National Partnership for Hospice Innovation
1299 Pennsylvania Ave., Suite 1175
Washington DC, 20004

November 19, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1693-P
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850

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

Dear Administrator Verma:

The National Partnership for Hospice Innovation (NPHI) greatly appreciates the opportunity to comment on this proposed rule to promote program efficiency, transparency, and burden reduction in the Medicare and Medicaid programs (CMS-3346-P). NPHI is a collaborative of the nation's most innovative, community-based, not-for-profit, hospice and palliative care providers that serve as a critical safety net in communities across the United States. In coming together, we work to identify, enhance, and spread the best practices in which our members are engaged. NPHI members have decades of experience in providing the highest-quality hospice and palliative care to those facing the final stages of their lives. This commitment is fundamental to our mission and distinguishes us as leaders whose innovative programs reflect the original intent of the Medicare Hospice benefit.

NPHI applauds CMS' commitment to the goal of reducing provider burden and putting patient needs over paperwork requirements, and we appreciate the efforts CMS has made in this rule to reduce reporting burden so that healthcare providers can spend more time focusing on delivering high-quality care. While there are a number of proposals in the proposed rule that NPHI concurs with, we do have concerns that some of the hospice-specific changes that CMS proposes would have a negative impact from a safety and quality-of-care standpoint on the ability of providers to deliver comprehensive, timely, person-centered care to patients and individuals with advanced illness and their families. We also feel that the proposed changes will not have a significant impact in reducing regulatory burdens on the hospice providers nor increase program efficiency. There are other actions CMS could take that would reduce burden in a more robust and efficient way.

We are pleased to be able to offer the following comments on certain programmatic and reporting changes in the proposed rule.

Removing the requirement that State licensure programs for hospice aides meet the specific training and competency requirements set forth in the federal Conditions of Participation (CoPs) in order for

such licensure to qualify an aide to work at a Medicare-participating hospice. CMS would instead defer to State aide licensure requirements regardless of their content or format. (*pg.35*)

Hospice aides deliver what many patients and families would consider the most vital and valuable aspects of end-of-life care by providing bathing and other personal care essential to patient comfort, and offering psychosocial and spiritual support. They often provide the interdisciplinary team with the most critical perspectives on the patient's fears, family dynamics, unresolved conflicts, or spiritual distress -- – in many cases, the hospice aide is named as the most important component of the interdisciplinary team in patient and family satisfaction surveys. As a result, vetting, hiring, and retaining competent and well-trained aides is critical to a hospice's capacity to deliver and sustain the provision of high-quality care. While NPHI appreciates CMS' intent to ease the burden associated with verifying aide applicants' state and federal licensure requirements, we have **concerns that simply eliminating the requirement that state licensure programs meet the requirements set forth in the federal Conditions of Participation (CoPs) will remove an important regulatory "floor" for licensure standards**. The federal CoP requirements ensure a minimally acceptable level of training and competency evaluation for aides providing care to Medicare hospice beneficiaries, some of the most vulnerable and medically complex patients served by the healthcare system, and it is in the interest of CMS to encourage aide training adequate to properly serve these patients and their families.

The burden reduction benefits of streamlining state and federal licensure requirements must be balanced against the potential that delinking these sets of standards and deferring to state requirements (for those states that have them), "*regardless of their content or format*" will result in a level of variability across the aide training and certification landscape that could impact patient safety in a way that compromises a hospice's ability to deliver care of a sufficient and universally accepted quality. While CMS states that 76% of states have their own hospice aide qualifications for licensure, certification, or registration (*pg. 37*), the question remains as to whether, in light of this proposed rule becoming finalized, states might, at some time in the future, modify their requirements in such a way that they no longer approximate those laid out in the federal CoPs, which were initially promulgated to ensure a baseline level of training necessary to ensure safe and appropriate care to hospice patients.

In the event that robust state-level standards are not in place, NPHI would have concerns about patient safety and care quality. However, we appreciate and agree with the spirit behind this proposed rule to reduce unnecessary regulatory burden on hospice providers. As a way to balance the need to guarantee a consistent training standard with the goal of reducing burden, we would suggest that a **potential solution could be to maintain the requirement that state licensure requirements meet those set forth in the federal CoPs, adding a waiver mechanism by which states with standards that exceed the CoP guidelines would not be required to meet the exact federal CoPs, and thus hospices in those states would not be required to confirm both the state and federal licensure requirements during the aide hiring process**. At the same time, by not removing entirely the requirement that state licensure requirements meet those set forth in the federal CoPs, CMS would guarantee that those states without robust standards of their own, or states without any requirements at all, would indeed remain accountable to meeting a minimum level of aide training sufficient to ensure patient safety and high-quality care.

Removing the requirement to have a pharmacist or drug management expert with special knowledge of hospice medications on staff or contracted with the hospice to ensure drugs prescribed to patients are appropriate. (*pg.39*)

NPHI has concerns with the proposal to remove the requirement in the CoPs that a hospice ensure that the interdisciplinary group confers with an individual with education and training in drug management to confirm that drugs and biologicals meet each patient's needs. We believe that removing the requirement and thereby decreasing the specificity around the standards of hospice drug management has potential safety implications for patients that outweigh any burden reduction associated with explicitly removing the requirement.

In the proposed rule, CMS states that between 75%-95% of hospices now contract with a pharmacy benefit management company (PBM) to provide drugs and pharmacist services to their patients, and that due to the proliferation of these PBMs and the fact that they often provide pharmacist services for each patient bundled with drug and biologics supply services, it is no longer necessary to include a regulatory requirement specifically related to the use of a pharmacology expert (*pg. 40)*. To begin, NPHI has concerns around the validity of the claim that 75%-95% of hospices currently contract with a PBM. As the proposed rule itself states, "*there have been no formal studies on the proliferation of pharmacy benefit management company use in hospice" (pg. 40)*, and CMS is basing these figures off of conversations with unidentified "industry experts". In the absence of rigorous data and evidence around the extent of hospice-PBM arrangements, it would seem that any regulatory changes based on the presence of these partnerships should be very carefully examined to ensure that they do indeed reflect the actual landscape of hospice-PBM contracting.

There are also concerns about the assumption that the increase in the use of PBMs or the number of hospices using PBMs automatically results in more positive patient outcomes. NPHI does not feel that there is enough evidence that exists to justify a claim that a hospice-PBM partnership, by its nature, produces better patient outcomes. We are also concerned about patient safety and outcomes for hospices who have contracts with PBMs that do not include significant involvement in medication review for individual patients and ongoing input with the interdisciplinary team.

Drug management and review for hospice patients is a complex clinical process that requires sophisticated clinical judgement by a provider with extensive and appropriate training and expertise in its methods. Removing the explicit requirement that hospices utilize an individual with such expertise has the potential to lower the standard of care, which could imperil patient safety and well-being. And for the hospices that do not contract with PBMs (5%-25% by CMS' own estimates), there is an added concern that they may be at an even greater risk of not ensuring expert drug management services, as removal of this requirement may signal that this expertise is not necessary.

We agree with CMS' assertion that hospice and palliative care nursing and physician specialists are increasingly obtaining the advanced skillsets necessary to assume the role of the drug management expert. However, we see this as an indication that there is an ongoing need for these skills to be available for every hospice, particularly in an era of opioid crisis, and as such, there is no reason to remove this regulatory requirement.

CMS' claims that hospices would save money and time by no longer being required to document that a specific conversation occurred with the medication expert may be unfounded, as a key component of the IDT discussion focuses on the comprehensive assessment of the patient, including medication management, including a review 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.

Additionally, there appears to be a tension between the proposal to remove this requirement and CMS' language in the same rule that "*To the extent that a hospice needs additional expert information or expertise beyond what is provided by hospice employees and the pharmacy expertise of any pharmacy benefit manager that a hospice may choose to use in order to meet a given patient's assessment, care planning, and care delivery medication-related needs, we would continue to require that it secure such information and expertise*." (*pg. 42)*. Questions are raised as to what additional expert information or expertise CMS would require hospices to furnish in the case of a complicated patient situation. Presumably, this expertise would be provided by the very kind of drug management expert that the rule is proposing to delink from the CoPs. If the expectation remains that a hospice would be required to continue to seek such expertise even if the formal regulatory requirement were removed, that would create confusion amongst providers as to whether or not they should indeed continue to employ or contract with a drug management expert. **For purposes of transparency and patient safety, NPHI would recommend that the requirement remain in the CoPs to ensure high-quality patient care and provider clarity on what is required of them.**

Replacing the requirement that hospices provide a physical paper copy of policies and procedures for management and disposal of controlled drugs with a requirement that hospices provide this information to the patient or patient representative, and family in a more user-friendly manner as decided by each hospice *(pg. 42)*

NPHI agrees with CMS that drug management and disposal policies are often written in dense, highly technical language that can be difficult for patients and families to understand fully. and We support the intent to ensure that important information on these issues is provided to hospice patients and families in a manner and method that is easily understood and facilitates more lay comprehension. However, we have concerns about the lack of definition or standardization around the term "user-friendly", and how CMS plans to ensure that the what any given hospice deems as "user-friendly" is indeed a form and format that is easily understood and comprehended by various patients and families. We would encourage CMS to develop guidelines on "user-friendliness" so that hospices can be certain that that they are fulfilling the spirit of the rule and the remaining CoP requirements related to educating patients and families on drug management and disposal procedures.

Additionally, we would draw CMS' attention to the fact that the recently passed *Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act)*, at Section 3222 (b)(iii)(II)(aa), requires that a hospice provide a copy of the written policies and procedures to the patient or patient representative and family. The proposed rule under consideration is in conflict with this statute, so it will be important for CMS to release additional guidance to clarify and reconcile the provisions of this rule with those of the SUPPORT Act. Failure to do so may increase provider burden and confusion, as hospices will be unsure of how to proceed with changes to their policy and procedure protocols.

Removing the requirement that hospice training of SNF & ICF/IDD facility staff be a standalone requirement, and instead moving it to the standard related to the written agreement established between hospices and facilities. (pg. 45)

NPHI believes that this change will not significantly impact hospice burden, and may indeed add burden in the event that a hospice has contractual relationships with multiple SNFs and or ICF/IDDs, which would necessitate the hospice having to change the written agreement language for each contract.

Annual Emergency Preparedness Testing: Proposing 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

NPHI is not in favor of these proposed changes to the emergency preparedness requirements for hospices. Reducing the number of exercises per year and pushing the requirement to review the annual plan to every other year has the potential to result in the deterioration of critical knowledge and skills that are required to safely and successfully manage a natural or man-made disaster or emergency. Every exercise conducted better prepares hospices for responding to emergency situations in a timely and coordinated way. As the consequences of poor healthcare facility emergency planning and preparation often results in serious injury, suffering, or death of patients, it is incumbent on CMS to ensure that hospices and other providers are adequately prepared to deal with dangerous and unpredictable emergency circumstances. Even with the current regulatory guidelines in place, there are many instances of poor emergency planning on the part of a healthcare facility directly contributing to patients' death. While the proposed changes would reduce some of the testing burden associated with emergency planning, the level of reduction is not sufficient to justify the potential negative impact on patient safety that a poorly prepared hospice in an emergency situation represents.

Ideas for Additional Regulatory Burden Relief

NPHI believes there are more impactful actions that CMS could take to reduce regulatory burden on hospices, especially those that are non-profit and community-based.

Most troublesome is the increasing trend of government contractor auditors routinely denying hospice claims based on an overly simplified and erroneous assessment of the hospice physician's complex prognostication of the individual's life expectancy. Auditors are using simple "rules of thumb" guidelines to deny claims after concluding that a patient's medical record fails to show "terminal decline," based on whatever unstated definition the auditor applies to that phrase. In doing so, the auditors elevate this undefined phrase (that does not exist in any statute or regulation) over the clinical judgment of the certifying physicians. "Rule of thumb" denials such as this are not aligned with the governing statutes or regulations and demonstrate a fundamental misapprehension of the hospice benefit by the auditors. Such denials improperly limit the scope of the hospice benefit to a degree that is inconsistent with Congress' mandate and intent, and jeopardize the availability of the hospice benefit to truly terminally ill individuals.

We request that CMS issue guidance to its contractors to stop using a "rule of thumb" as a means to deny payment for hospice care. It is not consistent with the statute, is creating a bigger logjam at the Administrative Law Judge (ALJ) appeals level, and is limiting access to care at a critical point in a person's trajectory of illness. Furthermore, it is an unsustainable regulatory burden on hospice providers, particularly community-based, non-profit providers, to supply hundreds of records in support of a standard that is not consistent with the law.

While the provisions of the proposed rule may provide some minimal burden reduction, it is a minimal amount and some of that reduction would come at the expense of patient safety and quality care. Much more important is that CMS work through a new program integrity regime based on congressional intent and the language of the law, and that data be assembled immediately to allow all stakeholders to

work collaboratively toward resolving the current crushing audit environment that is inappropriately focused on community-based, safety net providers

We thank you for the opportunity to provide input on this proposed rule and we look forward to continuing to work with CMS to ensure that program rules and regulations strike the right balance between reducing burden and ensuring high-quality, person-centered care for hospice patients and those facing advanced illness. If you have any questions regarding this letter, please contact Davis Baird at dbaird@hospiceinnovations.org.

Sincerely,

Tom Koutsoumpas
President and CEO
National Partnership for Hospice Innovation