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Jonathan D. Blum
Acting Principal Deputy Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Medicare Hospice Benefit Coverage of Drugs

Dear Mr. Blum:

I am writing to you on behalf of my client, the National Hospice and Palliative Care Organization ("NHPCO"), in follow up to your meeting with them last week. While I understand you discussed a number of issues, NHPCO has asked that I specifically address concerns regarding coverage of drugs provided to terminally ill Medicare beneficiaries who have elected to receive hospice care, under either Part A or Part D. NHPCO is concerned that CMS seems to be deviating from the policy that has been in place since the inception of the Medicare hospice benefit, and that at least some components of CMS may be proceeding with policy interpretations that are inconsistent with the Medicare statute and regulations, and CMS's historical interpretation of them. In particular, we are aware of some actions related to the Part D benefit that have raised concerns.

As you may know, the Medicare hospice benefit grew out of a 26 site demonstration project. 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, the statute has specified that this waiver is made with respect to "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."[1] 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.

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.[2] 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 individual's terminal illness are covered."[3] This regulatory provision regarding coverage of drugs has not changed since 1983. In addition, the 1983 regulation establishing the hospice condition of participation related to medical supplies stated that "Medical supplies and appliances including drugs and biologicals, must be provided as needed for the palliation and management of the terminal illness and related conditions."[4] 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]

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1 Social Security Act §1812(d)(2).

2 42 CFR §418.24(e)(2) in the original regulations; now found at 42 CFR §418.24(d)(2) (emphasis added).

3 42 CFR 418.202(f) (emphasis added).

4 42 CFR §418.96.

5 42 CFR §418.106 (emphasis added).

In 2008, in the final rule implementing the revised hospice conditions of participation, CMS responded to a comment requesting clarification regarding the relationship between the requirement that hospices must provide drugs for patients and the Part D benefit. CMS responded by noting that hospices were required to furnish all drugs related to the terminal illness and related conditions, but "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."[6]

Over the past year, in various issuances, divisions of CMS have cited a sentence from the Federal Register preamble to the original final rule establishing the Medicare hospice benefit, in support of a policy to limit Medicare coverage outside the hospice benefit for drugs provided to hospice patients. In particular, a statement was made in the preamble to the 1983 final rule 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 patients."[7] While NHPCO agrees that the waiver is broad, and that when a Medicare beneficiary elects to receive hospice care, the hospice generally assumes responsibility for most of the beneficiary's care needs, this single statement in a preamble cannot be viewed in isolation and taken out of context to support a policy that holds hospices responsible for all drugs, or all of any particular class of drugs, provided to beneficiaries who have elected to receive hospice care. Nor does it support a policy that denies Medicare beneficiaries' access to Part D drug benefits simply because they are terminally ill and have elected to receive hospice care. Yet NHPCO has been hearing that each of these policy positions has been put forth.

The statement made in the 1983 preamble was in response to commenters requesting further guidance on how to determine whether care was related or unrelated to the patient's terminal illness or related conditions; an issue that was difficult to determine 30 years ago, and continues to be difficult today. HCFA also stated in that preamble that "the unique physical condition of each terminally ill individual makes it necessary for

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6 73 Fed. Reg. 32145 (June 5, 2008).

7 48 Fed. Reg. 56010 (Dec. 16, 1983).

these decisions to be made on a case by case basis."[8] NHPCO agrees wholeheartedly with this statement and believes it points out the need for these determinations to be made individually, by clinicians who know the patient, and based on clinical evidence.

While NHPCO concurs that hospices do assume responsibility for the vast majority of care provided to beneficiaries once they elect the hospice benefit, "Virtually all" does not equal "all", and we respectfully assert that it is the hospices and physicians who are caring for these patients who are in the best position to assess and determine whether a particular drug provided to a particular hospice patient is used primarily for the relief of pain and symptom control related to the individual's terminal illness. Certainly, the determination of "relatedness" requires a patient-specific clinical evaluation, but many beneficiaries enter hospice taking a wide range of medications, some of which are for treatment of pre-existing conditions unrelated to their terminal diagnosis. The hospice makes an evaluation of which drugs should be continued and which drugs are medically necessary for the palliation and management of the terminal and related conditions. Because of the medical complexity of many hospice patients and the hospice clinicians' responsibility to take a comprehensive approach to the patient's care, the determination may be made to continue, or discontinue, medications used to treat conditions that are unrelated to the terminal illness. Hospice physicians who work daily with patients and have extensive clinical knowledge of patients and their complex conditions would be happy to discuss the issues of relatedness with CMS.

In fact, CMS itself, as recently as this past August, stated in the FY 2014 Hospice Wage Index final rule 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."[9] This exercise of clinical judgment is essential in order to ensure that beneficiaries continue to have access to the drugs they need and are

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8 Id.

9 78 Fed. Reg. 48254 (August 7, 2013).

entitled to, and that these drugs are covered and paid for by the appropriate component of Medicare. A policy determination that certain drugs or drug classes will always be hospice-related, or will never be covered, is simply inappropriate and unsupported by the law and regulations.

NHPCO readily concedes that there have been instances of Part D payment for drugs that should have been covered under the hospice benefit, and they have offered to work with CMS and the OIG to address the varied and complex reasons this may have happened. In fact, when CMS proposed in its Call Letter for Calendar Year 2014 that drug plan sponsors place a beneficiary-level Prior Authorization requirement on four categories of prescription drugs that are often used to treat symptoms during the end of life, NHPCO submitted comments offering to continue working with CMS to prevent the payment by Part D for drugs that should be covered under the Part A hospice benefit, and urging CMS to develop a system to ensure that determinations of whether use of a drug is related to a patient's terminal illness are made on an individualized basis.

As NHPCO noted in its comments to the proposed Call Letter, "When a patient elects to receive hospice care, the hospice develops an individualized "plan of care" for each hospice patient. This plan of care, which is updated as necessary, includes all services necessary for the palliation and management of the terminal illness and related conditions, including drugs necessary to meet the needs of the patient. While we agree that the proposed categories of drugs – analgesics, anxiolytics, anti-nausea medications, and laxatives – include medications that are commonly included in hospice patients' plan of care, some hospice patients take these drugs for reasons unrelated to their terminal diagnosis. Similarly, there are many other drugs not falling within these categories that are taken for reasons related to their terminal diagnosis, and those drugs should not be covered under Part D."

I also note, as NHPCO did in the response to the Call Letter, that this is a complex issue, not only in terms of the individualized clinical evaluation required to determine whether a drug is or is not "related" to a particular patient's terminal diagnosis, but also

the circumstances under which such drugs are obtained by beneficiaries. Hospices develop an individual plan of care for each patient, which includes the drugs determined to be medically necessary to manage pain and symptoms related to the terminal diagnosis and related conditions. Hospices are required to provide these drugs to patients under the Part A hospice benefit. However, hospices have no ability, historically or currently, to control a Medicare beneficiary's use of their Part D benefit. There are circumstances where a patient's family may pick up a drug at a pharmacy, as they have done for many years, and there are circumstances where the pharmacy may bill Part D without the knowledge of whether or not the hospice is responsible for payment[10].

I am particularly concerned about efforts already begun by Part D sponsors to stop Part D payment for drugs for beneficiaries who have elected the hospice benefit, or to recoup from pharmacies and hospices certain claims paid in prior years for analgesics provided to beneficiaries receiving hospice care.[11] Hospices should not be held financially responsible for drugs that they have not determined to be medically necessary for the palliation and management of a patient's terminal diagnosis, when the hospice may not even have been aware of the situation, and has had no ability to control patients' access to drugs outside the hospice benefit, through Part D. Efforts to recoup past payments raise a host of issues too complex to address in this letter, including co-payments made by beneficiaries and families.

In summary, there appears to have been some misunderstanding or miscommunication between Part A and Part D regarding coverage of drugs for beneficiaries receiving hospice care. NHPCO shares CMS's concern with ensuring that beneficiaries receive the benefits they're entitled to, and that these benefits are paid for appropriately, but in

[10] Just to provide one example that was included in NHPCO's comments on the Call Letter, a patient with Chronic Obstructive Pulmonary Disease (COPD) may enter hospice with a long history of using inhalers. The hospice may determine that these are ineffective for end-stage COPD and may not include them in the hospice plan of care, opting to treat the patient's symptoms with other drugs. However, the patient's family may continue accessing their Part D benefit to fill a long-standing inhaler prescription out of habit or because they continue to hope that it will help.

[11] See the attached documents.

developing appropriate policies to address this situation, it is essential that CMS consults and communicates with those most directly affected: hospices and the terminally ill beneficiaries they care for. I urge your staff to consult with NHPCO and other stakeholders to work through these complex issues and determine how best to achieve these goals.

Sincerely,

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