



August 12, 2019

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-6082-NC
P.O. Box 8016
Baltimore, MD 21244-8016

RE: CMS-6082-NC

Dear Sir/Madam:

The Home Care Association of New York State (HCA) appreciates the opportunity to comment on CMS's Request for Information (RFI) that solicits public comment on ideas for "regulatory, subregulatory, policy, practice and procedural changes that reduce unnecessary administrative burdens for clinicians, providers, patients and their families."

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), hospices, providers of various waiver programs, Managed Long Term Care plans, and others. HCA's home care providers are sponsored by hospitals, nursing homes and free-standing nonprofit, public and proprietary agencies.

We believe that our home health and hospice recommendations align with CMS's aim to make the health care system more effective, simple and accessible.

HOME HEALTH

Clinical Records

42 CFR 484.110(e) Standard: Retrieval of Clinical Records

Under this standard, a patient's clinical record (whether hard copy or electronic form) must be made available to a patient, free of charge, upon request at the next home visit, or within four business days (whichever comes first).

In our comments on the September 17, 2018 proposed rule, HCA supported CMS's proposal to remove the requirement that Home Health Agencies (HHAs) provide a copy of the clinical record to a patient, upon request, by the next home visit. However, we still have concerns with CMS's intention to retain the requirement that the copy of the clinical record must be provided, upon request, within four business days.

While four business days is an improvement over the next home visit, the four-day timeframe is still problematic. Many agencies centralize requests for records and have a detailed process for review prior to releasing any protected health information. If the record is to be mailed, the agency will have only one or two days to reproduce the record given the delivery lag; otherwise, they will be out of compliance with the timeframe outlined in the standard.

CMS maintains that agencies will not incur any additional burden with the requirement since making clinical records available to the appropriate authority is part of the survey and certification process. However, surveyors do not typically request archived records and are accustomed to viewing the active medical record using the agency's electronic health record (EHR). This is different from having to reproduce and review a record that can be very lengthy.

Recommendation: CMS should align §484.100(e) with the requirements of the Health Insurance Portability and Accountability Act at §164.524(b) (2), which provides 30 days for a health care entity to act upon on a request for a copy of the medical record.

Evaluation of Home Health Aide's Skills **42 CFR 484.80(c)(1) Standard: competency evaluation**

The Interpretive Guidelines (IGs) for the final Home Health Conditions of Participation (CoPs) state that aide competency evaluation standards are to "be evaluated by observing an aide's performance of the task with a patient." These include: communication skills; reading and recording temperature, pulse and respiration; appropriate and safe techniques in performing personal hygiene and grooming tasks that include bed bath, sponge, tub and shower bath, hair shampooing in sink, tub and bed, nail and skin care, oral hygiene, toileting and elimination; safe transfer techniques and ambulation; and normal range of motion and positioning.

This is similar to the prior regulatory language under which the IGs allowed HHAs to use a "pseudo-patient" for the competency evaluation. However, even though the regulations are essentially the same, CMS has clarified in a January 23, 2019 Home Health Agency FAQs that competency testing must be conducted on an **actual patient** and this does **not include a pseudo-patient**.

This restriction not only presents concerns for the agency's ability to perform competency evaluations for all skills, and, in particular, for those related to timely assessment of bathing and shampooing skills. We urge in the strongest terms that this important policy permitting the pseudo-patient be maintained.

Recommendation: We urge CMS to retain the longstanding policy of allowing the use of "pseudo-patients" when aides are tested on their competencies.

42 CFR 484.80(b)(3)(ix)(B) Standard: Content and duration of home health aide classroom and supervised practical training

(3) A home health aide training program must address each of the following subject areas:

(ix) Appropriate and safe techniques in performing personal hygiene and grooming tasks that include—

(B) Sponge, tub, and shower bath

(C) Hair Shampooing in sink, tub and bed

CMS recently revised the aide competency evaluation to require the aide to be competency trained/evaluated in performing personal hygiene and grooming tasks that include sponge, tub, **and** shower bath, and shampooing in sink, tub **and** bed, rather than the previous requirement which allowed competency training/evaluation in bathing to be demonstrated by a sponge, tub, **or** shower and hair shampooing in sink, tub **or** bed.

HHAs are required to train/evaluate aides in activities for bathing and shampooing on a live patient. However, home health patients typically do not bathe in tubs due to safety and mobility concerns (i.e. falls and difficulty getting in and out of the tub) or because they lack tubs. Since the implementation of the revised home health CoPs, agencies have expressed concern on the ability and safety to comply with this requirement.

The National Association for Home Care and Hospice (NAHC) conducted a brief nationwide survey of HHAs to ascertain the number of aides currently employed that have been competency evaluated in tub bathing and shampooing, and the availability of patients for which aides could be evaluated.

NAHC received over 350 responses from 26 states. Fifty-four percent of the respondents reported having none of their aides competency evaluated in tub bathing, even in a laboratory setting. In addition, 69% of respondents reported that either none or very few patients on service were able or willing to take a tub bath. HCA is concerned that this requirement will significantly delay competency evaluations and/or training while the agency locates patients for which the aide can be trained in all three bathing and shampooing methods.

Recommendation: Revise the regulation to require the aide be competency evaluated in bathing through demonstration of a sponge, tub **or** shower and bathing and hair shampooing in sink, tub **or** bed.

Physician documentation & certification requirements in the Medicare home health benefit 42 CFR 424.22(c) Determining patient eligibility for Medicare home health services

Medicare rules require that the physician certification of home health eligibility be fully supported solely on the basis of the records within the certifying physician's record. The certifying physician can rely upon records from other providers and practitioners, including the HHA, but only if the physician records indicate a specific written acknowledgement by the physician that these records were considered by the physician in determining whether to certify eligibility.

CMS has recognized that non-physician records are very useful in establishing a patient's eligibility for coverage, but continues to maintain a highly burdensome and confusing

requirement for including non-physician records as part of the eligibility evaluation. The accuracy and integrity of the eligibility is improved when both physician and non-physician records are considered.

Recommendation: CMS should eliminate its burdensome standard that results in erroneous claim determinations and require the Medicare Administrative Contractor to consider the home health agency's documentation (with or without this additional, discrete physician "sign-off") – not solely the physician's record – in making any determinations.

Patient Information

42 CFR 484.60(e) Standard: Written information to the patient.

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.*
- (5) Name and contact information of the HHA clinical manager.*

CMS chose not to finalize a proposed requirement that the agency provide the patient with a copy of the plan of care (POC). The requirement was not finalized due mainly to concerns by HHAs over the burden associated with providing this information to all patients. The information required to be provided under §484.60(e) is much of the same information as in the POC and would present the same kind of burden, especially if written information regarding **all** treatments is expected to be provided. The requirement to provide the name and contact information of the Clinical Manager is duplicative of the requirement for the agency to provide the contact information of the Administrator under 484.50(a).

Additionally, the benefit of providing this information to the typical patient served by Medicare certified HHAs is questionable. Patients easily become overwhelmed with too much information and commonly misplace or discard written information provided.

Further, §484.60(e) was not issued in the proposed rule but added in the final rule for the Home Health CoPs; therefore, there was not an opportunity for public comment on this requirement.

Recommendation: CMS should limit the information that must be provided so that it is no more extensive than: the visit frequency by each discipline (not visit schedules); medication schedule and instructions; and any other pertinent instructions related to patient care needs as

determined by the agency. Also, CMS should eliminate the requirement for agencies to give, in writing, an explanation of the treatments to be administered and name and contact information of the clinical manager.

42 CFR 484.55 Comprehensive assessment of patients

(a) Standard: Initial assessment visit. 1) A registered nurse must conduct an initial assessment visit to determine the immediate care and support needs of the patient; and, for Medicare patients, to determine eligibility for the Medicare home health benefit, including homebound status. The initial assessment visit must be held either within 48 hours of referral, or within 48 hours of the patient's return home, or on the physician-ordered start of care date.

CMS requires the registered nurse (RN) 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. The requirement for the RN to conduct the initial and comprehensive assessments when nursing and therapy are both ordered results in the waste of valuable resources (i.e., extra RN visits that are not reimbursable) in cases where the plan of care requires that the therapist visit prior to the RN.

Further, a therapist may currently conduct the initial and comprehensive assessment if therapy is the only discipline ordered. Therefore, there has always been precedent for a therapist to conduct the initial and comprehensive assessments.

Recommendation: 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.

HOSPICE

42 CFR 418.3: Definitions/Definition of Employee for Hospice Purposes

Under existing regulation, "*Employee* means a person who: (1) Works for the hospice and for whom the hospice is required to issue a W-2 form on his or her behalf; (2) if the hospice is a subdivision of an agency or organization, an employee of the agency or organization who is assigned to the hospice; or (3) is a volunteer under the jurisdiction of the hospice."

This definition casts doubt on the permissibility of hospices, in cases where they are part of hospital systems/organizations, to utilize system-employed nurse practitioners (NPs) in special circumstances for the sake of procedural efficiency and compliance. Namely, hospice association colleagues have reported that some hospices with a hospital or system parent organization would like to utilize system-employed NPs for purposes of assisting the hospice with fulfilling requirements related to hospice face-to-face documentation, and to do so under a strictly defined memorandum of understanding.

Whether such an arrangement is permitted hinges on whether or not the W-2 form for the NP and for hospice employees originates from the same source. In circumstances where the hospice is part of the hospital system but the W-2 is separately issued, CMS has indicated that hospices

would not be permitted to use system-employed NPs, regardless of whether the hospice is wholly owned by the system/organization. Under such circumstances, the hospice is required to employ an NP separately, which creates additional costs to the hospice and the system/organization. There are tax and personnel law implications that often prevent the hospice and the hospital/system from employing the same NP.

Recommendation: HCA believes that instead of requiring the hospice employees and NP to receive their W-2 from the same source, CMS should permit hospices to utilize system-employed NPs as long as the hospice is wholly owned by the system/organization and that the hospice and the system have established specific conditions which govern assignment of the NP to the hospice for specified time frames and circumstances.

42 CFR 418.100 Condition of Participation: Organization and administration of services/Establish Time Frames for Approval of Hospice Location Changes

Certification provisions require a hospice to receive CMS approval before opening a new location or moving to a new site from the hospice's surveyed, certified location in order to provide Medicare services from the new address. As part of the process, the hospice must:

- Submit all required documentation and an amended Form CMS-855A to its Medicare Administrative Contractor (MAC);
- Notify CMS and its state survey agency in writing of the planned change;
- If under deemed status, notify its national accrediting organization (AO) in writing; and
- Receive formal approval of the change in writing.

The CMS Regional Office (RO) may grant or deny the address change without a survey, or may determine that a survey is needed to establish that the new address complies with all applicable requirements. The opening of a new office (a "multiple location" application) must also be approved in advance, and CMS is expected to advise the provider of its findings.

However, CMS has not established specified timeframes within which a hospice can count on receipt of a definitive determination on its request for approval of such changes. A hospice may have invested significant resources to effectuate a move or create a new location but may receive no official communication for months relative to its request. This can create significant issues for an agency, its staff, and the patients and families it serves.

Recommendation: To address this, CMS should establish and enforce reasonable timeframes within which state survey agencies and MACs must respond to requests for approval of an address change or establishment of a new multiple location. CMS should also consider automatic approval for address changes in cases where a hospice is moving within the same geographical area and has a positive track record relative to its surveys. In cases where surveys are required to facilitate approval of the address change, CMS should establish a definitive process that includes access to expedited surveys and is minimally disruptive to the delivery of patient care.

42 CFR 418.64 Condition of participation: Core services/Waiver for Social Work Supervision Requirement

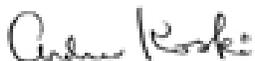
The 2008 revisions to the Hospice CoPs require that a hospice social worker either have a master's degree in social work (MSW) or be supervised by an individual with a MSW unless hired prior to December 2, 2008. Many rural hospices struggle to find and retain qualified social workers that meet the Medicare CoP requirement, especially in rural areas.

Most hospices across the nation serve fewer than 100 patients per day and many of these hospices are located in rural areas where they do not have access to qualified MSW-prepared social workers. The extensive distance between the rural hospice provider and its closest urban area is too great for the hospice in many cases to find an MSW-level social worker in the urban area who is willing to enter into an arrangement with the rural hospice.

Recommendation: HCA recommends that CMS create a waiver program under which hospices experiencing hardship in employing a MSW-level social worker may obtain an exception to the social work supervisory requirement. There is precedent for such waiver allowances, which already exist for the same reasons under the Medicare CoPs applicable to other disciplines, including waivers of the requirement that all nursing services be provided directly and waiver of the requirement that physical therapy, occupational therapy, and speech-language pathology be provided by a hospice.

Thank you for considering our comments. If you have any questions or need additional information, please call either of us at (518) 426-8764.

Sincerely,



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Vice President for Finance & Management