving health care professional or facility.

Lastly, we recommend that a transfer summary only be required if the agency is discharging a patient to a facility.

For transfers without an agency discharge, where the agency will be resuming care, we recommend requiring that a transfer summary be provided if requested by the receiving facility.

Quality Assessment and Performance Improvement (§484.65)

Background

CMS is proposing to replace two current 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).

HHAs will be required to 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 hospital admissions and re-admissions; and takes actions that address the HHA’s performance across the spectrum of care.

In addition, CMS is emphasizing that the HHA would be required to take actions to prevent and reduce medical errors as part of its overall QAPI program.

CMS contends that the current CoPs rely on a problem-oriented, external, after-the-fact (occurrence) approach to resolve patient care issues. The proposed QAPI CoP would require proactive performance monitoring through an effective, ongoing, agency-wide, data-driven QAPI program that is under the supervision of the home health agency governing body.

HHAs would also be required to maintain documentary evidence of its QAPI program and be able to demonstrate its operation to CMS.

Issues

HCA is very concerned with CMS’s belief that HHAs across the board will be able to implement a QAPI without exorbitant costs or additional resources. Specifically CMS stated the following: “We believe small and mid-size HHAs would be able to effectively implement this condition as easily as larger HHAs. The proposed QAPI CoP would provide HHAs with enough flexibility to implement the quality assessment and performance improvement process without inordinate expenditure of capital or human resources.”

While HCA recognizes CMS’s objective to require HHAs to implement a comprehensive QAPI program, we believe the proposed CoP will require significant investment in additional resources and result in new costs to HHAs. Many agencies do not have a QAPI program that meets all the proposed requirements. The CoP consists of five standards with very specific activities and expectations.

Recommendations

Given the time, effort and costs required to implement this new proposed CoP, HCA recommends that CMS allow HHAs a sufficient amount of time for all agencies to comply with the new CoP and consider phasing in the requirements of the proposed QAPI program. We also recommend that CMS appropriate funding to help HHAs develop the necessary systems to ensure an effective QAPI program.

We also believe that CMS needs to issue guidance in the creation and implementation of QAPI so that investments made by HHAs are done correctly.

Infection Prevention and Control (§484.70)

Background

CMS is proposing to establish a new CoP, “Infection prevention and control,” because CMS believes it is appropriate to address this important issue as a distinct part of the regulatory process.

The current HHA CoPs have no requirement for an HHA-wide infection control program; however, the current 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. CMS believes infection control practices are part of accepted professional standards and principles, and thus should not be new to HHAs.

Proposed section 484.70 would require an HHA to maintain and document an infection control program with the goal of preventing and controlling infections and communicable diseases. Specifically, HHAs would have to maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that is an integral part of the HHA’s QAPI program. Each HHA would also have to provide infection control education to staff, patients, and caregivers.

Issues

HCA supports the requirement that all HHAs have an effective infection control program. While many HHAs currently have some type of infection control program, they may not meet all the required elements CMS proposes.

Recommendations

Similar to our recommendations related to the proposed QAPI program and our overall recommendation of adequate time to prepare for the new CoPs, HCA requests that CMS provide sufficient time for HHAs to comply with the proposed infection control standards.

HCA also requests clarification on whether the required infection control education can be provided verbally or if it must be in writing.

Skilled Professional Services (§484.75)

Background

CMS is proposing to consolidate the current 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.

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

Proposed section 484.75 would require skilled professionals who provide services to HHA patients to participate in all aspects of care. 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. This section would also require skilled professionals to be actively involved in the HHA's QAPI program and participate in HHA in-service trainings.

Furthermore, there would have to be supervision of skilled professional services when provided by skilled professional assistants.

Comments

HCA supports CMS's decision to have a single CoP which governs all of the skilled interdisciplinary professionals who provide services to HHA patients in all aspects of care. HCA's only concern in this particular area is why therapists cannot conduct the initial and comprehensive assessment if nursing is ordered.

Home Health Aide Services (\$484.80)

Background

Some of the proposed changes in this section would:

- Expand on the current requirement that communication skills be part of home health aide training to include as part of communication skills the aide's ability to read, write and verbally report clinical information to patients, representatives, and caregivers, as well as to other home health agency staff. CMS states that it is not specifying the primary language for home health aides.
- Add a new skill requirement for aides related to recognizing and reporting changes in skin condition, including pressure ulcers.
- Require that aides be members of the interdisciplinary team, report changes in the patient's condition to a registered nurse or other appropriate skilled professional, and complete appropriate records in compliance with the home health agency's policies and procedures.
- Require home health aide supervision visits to assess the aide's success in following the patient's plan of care; completing assigned tasks; communicating with the patient, 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 patient rights.
- Require a registered nurse or other appropriate skilled professional to make an annual on-site visit to the patient's home in order to observe and assess the aide while he is she is performing care.
- Require that the aide be present during the registered nurse's (or other skilled professional's) onsite visit every 14 days (for skilled care) if a potential deficiency in aide services is noted by the nurse, so that the nurse can assess the aide while performing care.

- Require that if an aide performs a task that is considered “unsatisfactory,” a registered nurse (not an LPN) must supervise the performance of that task until it is performed in a satisfactory manner.
- Require that if a deficiency in home health aide services is verified by a home health aide supervisor during an on-site visit, the agency would then have to complete a competency evaluation of the aide.
- Allow other skilled professionals (i.e. physical therapist, occupational therapist, or speech-language pathologist), in addition to RNs, to assign HHAs to a patient.
- Allow training received while an aide furnishes care to a patient to be counted toward the 12 hours of annual in-service training requirement.
- Require the home health aide to complete another training program if the aide has not furnished home health aide services for 24 months.

Issues & Recommendations

HCA recommends that the effective date for compliance with the new aide requirements be phased in to accommodate those aides currently employed by an agency. We also recommend that CMS allow HHAs to provide the additional training through in-service programs.

HCA supports adding new requirements that home health aide training programs address the recognition and reporting of changes in skin condition and that home health aides be a member of the interdisciplinary team. Skin impairment has a major impact on patient morbidity and mortality. Greater proficiency in observing and reporting skin condition changes will provide a better opportunity to prevent negative outcomes. In fact, some of our provider members have already developed their own enhanced aide training in recognizing skin integrity issues.

While ensuring that aides have good communication skills is integral to the provision of excellent care, we ask for recognition that some aides have limited English proficiency and request that agencies be allowed to supplement this with translators and/or other ways to enhance communication. This is important for communities that include patients and aides who were not born in the United States and/or whose primary language is not English.

We don't agree with the requirement that if an aide performs a task that is considered “unsatisfactory,” a registered nurse (not an LPN) must supervise the performance of that task until it is performed in a satisfactory manner. We feel either an RN or LPN is qualified to supervise. And, in some cases, peer mentoring may be successful where a senior aide is proficient in a skill and has demonstrates that skill under a nurse's direction. In addition, we request that the RN or LPN be able to assess the aide's proficiency of the task in a laboratory setting in addition to the patient's home.

We also take issue with the proposed requirement that if a deficiency in home health aide services is verified by a home health aide supervisor during an on-site visit, the agency would then have to complete a competency evaluation of the aide. We recommend that remediation should be required on the skill that was deemed deficient rather than a complete competency evaluation.

Lastly, we request clarification on the requirement that the home health aide complete another training program if the aide has not furnished home health aide services for 24 months. If a home

health aide has been providing services at a lower level (i.e. as a personal care aide providing services under a state Medicaid program) for 24 months and these services include some tasks also provided by home health aides, the home health aide may not have to complete another training program. We recommend that this flexibility be clarified and/or incorporated into this requirement.

Compliance with Federal, State, and Local Laws and Regulations Related to Health and Safety of Patients (§484.100)

Background

CMS is proposing to retain, with minor changes, most of the provisions concerning compliance with federal, state, and local laws currently located at section 484.12, “Condition of Participation: Compliance with Federal, State and local laws, disclosure and ownership information, and accepted professional standards and principles.” However, the proposed CoP would now be set forth at section 484.100.

As part of proposed section 484.100(a), CMS would continue to require HHAs to comply with the requirements of part 420, subpart C by disclosing the names and addresses of all persons with an ownership or controlling interest; the name and address of each officer, director, agent, or managing employee; and the name and address of the entity responsible for the management of the HHA along with the names and addresses of the CEO and chairperson of the board of that entity. Because the business address of an agency is self-explanatory, the additional address CMS would request in the standard would refer to a residential address for all individuals to whom the rule applies. A Post Office Box address would not be considered a business or residential address and would not be satisfactory for purposes of compliance with this proposed requirement.

Lastly, at proposed section 484.100(c), if a HHA engages in laboratory testing outside of the context of assisting an individual in self-administering a test with an appliance that has been cleared for that purpose by the Food and Drug Administration, the testing must be in compliance with all applicable requirements of part 493 of this chapter. The HHA may not substitute its equipment for a patient’s equipment when assisting with self-testing.

Issues

Throughout the years, HCA has heard from many board members/officers of member agencies that have been very reluctant to provide their home addresses, and, in some cases, the State agencies have also asked for complete social security numbers (SSNs) as part of the requirements in Part 420 Subpart C.

Also, with regards to proposed section 484.100(c), some patients may not be able to afford self-testing equipment or may choose not to obtain the equipment. Additionally, some patients may only need self-testing for a limited period of time and, therefore, it would not be practical for these patients to purchase the equipment.

Recommendations

HCA asks that CMS consider allowing officers or Board Members with an ownership or controlling interest of the agency to be able to provide a post office box address but also provide to CMS and our state Department of Health (DOH) their full name and the last 4 digits of their

SSN which should provide enough information for CMS and our state DOH to undertake an adequate background check.

HCA also asks that CMS allow HHAs the flexibility to use their own medical equipment as determined by the patient's needs and choice when assisting with self-testing, due to it not being practical for some patients that may only need self-testing for a limited period of time to have to purchase the equipment.

Organization and Administration of Services (§484.105)

Background

This proposed CoP on organization and administration of services would revise current regulations at section 484.14, "Organization, services, and administration." CMS states that the proposed new CoP would simplify the structure of the current requirements, and focus on both essential organizational structures and performance expectations for the administration of HHA operations.

As part of this proposed section, HHAs would be required to organize, manage, and administer their resources to attain and maintain the highest practicable functional capacity, including overcoming those deficits that led to the patient's need for home health services, for each patient's medical, nursing, and rehabilitative needs as indicated by the plan of care. The HHA would also have to assure that administrative and supervisory functions are not delegated to another agency or organization, and all services not furnished directly are monitored and controlled. The HHA must set forth, in writing, its organizational structure, including lines of authority, and services furnished.

Proposed section 484.105(b), "Administrator," would describe the role of the Administrator and provisions for when the Administrator is not available. CMS proposes that the Administrator be appointed by the governing body, be responsible for all day-to-day operations of the HHA, and be responsible for ensuring that a skilled professional (as described in section 484.75) is available during all operating hours.

At any time when the Administrator is not available, CMS proposes that a pre-designated person, who is authorized in writing by the Administrator and governing body, would assume the same responsibilities and obligations as the Administrator, including the responsibility to be available during all operating hours.

In addition to the overall management of the HHA by the governing body and the Administrator, CMS proposes a new "clinical manager" role at section 484.105(c). The clinical manager would be a qualified licensed physician or registered nurse, identified by the HHA, who is responsible for the oversight of all personnel and all patient care services provided by the HHA, whether directly or under arrangement, to meet patient care needs. The supervision of HHA personnel would include assigning personnel, developing personnel qualifications and personnel policies.

Issues

HCA has concerns that the duties of the Administrator are expanded to include responsibilities of the day-to-day operations of the organization and that a skilled professional is required to be available during all operating hours. We are also concerned that many smaller agencies may have

a single individual who could serve as both the Administrator and the Clinical Manager. HCA requests confirmation that the CoPs allow for a single individual to serve in both roles.

Also the Clinical Manager is a new designation with responsibilities that appear to be a cross between the supervising nurse position in the current CoPs and a typical clinical manager. The duties of the Clinical Manager are broad and diverse and include the development of personnel qualifications and policies. In a large agency these duties may be difficult for one individual to execute and/or another department, such as human resources, handles some of the listed (*i.e.* personnel) responsibilities. Conversely, in a very small agency one individual may be able to serve as both the Administrator and the Clinical Manager.

Recommendations

HCA asks that CMS allow the Administrator to be shared among commonly owned organizations if they can demonstrate that the Administrator is able to fulfill all the proposed requirements. HCA requests that the proposed CoPs allow for a single individual to serve as both the Administrator and Clinical Manager, which is critically important for many smaller agencies.

HCA also asks that CMS allow HHAs to determine how they can best meet the requirements for the Clinical Manager. This might require delegating tasks to others in the management and/or human resources team for a large agency or combining the duties with the Administrator in a small agency. However, one individual would have the ultimate responsibility for ensuring compliance with the duties of the Clinical Manager.

Clinical Records (§484.110)

Background

The primary requirement under the proposed clinical records CoP would be that a clinical record containing pertinent past and current relevant information would be maintained for every patient who was accepted by the HHA to receive home health services. CMS proposes to add the requirement that the information contained in the clinical record would need to be accurate, adhere to current clinical record documentation standards of practice, and be available to the physician who is responsible for the home health plan of care and appropriate HHA staff. The information could be maintained electronically.

CMS also proposes to add requirements that reflect its “outcome-oriented” approach to patient care.

Specifically, proposed section 484.110(a) would require that the clinical record include:

- The patient’s current comprehensive assessment, including all of the assessments from the most recent home health admission, clinical visit notes, and individualized plans of care;
- All interventions, including medication administration, treatments, services, and responses to those interventions, which would be dated and timed;
- Goals in the patient’s plan of care and the progress toward achieving the goals;
- Contact information for the patient and representative (if any);

- Contact information for the 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; and
- A discharge or transfer summary note that would be sent to 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 within seven calendar days, or, if the patient is discharged to a facility for further care, to the receiving facility within two calendar days of the patient's discharge or transfer.

Issues

CMS proposes to impose a timeframe for which a discharge or transfer summary must be provided to the receiving health care professional or facility. The HHA must provide a discharge summary to the receiving primary care practitioner within seven calendar days of the patient's discharge. The HHA must provide a transfer summary to the receiving facility within two calendar days.

HCA is concerned that the proposed regulations do not ensure timely access to information for HHAs so that they can meet these timeframes and will create a significant burden on them.

HCA is also concerned that it may be unclear when the transfer summary would need to be provided. If summaries have to be provided any time a patient transfers to a facility, the agency may not be able to meet this requirement when it does become aware of the transfer for several days.

HCA also requests clarification on what is included in the requirement that the patient record include "all of the assessments from the most recent home health admission, clinical notes, plans of care, and physician orders."

Recommendations

HCA recommends the following changes to this proposed section:

- Eliminate the requirement that HHAs have to send discharge or transfer summaries to hospitals. In many cases, it is uncertain who at the hospital should receive the information and the information is not used in the diagnosis or treatment of the hospitalized individual.
 - If CMS retains the requirement to send transfer summaries to hospitals, change the timeframe for completion from two calendar days to four (4) business days of the notification of the transfer to accommodate when a patient may be transferred to a facility without the patient's knowledge.
 - Exclude the need to send a transfer summary to a hospital in instances where an individual has been both admitted to and discharged from the hospital prior to the HHA's knowledge of the admission.

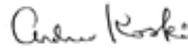
- Eliminate the requirement that HHAs have to send non-hospital organizations (e.g., hospices, skilled nursing facilities, and Medicaid long term care programs) transfer summaries for unplanned transfers.
- Change the timeframe for sending discharge or transfer summaries for planned transfers to non-hospital organizations such that the HHAs have four business days – instead of two calendar days – to do so.
- For planned transfers, permit HHAs to send only the information critical to facilitate the highest quality care for the patient and not the entire patient record. HCA recommends that HHAs share medications, diagnoses, disciplines providing services, and caregiver/representative information.

Thank you for the opportunity to offer our comments on the proposed CoPs. If you have any questions or need additional information, we can be reached at (518) 426-8764.

Sincerely,



Patrick Conole
Vice President for Finance
& Management



Andrew Koski
Vice President for Program Policy
& Services