VNAA
Visiting Nurse Associations of America

December 2, 2014

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

SUBJECT: CMS-10538 Prior Authorization Form for Beneficiaries Enrolled in Hospice

Dear Administrator Tavenner:

The Visiting Nurse Associations of America (VNAA) respectfully submits for consideration comments on CMS' proposal to implement a standard Prior Authorization form to facilitate coordination between Part D plan sponsors, hospices and prescribers.

VNAA is a national nonprofit organization that supports, promotes and advocates for community-based, mission-driven, nonprofit providers of home health, palliative care and hospice services. As safety net providers, VNAA members provide care to all patients regardless of ability to pay or to severity of illness and serve a mix of Medicare, Medicaid, privately insured and charity care patients. VNAA members have expertise in managing and delivering high quality care in a patient's home at a fraction of the cost of institutional settings.

VNAA is also a trusted leader in healthcare policy and a resource for policy makers, providers and healthcare partners. For example, VNAA's Blueprint for Excellence (www.vnaablueprint.org) is a free quality improvement and staff training tool assisting home health, palliative care and hospice providers to implement best practices for key service components focused on reducing unnecessary hospitalizations, reducing readmissions, improving patient outcomes and health status.

General Comments

VNAA has worked in coalition with patient advocacy, pharmacy and hospice industry organizations in the last year to assist CMS in resolution of Part D challenges. However, VNAA urges CMS to consider the growing disconnect between the original intent of the hospice benefit and the evolving payment-oriented rules of the benefit.

The intent of hospice has always been to provide interdisciplinary care encompassing all dimensions of being alive. Conceptually, hospice stops the divide between medical specialties and works with the multifaceted person. In this framework, hospices must evaluate, manage and balance all patient needs and components of health care while remaining mindful of the underlying causes as information and reference points. The key is that these underlying causes are not, have never been and should not be held as focal points in determining care. Hospice is intended to focus on the experience of living and

making that as easy and stress free as possible. That may mean using more medications, different medications or less medication. The goal is not to cure, but to cope and maximize potential and minimize suffering.

However, CMS has added to the "rules of the game" an arbitrary distinction between 'related and unrelated' conditions as distinct subsets within the idea of interdisciplinary care. This arbitrary division was created solely for the sake of payment. VNAA strongly believes this distinction directly contradicts the original vision and purpose of hospice care. This new distinction essentially says that there are components of a persons' experience which are connected to their death and those which are not. This new distinction sets up hospice providers to differentiate parts of a whole person and leads back to the fractured, over-specialized health care system that hospice was intended to remedy, if only for a short time at end-of-life. CMS' recent policy changes in this direction say that a terminal prognosis is composed of multiple diagnoses but that CMS will only pay for treatments necessary to manage the specific terminal condition. These policy directives prevent hospices from managing and supporting the whole person and force hospices to focus on and segregate the precise cause of dying.

VNAA believes that the real issue for CMS' consideration is not about defining 'related' and 'unrelated' but about ensuring efficacy and usefulness. The current policy separating hospice providers and Part D plan sponsors does not place efficacy and usefulness at the forefront but rather focuses on the secondary consideration of who should pay. The ultimate resolution of this issue, and the focus of future hospice policy, must be focused on patient need.

VNAA strongly urges CMS to refocus policy development to advance the original hospice ideals of interdisciplinary care, to break the mold of fragmented medicine and focus on identifying clinical indicators of care including cost, which provide a way to evaluate success.

Comments on the Proposed Part D Preauthorization Form

CMS proposes two primary uses for the standard prior authorization (PA) form: 1) to document that a drug is "unrelated" to the terminal illness and related conditions; and 2) to communicate a beneficiary's change in hospice status and care plan to Part D sponsors. VNAA presumes that the proposed standard PA form would be used only for the four categories of prescriptions drugs identified by the OIG as typically used to treat the common symptoms generally experienced during end of life care. CMS identified these four categories as: analgesics, antinauseants (antiemetics), laxatives, and antianxiety drugs (anxiolytics).

VNAA urges CMS to carefully consider and address a number of concerns and case examples that could impede coordination and ultimately harm beneficiaries. Of greatest importance, VNAA asks CMS to mandate use of the standard form as quickly as possible and to prohibit modifications by Part D sponsors. Further, and beyond the scope of this request, VNAA urges CMS to establish a clear process for resolution of coverage disputes between hospice organizations and Part D sponsors. The proposed PA form will simply be a tool to establish medication regimes if CMS does not establish specific processes for dispute resolution. Conflicts over responsible payer determinations will inevitably arise. Such conflicts can result in delay of communications and resolution which delay the delivery of necessary medications to hospice beneficiaries. Hospice organizations must have clear expectations of Part D sponsor response requirements if sponsors are permitted to reject hospice organization determinations on relatedness.

CMS seeks input on the proposed standard PA form in four specific areas:

1) *The necessity and utility of the proposed information collection for the proper performance of the agency's function*

VNAA believes the information requested in the proposed form is useful and appropriate. A key concern, however, is that the decision of a hospice organization on the issue of relatedness must be preeminent to any review by a Part D sponsor. The existing hospice Interdisciplinary Group (IDG) process already establishes the issue of related or unrelated drugs. The IDG team is responsible for the interdisciplinary care of the hospice beneficiary and develops and reviews the beneficiary's plan of care, including prescription medications related and unrelated to the terminal diagnosis. This existing process is effective and should not be duplicated or watered down by secondary review.

Further, VNAA seeks CMS guidance on submission of subsequent coverage determination in the event that a change in disease trajectory results in a change in drug relatedness status. As an example, on admission a patient may be noted to have urinary incontinence issues and be utilizing any number of agents specific to this problem. But if the patient's terminal prognosis is not related to urinary flow (i.e. lung cancer or COPD) the medication could be determined as unrelated on admission. However, after working with the patient and assessing their symptom burden, urinary incontinence could be identified as a cause of pain or distress which would lead the hospice provider to change the mediation to "related." Alternatively, symptoms could change requiring medications to be shifted from related to unrelated over time. For example, a CPD patient may enroll in hospice still able to achieve dyspnea relief from inhaled steroids as a related medication. But over time, the effectiveness of inhaled products is reduced related to the inability to take and hold deep enough breaths. A hospice would want to shift the patient to oral steroids and ideally determine the inhaled products to be unrelated. Another example would be a patient with multiple sclerosis who later suffers a heart attack and is diagnosed with congestive heart failure as secondary conditions. This patient might qualify to have diuretics and and nitrates covered for comfort as related conditions.

2) *The accuracy of the estimated burden*

VNAA questions CMS' methodology for establishing an estimated time and expense burden for hospice organizations. One key concern is that Part D sponsors will require PA forms to be completed or submitted by physicians instead of hospice nurses. CMS notes in the Supporting Statement–Part A that a hospice nurse or prescriber may complete the proposed PA form. VNAA urges CMS to direct Part D sponsors to accept verbal communications and submissions from hospice nurses. Currently, many hospices report that Part D sponsors will only accept guidance from physicians, especially in cases of hospice organization follow-up after denials for relatedness issues.

Further, VNAA notes that CMS does not propose additional reimbursement to hospices to support the additional administrative burden for every hospice beneficiary with Part D coverage. VNAA strongly cautions that the administrative burden will be greatly increased if individual Part D sponsors are permitted to customize the form in any way, including the additional of corporate logos. There is no need for corporate identification on the proposed standard PA form and VNAA urges CMS to prohibit any such customization.

3) *Ways to enhance the quality, utility and clarity of the information to be collected;*

VNAA notes that the proposed PA form appears comprehensive in the information requested but reiterates that utility of the information will be limited if the standard form is not accepted by all Part D sponsors. VNAA urges CMS to require Part D sponsors to accept non-customized PA forms on behalf of hospice beneficiaries.

4) *The use of automated collection techniques or other forms of information technology to minimize the information collection burden.*

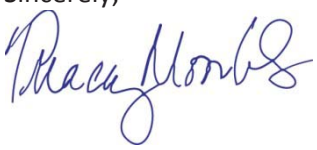
VNAA notes that CMS encourage Part D sponsors to facilitate electronic submission of the required information. In reality, many hospice organizations, including non-profit hospice organizations, do not have access to electronic medical or health record (EMR/EHR) platforms that would facilitate such submission and commonly rely on facsimile transmission for communication with Part D sponsors. VNAA urges CMS to not require electronic submission until and unless all EMR/EHR incorporate the elements of the proposed standard PA form.

Finally, VNAA remains concerned that CMS is taking a broad enforcement approach, increasing the financial and regulatory burden to an entire industry, for a problem caused by only a very few hospices. Specifically, CMS outlined, the proposed CY2015 Hospice payment rule, non-hospice spending for Hospice beneficiaries during an election period and highlighted analysis of hospice drugs paid through Part D sponsors. Specifically, CMS reported Medicare paid $1 billion in CY12 for non-hospice expenses associated with hospice beneficiaries. Of this, CMS identified $710 million in Part A and B spending (including 28.6 percent in inpatient care; 52 percent in Part B services and $268.4 million in ER expenses) and $335 million in Part D expenses.

To be clear, Medicare paid twice as much in non-hospice Part A and B expenses combined than in total hospice enrollee Part D expenses. Further, CMS noted that *fewer than 400 hospices (of 3,500 nationwide)* were responsible for more than half of these inappropriate expenses. In response to this analysis, VNAA reiterated long-standing recommendations for targeted program integrity interventions with hospices and other providers who have demonstrated an inability to appropriately comply with program regulations. A targeted approach by CMS would demonstrate CMS' commitment to program integrity, respect for honest program participants and good stewardship of the Medicare Trust Fund.

VNAA appreciates the opportunity to provide comments on the proposed PA form and stands ready to collaborate with CMS to ensure interdisciplinary hospice services.

Sincerely,



Tracey Moorhead
President and CEO