Center for
Medicare Advocacy

Submitted Electronically to www.regulations.gov

July 1, 2014

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1609-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: CMS-1609-P

To Whom It May Concern:

The Center for Medicare Advocacy (Center) is pleased to provide the Centers for Medicare & Medicaid Services (CMS) comments on the Notice of Proposed Rule Making (NPRM) CMS-1609-P published in the Federal Register on May 8, 2014.[1] The Center, founded in 1986, is a national, non-partisan education and advocacy organization that works to ensure fair access to Medicare coverage and to quality healthcare. Our health policy advocacy is based on our experience of assisting thousands of individuals and their families with Medicare coverage and appeals.

Introduction to Comments

Hospice care is holistic care for the dying and emotional and educational support for their caregivers. It became a Medicare benefit in 1983 and is available to those who have been diagnosed with a limited life-expectancy of six months or less. Once a patient is admitted, the hospice provider creates a plan of care that "includes all services necessary for the palliation and management of the terminal illness and related conditions…"[2] The provider is supposed to render the identified care. Generally speaking, for this care, Medicare pays the hospice provider a per diem.[3]

There is a concern that providers are "unbundling" hospice care[4] -- that is, encouraging patients to obtain alternative Medicare coverage for care and services that should be rendered by the hospice provider. If this is true, it means that Medicare is paying twice for hospice care and that the provider is failing in its duty to provide all services necessary for the palliation and management of the terminal illness and related conditions. To remedy this problem, CMS proposed new definitions for terminal illness and related

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[1] 79 Fed. Reg. 26538

[2] 42 C.F.R. § 418.56(c)

[3] 42 C.F.R. § 418.302

[4] See for example, Department of Health and Human Services, Office of the Inspector General (OIG), "Medicare Could be Paying Twice for Prescription Drugs for Beneficiaries in Hospice" (A-06-10-00059)(June 2012)

conditions as well as a new appeal process for medications. We appreciate CMS' concern regarding the unbundling of hospice services. However, we believe the suggested definitional changes are inconsistent with the Medicare statute and that the suggested appeal process inadequately protects the rights of Medicare beneficiaries and their families.

III. Provisions of the Proposed Rule

B. Solicitation of Comments on Definitions of Terminal Illness and Related Conditions

In the NPRM, CMS solicits comments on defining terminal illness to mean:

> Abnormal and advancing physical, emotional, social and/or intellectual processes which diminish and/or impair the individual's conditions such that there is an unfavorable prognosis and no reasonable expectation of a cure; not limited to any one diagnosis or multiple diagnoses, but rather it can be the collective state of diseases and/or injuries affecting multiple facets of the whole person, are causing progressive impairment of body systems, and there is a prognosis of a life expectancy of six months of less.

And it solicits comments on related conditions to mean:

> Those conditions that result directly from the terminal illness; and/or which interact or potentially interact with terminal illness; and/or which are contributory to the symptoms burden of the terminally ill individual; and/or which are conditions which are contributory to the prognosis that the individual has a life expectancy of 6 months or less.[5]

At first blush, these definitions seem to capture the holistic spirit of good hospice care. However, in reality, CMS seeks to re-define "terminal illness" and "related conditions" not to enhance the hospice benefit, but because the Statute and regulations create a difficult billing problem. A much broader definition of terminal illness and related conditions would alleviate much of the billing problem, by making "virtually all" medical care after a hospice election care related to the terminal illness and thus payment would almost always come from the hospice per diem.

Medicare beneficiaries are eligible for hospice care if they are certified as terminally ill.[6] Terminally ill is defined in the regulations to mean, "the individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course."[7]

Pursuant to the Medicare statute, when Medicare beneficiaries elect the hospice benefit, "except in such exceptional and unusual circumstances as the Secretary may provide," *they waive all rights to have Medicare payment made for*:

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[5] 79 Fed. Reg. 26554 – 26555(May 8, 3014)

[6] 42 C.F.R. § 418.20

[7] 42 C.F.R. § 418.3

> 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 or equivalent to (or duplicative of) hospice care…* (emphasis added).[8]

This waiving of Medicare coverage for care related to the terminal illness but not provided by the hospice (non-hospice care) is a serious business. It means, for instance, that if a patient whose terminal illness is chronic obstructive pulmonary disease (COPD) has a panic attack and is not able to breath, the family cannot simply call "911" and go to the emergency room. This is because the ambulance transportation and the emergency room visit will most likely not be covered by Medicare because the panic attack was probably related to the COPD and the ambulance transportation and emergency room visit were most likely not on the hospice plan of care. The act of calling 911 can, therefore, be an expensive mistake.

Due to the seriousness of this waiver of the patient's right to some Medicare coverage, when a beneficiary elects the hospice benefit, he must sign an election statement which, among other things, specifically indicates that he is waiving Medicare coverage for "Any Medicare services [not provided by or under arrangement with the hospice provider] that are *related to the treatment of the terminal condition…*" (emphasis added).[9]

A hospice election, however, does not mean the beneficiary waives all his rights to Medicare coverage of non-hospice care. For care not related to the terminal illness, Medicare coverage is still available. If the beneficiary sees a provider for such care, the provider simply bills the Medicare contractor using a "GW modifier" or "condition code 07." Contractors "process services coded with the GW modifier or condition code 07 in the normal manner for coverage and payment decisions."[10] So if a Medicare beneficiary has liver cancer and is certified as having a life expectancy of six months or less if the illness runs its normal course and she elects the hospice benefit, she waives non-hospice treatment for the liver cancer and related conditions, but she can continue to see providers rendering care for diagnoses not related to the terminal illness (for instance, high blood pressure) and Medicare will pay for this care, so long as the provider bills the Medicare contractor using the GW modifier or condition code 07.

As was indicated by CMS in its discussion about hospice payment reform in the NPRM, billing trends show that increasingly, hospice care is provided for non-cancer diagnoses. In 2013, the top 10 terminal diagnoses included: debility; Alzheimer's disease; adult failure to thrive; senile dementia; history of stoke; and dementia. Unlike a condition such as cancer, it is often difficult to determine what treatment is for or related to the terminal condition with these diagnoses. Moreover, CMS indicates that for CY 2012, Medicare paid approximately $159 million for 10,500 claims billed as non-hospice care after a hospice election.[11]

Based on these numbers, CMS fears that hospice providers are unbundling hospice care. That is, that they are receiving per diem payments, but allowing patients to receive care and services that should be on the hospice plan of care from providers not affiliated with the hospice. These providers are then billing Medicare for that care using the GW modifier or condition code 07. Thus Medicare may be paying twice

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[8] 42 U.S.C. § 1395d(d)(2)(A)

[9] 42 C.F.R. § 418.24(d)

[10] Medicare Claims Processing Manual, Chapter 11, § 50

[11] 79 Fed. Reg. 26549 (May 8, 3014)

for what should be hospice care. To remedy this potential problem, CMS seeks to redefine "terminal illness" and "related conditions" so broadly that *virtually all care* received after a hospice election will be through the hospice.

CMS justifies its position by noting that when the regulations were promulgated in 1983, the Health Care Financing Administration (HCFA- now CMS) stated, "It is our general rule that waiver required by law is a broad one and that all hospices are required to provide virtually all of the care that is needed by terminally ill patients."[12] This quotation certainly does seem to support the view, that since 1983, it was understood that once a beneficiary elects hospice care, she waives her right to Medicare coverage of all other medical care. However, when the quote is read in context, it is clear that HCFA was responding to comments about the "statutory exception" potentially permitting continued Medicare coverage in "exceptional and unusual circumstances" for "costly medical services needed by a terminally ill patient *for palliation or management of his or her symptoms*." (emphasis added)[13] Specifically, stakeholders asked HCFA to promulgate regulations *allowing for* non-hospice Medicare payment for expensive care such as ambulance transportation and palliative chemotherapy *related to the terminal illness*, to which HCFA responded that the hospice providers were responsible for virtually all, including expensive, care *related to the terminal illness.* In the end, HCFA decided that it would not implement the "exceptional and unusual" provision until it could "identify circumstances appropriate to the waiver."[14]

With respect to care *unrelated* to the terminal illness, and therefore, not provided by the hospice, HCFA actually stated:

> We recognize that additional claims processing guidelines will be needed to assure that Medicare intermediaries understand the nature of hospice coverage and are able to *process out-of-hospice claims properly*. We will be preparing these guidelines and issuing them to the intermediaries in the near future. We do not believe that these operational instructions are appropriately a part of these regulations.[15] (emphasis added)

Thus it has been the case since 1983 that HCFA (now CMS) has recognized that, pursuant to the Statute, regulations, and billing policy, when a person elects the hospice benefit, she only waives Medicare coverage for non-hospice care for the terminal illness and related conditions. Though always understood as a holistic benefit, a hospice election has never been understood to deprive Medicare beneficiaries of their right to Medicare coverage for their *other* medical conditions.

To create an all-encompassing hospice benefit, that is a benefit under which the hospice provider would be responsible for "virtually all" the beneficiary's care, might indeed solve the potential hospice "unbundling" billing problem. However, such a benefit cannot be created through definitions; Congress would have to re-write the Medicare statute.

CMS could address the issue of unbundling, as well as concerns regarding quality of care for hospice patients by adopting the recommendations made by the Office of Inspector General in its August 29, 2013

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[12] 79 Fed. Reg. 26542 (May 8, 3014)

[13] 48 Fed. Reg. 56010 (Dec., 26, 1983)

[14] 48 Fed. Reg. 56010-56011 (Dec., 26, 1983)

[15] 48 Fed. Reg. 56010-56011 (Dec., 26, 1983)

report, Recommendation Follow-up Memorandum Report: *Frequency of Medicare Recertification Surveys for Hospices is Unimproved.* In that report, the OIG finds:

> As of the index date of February 28, 2013, 17 percent of State-surveyed hospices had not been recertified within the preceding 6 years, with some hospices experiencing longer intervals since their most recent survey…We also found that in 12 States, more than 25 percent of hospices had not been recertified within the last 6 years. These findings (1) suggest that CMS's use of fluctuating annual targets does not ensure timely recertification surveys of all hospice and (2) raise concerns about whether CMS and contracted State survey agencies can ensure that hospices comply with Medicare CoPs and quality of care requirements for hospices.

The raw numbers in this report are absolutely alarming. For instance, in Oklahoma, where there were 109 hospices, 80 of the hospices (that's 73.4%), had not received a survey in the preceding 6 years. In Idaho, where there were only 29 hospices, 20 had not received a survey in the preceding 6 years. We concur with the OIG's recommendation that:

> CMS [should] set specific timeframes for the frequency of hospice recertification surveys. This should be accomplished by seeking legislation or promulgating regulations. Embedding in regulation a standard for survey frequency would elevate State responsibility to meet such a standard, and therefore better ensure that hospices are surveyed more timely. CMS could consider setting this survey frequency standard at 3 years, to match the 3-year interval used by accrediting organizations (as approved by CMS); however given resource limitations, setting a mandatory frequency…could help to ensure improvement in survey frequency and avoid lengthy intervals between surveys for individual hospices… [16]

We share the concerns voiced by the OIG and CMS that hospice providers are unbundling services and thus undermining quality of care. However, we do not believe that these concerns can be addressed through definitional changes. Instead, CMS must recognize that determining whether medical care is for a terminal illness or a related condition is a highly complex and individualized issue. The best way to determine whether hospice providers are providing all the necessary care to manage and relieve pain and other symptoms related to each patient's terminal illness is to review their actual case files on a routine basis. This should be done, as recommended by the OIG, through regular state survey review.

E. Proposed Timeframe for Filing the Notice of Election and Notice of Termination/Revocation

1. Proposed Timeframe for the Notice of Election

We appreciate the importance of the Notice of Election and support CMS' proposal that hospice providers be required to submit the election within three days. Additionally, we encourage CMS to enhance the educational component of the Notice of Election to discuss the implications for Part D. Hospices should be required to provide beneficiaries with a list of medications that will continue as part of their hospice plan of care, those that will be discontinued, and those that may continue to be covered under Part D.

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[16] https://oig.hhs.gov/oei/reports/oei-06-13-00130.asp

F. Proposed Addition of the Attending Physician to the Hospice Election Statement

Medicare beneficiaries who elect the hospice benefit have a right to choose their attending physicians.[17] This is a very important right as it helps ensure that the plan of care reflects what is best for the patient rather than what is most economical for the hospice provider. Therefore, we support CMS's proposal to add the attending physician to the Hospice Election Statement. However, rather than, as proposed, allowing hospices "the flexibility to include this information on their election statement in whatever format works for them," the Center encourages CMS to promulgate regulatory language that not only indicates that "an acknowledgement by the patient (or representative) that the designated physician was the patient's (or representative's) choice", but additionally will make very clear that the beneficiary or authorized representative *has a right to choose his or her attending physician* and that that physician need not be an employee of the hospice.

I. Solicitation of Comments on Coordination of Benefits Process and Appeals for Part D Payment for Drugs While Beneficiaries are Under a Hospice Election

In an alarming report, the Office of Inspector General (OIG) found that in 2009, Medicare Part D paid pharmacies $33,638,137 for 677,022 prescription medications that "potentially' should have been covered under the per diem payments made to hospice providers. In addition, beneficiaries spent $48.2 million in cost-sharing that should not have been required of them. The OIG recommended that 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.[18]

In response, CMS issued a memorandum on October 22, 2010, which directed all Part D plan sponsors to communicate with their network pharmacies regarding efforts to ensure that Medicare covered hospice drugs are not billed to Part D. Additionally, in the 2012 Call Letter, CMS clarified that all Part D sponsors had the ability to identify any Medicare enrollees who had elected hospice. Further, CMS directed that sponsors ensure their claims processor was notified of an enrollee's hospice election and that processes were in place to prevent Part D payment for hospice medications. Given the concerns of CMS that beneficiaries not lose access to their Part D medications, it "suggested that unless the plan has information available at point-of-sale to determine payment responsibility, sponsors should pay for the claims for drugs furnished to members enrolled in a hospice program that may be covered under the hospice benefit and retrospectively determine payment responsibility."[19]

We agreed with CMS' 2012 position that access to medications for dying patients is of utmost importance and that billing problems could be sorted out retrospectively. However, CMS has since shifted its

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[17] 42 C.F.R. § 418.52

[18] Department of Health and Human Services, Office of the Inspector General (OIG), "Medicare Could be Paying Twice for Prescription Drugs for Beneficiaries in Hospice" (A-06-10-00059)(June 2012)

[19] See FN 2, Appendix: Centers for Medicare & Medicaid Services Comments

position. Since May 1, 2014, due to a sub-regulatory "guidance", hospice patients currently cannot get their Part D medications unless they are able to negotiate a complex prior authorization process.[20]

As reflected in a letter to CMS, signed by 45 organizations representing beneficiaries, hospice providers, pharmacists and physicians, we believe this guidance was issued prematurely and harms beneficiaries. The current policy is subject to differing interpretation, and is already creating barriers for dying patients who are trying to access necessary medications. As such, we continue to urge CMS to rescind or suspend the current policy until such time that a more workable system, as suggested below, is put in place.

In the NPRM, CMS discusses two appeal processes:

1. The first is a proposed process to adjudicate the complicated Part D or hospice medication problem; and
2. The second is a system that supposedly already exists, allowing hospice patients Medicare coverage and payment for needed medications that the hospice has refused to pay for.

We think the first process is unworkable and will ultimately mean that hospice patients will lose access to their Part D medications and possibly not get the appropriate hospice medications. If CMS nonetheless proceeds with this proposed process, we offer suggestions below that aim to mitigate potential harm to beneficiaries.

As discussed below in comments to the "Beneficiary and Appeals" section of the NPRM, the second system is truly imaginary as it has no basis in law or fact. Given the importance of access to medications for dying patients to ensure relief from symptoms like pain, nausea, air hunger, and anxiety, we propose an expedited appeal process similar to the one currently in the regulations for untimely discharges from skilled nursing facility, comprehensive outpatient rehabilitation facility, home health, and hospice care.[21]

1. Part D Sponsor Coordination of Payment with Hospice Providers

CMS' proposed appeal process is designed to ensure that Part D sponsors will not inadvertently pay for medications that should be paid for and provided by the hospice under the hospice plan of care.[22] To do this, they outline a complex process, between two different payer sources and a prescribing physician which must be navigated by a dying beneficiary or grieving caregiver and which relies in part on the current Part D appeal process.

If this process is implemented, it will most likely be successful in the sense that less hospice medications will be erroneously paid for by Part D sponsors. However, its success will not mean that actual disputes are correctly decided. Instead, it will mean that fewer medications will be paid for by Part D plans because dying beneficiaries or their grieving caregivers will not be able to negotiate a complicated appeal process part of which is already known to be unworkable for even healthy beneficiaries.[23] We expect that dying beneficiaries or their grieving caregivers will not have the energy to argue with the numerous

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[20] Part D Payment for Drugs for Beneficiaries Enrolled in Hospice – Final 2014 Guidance (March 10, 2014)

[21] See 42 C.F.R. § 405.1200 et seq.

[22] 79 Fed. Reg. 26570 – 26572 (May 8, 3014)

[23] See, e.g., Sokolovsky, J., Shinobu, S. and L. Metayer, "Part D exceptions and appeals," (Presentation to MedPAC: September 2013), available at: http://www.medpac.gov/transcripts/part%20d%20exceptions%20&%20appeals.pdf

players about coverage for their medications and will simply go without or revoke their hospice election. Neither scenario is acceptable.

Despite the objections outlined above, if CMS proceeds with its proposed appeal process, we assert that minimum safeguards must be put in place in order to protect beneficiaries' timely access to medically necessary drugs. To that end, we provide the following comments.

"Coordination with Medicare hospices" requirements for Part D sponsors: We support CMS' intention that hospice providers and Part D sponsors communicate and coordinate to ensure appropriate drug coverage. Yet, we are concerned the requirements outlined in the proposed rule are not strong enough. CMS proposes that Part D plans will be required to coordinate once a hospice provider provides information on a beneficiary's hospice election, drug profile or both. We strongly urge that both payers be subject to strict requirements to initiate communication, whenever either party is first made aware of the hospice election from any source. We believe that requirements on both payers will ensure active communication and coordination, as envisioned by CMS.

Information provided by hospice providers to Part D sponsors: Additionally, CMS should specify the exact information that each party should provide to the other, and ask that this specification be as detailed as possible. In the case of hospice outreach, we suggest that CMS *require* that hospice providers provide the drug profile described in the rule. In the case of Part D outreach, we suggest that CMS *require* that Part D sponsors provide a list of recent beneficiary claims.

We also suggest that CMS require Part D plans and hospice providers to accept this information, and any prior authorization information, in any form that is understandable and contains all necessary information, including verbally, via fax or electronically. To best facilitate this communication, we encourage CMS to create a standardized prior authorization form for use in these cases. We strongly support CMS' consideration of a *requirement* that Part D sponsors use information provided by hospice providers at the time of election, prior to a claim submission.

Prior authorization requirements: We firmly oppose CMS' suggestion that Part D sponsors initiate prior authorization for *all* drugs at the point-of-sale. In short, we believe this policy is overly burdensome and devalues the Part D benefit for hospice beneficiaries. In the absence of strict requirements on the involved payers, like those described above, we are concerned that blanket prior authorization will lead to both confusion and delayed access to needed medications for terminally ill Medicare beneficiaries.

Finally, CMS suggests that both point-of-sale messaging and the standardized pharmacy counter notice will be sufficient forms of education for hospice beneficiaries rejected at the point-of-sale due to prior authorization. Yet, the existing standardized notice lacks information on hospice (Part A) versus Part D coverage requirements. As such, this notice is insufficient for the purpose described in the proposed rule.

Should CMS move forward with a policy that involves use of prior authorization, we strongly encourage CMS to develop a tailored notice for hospice-related denials. At a minimum, the notice should include:

- A statement explaining that Part D continues to be responsible for medications unrelated to the hospice condition and that the hospice should cover medications related to the condition;
- A plain language definition of "relatedness" as developed in formal rulemaking;

- A plain language explanation of the process for requesting a coverage determination;
- A plain language explanation of the information to supply to meet the prior authorization requirement; and
- A directive to contact the prescribing provider, hospice provider and Part D plan for assistance

In addition, we strongly encourage CMS to consider developing educational content for Medicare beneficiaries on hospice (Part A) and Part D coverage rules at the time of hospice election. Further, information on the final policy should be incorporated on Medicare.gov and in the annual "Medicare and You" handbook. All beneficiary-directed content should be developed by CMS and standardized for use by both hospice providers and Part D plans.

2. Hospice Coordination of Payment with Part D Sponsors and Other Payers

We appreciate CMS' concerns regarding the inappropriate payment by Part D sponsors for medications related to the hospice condition. We strongly support the statements in this section reaffirming the obligation of the hospice provider to meet all of the clinical needs of the hospice patient, including, when necessary, providing medications that are not a part of the hospice formulary. We also support CMS requiring that hospices provide timely lists of medications to Part D sponsors, and that Part D sponsors are required to act upon that information, as well as the requirement that post-delivery payment resolution take place within 45 days and that it provide for timely refunding of any beneficiary cost-sharing.

With respect to the development of a Part D sponsor-hospice dispute resolution system, we are concerned about delays in access while the payers resort to such a system. Should CMS move forward with such a system, a temporary payment mechanism must be in place so that questions about which entity pays for the covered medication does not interfere with beneficiary access to medically necessary prescription drugs.

3. Beneficiary Rights and Appeals

As noted above, CMS discusses two appeal processes in the NPRM. The first, as described above, would attempt to adjudicate the complicated Part D or hospice medication problem. The second appeal process described by CMS -- one that allows hospice patients Medicare coverage and payment for needed medications that the hospice has refused to pay for -- supposedly already exists. CMS believes that if a beneficiary is not getting the pain relief she needs from the medication regimen provided by the hospice, she can purchase another medication either from the hospice or from a pharmacy and then submit that medication directly to a CMS contractor for payment using the CMS-1490 form.[24]

This second appeal process is fictional. In order for a beneficiary to get a medication, especially a highly addictive narcotic, a physician must write a prescription for it. If the patient's pain is poorly managed by the medications provided by the hospice provider, and the family wants a different medication, it is absurd to think that the same hospice physician who is not providing the correct medication regimen through the hospice provider would write an order for the correct medication, not to be provided through the hospice. And it would be poor medical care for another physician to order another pain medication

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[24] 79 Fed. Reg. 26575 (May 8, 3014)

without seeing the patient and without being familiar with the hospice plan of care. Even if a prescription was written, medications needed at the end of life are expensive, and thus many beneficiaries could not pay for them out of pocket. Since most pharmacies will not provide medications without payment, patients would not get the prescribed medication. And finally, the Medicare statute is clear, when a Medicare beneficiary elects the hospice benefit, she *waives* all Medicare payment for non-hospice care related to the hospice benefit. Even assuming the beneficiary could get a prescription, could pay out of pocket for the medication, and then submitted the bill to Medicare using the CMS-1490 form, once reviewed, the Medicare contractor could not pay for it. This is because since the beneficiary waived Medicare for all care related to the terminal illness not provided through the hospice, there **is simply no Medicare payment available.**[25]

If the hospice patient is not receiving adequate pain relief, the problem is two-fold. It is both a denial of Medicare covered care and evidence of poor quality of care. In the NPRM, CMS acknowledges the issue of quality of care and remarks, "the beneficiary may submit a quality of care complaints to a Quality Improvement Organization."[26] This is true, but the Quality of Care complaint process is not sufficiently regulated, expedited, nor designed in such a way that it will ensure hospice patients get the care they are legally entitled to and that is necessary to prevent needless suffering.[27]

When the hospice regulations were first promulgated in 1983, commenters suggested that the Health Care Financing Administration (HCFA) augment its proposed quality assurance requirements. To which HCFA naively responded:

> We have not accepted the suggestions for more detailed requirements or for the involvement of an outside party. We believe that the nature of hospice care under this benefit, which relies on the interdisciplinary group for the development of a comprehensive plan of care, supervision or provision of the care, and continuous evaluation and revision of the plan of care, is one which inherently involves continuous peer review…We also believe that the safeguards built into the survey and certification procedures, as well as into the claims review process, are an adequate external measure of the hospice's quality assurance mechanism.[28]

Sadly, the days of believing all hospice providers follow the rules and take excellent care of their patients are over. As CMS discussed at length in the NPRM, there is growing evidence that hospices are unbundling services, gaming the payment system, not providing appropriate and necessary care, and even not visiting patients during their last days of life.[29] At the Center for Medicare Advocacy, we hear from hospice patients and their families from all around the country. What we often hear is how much they need and appreciate the excellent care they receive from hospice providers. However, we also hear from

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[25] When Medicare beneficiaries elect the hospice benefit, except in such exceptional and unusual circumstances as the Secretary may provide, they waive all rights to have Medicare payment made for 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 or equivalent to (or duplicative of) hospice care… 42 U.S.C. § 1395d(d)(2)(A)

[26] 79 Fed. Reg. 26575 (May 8, 3014)

[27] http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/qio110c05.pdf

[28] 48 Fed. Reg. 56013, 56014 (Dec., 26, 1983)

[29] 79 Fed. Reg. 26544 – 26549 (May 8, 3014)

patients and families who are not receiving adequate pain control, appropriate therapies, durable medical equipment, or enough nursing or aide visits.

To remedy this problem and the payment problem created by the hospice waiver provision created by the Statute, CMS should promulgate regulations that provide hospice patients the right to expedited (within 24 hours) review by an independent review agency. The regulations should require hospice providers to submit the plan of care for each Medicare beneficiary to the State Quality Improvement Organization (QIO) and to keep it updated. Among other things, the plan of care would list all of the beneficiary's prescribed medications and indicate clearly which ones were related to the treatment of the terminal condition and which ones should be billed to Medicare Part D as unrelated to the terminal condition. The QIO professionals would be adequately trained specifically in hospice law, philosophy, and end of life care. The QIO would review each plan of care and let the hospice know whether it was in accord with its designations regarding payment responsibility. So long as the QIO agreed with the hospice provider, when medications were billed to the Medicare Part D plan, the sponsor would presume they are not related to the terminal illness and pay for them as appropriate.

Additionally, the new appeal process would require that when Medicare beneficiaries elect the hospice benefit, they would be given a written statement explaining what care and services should be provided by the hospice provider and a 1-800 telephone number to reach the QIO in the event that services were inadequate. When the QIO was called by a hospice patient or caregiver, the QIO would already have the plan of care and would investigate the complaint immediately. If it was determined that services or care were not meeting the patient's needs, the QIO would revise the plan of care as appropriate. The additional care and services would be added to the plan of care and payment for the additional care and services would be the provider's responsibility.

Conclusion

We share CMS' commitment to ensuring that hospice patients do not experience unnecessary pain and suffering and that their caregivers have appropriate support. To this end, we appreciate the opportunity to submit these comments. For additional information, please contact Terry Berthelot or David Lipschutz.

Sincerely,

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