

Medicare Part D Plans Burdened by Hospice Payment Reform

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hrough recent issuances, CMS has exhibited serious concern about the appropriate billing of services, including prescription drugs given to beneficiaries in hospice care. This is one part of the "beam of scrutiny" now focused on the Medicare hospice program because of coverage discrepancies that will have a significant impact on prescription drug plans (PDPs), Medicare Advantage plans offering prescription drug benefits (MAPDs), and prescription benefit management companies (PBMs) providing Part D services.

BACKGROUND

Hospice care is an interdisciplinary approach to providing end-of-life care for terminally ill individuals. Using a broad spectrum of professionals and other caregivers, the goal is to help these individuals to continue life with palliative care primarily in their homes, without the inconveniences and disruptions of a nonhospice inpatient environment. Although the concept of hospice care in the United States was introduced in 1963, Congress did not expand the scope of benefits under Medicare Part A to authorize coverage for hospice care until nearly 20 years later, in 1982.¹ Since implementation of the hospice benefit, a greater percentage of individuals in hospice care are dying in the comfort of their homes instead of in hospitals or other institutional care settings.²

By design, hospice coverage is an elective for those individuals with a life expectancy of 6 months or fewer if the terminal illness runs its normal course. By electing coverage, the beneficiary is deemed to have waived payments for certain other benefits, except in "exceptional and unusual" circumstances.¹ In return, hospices are expected to cover all services, including drugs and biologics, that are used for the palliation and management of the terminal illness and related conditions.³ Payment for these services is reimbursed to hospices through a fixed, per day, per level of care payment structure (per diem payment). This fixed-payment system results in hospices being **Background:** In an effort to reform the current hospice payment system, CMS has taken steps to address its concerns through guidance and proposed rule making, focusing on proper determination and payment of drugs for beneficiaries during a hospice enrollment. That is, should the Part A hospice benefit or Part D pay for prescribed drugs obtained at a pharmacy?

Objectives: To outline the key Medicare Part D provisions of the CMS 2014 guidelines and the proposed new rules for the hospice program, and to describe the resultant impacts of these changes to Medicare Part D plans.

Description: Part D plans need to be aware of and prepare for changes to the process of handling drug claims for hospice beneficiaries as a result of the 2014 guidelines and the proposed rule for 2015 hospice payments.

Conclusions: Medicare Part D plans are being affected by new guidance and face additional administrative burdens if proposed rules are finalized, as CMS attempts to implement reforms and better determine payment responsibility for drugs used by hospice beneficiaries.

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financially responsible for costs exceeding the payment amount, but able to profit from costs that are below the fixed payment amount. An aggregate cap exists to limit the total payments an individual hospice can receive in a fiscal year for all patients under its care. Hospices are responsible for reimbursing Medicare for any payments that exceed the aggregate cap. This fixed payment structure has been in place since 1983, with little change since that time.¹

Need for Reform

The Affordable Care Act authorized the Secretary of Health and Human Services to collect additional data and information to revise payments for hospice care and for other purposes beginning no later than January 2011. Furthermore, it required the Secretary to use the data to implement changes to the payment system for hospice care no earlier than October 1, 2013.⁴

Consulting with hospice programs and the Medicare Payment Advisory Commission, and working with its hospice reform contractor, CMS analyzed potential hospice payment system vulnerabilities. Results thus far have identified utilization trends that cause concern about the viability of the Medicare hospice program. These include a 153% growth in hospice beneficiaries and a 421% growth in hospice expenditures between fiscal years 2000 and 2013. Also of concern is a 45% drop in the mean daily hospice drug costs per patient day between 2004 and 2012, a period that includes the start of the Medicare Part D drug benefit.¹

One area of serious concern was the amount of nonhospice spending on prescription drugs for hospice beneficiaries. Analysis of data for calendar year (CY) 2012 showed more than \$1.2 billion in nonhospice expenditures for hospice beneficiaries during a hospice enrollment (Table).^{1,5}

Digging deeper into CY 2012 Part D drug data, it is estimated that more than \$108 million of the total Part D drug expenditures were for likely covered hospice drugs in the following categories: analgesics; antiemetics; drugs used to treat constipation; drugs related to chronic heart failure, chronic obstructive pulmonary disease, and other noninfectious respiratory conditions; and any other drug filled for a patient admitted with diagnosis of debility or adult failure to thrive. Of this gross amount, it is estimated that \$86.6 million was paid for by Medicare, \$13.6 million by beneficiaries, and \$5.4 million by other payers.⁵

2014 GUIDANCE

In a March 10, 2014, memo to Part D plan sponsors and hospice providers, CMS issued its final 2014 guidance

PRACTICAL IMPLICATIONS

Recent guidance and proposed rule making by CMS for the Medicare hospice program will require changes for Medicare Part D plans.

- Key provisions include implementing beneficiary-level point-of-sale edits, accepting and storing all received hospice indicators, working with new definitions for "terminal illness" and "related conditions," working around defined timelines for hospice organizations to file notification of election and termination/revocation forms, and ability to communicate and coordinate with hospice programs when conducting drug reviews.
- Part D plans will have increased administrative costs, additional responsibility, new risks, audit exposures, new operational procedures, and required system changes.

regarding Part D payment for drugs for beneficiaries enrolled in hospice care.3 Numerous hospice and healthcare organizations opposed this guidance and gathered congressional support in an attempt to get CMS to immediately suspend it.^{6,7} Driven by concerns surrounding impacts to beneficiary access and operational challenges for hospice providers, Part D plans, PBMs, and pharmacies, CMS met with key industry stakeholders in late June 2014. As a result, CMS issued a memorandum in mid-July 2014 containing revised guidance that supersedes portions of the March guidance and restated guidance from March that remains in effect. Although the effective date of this new "blended guidance" is immediate, CMS expects plan sponsors to have it implemented by October 1, 2014.8 Key highlights of this blended guidance relate to payment responsibility, administrative procedures, the standardized hospice prior authorization form, network pharmacy involvement, and best available evidence.

Payment Responsibility

The guidance outlines in clear terms the respective drug payment responsibilities among "parties" and under what specific circumstances each party is responsible for the drug costs:

- Hospices are responsible when a drug is used for the palliation and/or management of the beneficiary's terminal illness or related conditions.
- Part D is responsible when a drug is used for the treatment of a condition that is completely unrelated to the terminal illness or related conditions.
- Beneficiary is responsible (1) when hospice determines a drug is not reasonable and necessary



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Payer	Medicare A+B Services (in millions of dollars)	Medicare D Drug Spend (in millions of dollars)	Total Expenditures (in millions of dollars)
Medicare	710.1	334.9	1045
Beneficiary	135.5	48.2	183.7
Other	_	34.8	34.8
Total	845.6	417.9	1263.5

Table. Nonhospice Expenditures for Hospice Beneficiaries, Calendar Year 2012^{1,5}

for the palliation of pain and/or other symptom management, but the beneficiary still chooses to have the medication, and (2) when the beneficiary opts to use a nonformulary drug to manage the terminal illness or related condition without trying a hospice formulary alternative first.^{3,8}

Administrative Procedures

After notification of a Medicare member's hospice election, CMS strongly encourages Part D plans to implement point-of-sale, beneficiary-level prior authorizations on the following 4 categories of prescription drugs: analgesics, antiemetics, laxatives, and anxiolytics. Drugs within these 4 categories are typically used to treat common symptoms experienced by hospice beneficiaries during the end of life, regardless of the type of terminal illness. Therefore, these drugs would most often be expected to be covered under the hospice per diem, not the Part D prescription drug benefit.⁸ This is a change from earlier guidance, which encouraged prior authorizations on *all* drugs used by beneficiaries who have elected hospice.³

Additionally, plans are expected to communicate with hospices and prescribers to make appropriate determinations of payment and must have procedures in place to handle the following types of determinations³:

- **Prospective.** Prior to a claim submission, hospice organizations may initiate communication with a Part D plan to provide documentation that satisfies the beneficiary-level prior authorization requirements.³ To avoid any negative impact on beneficiary access, CMS encourages hospices to initiate communication proactively with Part D plans.⁸
- **Concurrent.** Originally, the guidance indicated that after submission of a claim, the prior authorization should be subject to Medicare Part D coverage determination requirements (including appeals) and should be processed accordingly by Part D plans.³ Although a coverage determination could still be initiated if circumstances warrant, CMS

will now allow hospices to provide information similar to the prospective method described above—after submission of a claim and before submission of a coverage determination to satisfy the beneficiary-level prior authorization requirements. Part D plans should accept this documentation without requiring the beneficiary, or other applicable parties, to request a coverage determination.⁸

Retrospective. In the event a Part D plan has already paid claims before receiving the notification of hospice election for a given individual, it must conduct retrospective reviews of all Part D claims for drugs in the 4 designated categories previously described for that individual and coordinate efforts to reconcile payments with hospice providers and/or beneficiaries.3,8 Because of the recent CMS guidance change from placing edits on all drugs to only drugs in the 4 categories, there may be outstanding claim rejections or pending coverage determinations for drugs outside the 4 categories.8 Because of the focus on the beneficiary's access to care, it is the authors' opinion that plans should conduct retrospective reviews of these claims to determine coverage as part of their transition plan to the new guidance. In addition, there may be scenarios whereby drugs are provided by the hospice as "compassionate first fills" to beneficiaries at point of sale that require retrospective review and possible reconciliation between the hospice and Part D plan sponsor.8

Standardized Hospice Prior Authorization Form

Included with the July guidance is a draft standardized prior authorization form for use by the hospice or prescriber to communicate information for drug approval, including prospective or concurrent requests.^{8,9} The first page of the form contains the information necessary to indicate Part D drug coverage as well as hospice election/termination. Part D sponsors must accept this form but cannot solely require the use of this form. Regardless of the form used, Part D plan sponsors must accept any statement indicating the "unrelatedness" of the drug to the terminal illness or related condition.⁸ Unlike previous 2014 guidance that required documentation of a "clinically coherent reason," this documentation could be as simple as including the letter "U" or word "unrelated," as well as merely listing the drug on the first page of the draft stan-dardized form.^{8,10}

Network Pharmacy Involvement

Part D plan sponsors should encourage network pharmacies to assist beneficiaries in their understanding of the point-of-sale rejection, and direct them to initiate a coverage determination or have the hospice provide information to satisfy the beneficiary-level prior authorization. Also, plans should encourage network pharmacies to assist plan members by faxing any documentation or evidence (eg, prescriber-initiated prior authorization form, hospice benefit termination) to Part D plans that would help provide beneficiaries with immediate access at point of sale.⁸

Best Available Evidence

Seventy percent of all medication-related hospice beneficiary complaints submitted in May 2014 were related to issues regarding the beneficiary's hospice election/ termination. The majority of these complaints came from beneficiaries unable to receive medications because of point-of-sale edits, despite claiming their hospice benefit terminated.8 Until future rule making can create specified time frames for the submission of the hospice notice of termination/revocation, Part D plans should accept any of the following as evidence of termination submitted by a beneficiary, hospice provider, or prescriber: beneficiary's written statement of revocation, proof of submission of a final claim indicating revocation, notice of Medicare noncoverage, discharge summary from hospice provider, or page 1 of the draft standardized prior authorization form.8

PROPOSED HOSPICE REGULATIONS

On May 8, 2014, CMS released for public comment a proposed rule on hospice payment and other provisions for 2015.¹ When released, the proposed rule supported and expanded upon the guidance released in March. At the time of this writing, it is unclear how this new July 2014 blended guidance will impact CMS' final rule making. In the proposed rule, CMS introduced numerous changes impacting the hospice program, including the following 3 key provisions related to Part D:

1. Definition of Terms. The cornerstone to an appropriate determination starts with a clear definition of the terms "terminal illness" and "related conditions." Current regulations define terminal illness as "the individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course."¹¹ Through this proposed rulemaking, CMS suggests the definition for terminal illness be expanded to:

Abnormal and advancing physical, emotional, social and/or intellectual processes which diminish and/or impair the individual's condition 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 6 months or less.¹

Although related conditions have not previously been defined, CMS is now proposing the following definition:

Those conditions that result directly from terminal illness; and/or result from the treatment or medication management of terminal illness; and/or which interact or potentially interact with terminal illness; and/or which are contributory to the symptom burden of the terminally ill individual; and/or are conditions which are contributory to the prognosis that the individual has a life expectancy of 6 months or less."¹

CMS anticipates that a clear definition of these terms will assist Part D plans and hospices to determine appropriate payment responsibility. Although these definitions will certainly help, the subjectivity of a case-by-case basis review will continue to pose challenges for hospices and Part D plans.

2. Timeline for Filing Notice of Election and Notice of Termination/Revocation. After election of hospice care by a beneficiary, the hospice program is required to file a Notice of Election (NOE) with a Medicare administrative contractor. This is designed to inform Medicare and other providers of Medicare services of the election to properly determine appropriate payment for services. A survey of 4 Medicare administrative contractors showed that fewer than 20% of NOEs were filed within 2 days of effective date of election, fewer than 40% were filed within 5 days, and fewer than 65% were filed within 10



Case Study

ES is an 82-year-old male who elected to enter hospice care after receiving a primary terminal diagnosis of chronic obstructive pulmonary disease (COPD). His COPD is being managed using oral corticosteroids. His type 2 diabetes, diagnosed prior to the development of COPD, is well managed with the use of oral hypoglycemic medication. Upon admission, the hospice reviews ES's medications to determine which ones are related to the terminal illness or related conditions. The hospice completes the review and informs the patient that the corticosteroid is covered by the hospice; however, the diabetes medication is not covered by hospice, because the diabetes is unrelated to COPD. The hospice instructs the patient to obtain his oral hypoglycemic medication through his Part D prescription drug plan.

Is the hospice correct in the determination that ES's oral hypoglycemic medication is unrelated to the terminal illness or related conditions?

Answer: No, in this example the hospice should cover both the corticosteroid and the hypoglycemic agent. Increased glucose levels are common with the use of corticosteroids. Because the use of corticosteroids is for the treatment of the terminal illness (COPD), and the treatment has the potential to affect glucose levels, it is considered related to the patient's related condition. This determination is supported in the proposed definition of related conditions.

This example is drawn from content in the proposed rule published in the Federal Register on May 8, 2014.

days.¹ These late filings, coupled with the time it takes for Medicare to process the NOE, could result in more than a week's delay for other payers to receive information regarding a beneficiary's election of hospice. This delay may also contribute to unnecessary nonhospice expenditures for beneficiaries in the hospice program.¹ In an effort to reduce this lag time, CMS is proposing implementing a 3 calendar day time frame after hospice election within which hospices must file the NOE. Any hospice exceeding this time frame will not receive payment for any days from the hospice effective date to the filing the NOE. These days would be the financial responsibility of hospice and could not be passed on to the beneficiary.¹

Although the reasons for discharge from hospice are limited, upon revocation of the hospice enrollment, a beneficiary resumes the Medicare coverage that had been previously waived. Thus, in order to ensure beneficiaries have proper and timely access to needed services after a discharge from hospice, CMS is proposing that hospices must file the Notice of Termination/Revocation within 3 calendar days after the effective date of a beneficiary's discharge or revocation.¹

3. Part D and Hospice Communication and Coordination. To assist hospices and Part D plans, CMS proposes a standardized process to be used for the determination of payment responsibility. This proposed process further supports current guidance requiring Part D plans to promptly upload hospice indicators received from CMS as a result of a hospice filing a NOE.^{1,3} In addition, plans are to use beneficiary-level point-of-sale edits using specified National Council for Prescription Drug Programs codes, and communicate and coordinate with hospices during prospective or concurrent medication reviews. Because of the known lag time in the process of receiving hospice indicators, Part D plans should accept information initiated from a hospice prior to claim submission and utilize it to prospectively make a determination of payment responsibility.¹

After claim submission, a concurrent review to determine payment responsibility should follow the current coverage determination process and timelines as outlined in the regulations and chapter 18 of the Medicare Prescription Drug Benefit Manual.^{1,12,13} Only the beneficiary, the beneficiary's appointed representative, or the prescriber, and not the hospice can initiate a coverage determination. However, hospices will be expected to promptly provide information supporting the reason for the drug being unrelated to the terminal illness or related conditions when a coverage determination is initiated.^{1,12} After submission of an expedited coverage determination, Part D plans are required to review the request, make a decision, provide notification, and when applicable, effectuate (authorize the drug) within 24 hours. For standard drug requests the time frame is 72 hours; for member reimbursement requests it is 14 days. Plans should be mindful to conduct coverage determinations (and appeals) as expeditiously



as the enrollee's health condition requires, which could mean less than these noted time frames.⁸ If the request involves a drug not on the Part D plan formulary, this is an exception-type coverage determination, and the above time frames do not begin until the Part D plan has received the prescriber's supporting statement.^{1,12}

It will be the responsibility of the Part D plan to determine whether the information provided by the hospice satisfies the requirement of the drug being unrelated to the terminal illness or related conditions. If the sponsor disagrees with the information provided by the hospice, the Part D sponsor should initiate conversation with the hospice in an attempt to resolve the dispute. If a resolution cannot be achieved, the Part D sponsor will be able to seek review by an Independent Review Entity (IRE) who is contracted with CMS. Plans will have to file a written request within 5 calendar days from the date the plan received information from the hospice. The IRE decision will be binding for both the Part D sponsor and hospice, and the decisions are not subject to appeal.¹ This IRE process is separate and distinct from the IRE reconsideration process that is 1 of the levels of appeal available to beneficiaries after an adverse coverage determination.^{1,13,14} Finally, plans will be required to review and process retrospective claims, make adjustments, and issue requests for repayment and or refunds within 45 days.¹

How Do These Changes Impact Part D Plans?

With the 2014 guidelines and the possibility of proposed rules being finalized, Part D plans will experience many impacts, including the following:

Increased Administrative Burdens. In the following new processes, plans will see an increased volume of activity, such as managing point-of-service edits and processing more coverage determinations, and increased resource consumption in numerous operational areas, resulting in increased costs. Additional efforts will be required to train staff members, update policies and procedures, and modify operational work flows. The recent shift in guidance will result in more work for Part D plans. Having already incurred costs to meet the March guidance, plans may experience a "Groundhog Day-like" feeling and incur additional costs to comply with the new blended guidance before October.

Part D Plans Becoming the Gatekeepers. Given the growth in Part D drug utilization by hospice patients, Part D plans have an increased responsibility to manage this utilization and to actively direct drug payment responsibility to the correct payer.^{1,3} Part D plans and hospice organizations must work together to resolve payment issues, with PDPs, MAPDs, and PBMs central to the final outcome.³ Plans are expected to determine which drugs to include in the 4 categories of drugs for which beneficiarylevel prior authorizations are to be placed. While stating plans are to use "standard industry classifications that are available through drug listing services or otherwise," CMS does not provide more specificity, and this could result in conflicts of interpretation between plans and hospice providers.8 With no mediation process in place for 2014, CMS expects plans to accept the hospice's explanation of unrelatedness of the drug, make subsequent payment under Part D, and maintain the documentation in the Part D plan sponsors' systems.8,10 If the related provisions of the proposed rule are finalized for 2015, Part D plans will be expected to apply the updated definitions of "terminally ill" and "related conditions" when determining Part D coverage. For any disputes that may arise, a mediation process will be available, thus thrusting not only the responsibility of an appropriate determination on Part D plans, but also the onus of determining if and when to seek a binding decision from the IRE.¹

Increased Reconciliation Efforts. Because of a multistep data flow of hospice indicators, plans may receive delayed notification of hospice enrollments as well as terminations/revocations.³ The result is in an increased need to conduct retrospective reviews and subsequent reconciliation of claims. If proposed regulatory changes regarding time frames for NOEs and Notices of Termination/Revocation are adopted, delays should be reduced, but the need for reconciliation will continue to exist.

Systems Must Accommodate Guidance Changes. Plans will need to conduct system modifications to accommodate everything from the appropriate storage of all hospice indicators for the enrollment to the coding of beneficiary-level prior authorizations.¹

New Audit Risks. Part D plans are expected to retain all documentation related to any prospective, concurrent, or retrospective review.¹ Plans may be challenged in storing and retrieving all relevant documentation because of variations of entry points among the different types of reviews and the use of multiple tracking systems. The burden of proof to provide acceptable documentation supporting appropriate hospice versus Part D coverage will likely shift from hospice plans in 2014 to Part D plans in 2015 and beyond. With payment determination under scrutiny, Part D plans can expect this to be a focal area for future performance and financial audits conducted by CMS.

CONCLUSION

CMS provides strong evidence suggesting prescription drugs are often unbundled from hospice services and



billed to Part D.¹⁵ This unbundling has the potential to result in Medicare paying twice (under the hospice per diem and under Part D) for drugs intended only to be covered under hospice, beneficiaries incurring additional true outof-pocket expenses, Part D plans incurring additional drug costs, and hospices receiving payments for services and drugs while not incurring rightful costs.

Based on feedback from the industry and the resultant changes in guidance, it is apparent CMS is still seeking the ideal solution to a difficult problem. Although the recent guidance may alleviate some operational challenges, it is not likely to satisfy the entire need for reformation. The path leading to Part A versus Part D reform has changed and will likely change again—but the beam of scrutiny on payment for drugs when a beneficiary has elected hospice will continue.

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