Mary Carr  
Vice President for Regulatory Affairs  
National Association for Home Care & Hospice  
228 Seventh Street, SE  
Washington, DC 20003

RE: CMS-3819-F Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies Interpretive Guidelines – DRAFT

Dear Ms. Carr,

The Association of Home Care Coding and Compliance (AHCC), the national membership organization for home health coding and compliance professionals, together with the Board of Medical Specialty Coding and Compliance (BMSC), the credentialing arm of AHCC, appreciate the opportunity to comment on the draft version of the home health Conditions of Participation Interpretive Guidelines.

Several areas in the draft Interpretive Guidelines lack the details necessary for home health agencies to ensure compliance. Without further clarification, agencies will have difficulty knowing how to meet these standards. We hope that the final Interpretive Guidelines will clarify the following areas.

§484.45(b) Standard: Accuracy of encoded OASIS data.

In §484.45(b), the draft guidelines explain that “‘Accurate’ means that the OASIS data transmitted to CMS is consistent with the current condition(s) of the patient.” What will the surveyor want to see to verify compliance with this standard? This explanation is brief, and with many OASIS transmissions done remotely, how can agencies assure that the OASIS shows the “current condition(s)” of the patient at transmission?

§484.50 Condition of Participation: Patient Rights

§484.50(a)(1) requires agencies to “Provide the patient and the patient’s legal representative (if any), the following information during the initial evaluation visit, in advance of furnishing care to the patient: ...”

Yet §484.2 explains that “In Advance means that HHA staff must complete the task prior to performing any hands-on care or any patient education.”

The timeframe for the provision of rights conflicts with this definition of “in advance.” Rights provided “during the initial evaluation,” wouldn’t be done “in advance” as further described in §484.50(a)(1): “In
advance means that HHA staff must complete the task prior to performing any hands-on care or any patient education.” How can agencies conduct these tasks to satisfy this requirement?

Please also clarify whether the patient should always receive patient rights and other information during the initial evaluation visit, whether or not the patient has a legal or patient-selected representative.

**Interpretive Guidelines for §484.50(a)(1)(i)** instruct “It is expected that HHA patients will be able to confirm, upon interview, that their rights and responsibilities as well as the transfer and discharge policies of the HHA were provided to them in a language they understood and in a manner which accommodated any disability.”

**Comment:** Based on the final rule, we were under the impression that agencies could provide a summary of transfer and discharge policies. This standard appears to indicate that agencies must actually leave a copy of these policies in a language and manner the patient understands. Further clarification would be helpful here.

**Interpretive Guidelines for §484.50(a)(1)(i)** detail how agencies must ensure patients receive appropriate notification.

According to this standard, written notice can be given in hard copy “unless the patient requests that the document be provided electronically.” If a patient requests an electronic copy, agencies will need further direction on the acceptable timeframe and how to maintain compliance with the “in advance” requirement.

This standard further instructs that, “All agency staff should be trained to identify patients with any language barriers ... Staff that have on-going contact with patients who have language barriers, should be trained in effective communication techniques ...”

**Comment:** What would a surveyor consider an acceptable training in effective communication techniques?

**Interpretive Guidelines for §484.50(a)(3)** indicate that “… the HHA may delay the notification of rights and responsibilities until an interpreter is present (physically, electronically or telephonically) to verbally translate. However, this may be delayed no later than the second visit.”

**Comment:** Once again, this instruction appears to break with the “in advance” definition.

**Interpretive Guidelines for §484.50(b)(3)** require that “The HHA should include official documentation of any adjudication by the courts which indicate that a patient lacks capacity to make their own decisions ...”

**Comment:** To date it has been extremely difficult for agencies to get a copy of any Advance Directives. What will Surveyors expect in terms of documentation from the court? An actual court document?

**Interpretive Guidelines for §484.50(c)(4)** requires agencies to ensure that “… patient participation takes place on an ongoing basis as care changes and evolves during the episodes of care. Initially and as
changes occur in the care, there is evidence in the medical record that the patient was consulted and consented to planned services and care.”

Comment: Will surveyors require multiple consents signed by patients or representatives when frequent changes take place? Currently, agencies create just one consent to begin care.

**Interpretive Guidelines for §484.50(d)(4)** advise “It is a patient’s right to refuse [services]. It is agency’s responsibility to educate the patient on the risks and potential adverse outcomes from refusing services.”

Comment: What will surveyor expect to see? Should a “Refusal of Care” form be created outlining requirements here?

**§484.55 Condition of Participation: Comprehensive assessment of patients**

This standard requires agencies to verify the patient’s eligibility “both at the time of the initial assessment visit and at the time of the comprehensive assessment.”

Comment: We would like to see some clarification here. The initial assessment and comprehensive assessment are typically done simultaneously. Are agencies expected to determine eligibility twice, or are agencies expected to confirm eligibility each time a comprehensive assessment is completed, including at recertification?

**Interpretive Guidelines for §484.55(c)(5)** say “In therapy cases, the therapist submits a list of the medications …”

Comment: Will the surveyor expect that all therapy cases require nursing to intervene with medications even though medication monitoring and education is included in Therapy Standard of Practice?

**Interpretive Guidelines for §484.60(b)(2)** require agencies to develop a written policy that addresses vaccination screening for safety exclusions and assessing contraindications in consultation with a physician.

Comment: What kind of documentation will surveyors expect to see to determine whether a physician was involved in writing the policy on vaccines?

**Interpretive Guidelines for §484.60(c)(1)** state “if there is a significant change in the patient’s condition and the services to be provided by the HHA, the revised plan of care is sent to the responsible physician for review and approval which restarts the 60 day period for review of subsequent plans of care.”

Comment: Does this mean that agencies must send another plan of care to the doctor every time there is a SCIC and that this resets the 60-day period? This would cause significant confusion with payments, HRRG’s, etc. If resetting the 60-day period for review of subsequent plans of care does not apply to the payment episode, does this mean no physician review of the care plan is needed for the next recertification?
Interpretive Guidelines for §484.60(d)(3) discuss the requirement for agencies to manage patient scheduling “taking into consideration the type of services that are being provided on a given day ...”

Comment: To comply with this standard, will it be possible for a clerical staff member to schedule aides or assistants? Also, will the schedule require review by a clinical staff member such as the Clinical Manager on a daily basis to prevent scheduling too many visits within a single day or within a specific time frame?

The interpretive guidelines for this standard go on to say, “The agency manages pain during physical therapy or physical care (i.e. dressing changes or wound care) in order to minimize patient discomfort while maximizing the effectiveness of the therapy session.”

Comment: What sort of documentation of agency management of pain will surveyors expect to see? How will this differ if nursing is not involved in the case?

Interpretive Guidelines for §484.60(e)(2) state “The written information regarding the patient’s medication regimen is provided to the patient and/or caregiver and based on the results of the medication review conducted at §484.55 (c) (5). The medication administration instructions must be written in plain language avoiding the use of medical abbreviations. This information is also provided in therapy only cases. See §484.55 (c) (5) for communication between the therapist and the HHA nurse regarding medications.”

Comment: Again, this interpretation seems to indicate that therapy will not be involved in medication issues with patients. Please clarify what is expected.

§484.65(d) Standard: Performance improvement projects

“Beginning January 13, 2018, HHAs must conduct performance improvement projects.”

Comment: This is the only mention of the January 13 QAPI (PIP) date in the draft Interpretive Guidelines. There is no indication that CMS will give the Agency six months after that date to collect data (as referenced in the original rule).

Please clarify what surveyors will expect to see on Jan 13 (for example, policies, work flows, improvement identifiers, etc.) and on what date surveyors will expect specific data.

Interpretive Guidelines for §484.65(d) state “The HHA should have one performance improvement project either in development, on-going or completed each calendar year.”

Comment: Does this indicate that an agency only needs to do one PIP at a time? If that is not the case, what documentation is expected to justify the number of PIPs an agency decided to pursue? And how can an agency’s “number and scope of distinct improvement projects conducted annually reflect the scope, complexity, and past performance of the HHA’s services and operations?”
Interpretive Guidelines for §484.75(b)(9) require that “Each skilled professional discipline attends all in-service training sessions and programs required by the HHA.”

Comment: Please clarify what is expected to meet this requirement and how part time and contract staff can meet this standard.

§484.75(c)(1) Nursing services are provided under the supervision of a registered nurse that meets the requirements of §484.115(k).

Interpretive Guidelines for §484.75(c)(1) state, in part “Only the skilled therapist may perform comprehensive assessment, evaluations, care planning and discharge planning.”

Comment: This should say "Only the registered nurse may perform comprehensive assessment, evaluations, care planning and discharge planning."

§484.75(c)(2) Rehabilitative therapy services are provided under the supervision of an occupational therapist or physical therapist that meets the requirements of §484.115(e, f) or (g, h), respectively.

Interpretive Guidelines for §484.75(c)(2) state in part “Only the skilled therapist may perform comprehensive assessment, evaluations, care planning and discharge planning.”

Comment: Interpretive guidelines under §484.75(c) Standard: Supervision of skilled professional assistants indicate that licensed disciplines are provided under the supervision of their respective disciplines. For example, RNs will supervise licensed practical nurses while physical therapist supervise physical therapist assistants.

Please clarify how the Clinical Manager will work in this regard. While §484.115(c) Standard: Clinical Manager explains that the Clinical Manager can be a licensed physician, physical therapist, speech-language pathologist, occupational therapist, audiologist, social worker, or a registered nurse, it seems that there is a conflict with the requirement for supervision by the related discipline. For example, if a Clinical Manager is a physical therapist, how could that Clinical Manager oversee an RN?

§484.100(c)(2) states “If the HHA refers specimens for lab testing, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of part 493 of this chapter.”

Comment: What will the surveyor require from the agency with regard to verifying outside lab specialties?

§484.102 Condition of participation: Emergency preparedness.

Comment: Throughout this section there are references to requirements for facilities. The description of a “facility” generally connotes a building in which patients are housed and/or treated – a much different circumstance than what home health agencies face. With so broad a description of emergency preparedness requirements community-wide, requirements for home health agencies are difficult to sift out and study.
Interpretive Guidelines for §484.105 state “The roles of the governing body, administrator and clinical manager may not be delegated.”

Comment: Please clarify this requirement. For example, coordination of referrals is often handled by intake staff. What will Surveyors expect to see indicating that this task is not delegated?

Interpretive Guidelines for §484.110(a)(6) outline a list of typical items included in discharge summaries.

Comment: Will this list of typical discharge summary items be expected during surveys?

Again, we appreciate the opportunity to comment on the draft Interpretive Guidelines. We hope CMS will provide clarifications in the final guidelines.

Sincerely,
The Association of Home Care Coding and Compliance

Tricia A. Twombly

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