January 10, 2014

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Department of Health & Human Services
Centers for Medicare and Medicaid Services
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Baltimore, MD 21244-1859
Submitted via email to: PartDBenefitImpl@cms.hhs.gov

Subject: Request for Comments: Part D Payment for Drugs for Beneficiaries Enrolled in Hospice

Dear Directors Tudor, Wilson and Majestic,

NHPCO appreciates the opportunity to comment on CMS’s proposed new policy on handling Part D payment for drugs provided to beneficiaries enrolled in hospice. NHPCO is the largest membership organization in the country representing the entire spectrum of not for profit and for profit hospice and palliative care programs and professionals in the United States. We represent over 3,500 hospice locations and more than 44,000 hospice professionals in the United States, caring for the vast majority of the nation’s hospice patients. The organization is committed to improving end-of-life care and expanding access to hospice 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.

While NHPCO has always acknowledged and accepted that there have been instances of Part D payment for drugs that should have been covered by hospice under the Part A hospice benefit, we have significant concerns about how CMS has handled this issue so far, the speed with which CMS is rushing to implement such a major change, the continued lack of detail about the proposed new processes and how they would work, and a seeming lack of understanding about the complexities of this issue and of the clinical realities of terminally ill patients. As we have stated repeatedly in the past, NHPCO would welcome the opportunity to work collaboratively with CMS and the other stakeholders affected by this issue, to develop processes that would ensure appropriate payment for drugs and would be least burdensome for all concerned, most importantly for the terminally ill Medicare beneficiaries themselves. We also continue to assert that CMS’s policy of recoupment of all Part D analgesic claims for hospice patients, with no mechanism for determining
whether the drugs were for uses related to the terminal condition, is not legally supportable and must be changed.

Below we set forth our major concerns, raise certain issues and questions that have not been addressed, and propose some possible solutions, but it is difficult to comment on some of the proposals when so little detail has been provided.

**The Medicare Hospice Benefit - The Statutory & Regulatory Framework**

As we have conveyed in previous communications with CMS, since the heart of this issue concerns the very nature of the Medicare hospice benefit, we feel it is important to return to the provisions of law and regulations that establish the scope of the benefit, and the services that hospices are, and are not, required to provide.¹

**Statutory Framework:** The Medicare hospice benefit grew out of a 26 site demonstration project, and Congress structured it to give the hospice the responsibility for managing the patient’s care related to their terminal illness, and determining which services were necessary for the palliation and management of their terminal illness. Hospice became a Part A Medicare benefit through legislation passed by Congress in 1982, and the first hospice regulations were promulgated in late 1983. The Medicare hospice benefit requires beneficiaries to affirmatively elect to receive hospice care, and in so doing they must waive their right to Medicare payment for certain other services. From the outset, however, the statute has specified that this waiver is limited to other “services furnished during the period that are determined (in accordance with guidelines of the Secretary) to be related to the treatment of the individual’s condition with respect to which a diagnosis of terminal illness has been made.”² Therefore the hospice is responsible for care related to the treatment of the individual’s terminal illness and related conditions, but beneficiaries do not otherwise waive their right to Medicare coverage for other items and services, including drugs if they are enrolled in Part D.

**Regulatory provisions:** In implementing this statutory provision, CMS has reiterated in several regulatory provisions that the hospice’s responsibility is limited. In the original regulations established to implement the hospice benefit in 1983, HCFA (now CMS) addressed the coverage of drugs in several places, and for the most part these regulatory provisions have changed little, if any, over the past 30 years. With respect to the waiver referenced in the statute, the regulation regarding the election of hospice care stated in 1983 that an individual waived all rights to Medicare payments for “Any Medicare services that are related to the treatment of the terminal condition for which hospice care was elected or a related condition”, and the current version of this regulatory provision has not changed.³ Similarly, in the definition of “covered services”, the regulation specifies that “only drugs as defined in section 1861(t) of the Act and which are used primarily for the relief of pain and symptom control related to the

¹ In particular, we reference the letters from NHPCO and our outside legal counsel that were sent to CMS on September 26 and October 28, 2013, which are attached, as well as our meetings with CMS staff regarding this issue, on September 18 and October 25, 2013.
² Social Security Act §1812(d)(2).
³ 42 CFR §418.24(e)(2) in the original regulations; now found at 42 CFR §418.24(d)(2) (emphasis added).
individual’s terminal illness are covered.”4 This regulatory provision regarding coverage of drugs has not changed since 1983. Similarly, the current regulation establishing the hospice condition of participation related to drugs and biologicals, medical supplies, and durable medical equipment states that “drugs and biologicals related to the palliation and management of the terminal illness and related conditions, as identified in the hospice plan of care, must be provided by the hospice while the patient is under hospice care.”5

Related to the Terminal Illness

Based on this statutory and regulatory framework, it is clear that the key issue for determining hospice coverage concerns “relatedness.” Throughout the history of the Medicare hospice benefit CMS has recognized that these determinations of “relatedness”, on which payment responsibility rests, require clinical evaluations that must be made case-by-case, based on each Medicare beneficiary’s medical condition, and that the determination is a medical decision to be made by the hospice physician, who is most involved, and most familiar with, each patient’s care.

Comments in FY2014 Hospice Wage Index Final Rule: CMS stated in the FY 2014 Hospice Wage Index final rule in August 2013 that “It is also the responsibility of the hospice physician to document why a patient’s medical need(s) would be unrelated to the terminal prognosis. We expect that hospice providers will use their best clinical judgment in determining which diagnoses and conditions are related to the terminal prognosis of the individual receiving hospice care.”6 This exercise of clinical judgment is essential in order to ensure that beneficiaries continue to have access to the drugs they need and are entitled to, and that these drugs are covered and paid for by the appropriate component of Medicare.

Re-interpretation of Medicare Hospice Benefit: Now, however, we are very concerned that CMS seems to be re-interpreting the Medicare hospice benefit as being essentially all encompassing, and taking the position that once a beneficiary is determined to be eligible for hospice care, every aspect of their clinical condition becomes related to their terminal condition and all of the medications they take, regardless of the indication for the medication and length of time that they have been taking it, should be discontinued or will be considered to be related to their terminal diagnosis. CMS does acknowledge that a beneficiary “may be prescribed a medication for a condition that is completely unrelated to the terminal illness or related conditions,” but states that such situations will be “extremely rare,” and provides no examples of when that might be the case. Such a limited interpretation isn’t clinically supportable, and is far from the experience of our 2,700 hospice provider members. We have serious concerns that the policy, as proposed by CMS, has the potential to have harmful effects on beneficiary access to hospice and will likely result in greater out of pockets costs for beneficiaries, as well as increase the confusion and chaos now currently occurring with Part D and hospice. It is on this issue that CMS appears to have an incomplete understanding of terminally ill patients and the broad variability of the medical conditions experienced by terminally ill patients.

In support of this reinterpretation of the hospice benefit, CMS repeatedly cites one phrase from the preamble to the final rule establishing the first hospice regulations published in 1983. In that final rule,

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4 42 CFR 418.202(f) (emphasis added).
5 42 CFR §418.106 (emphasis added).
CMS noted that it had received questions regarding the requirement that beneficiaries waive certain coverage upon election of the hospice benefit, and “what constitutes care for a patient’s terminal illness or related conditions (which is the responsibility of the hospice) and what constitutes care for unrelated conditions (for which out-of-hospice Medicare payment may be made).” CMS responded that the unique physical condition of each terminally ill individual makes it necessary for these decisions to be made on a case-by-case basis, and went on to state that “it is our general view that the waiver required by the law is a broad one and that hospices are required to provide virtually all the care that is needed by terminally ill individuals.”

It is this phrase “virtually all” that CMS has most recently and repeatedly cited to support its view that a beneficiary’s need for medications unrelated to their terminal condition will be “extremely rare.” However, this single phrase used once in a preamble to a rule 30 years ago, during a time when patients were in hospice primarily to manage symptoms from end stage cancer and before Medicare even had much experience with hospice care, should not be used to re-invent the Medicare hospice benefit and the structure established by Congress. The deciding factor is and has always been, whether or not the services are “related to the treatment of the individual’s condition with respect to which a diagnosis of terminal illness has been made,” whether that constitutes all, virtually all, or very little of the care that a particular patient requires. CMS, instead, seems to be defining all medical care required to manage a patient’s multiple comorbidities and pre-existing conditions as “hospice care” and then requiring an extraordinarily high standard for the hospice to prove otherwise.

Determining Relatedness: Determining whether care is related or unrelated to the patient’s terminal illness is not always straightforward. It was a challenging issue 30 years ago, and it can be even more complex today when patients are living longer with more medical conditions, there are so many more medications available, and as hospices have begun to care for patients with a broader range of terminal diagnoses. But now, as then, these decisions must be made on a case by case basis.

We agree that hospices are responsible for all drugs used for the relief of pain and symptoms related to the individual’s terminal illness and related conditions, as set forth in the patient’s plan of care, and that the “related” drugs a patient needs may change over time. We concur that when a hospice patient’s terminal prognosis is based on multiple diagnoses, then drugs related to those multiple diagnoses would be the hospice’s responsibility. We also agree that the decisions about medications related to the terminal illness and related conditions are the responsibility of the hospice physician, working with the hospice interdisciplinary group. This interdisciplinary group is charged with developing and overseeing the patient’s plan of care, reviewing and updating it every 15 days, or more often if necessary, based on clinical assessment of patient status and needs. This assessment includes evaluating medications and their use, continuation, and possible discontinuation or any other related changes on an ongoing and iterative basis.

Unrelated medications not “extremely rare”: In contrast to CMS’s statement in the proposed guidance, it is not “extremely rare,” and in fact is quite common, for patients to be admitted to hospice taking

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8 Id.
9 Social Security Act §1812(d)(2).
drugs for a multitude of medical conditions that are unrelated to the reasons for their hospice eligibility. These drugs should be continued when medically necessary and appropriate for the patient/family while the patient is receiving hospice care, or until they no longer meet the goals for which they were prescribed or become burdensome. When these medications are determined to be unrelated to the terminal illness, yet medically indicated, they should be covered by the current payor in the same fashion as they were obtained prior to the election of the hospice benefit. Examples below illustrate this point:

**Example 1:** A patient is admitted to hospice with a terminal diagnosis of congestive heart failure with related conditions of atrial fibrillation, coronary artery disease, pulmonary hypertension and cachexia. In addition, the patient also has a 30 year history of a seizure disorder which has been well controlled with anti-seizure medication. The seizure disorder is a preexisting condition that is unrelated to the patient’s terminal illness and related conditions, and payment for the medications used to control the seizures should not be the responsibility of the hospice. Stopping the anti-seizure medication(s) because the patient has elected to receive hospice care would not be advised since the anti-seizure therapy is managing an unrelated condition which requires continued drug therapy to avoid adverse outcomes and a negative impact on the patient’s quality of life. Therefore, upon review by the hospice physician and interdisciplinary group, the anti-seizure medication(s) would be considered unrelated but medically necessary.

**Example 2:** A patient enters hospice with a diagnosis of lung cancer, current DVT from cancer associated coagulopathy, dysphagia with aspiration, and a recent upper respiratory infection. The patient also has a long history of non-insulin dependent diabetes which has not been influenced by the use of glucocorticoid steroids used in the treatment of his lung cancer. The patient’s terminal diagnosis is unrelated to his diabetes, but the beneficiary continues to need oral medications to manage his diabetic condition.

**Example 3:** A patient is admitted to hospice with end-stage emphysema, which is significantly limiting his functional capabilities, such that his life expectancy is in the range of four to six months. The hospice physician made the determination that the patient should continue taking his glaucoma and antihypertensive medications as well as his thyroid replacement therapy, all of which are for stable and controlled medical conditions unrelated to his terminal illness. The physician will reconsider their use in subsequent medication reviews.

Patients such as those described above are common, especially when admitted with months rather than weeks to live. While some medications unrelated to the terminal illness will be discontinued over the course of a patient’s stay in hospice, and it is eventually true that virtually all necessary medications will be related when a patient’s prognosis is a matter of hours or days to live, that is not the case for patients with prognoses of weeks or months.

**Provider review of charts for unrelated medications:** A large multi-site hospice provider conducted an independent review of 104 hospice charts, randomly chosen from among new hospice admissions across 30 states during the week of December 4, 2013. The charts were independently reviewed by four nationally prominent, hospice & palliative medicine board certified hospice specialists. Using criteria that were intended to be the most inclusive, looking at any diagnosis and associated medication that
might be related to either the terminal diagnosis or the terminal prognosis, medications that the patients were taking upon hospice admission were classified as either being hospice related/covered or not. In this review, 74.1% of patients had at least one unrelated medication that needed to be continued. For a majority of patients, multiple medications were determined to be unrelated/not covered.

While some drugs taken by beneficiaries prior to their hospice election will be determined to no longer be medically appropriate and will be discontinued, scenarios such as those described above are not rare, and it is often the case that for at least some period of time after electing to receive hospice care, a beneficiary will need to continue taking drugs for conditions unrelated to their terminal diagnosis. In such cases, the hospice should not be held responsible for providing these medications which are unrelated to the patient’s terminal diagnosis, and the beneficiary should be able to continue using the Part D benefit to which they are entitled, to obtain these medically necessary and appropriate drugs.

**Determination of relatedness should continue to be made by the hospice physician:** We ask CMS to consider the broad spectrum of hospice patients encountered, whose prognoses at admission literally extend from minutes, in some cases, to months in others. This range of life expectancy, combined with the wide array of terminal conditions typically managed by hospice in 2014 compared to 1983 means that such a broad generalization as “virtually all” is not a helpful metric that can be applied to the practice of hospice care and this is increasingly evident with today’s hospice patients. It is absolutely essential that determinations of “relatedness” continue to be made on a case-by-case basis, and that they be made by the hospice physicians who are most familiar with the patient’s clinical needs, both as they exist at admission to hospice and as they evolve during the course of the terminal illness.

**Hospice and Part D – CMS History**

To the best of our knowledge, CMS first identified concerns about inappropriate Part D payment for drugs provided to hospice patients in a memo issued to Part D plan sponsors on October 22, 2010. In that memo, CMS noted that it had become aware that Part D sponsors might be paying for drugs that should be the responsibility of hospice providers, particularly in long term care facilities. CMS promised systems changes and instructed plan sponsors to work with pharmacies, particularly long term care pharmacies, to ensure appropriate billing. There was no communication with the hospice provider community.

**Development of OIG 2012 Report:** Subsequently, the Office of Inspector General (OIG) began a review of Part D claims paid while patients were enrolled in hospice during calendar year 2009. Early in their review, OIG investigators met with NHPCO staff to discuss the direction of the study and to learn more about what drugs are used in hospice, how the hospice prescribes and obtains medications and what drugs would be considered related to the terminal illness. Specifically, they asked clinicians at NHPCO for an evaluation of whether certain drugs or classes of drugs would always be related to the terminal illness. The response from clinicians who are specialists in hospice and palliative care was no, that while some drugs are frequently associated with hospice care, there are any number of individual patient circumstances in which the drug might be used for a reason unrelated to the terminal illness. As CMS
itself has noted over the years, “the unique physical condition of each terminally ill individual makes it necessary for these decisions to be made on a case-by-case basis.”

**Recommendations in OIG 2012 Report:** When the OIG’s report on Part D and hospice was published in June 2012, the OIG made the following three recommendations for action by CMS:

- educate sponsors, hospices, and pharmacies that it is inappropriate for Medicare Part D to pay for drugs related to hospice beneficiaries’ terminal illnesses;
- perform oversight to ensure that Part D is not paying for drugs that Medicare has already covered under the per diem payments made to hospice organizations; and
- require sponsors to develop controls that prevent Part D from paying for drugs that are already covered under the per diem payments.

CMS concurred with the recommendations to provide education regarding Part D payment for drugs provided to hospice patients, and to require Part D plan sponsors to develop controls to prevent inappropriate payments by Part D, but they did not concur with the recommendation to perform oversight because, they stated, they “would need conclusive evidence that there is such an issue before making payment adjustments.” Even with CMS’s concurrence with the OIG’s recommendation for additional education for all providers, there was no outreach to the hospice community and no mention of Part D coverage in any communication to hospice providers until late 2013, months after CMS began issuing memos to Part D plan sponsors, and after recoupment of payments for **ALL** analgesics had already begun.

**2014 Call Letter and NHPCO Comments:** Although CMS included references to Part D drugs provided to hospice patients in its annual Call Letters to Medicare Advantage and Part D plans in recent years, the only reference to Part D in communications to hospice providers was addressed in the preamble to the 2008 Final Rule establishing new Hospice Conditions of Participation. In response to a comment requesting clarification on the relationship between the Part D benefit and the hospice’s requirement to provide certain drugs, CMS stated that hospices “may not expect patients to obtain drugs related to the terminal illness and related conditions through the Medicare Part D benefit. If a patient requires drugs that are not related to the terminal illness and related conditions, then it may be possible for the patient to obtain those unrelated drugs through the Medicare Part D benefit.” Again, the determination of which drugs were “related” was left to the hospice, as it had been historically.

**CMS Communication to Part D and Hospice Providers:** During 2013, CMS issued at least four memos to Part D plan sponsors regarding payment for analgesics provided to hospice patients from 2011 to 2013, including directives to recoup payment for all such claims. However, except for the brief reference included in the preamble to the 2008 Hospice Conditions of Participation, the only communication CMS directed to the hospice provider community regarding Part D payment for drugs prior to the December 6, 2013 memo was a two paragraph notice posted in the Hospice Center of the CMS website on

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13 Id.
14 73 Fed. Reg. 32145 (June 5, 2008)
November 5, 2013, referring readers to an October memorandum that had been issued to Part D plans.\textsuperscript{15}

We note this history to illustrate why the hospice community, which is the provider community most affected by this new policy, believes so strongly that CMS must delay implementation of this change. We request an opportunity to collaborate and communicate with CMS and all of the stakeholders to address the many reasons that can result in inappropriate Part D payment for drugs, and to develop solutions that are least burdensome and workable for all affected.

\textbf{Recoupment Efforts}

Separate from the proposed guidance for prospective handling of Part D claims for beneficiaries enrolled in hospice, CMS also states in the December 6\textsuperscript{th} memorandum that Part D sponsors are to “follow prior CMS instructions concerning the denial of Part D payments for pain medications for hospice beneficiaries.” This prior guidance had stated that CMS presumed that all analgesics provided to hospice patients and covered by Part D plans back through 2011 were used for the palliation and management of the terminal illness and/or related conditions, and therefore were the payment responsibility of the hospice.\textsuperscript{16} Therefore, CMS stated, “a case-by-case analysis to determine relatedness is not required,” and the “PDE reflects an overpayment that should be recovered from the hospice.”\textsuperscript{17} There is simply no legal basis to establish such an irrebuttable presumption, and to recoup the cost of all analgesics back to 2011.

\textbf{Recoupment of all analgesics:} While we certainly acknowledge that the great majority of analgesics provided to hospice patients have been, and will continue to be, related to the patient’s terminal diagnosis or related conditions, there are exceptions. CMS cannot use “administrative ease” as a basis for shifting payment responsibility to hospices for an entire class of drugs, even when a beneficiary requires a drug for a reason unrelated to their terminal diagnosis. This policy seems to be based on assumptions that all pain experienced by a patient once they are determined to be terminally ill must be caused by the terminal illness, and that all terminal illnesses result in pain. Neither of these presumptions can be supported as medical fact, and they ignore the clinical complexity of terminal illness, and diminish the important role of hospice physicians with their expertise in evaluating and treating patients facing the end of life.\textsuperscript{18}

While there are countless scenarios that would demonstrate this point, we provide several examples for illustration.

\textsuperscript{15} Notice posted to CMS Hospice Center, “Clarification of Recovery of Part D Payment for Pain Medications for Beneficiaries Enrolled in Hospice”, November 5, 2013.

\textsuperscript{16} Memorandum to All Part D Plan Sponsors from Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C & D Data Group and Mark Majestic, Director, Medicare Program Integrity Group, October 30, 2013.

\textsuperscript{17} Id.

\textsuperscript{18} CMS itself has even acknowledged this, stating in the final rule establishing the hospice Conditions of Participation that “It is acceptable for hospices to refer pain and symptom control issues unrelated to the terminal illness and related conditions to other providers.” 73 Fed. Reg. 32099 (June 5, 2008).
Example 1: Patient is admitted to hospice with a diagnosis of congestive heart failure (CHF). He was diagnosed several years ago with lumbar stenosis and associated pain, for which he has been and continues to be treated with a Fentanyl patch. The lumbar stenosis is not related to his terminal diagnosis of CHF and the hospice should not be responsible for payment for the analgesic medication used to manage the pain associated with this unrelated condition.

Example 2: A patient’s terminal diagnosis is Chronic Obstructive Pulmonary Disease (COPD). Although associated with a number of distressing symptoms, COPD does not typically cause pain. Upon admission to hospice, the patient is taking a prescription analgesic for arthritis pain, which is unrelated to the COPD diagnosis and to her 6 month prognosis. The hospice should not be responsible for the cost of an analgesic prescribed to treat arthritis pain unrelated to the patient’s terminal diagnosis or a related condition, but the analgesic continues to be medically reasonable and appropriate to address the patient’s arthritis pain.

No clinical or legal justification: Again, these are just two examples to illustrate why CMS has no clinical or legal justification for implementing a policy that presumes all analgesics provided to hospice patients from 2011 forward were related to the patient’s terminal diagnosis, and to recoup the cost of those drugs from hospices, without giving them an opportunity to submit evidence to the contrary. As we have stated in past communications with CMS and in meetings with CMS staff, while we understand that it would be administratively easier to establish a policy that certain drugs or drug classes are always related to patient’s terminal diagnosis, and therefore are always the hospice’s responsibility, this is simply not the case. Under the language of the statute, hospices are only responsible for drugs related to the terminal diagnosis and related conditions. This is the statutory standard for determining coverage, and CMS must provide hospices with an opportunity to submit evidence to rebut the presumption that an analgesic provided to a particular beneficiary was related to that beneficiary’s terminal diagnosis or related conditions. CMS’s current recoupment policy is not legally sustainable.

Inconsistency with December 6 2013 proposed policy: This policy of recoupment also is inconsistent with CMS’s own proposed policy set forth in the December 6 memo, which would allow hospices to submit documentation that any drug, including analgesics, was medically necessary for reasons unrelated to the terminal diagnosis, and reimbursable under Part D. How can CMS presume that past use of analgesics was always related to the patient’s terminal diagnosis, while acknowledging going forward that the hospice may be able to document that a drug is unrelated to the terminal diagnosis and should be covered by Part D?

Hospice Community Challenges

This proposed new policy will require major changes in hospice processes and impose significant administrative burdens at a time when the hospice community is struggling with financial strains, has undergone massive changes in regulatory requirements over the last several years and is reeling from the exponentially increased burdens. These include the implementation of the brief physician certification narrative, the face-to-face encounter, visit and visit intensity reporting on the claim form, more frequent MAC medical review and increased ADR activity, increased scrutiny and medical review by other CMS contractors, such as ZPICs, MICs and RACs, as well as new quality reporting requirements.
Reimbursement cuts have continued, including the phase out of the budget neutrality adjustment factor (BNAF), productivity adjustment and sequestration. 2014 brings additional requirements for providers, including the requirement for additional information on the claim form, implementation of the Hospice Item Set and a more extensive set of quality measures, a new hospice cost report, and the switch to ICD-10, while we continue to watch for CMS announcements regarding hospice payment reform. For many hospice program, revenue and/or cash flow has been negatively affected by the costs of responding to the increase in various CMS contractors requesting prepayment review of medical records. The recently implemented regulatory requirements and those set for 2014 implementation have put a great strain on hospice provider staffing and finances, with staffing resources having to be moved from patient care to quality and compliance.

**Economic Impact Survey:** NHPCO conducted an economic impact survey of hospice provider members in late 2013 to investigate how current and proposed regulatory changes, together with the general economic environment, were affecting hospice operations. Analysis of the survey responses yielded the following:

- **Reductions in Revenue:** Since 2009 hospice reimbursement has endured a series of reductions: the Budget Neutrality Adjustment Factor (BNAF) rate cut (4.2%); sequestration (2%); and the “productivity adjustment” instituted by the Affordable Care Act (ACA) (11.8% over ten years). A majority of hospices surveyed indicated that they experienced a moderate to severe effect from the combination of these cuts and even more anticipate a similarly significant effect in 2014. Hospices also report decreased revenue in 2013 due to multiple additional causes, most prominently a reduction in number of referrals, sustained reduction in average daily census, and reduction in number of patient days.

- **Increase in Expenditures:** At the same time hospices are adapting to lower reimbursement rates, a series of new regulatory requirements and increased data collection requirements have also been applied to hospice, and compliance with them has imposed an additional financial burden. Compliance with these requirements will necessitate increased expenditures related to software and patient record updates, staff training, development of new processes for data collection and oversight, and vendor contracts. In addition, 64% of hospices report having to hire additional staff to comply with the face-to-face requirement. Hospices also reported increased expenditures relating to benefits and compensation (85%), medication and supplies (83%), overhead costs (70%), and uncompensated care (68%). Because of the slow economic recovery across the country many hospices are receiving greater numbers of requests for charity care but finding it more and more difficult to accommodate these patients.

- **Consequences and Actions:** In response to decreased revenue and increased expenditures, the vast majority of hospices in the survey (89.6%) reported that they had implemented measures to reduce spending in 2013 and even more (91.7%) anticipate doing so in 2014. Virtually all of these measures directly or indirectly affect hospice staff. Three-quarters of hospices have increased workload and/or caseloads (in lieu of hiring additional staff) and just under two-thirds have consolidated non-clinical positions. Just under one-half have consolidated clinical positions (primarily management), almost half have postponed hiring new clinical positions, and a quarter
have instituted a hiring freeze. Close to half have modified salary increases and over two-thirds are spending less on staff education. Despite implementing an array of measures to preserve staffing positions, 21% of hospices have laid off non-clinical staff and 18% have laid off clinical staff.

The December 6 Draft Guidance

Below we address specific provisions of the proposed policy, and pose questions as well as offer potential solutions.

Targeted Review of Hospices Associated with Problematic Part D Billing: In the December 6, 2013 draft guidance, CMS notes that in its analysis of this issue, problematic billing practices were concentrated in certain types of hospices and in certain settings. For example, 51% of Part D analgesic claims for hospice patients were attributable to only 10 percent of hospices (350 hospice providers), and these hospices tended to share certain characteristics. In addition, 50% of the analgesic claims were for hospice beneficiaries residing in nursing facilities. Clearly, the majority of the problem with potentially inappropriate Part D payment for hospice drugs lies with a subset of providers, and in specific settings. Instead of targeting compliance efforts to address identified problem providers or problematic settings, NHPCO notes that CMS is not proposing any defined process for additional review of these identified providers and their prescription drug practices. We have offered, and continue to offer, to work with CMS and other stakeholders to address problems, but just as the reasons for appropriate billing vary, so do the solutions.

Possible Solutions

• We request that CMS involve the Medicare Administrative Contractors (MACs) to follow up with medical review and provider-specific edits to assist the providers identified in CMS’s review with correct procedures in paying for medications related to the terminal illness.

• We are committed to working with hospice providers and long term care pharmacies in creating practices that will identify hospice patients’ related medications, ensure that they are correctly billed to the hospice, and in helping to educate providers and implement workable policies throughout the country.

• NHPCO stands ready to actively work with CMS, the MACs and other stakeholders in a deliberative and consultative process with all stakeholders on additional education that may be needed for hospice and pharmacy providers.

Use of Hospice Formularies: NHPCO appreciates that CMS recognizes that a hospice may use a formulary to manage medications and their use. We agree that a formulary should not be a limitation for a hospice’s responsibility to provide medications that provide relief of pain and symptoms when those on the hospice’s formulary do not meet the patient’s needs and desired outcomes. The hospice must ensure that adequate patient and family education is completed during the admission process. This includes education regarding the hospice’s formulary, and the possibility of using non-formulary medications for pain and symptom relief, as well as recognition that Part D is not paying for medication
related to the terminal illness and that the patient may be financially liable under certain circumstances. This includes when they choose to continue a drug that the hospice physician, who is familiar with the patient, has identified as no longer efficacious for that patient’s disease process or when the patient insists on a non-formulary drug even though the hospice physician believes a different drug on the hospice’s formulary will be equally effective in addressing the patient’s pain or symptoms.

**Possible Solutions**

- Hospice admission materials should include information the medication coverage for those drugs related to the terminal illness and related conditions and how medications that are not related will be handled.

- The hospice should document conversations with the patient and family about the hospice formulary, the hospice’s role in providing medications, the choices for off-formulary drugs as needed for the patient for pain and symptom control, and the possibility that the patient may be financially liable if they choose to continue a drug not determined by the hospice physician to be efficacious for the patient at their stage in the disease process.

- We note that on page 10 of the draft guidance, CMS states that “if the hospice does not provide the medication, the hospice is not obligated to provide any notice of non-coverage (including the Advance Beneficiary Notice of Non-coverage or ABN).” The hospice would be required to fully inform the beneficiary of his or her financial liability but is not required to provide an ABN to clarify that with the beneficiary. This will be confusing for patients and their families who may not understand all the nuances of hospice and Part D. We request that CMS consider the use of the Advance Beneficiary Notice (ABN) when a patient elects to continue the use of a drug which the hospice physician has determined is no longer effective.

**Hospice Notice of Election (“NOE”) Filing and Related Issues:** NHPCO has been involved in many discussions with hospice providers, pharmacies and Part D plan sponsors about the various issues at the intersection of Part D and hospice. Many point to the lag time in the notification to Part D plan sponsors that the beneficiary has elected hospice care as being a key problem. That information is available through the Common Working File but it regularly has a lag time of 3-6 days after the Notice of Election (NOE) is manually entered into the system. This delay in hospice election notification is a system issue that is at the core of the problems related to ensuring the appropriate payer is responsible for drugs. This delay is not caused by the hospice or the Part D plan sponsor – it is a system issue for CMS to address. NHPCO has provided more detail on the issue below, as well as possible solutions. Attention to the timely notification of the election, revocation and live discharge of Medicare beneficiaries into and out of the hospice program is paramount to any solution that is developed.

**Timeliness of Common Working File Process During Hospice Election:** There has been significant discussion about the timing of the filing of the Notice of Election (NOE) and how soon this information is available in the Common Working File. For instance, when the NOE is filed on the day of election and posted via Direct Data Entry (DDE) to the FISS system, Common Working File availability still could take 3-6 days after the DDE entry. During that time, prescriptions would
continue to be filled by the pharmacy and billed to Part D, with no knowledge of the hospice election.

According to the Hospice Claims Processing Manual, Hospice providers must send the NOE by mail, messenger or DDE (Direct Data Entry into the Medicare system). This manual process is time consuming to hospices. While an electronic method such as batch billing may not reduce NOE processing time, it will definitely reduce data entry time and would also eliminate manual key entry errors. CMS acknowledges that the majority of NOEs are filed electronically through DDE. However, that “electronic” method is not very efficient since this is still a manual process requiring staff to enter each patient into the system individually.

NHPCO has identified this system issue as a significant contributor to the lack of timely hospice election information, even when the hospice has filed the NOE on the day of hospice election, and this will result in payment errors and the later need for burdensome payment reconciliation.

**Possible Solution -- Timely Filing of the Notice of Election (NOE) – Initial Election**

- Batch filing NOEs directly from the Hospice’s EMR would be another opportunity for hospices file NOEs without manual data entry. With the advancement of technology, the sophistication of EMR systems, and the efficiency of batch processing, DDE is becoming a thing of the past. CR 8248 contains the termination of the Common Working File ELGA and HIQA along with important hospice updates to the HETS system in April. After that, hospices can batch process 270/271 for eligibility, file a batch of claims with an 837, check claim status with a 276/277, and receive payment information with an 835. With so many EDI transactions, it just makes sense for the NOE to be submitted the same way.

- The change suggested here would be simple for MACs but the benefits will be huge for providers. This change would allow hospices to file a more timely NOE and would reduce traffic in the DDE system, benefitting both claims processing systems and providers alike.

- The patient status is not currently permitted on the NOE but the 5010 claim format requires one. If MACs would allow a patient status code on all hospice claims including NOEs, hospices could file the claims electronically through EDI with no changes to front end claim edits just as some hospices did with 4010. Alternatively, if MACs would make a change to front end claim edits and once again accept NOEs through EDI even when the patient status is missing, hospices could file NOEs electronically through EDI without adding a status code.

- We request the ability to submit an electronic file to CMS for all NOEs.

- As noted below in the section regarding Prior Authorization (PA), use and acceptance of a standardized PA form could facilitate more timely notification to Part D plan sponsors that the plan enrollee had elected hospice.

**Timeliness of Common Working File Update – Hospice Revocation or Live Discharge:** In addition to concerns about Part D plan notification that a beneficiary has elected to begin receiving hospice benefits, NHPCO has concerns about the continued communication of a beneficiary’s hospice status.
through the Common Working File when the patient discontinues hospice care through revocation or discharge. Revocation is a patient’s right at any time during the hospice election. The patient may also be discharged alive from hospice, as set forth in the hospice regulations. In each of these cases, the patient immediately reverts back to their regular Medicare benefits, including Part D coverage if they have it. However, the CWF is dependent on the final hospice claim to communicate the discontinuation of hospice coverage.

To our knowledge, CMS has no system currently for immediate notification to Part D plans of either revocation or discharge from hospice, which impacts the coverage of medications that the patient may urgently need. This might include new medications, or those previously provided by the hospice but which would no longer be covered by them.

We raise concerns about the weakness and inadequacies in the system that cannot keep up, in real time, with the election, revocation and discharge of hospice patients on a day to day basis, when care needs and medications change frequently and are likely to be needed immediately.

**Possible Solutions and Questions:**

- Notification of changes in election status, including revocation or discharge, should also be considered as a part of the submission of a batch electronic file so that immediate notification is available and beneficiaries have immediate access to the benefits to which they’re entitled.

- If a beneficiary elects to receive hospice benefits, opts to continue their Part D enrollment, but subsequently discontinues hospice services, may they re-enroll for Part D coverage?

**Changes in Hospice Admission Process**

**Additional language added to Notice of Election:**

We believe changes should be made to the hospice Notice of Election. A sample could be:

*The relationship between the Medicare Hospice Benefit and Medicare Part D coverage has been explained to me. I understand that the hospice program will review my medications after my initial nursing assessment and notify me regarding medications that will be covered by the hospice, medications for which they will be requesting coverage under Medicare Part D and medications that I am financially responsible for if I wish to continue them.*

**Information collected from the patient’s Part D drug card:** Hospices will need to adjust admission practices for eligible hospice patients and obtain information about Medicare Part D coverage. During the admission process, hospice staff will ask about the patient’s Part D coverage, obtain the pharmacy benefit card and number. The collection of this data will be entered into the medical record and provides information on Part D coverage that the hospice can use to begin the notification process to Part D that the Medicare beneficiary has now enrolled in hospice.

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19 42 CFR §418.26
**Additional information for patients and families:** Hospices will have to provide additional information to the patient and family about drug coverage – both what the hospice will cover and what the hospice will not cover. The patient and family have the right to know what drugs would be covered by the hospice, what drugs would not be covered by the hospice and would be covered by Part D; as well as any formulary substitutions/recommendations; and what drugs would be considered no longer helpful for the patient and would become the patient’s financial responsibility if the patient wishes to continue. All of this is part of the hospice medication review process that may take days to finalize. In the meantime, hospices must procure needed medications and will need to recoup payment from the Part D plan or patient later if a medication is deemed not be related to the terminal illness or related conditions.

**Possible Solutions:**
After final guidance is issued, hospices will need time to:
- Develop the appropriate patient information forms to notify patients of policies for drug coverage;
- Develop policies and procedures to implement these changes;
- Educate staff in answering patient and family questions.

**Medication coverage for hospice patients in nursing homes:** In the Abt Associates 2010 analysis of analgesics paid by Part D after the patient had elected hospice, the data analysis presented to the Technical Expert Panel reflected 63% of medications billed to Part D were for patients in nursing homes and assisted living, an even higher percentage than the 50.3% reported in the draft guidance. Clearly, a key issue in solving the problem of inappropriate Part D payment for drugs is identifying communications problems or systems barriers in this setting, and determining how to fix them.

NHPCO has held discussions with hospice providers about the procedures that hospices use to notify the nursing home of medications related to the terminal illness, which should be billed to the hospice, and those medications that should be billed to another payer. Some providers have affixed labels to patient charts, med carts, and prescription pill bottles to further remind the nursing home staff that particular medications should be billed to hospice. Providers inform us that since the pharmacy billing function is often separate and distinct from the care that is provided in the nursing home, billing errors continue to occur, thereby necessitating changes in notification methods or processes to alert the nursing home billing staff or the billing staff of the LTC pharmacy.

**Possible Solutions:**
- A standardized process should be developed for the hospice to provide the nursing home, especially the nursing home and LTC pharmacy billing staff, with immediate notification of hospice election and a summary of the drugs that should be billed to the hospice.
- The nursing home, especially the nursing home or LTC pharmacy billing staff, should provide a standardized confirmation of the billing process for billing the related medications to the hospice.
• Hospices will need to implement ongoing audits of their bills in providing drugs to patients in nursing homes, to ensure that they are actually being billed and are paying for the drugs identified as related to the terminal illness.

• Collaborate with nursing homes and long term care pharmacies to determine workable solutions to these billing issues and provide guidance and implementation solutions for the nursing home, hospice and LTC pharmacy organizations.

Prior Authorization

A key element of CMS’s proposed Part D policy concerns implementation by Part D plan sponsors of a beneficiary level prior authorization (“PA”) requirement on all drugs for hospice patients, to determine whether they are covered under Part D. In the interim, at least, CMS has stated that it expects the plan sponsors to accept any written documentation submitted by the hospice or prescriber establishing that the drug is not related to the terminal illness, and to process the claim under Part D. However, so little guidance or information is provided regarding this new PA requirement and process that it is very difficult to anticipate how it will work or to provide substantive comments.

Prior Authorization first announced: To our knowledge, CMS first introduced the idea of implementing a Part D prior authorization (“PA”) requirement for certain drugs provided to hospice patients in February 2013, in its “Advance Notice of Methodological Changes for Calendar Year 2014 for Medicare Advantage Capitation Rates, Part C and Part D Payment Policies and 2014 Call Letter.” At that time, CMS proposed that Part D sponsors place a beneficiary-level PA requirement on four categories of prescription drugs identified by the “OIG” as typically used to treat symptoms generally experienced by hospice beneficiaries during the end of life (analgesics, antinauseants, laxatives, and antianxiety drugs).

Although this notice was not directed at hospice providers, NHPCO submitted comments to CMS in response to this proposal, and we expressed concerns about the apparent assumption that all uses of specific categories of drugs by a hospice patient would be related to the patient’s terminal diagnosis, and therefore would be the hospice’s responsibility.20 We stated as our primary concern that the hospice must be able to determine which drugs are included on the hospice plan of care, and which drugs are related to the terminal diagnosis and related conditions, based on each individual patient’s pain and symptoms. We offered suggestions regarding the proposed PA requirement, and a willingness to collaborate with CMS and other stakeholders to develop a PA system that would ensure appropriate payment for drugs, be least burdensome to all participants and ensure that beneficiaries are not denied access to needed medications.

2014 Call Letter: In its final 2014 Call Letter, issued on April 1, 2013, CMS acknowledged problems with data flow and the timely notification of Part D plan sponsors regarding a beneficiary’s election of hospice, and that retroactive payment adjustments would be required, but nonetheless CMS “strongly encouraged” sponsors to place PA requirements on the four categories of prescription drugs. This would result in pharmacies receiving a reject code for these drugs, and the pharmacy would then “need
to initiate dialogue between the parties to resolve payment responsibility.” However, CMS offered no guidance on the prior authorization process, either in terms of the documentation the hospice should submit to the pharmacy or the plan sponsor, or the criteria that should be used to determine payment responsibility.

**PA in proposed guidance:** Most recently, in its December 6, 2013 proposal, CMS has now proposed instructing Part D plan sponsors to place beneficiary level PA requirements on all drugs for hospice patients, in lieu of the four drug categories outlined in the 2014 Call Letter. CMS states that in the “extremely rare” circumstances when a beneficiary who has elected hospice requires a medication for a condition that is “completely unrelated to the terminal illness or related conditions”, the hospice provider or prescriber must “immediately provide, to the Part D sponsor, the written documentation necessary to satisfy the PA.”

CMS goes on to state that they “expect the sponsor to accept the documentation that the drug is unrelated... Therefore, the drug is reimbursable under Part D and the claim should be processed.” Similarly, if Part D pays for drug claims prior to receiving notification of a beneficiary’s election of hospice, the plan should make a retrospective determination of payment responsibility, and CMS would expect the hospice or prescriber “to provide the necessary written information, as requested by the sponsor.” CMS provides no guidance on the documentation they would expect hospices to submit or how plans are to evaluate that documentation, other than to note that the plan sponsor may seek a determination from an independent reviewer, once that process is in place, if they disagree with the hospice’s determination that the drug is unrelated to the terminal illness.

**Documentation of Unrelated Drugs:** NHPCO very much appreciates that CMS is requiring that the plan sponsor accept the documentation submitted by the hospice or prescriber that the drug is unrelated and allow the Part D claim to be processed, and we urge CMS to maintain this requirement. This preserves the essential role of the hospice physician in making such determinations, and also ensures that the beneficiary is not denied access to medication because of a dispute over payment responsibility.

However, if CMS requires a PA process it must be fair and administratively feasible. We request that CMS work collaboratively with hospice providers, Part D plan sponsors and pharmacies to develop a standard PA form and process to be utilized by all parties for the submission of clinical documentation supporting a hospice patient’s use of a drug as unrelated to their terminal illness or related conditions. Otherwise, hospices, Part D plans, pharmacies and beneficiaries would be burdened with an administrative nightmare in sorting through multiple documentation standards and requirements, resulting in disparate outcomes. Currently, there are over 3500 hospices and over 1500 Part D plans in the United States. Without a uniform standard, each of these plans might establish different documentation requirements and develop their own criteria for determining “relatedness.” This would create a completely unworkable administrative burden for hospices, each of which could be dealing with dozens of different Part D plans. In addition, beneficiaries would be subjected to differing rules for drug coverage depending on the particular hospice and Part D plan involved.

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Possible Solutions:

- CMS should maintain the requirement that Part D plan sponsors accept hospice documentation that a drug is unrelated to the terminal illness and related conditions, and process the claims under Part D. If the Part D plan disputes the hospice’s determinations, they can seek an independent review. Given the patient population, it is critically important that timely review be considered paramount in the design of the independent review process.

- CMS should consult with appropriate stakeholders, including but not limited to the hospice community, to develop and implement a standardized beneficiary-specific PA form and process that is **required to be used by all Part D plan sponsors and hospice providers**. This will streamline the process and address the concern that many hospices have about the wide disparity in documentation requirements, forms, and criteria that would be used by different plans. Notification through the Prior Authorization form may be the first notification the plan receives that the patient has elected hospice care, prior to the updates in the Common Working File.

- In the 2015 Call Letter, CMS should modify the “strongly encourage” language now found in the 2014 Call Letter and state that “plan sponsors must use the CMS developed beneficiary-specific prior authorization form when a patient has enrolled in hospice.”

**Part D Payment Reconciliation with the Medicare Hospice or the Beneficiary**

As CMS notes, payment reconciliation will sometimes be required because of delays in notification of hospice status and after disputes over payment responsibility have been resolved. In some cases this may even require recovery from beneficiaries. While we agree that hospices may need to participate in this reconciliation process, we are not sure that the proper resolution is for the hospice to reimburse Part D plans for drugs that were incorrectly paid by the plan. If a hospice has financial responsibility for a drug, the billing and payment for that drug typically is controlled by the contract between the pharmacy and the hospice or the hospice’s pharmacy benefit manager. CMS must take into consideration the contracts the hospice has in place for covered services and cannot, as proposed, institute processes that have the effect of circumventing such agreements.

**Payment Reconciliation between the Hospice and Part D:** When a Part D plan pays a pharmacy for a drug that should have been covered by the hospice as related to the terminal illness, CMS’s position is that the Part D plan should work with the hospice to reconcile the payment issues, and delete the Prescription Drug Event (PDE) record without involving the pharmacy. CMS indicated in its October 30, 2013 memo to Part D plan sponsors that the proper resolution of such matters is for the hospice to reimburse the Part D plan sponsor in the amount the plan paid to the pharmacy for the drug. We believe this resolution raises serious concerns.

As the OIG recommended in its report on Medicaid pharmacy claims for hospice patients, it is the pharmacy’s responsibility to repay Medicaid amounts that were incorrectly billed and then seek...
payment from the hospice.\(^\text{22}\) We believe a resolution such as this may be appropriate and in alignment with the hospice's responsibility under 42 C.F.R. 418.100(e) to arrange and contract for care that is related to and medically necessary for the palliation and management of a patient's terminal illness. CMS's proposal that Part D plans seek payment from the hospice has the effect of circumventing the hospice's established pharmacy arrangements.

In addition to not taking into consideration the underlying contractual relationships between hospices and pharmacies or PBMs, the proposed recoupment of funds from the hospice fails to take into account the complexities and differences in the arrangements pharmacies have with various payers. For example, the rates a Part D plan pays a pharmacy may be different than those paid by a hospice's pharmacy benefit manager, which also may differ from those paid by the hospice to its pharmacy benefit manager. A hospice may pay a pharmacy benefit manager a per diem amount for all drugs or a per drug rate that is lower than the amount the pharmacy would have received from the Part D plan. It would be problematic to have a process that requires the hospice to pay the Part D plan for drugs that it may have already covered under its per diem with the pharmacy benefit manager or that may be higher than the rate established in its pharmacy contract.

The only support cited for the proposed resolution is guidance from the Medicare Prescription Drug Benefit Manual that addresses scenarios where a Part D plan reimburses other payers providing prescription drug coverage. It appears that even CMS understands that this guidance is not relevant to the current scenario and it cannot simply bridge this gap by stating that the "inverse" of the guidance should apply. As outlined above, there are meaningful factual, contractual and legal distinctions that make it unworkable to simply apply the "inverse" of this provision that was drafted to address payment issues in a different context.

Further, CMS's prior guidance to Part D plans indicates that there are other options for handling claims that have been incorrectly paid by Part D. Most notably, CMS has recognized that Part D plans can zero out or delete a pharmacy's claims that should be covered by the hospice,\(^\text{23}\) and the pharmacy can bill the drugs to the hospice or the hospice's pharmacy benefit manager in accordance with the processes and terms set forth in their contractual arrangement.

**Possible Solutions:**

- CMS needs to confer with hospices, Part D plan sponsors, pharmacies and PBMs to determine how best to handle payment reconciliation, and to take into account the existing legal and contractual obligations of the parties.
- The Part D plan and pharmacy can work together to resolve any issues related to beneficiary cost sharing.

**Payment Reconciliation for the Beneficiary:** In instances where a Part D plan has paid for a drug that was determined to be the beneficiary's financial responsibility, we agree that recovery should be sought from the beneficiary. These recovery efforts must be the responsibility of the Part D plan.

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sponsoring, as the plan sponsor is the party seeking reimbursement and the hospice is not a payer for these services and has no financial responsibility for these drugs. To this end, it must be the obligation of the plan sponsor, not the hospice, to work directly with beneficiaries or their legal representatives to bill and collect appropriate amounts, including reconciling any cost sharing amounts.

**CMS' Independent Reviewer**

CMS is exploring incorporating an independent reviewer function to handle disputes between hospices and Part D plans regarding payment responsibility for certain drugs provided to hospice patients. Unfortunately, little detail is provided, although CMS does state that the details of this process will be outlined in future guidance, providing “adequate notice to all affected parties.”

**Hospice physicians to make individual determinations on medications:** As noted above, NHPCO requests that CMS continue to allow hospice physicians, who are most familiar with the terminally ill patient’s clinical needs, to make an individual determination regarding which drugs are related to the patient’s terminal diagnosis and related conditions, and therefore are the responsibility of the hospice, and which drugs are unrelated. However, we recognize that there may be circumstances where a Part D plan sponsor may dispute the hospice’s determination.

**Establishing the independent reviewer process:** NHPCO requests the opportunity to work with CMS on this issue, and can facilitate access to hospice clinicians and pharmacists to provide input for establishing an appropriate and fair independent reviewer process. We request that CMS undertake formal notice and comment rulemaking to ensure that all stakeholders have an opportunity to provide input regarding this important process. Of key concern is the criteria that the independent reviewer will use to evaluate whether a specific patient’s use of a drug is “related to the terminal illness”, and it is absolutely essential that the reviewers have extensive clinical expertise and experience in a hospice setting or in palliative care. There will be an ongoing need for education so that all parties understand the standards and criteria being used for decisions being made by the independent reviewer.

**Timeliness:** Unless CMS maintains the policy of requiring the Part D plan to accept the hospice’s documentation that a drug is unrelated and process the claim, with the option of later seeking independent review, then timeliness of the independent reviewer’s response will be the most important factor in the independent review process. In many such cases, the dispute will need to be decided *in the same day* that the dispute arises because continued access to a drug may be essential. In those cases, delays of even a few days represent a significant portion of the rest of that patient’s life, meaning delays are ethically impermissible. And timeliness is important even if Part D coverage is provided initially, pending an appeal to the independent reviewer, in order to avoid the need for lengthy and burdensome payment reconciliation processes long after the fact, and after the patient’s death. We believe that it will be important for all stakeholders to be aware of the time frames for the independent review process.

**Transparency of Criteria and Process:** It also is important that the criteria used and the process followed be transparent to interested parties, and that it be objective and unbiased, and afford sufficient due process for all involved. And while the confidentiality of beneficiary health information would make public reporting of the independent reviewer’s determinations difficult, if not impossible,
we urge CMS to consider ways to communicate as much information as possible regarding the reviewer’s decisions back to both the hospice and the Part D plan.

**Appeals Process after Independent Reviewer:** Finally, it is not clear to whom the independent reviewer would be accountable, and we are concerned that CMS is proposing that the independent reviewer’s decision will be binding, with no opportunity to appeal. We request that CMS provide hospices and plans with the option of at least one level of appeal above the independent reviewer. Given the potential effects of the independent reviewer’s decision, and the amount of money that may be involved, we believe due process requires that there be an option to appeal the independent reviewer’s determination.

**Possible Solutions**

- Engage the hospice and Part D plan sponsors in discussions about the appropriate criteria and standards for the independent reviewers to follow, and engage in formal notice and comment rulemaking so that all interested parties have an opportunity to review and comment on the specifics of CMS’s proposal.

- Ensure that the independent reviewers have extensive clinical expertise and experience in a hospice setting or in palliative care

- Specify timeframes for each component of the process, including timeframes for the Part D plan to appeal the determination of relatedness, as well as the timeframes for the independent reviewer to make a determination after it has been requested.

- Establish a mechanism for the hospice and Part D plan sponsors to appeal the decision of the independent reviewer.

**Guidance to Part D Plans Prior to Effective Date of December 6 Guidance**

In its October 30, 2013 memo to Part D plan sponsors, CMS requested that plan sponsors limit any hospice-related recovery efforts to claims for analgesics identified in previous Center for Program Integrity (CPI) communications. Some plans, however, have already begun a 100% block on fills for all medications when the beneficiary is enrolled in hospice. Other Plans are asking for guidance about processing claims between now and the date this guidance becomes final.

As we write this comment letter, hospice providers are reporting that their patients are being denied access to unrelated medications through their Part D plan when requested at their pharmacy. Several “real life” examples reported by our members demonstrate what beneficiaries are experiencing:

**Example 1:** The hospice spoke with the daughter of a new hospice patient. The daughter reported that the medications her mother is taking are not being covered by hospice are no longer going to be covered by the Part D plan because “hospice is involved.” The daughter spoke with the pharmacy which informed her that changes in Medicare that are scheduled to go into effect in March (but can be enforced immediately) have resulted in all non-hospice covered medications that
a hospice patient is taking are no longer be covered by supplemental insurance. The daughter then followed up with a billing person at the Part D plan who concurred that this was now the case.

**Example 2:** The hospice received a call from Director of Nursing at XXX SNF. Long term care pharmacy is insisting that all hospice patients are not covered by their insurance for their medications; that it is the responsibility of the hospice to pay for all the meds. Some of our patients require insulin. The LTC pharmacy would not deliver the meds unless the hospice paid for them. The SNF has decided to admit no future patients onto hospice until this is worked out. The facility is “in a panic over not having hospice expertise for their patients.”

Since no guidance on this issue has been posted for hospice providers, what is CMS’s expectation for hospice providers during the interim period before the December 6 2013 draft guidance is finalized and released?

**Effective Date of Guidance**

Given the lack of clear guidance on many key issues, the extensive work that will be required by hospice providers, Part D plan sponsors, and CMS to develop standardized forms, create an industry-wide prior authorization process and communicate the new processes to all involved stakeholders, NHPCO respectfully requests that:

1. the implementation date be extended to at least October 1, 2014, and
2. CMS further engage the affected parties to collaborate on workable solutions, preferably through formal notice and comment rulemaking.

For hospice patients and their loved ones, there is no more vulnerable or frightening time than the end of life, and they deserve a thoughtful and deliberative process to ensure that they continue to have access to hospice care when they need and want it, and to receive the medications they need, whether related to their terminal illness or not.

We appreciate the opportunity to comment on this complex and challenging issue and stand ready to collaborate with CMS on solutions to the issues we raised.

Sincerely,

J. Donald Schumacher, PsyD
President and CEO