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CMS FINALIZES NEW CONDITIONS OF PARTICIPATION FOR HOME HEALTH: PART 2

Review of the New Home Health Conditions of Participation - Release of Patient Identifiable OASIS information, Reporting OASIS Information and Comprehensive Assessment of Patients; and Care Planning, Coordination of Services and Quality of Care.

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

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

RELEASE OF PATIENT IDENTIFIABLE OASIS INFORMATION - SECTION 484.40

Executive Summary. The Final CoPs move this CoP from Section 484.11 to Section 484.40 and retain the requirements to ensure the confidentiality of all patient identifiable information.

Detailed Summary. Prior regulations at Sec. 484.11 address the requirements to ensure the confidentiality of all patient identifiable information. The Final CoPs retain the requirements of the prior section but move the section to Sec. 484.40. In Sec. 484.40, CMS restates the current requirements of Sec. 484.11, which require HHAs and their agents to ensure the confidentiality of all patient identifiable information in the clinical record, including Outcome and Assessment Information Set ("OASIS") data. In addition, HHAs may not release patient identifiable OASIS information to the public.

REPORTING OASIS INFORMATION - SECTION 484.45

Executive Summary. The Final CoPs move Section 484.20 to Section 484.45 and retain the requirements to report OASIS information to the CMS system.

Detailed Summary. The Final CoPs move Section 484.20 to Section 484.45 and retain the requirements to report OASIS information to the CMS system. In this CoP, CMS continues to require the electronic reporting of the OASIS data. The final regulations remove the requirement that an HHA transmit data using electronic communications software that provides a direct telephone connection from the HHA to the state agency or CMS OASIS contractor. In its place, CMS added a requirement that the OASIS data be transmitted in accordance with the current CMS transmission policy, which currently requires HHAs to transmit data using electronic communications software that complies with the Federal Information Processing Standard.

COMPREHENSIVE ASSESSMENT OF PATIENTS - SECTION 484.55

Executive Summary. The Final CoPs retain and revise Section 484.55 that describes the comprehensive assessment requirements for patients. The Final CoPs added a requirement at Section 484.55(c)(6)(i) and (ii) that the comprehensive assessment must include information about caregiver willingness and ability to provide care and availability and schedules.

Detailed Summary. CMS retained a majority of the requirements of current Section 484.55, with significant reorganization. Section 484.55 requires an HHA to conduct, document and update, within a specific time frame, a patient-specific comprehensive assessment. For Medicare beneficiaries, the HHA is required to verify the patient's eligibility for the Medicare home health benefit, including the patient's homebound status, at the specified timeframes. Section 484.44(c) of the Final CoPs establishes a new standard called "Content of the Comprehensive Assessment." The standard requires the comprehensive assessment to accurately reflect the patient's status. When performing the comprehensive assessment, the clinician must assess or identify:

- Patient's current health, psychosocial, functional and cognitive status;
- Patient's 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;

- Patient's continuing need for home care;
- Patient's medical, nursing, rehabilitative, social and discharge planning needs;
- A review of all medications the patient is currently using;
- Patient's primary caregiver(s), if any, and other available supports, including their caregiver willingness and ability to provide care and their availability and schedules; and
- Patient's representative (if any).

CMS added new a few content requirements, such as an assessment of psychosocial and cognitive status to provide for a more holistic patient assessment.

Several commenters sought more information regarding the extent to which these proposed elements may or may not differ from similar OASIS items, the meaning and intent of the term "psychosocial" and the goals that CMS wants to achieve as a result of requiring an HHA to assess psychosocial and cognitive status.

CMS responded that assessing a patient's psychosocial status refers to an evaluation of his or her mental health, social status and functional capacity within the community by looking at issues surrounding both a patient's psychological and social condition (for example, education and marital history). Also, CMS acknowledged that this provision is intended to be a screening for potential issues that may complicate or interfere with the delivery of HHA services and the patient's ability to participate in his or her own care. According to CMS, assessing a patient's "cognitive status" refers to an evaluation of the degree of his or her ability to understand, remember and participate in developing and implementing the plan of care. CMS identified that numerous screening tools are available that HHAs may choose to use in order to implement this requirement and that it is not requiring the use of any particular tool or the extent of the cognitive status assessment.

Under Section 484.55(d), the comprehensive assessment is required to incorporate items from the information set out in the OASIS data set. CMS also added a requirement that the assessment include physician ordered resumption of care date. This is in place of the fixed 48-hour time frame for a post-hospital reassessment. This change allows physicians to specify a resumption of care date that is tailored to the particular needs and preferences of each patient.

The CoP provides that the comprehensive assessment must be completed within five calendar days after the start of care. A commenter stated that the five-day time frame within which HHAs must complete the comprehensive assessment may not be sufficient to capture the full extent of some of these proposed factors in the comprehensive assessment, such as psychosocial and cognitive status, for certain patients. CMS did not agree that a period of greater than five days is necessary to gather information regarding all elements of the patient assessment. CMS stated that HHAs are already accustomed to completing the current assessment requirements within five days, and there is no evidence that patient care has suffered because of the failure of additional conditions to manifest themselves within that timeframe.

CARE PLANNING, COORDINATION OF SERVICES AND QUALITY OF CARE - SECTION 484.60

Executive Summary. The Final CoPs retain and revise Section 484.60 that describes care planning, coordination of services and quality of care. Section 484.60 incorporates many of the written care plan requirements under the former Section 484.18.

Detailed Summary. The CoP in Section 484.60 specifies that the HHA must provide the patient a plan of care that would set out 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. The plan of care must also specify the patient and caregiver education and training specific to the patient's care needs.

- Section 484.60(a) requires that each patient's written plan of care be established and periodically reviewed by a doctor of medicine, osteopathy or podiatry. CMS recognized in its responses to provider comments that this requirement should not be a burden for Medicare patients but may cause additional time for non-Medicare patients.
- The Final CoPs revised the § 484.60(b)(1) to permit drugs, services and treatment to be ordered by any physician, not just the one responsible for the patient's plan of care.
- The Final CoPs revised § 484.60(b)(4) to permit any nurse acting in accordance with state licensure requirements to receive verbal

orders from a physician and document the orders in the clinical record and date and sign them and record the time. 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.

A few commenters expressed confusion regarding the relationship between the concept of "verbal orders" and orders that are faxed or otherwise transmitted through other electronic methods. The commenters were unclear as to whether faxed or other HIPAA-compliant electronic orders are considered to be "verbal orders." One commenter suggested that emailed and faxed orders would be followed up by a written order signed by the physician. CMS directed commenters to the definitions set forth in § 484.2, that state that a verbal order means a physician order that is spoken to appropriate personnel and later put in writing for the purposes of documenting as well as establishing or revising the patient's plan of care. CMS's response stated that faxed and other electronic orders are not considered verbal orders because they do not meet this definition. However, all orders need to be appropriately authenticated.

The proposed rule stated that, when services are provided on the basis of a physician's verbal orders, the clinician receiving the order(s) must document it in the patient's clinical record and sign, date and time the order(s). While a single commenter supported this proposal, the vast majority of commenters who submitted comments regarding this proposal disagreed with the requirement that verbal orders must be timed, questioning the relevancy and necessity of a requirement in the home health care setting. A commenter also stated that it is unclear whether the "timed" requirement applies to the time that the care was provided or activity occurred, when the verbal order was documented or when the verbal order was signed by the physician.

CMS acknowledged that most HHA patients do not typically require rapidly changing orders but that it believes that timing the receipt of verbal orders is necessary for those infrequent occasions when such situations do arise. CMS wrote that there are times when a patient's condition rapidly changes and clinicians are not necessarily able to effectively predict when such situations are about to occur. Therefore, it believes that it is necessary and appropriate to proactively record the time of day that each verbal order is received by an HHA clinician from a physician. CMS wrote that this requirement corresponds with the clinical record authentication requirements at § 484.110(b), which require all entries in the clinical record to be timed.

A few commenters stated that other licensed practitioners, such as physician assistants and nurse practitioners, should be permitted to give verbal orders for treatment and requested additional clarification of the word "spoken."

CMS responded that law requires the HHA plan of care to be under the direction of a physician. CMS stated it does not have statutory authority to allow other licensed practitioners to give verbal orders for treatment, as such an allowance would mean that the plan of care would no longer be under a plan established by a physician because pieces of that plan would be established by non-physicians. CMS intends a plain language meaning of the term "spoken" as meaning a communication that is said aloud or communicated by sign language.

- Section 484.60(c) requires an HHA to review, revise and document the plan on a timely basis.
- Section 484.60 (c)(3) requires an HHA 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 change in the patient's health status. An HHA must also notify the patient, representative (if any), caregivers and the physician who is responsible for the HHA plan of care when the HHA makes updates related to plans for the patient's discharge.
- The Final CoPs added requirements at Section 484.60(d)(1) and (2) that HHAs must ensure communication with all physicians involved in the plan of care and integrate orders from all physicians involved in the plan of care to ensure the coordination of all services and interventions provided to the patient.
- The Final CoPs added a requirement at Section 484.60(d)(5) that the patient and caregiver receive education and training regarding care and services identified in the care plan. This would include 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 plan.
- CMS added a new CoP in Section 484.60(e), "Written Information to the Patient." Section 484.60(e) is a new provision that was added

based on comments. This new standard partially replaces the proposed patient's rights requirement that a copy of the plan of care be provided to the patient[1]. This provision requires that the HHA provide written instructions to the patient and caregiver outlining visit schedule, including frequency of visits, medication schedule/instructions, treatments administered by HHA personnel and personnel acting on the behalf of the HHA, pertinent instructions related to patient care and the name and contact information of the HHA clinical manager. This replaces the requirement to provide the plan of care to the patient.

Most commenters expressed strong support for the overall concept of an HHA developing a patient-specific, patient-centered plan of care for each patient. The commenters stated that the revised requirement would better ensure that the patient will, indeed, receive all the services and education called for in the plan of care. One commenter suggested that the requirement should specify that each plan of care be individualized to the patient's needs, as reflected in the comprehensive assessment.

CMS agreed that the plan of care should be based on the assessment and that it is important for the plan to specify patient education and training. CMS understands that it is standard practice for the patient to receive written care information based off the individualized plan of care from the HHA outlining the medication schedule/instructions, visit schedule and any other pertinent instruction related to the patient's care and treatments that the HHA will provide. CMS believes that this is critical information to improve the patient and caregiver comprehension of diagnosis and treatment, improve compliance with medications and treatment schedules and promote high quality care for the patient. Therefore, in response to comments, CMS revised the proposed rule to create a new standard at § 484.60(e), "Written Information to the Patient."

This revision will require HHAs to develop the necessary procedures and forms to provide the patient with the required written information. Based upon CMS's comments, this requirement will not be met by providing the patient with a copy of the Plan of Correction.

PRACTICAL TAKEAWAYS

- HHAs and their agents need to ensure the confidentiality of all patient identifiable information in the clinical record.
- HHAs must transmit OASIS data using electronic communications software that complies with the Federal Information Processing Standard.
- A patient's comprehensive assessment must include information about caregiver willingness and ability to provide care and availability and schedules.
- CMS revised the process on how verbal orders are handled, clarifying that fax orders or other electronic orders do not fall under this rule and that the nurse must sign, date and log the time the verbal order was received. This will require new practices and procedures for HHAs.
- HHAs must consider how they will address providing the written instructions required by the revised CoPs. This will include developing the procedures and forms necessary to provide written instructions to the patient and caregiver outlining visit schedule, including frequency of visits, medication schedule/instructions, treatments administered by HHA personnel and personnel acting on the behalf of the HHA, pertinent instructions related to patient care and the name and contact information of the HHA clinical manager. Agencies will need to have a process to document delivery of this material. Agencies will finally need to develop these new procedures in time to allow for training staff on these new requirements prior to the July 13, 2017 compliance date.

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[1] For more on this change, see the upcoming Hall Render Health Law News article: Review of the New Home Health Conditions of

Participation on Patient Rights.

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