November 19, 2018

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
ATTN: CMS-3346-P
PO Box 8016
Baltimore, MD 21244-8016
Via www.regulations.gov

RE: CMS-3346-P

Dear Administrator Verma:

The Home Care Alliance of Massachusetts (HCA of MA) - on behalf of our 100 home health agencies serving more than 110,000 Medicare patients annually - appreciates the opportunity to comment on the Proposed Rule: *CMS-3346-P Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency and Burden Reduction.*

The HCA commends CMS' efforts to reduce provider burden while maintaining high quality care for beneficiaries, and we look forward to assisting in those efforts moving forward. We hope that you will consider the following recommendations to proposed rule CMS-3346-P:

Provisions of the Proposed Regulations: (F) Home Health

I. Patient Rights §484.50 (a)(c)

We support CMS' proposal to delete the requirement that home health agencies (HHAs) must provide verbal notification of all patient rights. Under the new proposal, CMS will instead limit the requirement of HHAs to only discuss payment and patient financial liability while maintaining the requirements at §484.50 (a)(f) with respects to written notice of patient rights and accessibility.

The HCA agrees with CMS' conclusion that no such evidence exists showing improvements in patient safety or care with this requirement, and that HHAs could instead provide hands-on patient care during this time.

II. Home Health Aide Services § 484.80 (H)(3)

CMS' is proposing to eliminate a requirement under Section 484.80 (h)(3) of the 2017 HHA CoP Final Rule 82 FR 4504 which established that when a supervisory visit identifies a deficiency in a home health aides skills, the home health agency must conduct a full competency evaluation of all aide skills and identify other deficiencies.

This provision is burdensome to agencies and the HCA supports CMS' proposed changes to eliminate the requirement and replace it with a new requirement to retrain the aide in the deficient skill(s) and require the aide to complete a competency evaluation as it relates only to that identified deficient skill(s).

III. Clinical Records § 484.110 (e) Standard: Retrieval of Clinical Records

CMS is proposing to eliminate a requirement that a patient's clinical record be made available on request, free of charge, at the next home visit. CMS' proposal will maintain the requirement of HHAs to produce the clinical record within (4) business days.

The HCA of MA supports the elimination of the requirement 'by the next home visit' but remains concerned with the 'within four business days' and 'free of charge' requirement. A four-day time period is not sufficient enough for many agencies and it is not uncommon for agencies to have comprehensive processes prior to the release of any protected health information.

CMS argues that the requirement of making clinical records available is part of the certification process, however surveyors do not typically request archived records and usually access an agency's Electronic Health Record. This process is significantly different than having to reproduce a large record, and in some cases mail that record, which would take 1-2 days out of the proposed four-day time period.

It is also important to note that the Health Insurance Portability and Accountability Act (HIPPA) allows Medicare-certified home health agencies 30 days to provide the medical record from the date of request and permits a cost-based charge.

Recommendation: HCA recommends that CMS align §484.110 (e) with the 30-day allotment, and give agencies the ability to charge a cost-based fee for copies of a medical record per the requirements of HIPPA.

Additional Regulatory Burden Relief Recommendations for Home Health

I. Physician Documentation and Certification Requirements in Home Health Benefit at 42 CFR 424.22 (c)

CMS requires that physician certification of home health services is supported solely on the basis of the records within the certifying physician's records. The certifying physician can rely on records from other providers and practitioners, including HHAs, but only if those records indicate written acknowledgement by the physician that the records were considered in the determination of eligibility.

CMS has acknowledged that the non-physician records are useful in determining a patient's eligibility for home health services, but the written acknowledgement requirement remains a highly burdensome requirement.

Recommendation: CMS should eliminate this burdensome standard. Allowing the entire record of a patient to be considered, the accuracy and integrity of eligibility is greatly improved.

II. Conditions of Participation 42 CFR 484.60(e) Standard: Written information to the patient:

Home Health Agencies are required to 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.
5. Name and contact information of the HHA clinical manager.

The information required to be provided to a patient under this section is similar to the information within a Plan of Care (POC). Earlier this year, CMS chose not to require agencies provide the POC to the patient in its final rule, citing a possible burden to HHAs.

Recommendation: The HCA recommends that CMS limit the information provided to medication schedule, instructions, and any other pertinent information related to patient care needs. CMS should eliminate the requirement to provide, in writing, all treatments to be administered.

III. Condition of participation: Core services. 42 CFR 484.80(b)(3)(ix)(B) Standard:

CMS revised home health aide competency evaluation requirements, requiring an aide to be trained/evaluated in performing personal hygiene and grooming tasks. These evaluations include sponge, tub, ***and*** shower bath, and shampooing in sink, tub ***and*** bed.

The previous requirement allowed competency training/evaluation in bathing to be demonstrated by a sponge, tub ***or*** shower and hair shampooing to be demonstrated in a sink, tub ***or*** bed.

HHAs are also required to train and evaluate aides for these activities on a live patient. Home health patients typically do not bath in tubs due to safety and mobility concerns. Since implementation of the Home Health Conditions of Participation, HHAs have expressed deep concern for their ability to comply with these requirement. Most training is done in simulation settings, and most patients are unable or unwilling to take a tub bath.

Recommendation: HCA of MA recommends CMS revise the regulation to require the aide be evaluated in bathing by demonstration of a sponge, tub ***or*** shower and evaluated for hair shampooing in a sink, tub ***or*** bed.

HCA of MA further recommends that the Interpretive Guidelines relative to this section of the Conditions of Participation be modified to clarify that training in these skills can be done with a patient or in a simulation lab training.

Provisions of the Proposed Regulations: Emergency Preparedness for Providers and Suppliers (L)

HCA of MA applauds CMS' recognition that necessary changes to Emergency Preparedness requirements give flexibility to providers to tailor readiness plans to each provider's needs.

Specifically:

- HCA agrees with the change in requiring providers to review emergency preparedness plans every two years instead of annually.
- HCA also agrees with the proposal to delete the requirement that cooperation efforts with local, tribal, regional, State and Federal official's is documented separately and in addition to being documented within a provider's emergency preparedness plan.
- HCA also supports CMS' revision in the frequency that providers must test their emergency preparedness programs as well as the clarifications to the types of tests that should be performed (full scale exercise or functional exercise).

Again, we thank you for the opportunity to submit comment on these regulatory burdens. We look forward to continuing our work together in ensuring a high-quality, efficient home health benefit. Please let me know if we can be of any assistance as it relates to these issues, as well as any others.

Sincerely,

Patricia M. Kelleher
Executive Director