National Hospice and Palliative Care Organization

November 19, 2018

Seema Verma, Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health & Human Services
Attention: CMS-1692-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-3346-P, Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction

Submitted through www.regulations.gov

Dear Administrator Verma,

The National Hospice and Palliative Care Organization (NHPCO) is pleased to offer comments on CMS-3346-P, Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction, published on September 20, 2018.

NHPCO is the largest membership organization representing the entire spectrum of hospice and palliative care programs and professionals in the United States. We represent over 4,000 hospice locations and more than 57,000 hospice professionals in the United States, caring for the vast majority of the nation's hospice patients. NHPCO is committed to improving end-of-life care and expanding access to hospice and palliative care with the goal of creating an environment in which individuals and families facing serious illness, death, and grief will experience the best that humankind can offer.

NHPCO is pleased to provide comments on the proposed changes in the reduction of burden for hospice providers. While we appreciate the proposed changes, NHPCO believes that they will not significantly reduce burden for providers or professionals. NHPCO has also included other issues that hospice providers throughout the United States have suggested would help with the reduction of burden. Our comments follow:

1) **Hospice Aides**

Revise § 418.76(a)(1)(iv) to remove the requirement that a State licensure program meet the specific training and competency requirements set forth in § 418.76(b) and (c) in order for such licensure to qualify a hospice aide to work at a Medicare-participating hospice.

NHPCO Comments: *NHPCO supports this change in the training and competency requirement for hospice aides. We recognize that states may have significant variability in the State licensure requirements for aides, and states can determine what requirements are needed for aides in that State.*

2) **Pharmacy Services**

A. **§ 418.106(a)(1): CMS proposes to delete the requirement relating to having on the hospice staff an individual with specialty knowledge of hospice medications.**

CMS comments on this change: "Although there have been no formal studies on the proliferation of pharmacy benefit management company use in hospice, conversations with industry experts lead us to estimate that, at minimum, 75 percent of existing hospices use such services. Experts estimate that the more likely number is between 90 and 95 percent of hospices due to various factors that hospices find to be desirable, such as predictable capitated medication fees and direct to the patient door medication delivery services. Since the use of pharmacology experts has become routine due to the proliferation of pharmacy benefit management companies that provide pharmacist services for each patient bundled with drug and biologics supply services, we believe that it is no longer necessary to include a regulatory requirement specifically related to the use of a pharmacology expert."

NHPCO Comments: *NHPCO vehemently opposes this change, as knowledge about hospice medications is an important component of the care provided to every hospice patient. Removal of this requirement may have the unintended impact of sending a message to some providers that this component of care is no longer important or necessary.*

1. *The regulatory requirement does not require the "use of a pharmacology expert," only that there is someone on the staff with knowledge of hospice medications, specifically calling out that expertise. A pharmacist can work with the team on therapeutic options for hospice patients, including reducing or eliminating symptom burden, opportunities for discontinuation of medications, and assessment of drug interactions, to name a few. The pharmacist is the medication expert for the team, with extensive knowledge of medications and their efficacy. If there is a way to ensure that physicians and nurses have up-to-date knowledge of hospice*

medications, then the hospice should document that knowledge. That function is still very important to ensure patient safety and appropriate use of medications.

2. *To be in compliance with Medicare hospice CoPs, the hospice must be able to prove that they have resources available to provide individualized plans of care and medication review, as indicated in § 418.106(a)(1). Removing this requirement may signal that medication review is no longer important or necessary. This change has the potential for significantly impacting patient safety at a time when patients are dependent on the skills of the hospice team for their comfort and quality of life. The practice of pharmacy, like that of other medical disciplines, has become highly specialized. While the utilization of pharmacy benefit managers by hospices is now common, changing the CoPs to eliminate the requirement to "use someone with knowledge of hospice medications" introduces the possibility that hospices could contract with PBMs that do not have the resident clinical expertise to communicate with the hospice team and safely and efficiently manage the medication plans of hospice patients.*

3. *We are concerned about the assumption that the increase in the use of PBMs or the number of hospices using PBMs equals better outcomes because hospices can access pharmacy services with capitated fees, a formulary, and a delivery service. We are also concerned about patient safety and outcomes for the hospice whose work with a PBM does not include significant pharmacist involvement in medication review for individual patients and ongoing input with the interdisciplinary team.*

4. *For hospices that have a PBM, there may be emergency medication needs that must be delivered by a local pharmacist. The hospice will be relying on someone with specialty knowledge of hospice medications – the physician, nurse or pharmacist – to ensure that the emergency medication meshes with other medications that the patient is taking, carrying out the function of an "individual with specialty knowledge of hospice medications."*

5. *For hospices that do not use a PBM, removing this requirement may signal to the hospice that having expertise for hospice medications is not necessary.*

B. 418.106 (a) (1) Hospice and Palliative Care Specialty Training

CMS comments on this change: Since publication of the 2008 Hospice CoP final rule (73 FR 32088), the number of hospice and palliative care nursing and physician specialty training and certification programs has rapidly expanded. As more hospice and palliative care nursing and physician specialists have entered the job market, more hospices are employing these clinicians with advanced skill sets. In hospices that do not use a pharmacy benefit management service, these clinicians typically fill the role of the required individual with education and training in

drug management in addition to being the regular physician or nurse member of the interdisciplinary group. As these clinicians are already members of the core interdisciplinary group in accordance with the requirements at § 418.56(a), we believe that hospices will continue to benefit from their expertise in the absence of Federal regulations. For these reasons, we conclude that the requirements at § 418.106(a)(1) are no longer necessary to assure patient safety and the effectiveness of hospice care."

> ***NHPCO Comment:*** *We agree that there has been significant increase in available training for hospice nursing and physician specialists with advanced skill sets. They are available to meet the requirement for medication management. There is no reason to remove this requirement because there are more clinicians with specialty training. Rather, this requirement calls attention to the continuing need for these skills to be available for every hospice.*

C. 418.106 (a)(1) Cost Savings Projections

CMS comments on the cost savings of this proposed change: "Furthermore, we believe that hospices may achieve a cost savings upon removal of this requirement because they will no longer need to assure a dedicated time in each interdisciplinary group meeting in order to be able to document that a specific conversation occurred among group members, and thus document compliance with the regulation."

> ***NHPCO Comment:*** *This comment assumes that there should not be a dedicated time to discuss each patient's medication needs and document it. A key component of the IDT discussion focuses on the comprehensive assessment of the patient which includes a review of the patient's medications, including a review of what is prescribed, what should be changed, what should be discontinued, as well as any drug interactions and other considerations. Assuming that removing this requirement results in cost savings is inaccurate, as this focus is always a part of the interdisciplinary group meeting.*

CMS comments on the dollar value of this proposed change: "Additionally, we believe that this change would reduce the specialist nursing time spent specifically on advisement services. We believe that moving away from a regulatory compliance "check box" approach would allow the specialist nurse to incorporate medication management more seamlessly into regular clinical practice. The 2008 Hospice CoP final rule (73 FR 32088) estimated a 1 hour burden per patient for expert pharmacy services (30 minute initial advisement per patient + 2 15 minute update advisements) for a total cost of $69 per patient for all advisement services (updated to 2017 dollars). We estimate that this proposed change would reduce that time by 50 percent, to 30 minutes per patient, resulting in a $35 per patient savings. Based on the assumption that 25 percent of hospices use their own employees to perform this function, we

estimate that this reduction would occur for 400,000 patients nationwide (25 percent of 1.6 million hospice patients), for a total annual savings of $14,000,000. Together with the previously stated estimate, total savings would be $47,840,000 + $14 million = $61,840,000 annually.

> ***NHPCO Comments:*** *The estimated savings from this proposal may inadvertently increase costs to the Medicare program. By allowing a hospice to parse out medication management and advisement from the interdisciplinary group meetings, it will cause unintended consequences that will result in increased cost to the Medicare program with lower patient and family satisfaction and unnecessary increased utilization of GIP and CHC for uncontrolled pain and symptoms. Hospices do not use a "check box" approach in interdisciplinary team meetings; therefore, this proposal would disrupt the comprehensive conversations necessary to provide high quality care to beneficiaries. The value of reducing the overall discussion time is not a meaningful measure since the whole team must be informed about the pain and symptoms of the beneficiary in order to provide complementary specialized care to address the psychosocial and spiritual aspects of care.*

D. Medication policies and procedures

§418.106: CMS proposes to replace the requirement that hospices provide a physical paper copy of medication policies and procedures to patients, families and caregivers since these are written to guide the actions of hospice staff. Instead, CMS proposes that hospices provide information regarding the use, storage, and disposal of controlled drugs to the patient or patient representative, and family in a more user-friendly manner, as determined by each hospice.

> ***NHPCO Comment:*** *NHPCO supports this change in how information is provided to patients and families to ensure that the information is more user-friendly and understandable. However, H. R. 6, the SUPPORT for Patients and Communities Act, specifically spells out changes in the disposal of unused controlled substances by allowing qualified hospice professionals to dispose of these medications on site. In addition, the law specifies that the hospice will provide a written copy of the hospice's policies and procedures concerning medication management. Hospice providers will require additional guidance on what should be provided to patients and families to be in compliance with the new law.*
>
> *NHPCO supports any opportunity that a hospice might have to develop tools and resources to present information on the hospice's medication policies and procedures, including brochures, videos and other teaching tools. Topics should include the use, storage, and disposal of controlled drugs and should have the ability to be updated as changes in the law or procedures occurs.*

3) **Nursing Facilities**

§ 418.112(f): Previously the requirement for educating nursing facility staff about hospice was solely the responsibility of the hospice. The proposed change moves this requirement from § 418.112(f) to a new section § 418.112(c)(10) that requires this orientation for facility staff to be addressed in the Written Agreement standard.

NHPCO Comment: *NHPCO does not support this change. In discussions with hospice providers throughout the country, they have identified an added burden since this change would require a modification in what is included in the Written Agreement with each nursing facility or ICF/IID with whom the hospice has a contract. For many hospices, that would require a change in hundreds or even thousands of agreements.*

NHPCO Recommendation: *As an alternative, we note that there is language in the Nursing Facility Mega Rule Surveyor Guidance that addresses this issue. There, referring to* ***§ 418.112(f)*** *in section* ***§ 438.75(t)****, CMS indicates "It may not be necessary for each hospice to provide information to nursing home staff regarding the hospice philosophy and principles of care if the nursing home staff has received this information and are aware of the philosophy and principles of care." We recommend that this wording be added to the Hospice Surveyor Guidance so that there would be consistency between the two and CMS' desire to decrease this burden would be understood by surveyors without any need to change the hospice regulations.*

4) **Annual Emergency Preparedness Testing**

§ 418.113(d)(2): CMS proposes to reduce the current requirement to conduct two testing exercises per year down to one testing exercise per year, except for hospice providers with inpatient facilities, and to provide flexibility for inpatient providers regarding the type of "functional exercises" conducted.

NHPCO Comment: *NHPCO does not support this change in regulatory requirements. At a recent NHPCO meeting in the beginning of November, NHPCO had the opportunity to meet with a group of hospice providers recently impacted by natural disasters in 2018 – Hurricanes Florence and Michael as well as the California wildfires. We specifically asked for their thoughts about this proposed change. Overwhelmingly, the providers said that every exercise they conducted prepared them for responding to these natural disasters in a timely and coordinated way. They were not supportive of any reduction in the required number of exercises needed for compliance.*

Suggestions for Other Changes in the Medicare Hospice Conditions of Participation to Reduce Regulatory Burden

Subpart B—Eligibility, Election and Duration of Benefits

1. **§ 418.30 Change of the designated hospice.**

   NHPCO Recommendation: *Remove the limitation that a transfer may only occur once in an election period. If this limitation was removed, if a patient transfers from one hospice to another, the need for a face-to-face encounter would be reduced or eliminated.*

Subpart C—Conditions of Participation—Patient Care

2. **§ 418.64 Condition of participation: Core services - dietitian.**
   A hospice must routinely provide substantially all core services directly by hospice employees.
   (d) Standard: Counseling services.
   (2) Dietary counseling. Dietary counseling, when identified in the plan of care, must be performed by a qualified individual, which include dietitians as well as nurses and other individuals who are able to address and assure that the dietary needs of the patient are met.

   NHPCO Recommendation: *If the services of a dietitian are needed to assure that the dietary needs of the patient are met, allow those services to be available under contract with a dietitian rather than requiring the dietitian to be a hospice employee.*

Further Recommendations for Hospice Burden Reduction

In other testimony and communications with the Congress and with CMS, NHPCO has shared recommendations for reducing regulatory burden for hospice providers. We also include them here as other issues that the Administration could consider as reforms and burden reduction are considered.

1. Continuous Home Care

a. Hospice patients who are in crisis sometimes require continuous home care so that they can stay in their homes and with loved ones. Unfortunately, CMS regulations require the hospice to provide the continuous home care nursing care with employees. Since this is needed urgently

but not every day, it makes it difficult for hospices to plan for the staffing necessary to provide for these services.

> ***NHPCO Recommendation:*** *It could be more appropriate and cost-effective to allow hospices to contract for nursing services to provide continuous home care, allowing the hospice the flexibility to contract for nursing staff to provide these essential but occasional services as they see fit. This is a simple change that would improve patient care, provide administrative relief for providers, and cost nothing to the tax payer.*

2. <u>Audit education/transparency/relief</u>

Hospice providers report a substantial increase in the number and scope of government audits. Often auditors have a lack of understanding about the hospice benefit and hospice regulations and often cite the hospice for issues that are clearly allowed in the hospice regulations but may not be allowed for other Medicare provider types.

> ***NHPCO Recommendation:*** *NHPCO encourages CMS to provide additional training for audit staff, ensure that government auditors are subject to, and follow, established audit deadlines, CMS directives and legal standards for waiver of liability, and take other measures to minimize auditor duplication and overreach. The following provides a list of concerns related to hospice audit findings and the challenges hospices are experiencing.*

1. *ZPIC/UPIC applied improper standards for determining whether certain hospice patients were terminally ill.*
2. *ZPIC/UPIC does not recognize difficulties of determining prognosis.*
3. *ZPIC requires hospice to show decline in order to continue on hospice benefit.*
4. *ZPIC/UPIC misapplies Local Coverage Determinations (LCDs) and does not consider them guidelines.*
5. *ZPIC/UPIC improperly and solely relied on beneficiary interviews to deny claims.*
6. *ZPIC/UPIC initiates auto-denial of payments after beneficiary interviews without medical record review.*
7. *ZPIC/UPIC Denials Often Unsubstantiated on Appeal.*

3. <u>Hospice Face to Face Encounters</u>

The ACA included a requirement that a hospice physician or nurse practitioner must have a face-to-face encounter with a hospice patient before the end of a second benefit period (the first two benefit periods are 90 days each) and again for each 60-day recertification after that date. The hospice community supports the intent of the face-to-face encounter requirement but has found staffing limitations and timelines to be unduly burdensome.

NHPCO Recommendation: *We encourage Congress to enact legislation – and CMS to consider a demonstration – that would also allow physician assistants and nurses to perform face-to-face visits, and to make modifications to the timeframe in which face-to-face encounters can take place.*

Thank you for the opportunity to comment. NHPCO is always available to discuss these comments and recommendations more fully and stands ready to help in any way.

Sincerely,

Edo Banach, JD
President and CEO