



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



June 28, 2012

TO: Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services

FROM: /Daniel R. Levinson/
Inspector General

SUBJECT: Medicare Could Be Paying Twice for Prescription Drugs for Beneficiaries in Hospice (A-06-10-00059)

The attached final report provides the results of our nationwide review of prescription drugs for beneficiaries in hospice for the period January 1 through December 31, 2009.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that the Office of Inspector General (OIG) post its publicly available reports on the OIG Web site. Accordingly, this report will be posted at <http://oig.hhs.gov>.

If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Brian P. Ritchie, Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or through email at Brian.Ritchie@oig.hhs.gov. We look forward to receiving your final management decision within 6 months. Please refer to report number A-06-10-00059 in all correspondence.

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE COULD BE PAYING TWICE
FOR PRESCRIPTION DRUGS FOR
BENEFICIARIES IN HOSPICE**



Daniel R. Levinson
Inspector General

June 2012
A-06-10-00059

Office of Inspector General

<http://oig.hhs.gov>

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The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

EXECUTIVE SUMMARY

BACKGROUND

Hospice care is a Medicare Part A benefit, and prescription drugs related to beneficiaries' terminal illnesses are covered under the per diem payments made to hospice organizations; therefore, Medicare Part D should not pay for them. When Part D pays for these drugs, the Medicare program, in effect, is paying twice. In previous investigative and audit work, the Office of Inspector General identified duplicate payments made by Part D for prescription drugs that should have been covered under the per diem payments.

To be eligible for Medicare hospice care, a beneficiary must be entitled to Part A of Medicare and be certified as terminally ill (i.e., having a medical prognosis that life expectancy is 6 months or less if the disease runs its normal course). Hospice is an approach to caring for terminally ill individuals through palliative care rather than traditional medical care and curative treatment. The goal of palliative care is to improve an individual's quality of life through pain management and symptom relief.

The Medicare hospice benefit has four levels of care, and each level has an all-inclusive per diem payment. The Centers for Medicare & Medicaid Services (CMS) makes the per diem payment to a hospice organization for each day that a beneficiary is in hospice care, regardless of the number of services furnished. Drugs used primarily for symptom control and the relief of pain related to the individual's terminal illness are covered under the hospice benefit, and the cost of providing these drugs is included in the per diem rate. As a result, hospice organizations should pay the dispensing pharmacies for these drugs.

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 amended Title XVIII of the Social Security Act by establishing the Medicare Part D voluntary prescription drug benefit. Under the Medicare Part D program, which began January 1, 2006, individuals entitled to benefits under Medicare Part A or enrolled in Medicare Part B may obtain voluntary coverage for prescription drugs. Prescription drug coverage is offered by nongovernmental entities known as prescription drug plan sponsors (sponsors), which contract with CMS. CMS makes estimated monthly subsidy payments to sponsors for each enrolled beneficiary. Sponsors contract with pharmacies to provide prescription drugs to enrolled beneficiaries and pay the pharmacies when they dispense prescription drugs to the beneficiaries.

Beneficiaries enrolled in a Medicare Part D prescription drug plan are responsible for copayments for the prescription drugs they receive. When these beneficiaries fill covered prescriptions under Part D, sponsors must submit prescription drug event (PDE) data to CMS. PDE data include drug cost and payment information that enables CMS to administer the Part D benefit, but the data do not include diagnosis-related information.

In an October 2010 memorandum to all Medicare Part D sponsors, CMS said that sponsors may be paying for drugs that should be the responsibility of hospice organizations.

Hospice beneficiaries generally experience common symptoms during the end of life, regardless of their terminal diagnoses. These symptoms include pain, nausea, constipation, and anxiety. Four common categories of prescription drugs are typically used to treat these symptoms, and hospice organizations should generally pay for these drugs because the drugs are covered under the hospice per diem payments. The categories are: analgesics, antinauseants, laxatives, and antianxiety drugs.

Additionally, we identified prescription drugs that are commonly used to treat two terminal diagnoses: chronic obstructive pulmonary disease (COPD) and amyotrophic lateral sclerosis (ALS). These drugs should be covered under the per diem payments made to hospice organizations. Various drugs are used to treat COPD; only one prescription drug is commonly used to treat ALS.

OBJECTIVE

Our objective was to determine whether Medicare Part D paid for prescription drugs that likely should have been covered under the per diem payments made to hospice organizations.

SUMMARY OF FINDING

During calendar year 2009, Medicare Part D paid for prescription analgesic, antinausea, laxative, and antianxiety drugs, as well as prescription drugs used to treat COPD and ALS, that likely should have been covered under the per diem payments made to hospice organizations. As a result, the Medicare program could be paying twice for prescription drugs for hospice beneficiaries: once under the Medicare Part A hospice per diem payments and again under Medicare Part D. Hospice beneficiaries could also be unnecessarily paying copayments for prescription drugs under Part D.

We identified 198,543 hospice beneficiaries who received 677,022 prescription drugs through the Medicare Part D program that potentially should have been covered under the per diem payments made to hospice organizations. Part D paid pharmacies \$33,638,137 for these prescription drugs, and beneficiaries paid \$3,835,557 in copayments. We contacted the Part D sponsors for five plans and found that, during our audit period, they did not have procedures to identify prescription drugs that should have been covered under the per diem payments.

RECOMMENDATIONS

We recommend 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.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

CMS concurred with two of our three recommendations. CMS did not concur with our second recommendation that it 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. CMS stated that it would need conclusive evidence that there is such an issue before making payment adjustments and that implementing our methodology for an ongoing oversight program would be difficult and costly. CMS indicated that, despite our developing and implementing an elaborate research methodology, we were unable to definitively determine that duplicate payments were made. However, CMS stated that it would consider whether it is possible to develop a cost-effective methodology that will yield conclusive findings suitable to make Part D plan payment adjustments. CMS's comments are included in their entirety as the Appendix.

OFFICE OF INSPECTOR GENERAL RESPONSE

In our second recommendation, we did not recommend that CMS make payment adjustments or implement our methodology. We were suggesting that, because of the potential cost savings to Medicare, CMS do more to address this issue. Our methodology was complex, but CMS and hospice industry officials endorsed it and assisted us in its development. Our prior audit work, in which we worked with hospice medical and pharmacy staff, proved that duplicate payments were made. This audit shows that duplicate payments are potentially being made on a national level and that the issue warrants CMS's increased attention.

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INTRODUCTION

BACKGROUND

Hospice care is a Medicare Part A benefit, and prescription drugs related to beneficiaries' terminal illnesses are covered under the per diem payments made to hospice organizations; therefore, Medicare Part D should not pay for them. When Part D pays for these drugs, the Medicare program, in effect, is paying twice.

In previous investigative and audit work, the Office of Inspector General identified duplicate payments made by Medicare Part D for prescription drugs that should have been covered under the per diem payments made to hospice organizations. For example, a review of a large, nonprofit hospice organization that appeared to have strong controls for ensuring that it paid for the appropriate prescription drugs found that Medicare Part D paid for some prescription drugs for which the hospice organization should have paid.

Medicare Hospice Benefit

Hospice is an approach to caring for terminally ill individuals through palliative care rather than traditional medical care and curative treatment. The goal of palliative care is to improve an individual's quality of life through pain management and symptom relief. Hospice focuses on helping individuals be comfortable by addressing physical and emotional pain. Hospice care may be provided to beneficiaries residing in their homes or elsewhere, such as a nursing facility.

The Tax Equity and Fiscal Responsibility Act of 1982 created the Medicare hospice benefit. To be eligible for Medicare hospice care, a beneficiary must be entitled to Part A of Medicare and be certified as terminally ill (i.e., having a medical prognosis that life expectancy is 6 months or less if the disease runs its normal course). When a beneficiary elects hospice care, a hospice organization assumes the responsibility for medical care related to the beneficiary's terminal illness and related conditions.

The Medicare hospice benefit has four levels of care, and each level has an all-inclusive per diem payment. The Centers for Medicare & Medicaid Services (CMS) makes the per diem payment to a hospice organization for each day that a beneficiary is in hospice care, regardless of the number of services furnished. Drugs used primarily for symptom control and the relief of pain related to the individual's terminal illness are covered under the hospice benefit, and the cost of providing these drugs is included in the per diem rate. As a result, hospice organizations should pay the dispensing pharmacies for these drugs.

National Hospice and Palliative Care Organization

The National Hospice and Palliative Care Organization (NHPCO) represents approximately 70 percent of hospice organizations nationwide and is the largest nonprofit membership organization representing hospice and palliative care organizations and professionals in the United States. NHPCO states on its Web site that it is committed to improving end-of-life care and expanding access to hospice care.

Medicare Part D Program

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 amended Title XVIII of the Social Security Act by establishing the Medicare Part D voluntary prescription drug benefit. Under Part D, which began January 1, 2006, individuals entitled to benefits under Medicare Part A or enrolled in Medicare Part B may obtain voluntary coverage for prescription drugs.

Prescription drug coverage is offered by nongovernmental entities known as prescription drug plan sponsors (sponsors), which contract with CMS. CMS makes estimated monthly subsidy payments to sponsors for each enrolled beneficiary. Sponsors contract with pharmacies to provide prescription drugs to enrolled beneficiaries and pay the pharmacies when they dispense prescription drugs to the beneficiaries.

Beneficiaries enrolled in a Medicare Part D prescription drug plan are responsible for copayments for the prescription drugs they receive. When these beneficiaries fill covered prescriptions under Part D, sponsors must submit prescription drug event (PDE) data to CMS. PDE data include drug cost and payment information that enables CMS to administer the Part D benefit, but the data do not include diagnosis-related information or any indication that the prescription was related to hospice care.

Centers for Medicare & Medicaid Services Efforts To Notify Sponsors About Duplicate Payments

In an October 2010 memorandum to all sponsors, CMS said that sponsors may be paying for drugs that should be the responsibility of hospice organizations. In April 2011, CMS issued a Call Letter to all sponsors saying that because hospice care is a Medicare Part A benefit, prescription drugs related to beneficiaries' terminal illnesses are covered under the per diem payment to hospice organizations, and Medicare Part D should not pay for them. Each month, CMS sends to all sponsors beneficiary data that include information indicating whether a beneficiary has elected hospice care.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Medicare Part D paid for prescription drugs that likely should have been covered under the per diem payments made to hospice organizations.

Scope

Our review focused on Medicare Part A hospice claims and Medicare Part D PDE records with dates of service during calendar year (CY) 2009.¹

¹ We obtained Medicare Part A hospice and Medicare Part D PDE records from the Services Tracking, Analysis, and Reporting System (STARS) on August 3, 2010. STARS is a PC-based system used for querying and reporting information from the national data warehouse, which contains all Medicare fee-for-service claims for the most recent 3 years.

Our objective did not require an assessment of internal controls related to hospice organizations or Medicare Part D.

We performed our audit work from March 2010 to August 2011.

Methodology

Based on discussions with CMS and NHPCO officials and on our research and previous work, we learned that hospice beneficiaries generally experience common symptoms during the end of life regardless of their terminal diagnoses. These symptoms include pain, nausea, constipation, and anxiety. Four common categories of prescription drugs are typically used to treat these symptoms: analgesics,² antinauseants, laxatives, and antianxiety drugs.

Prescriptions written for drugs in the four common categories are not always related to a hospice beneficiary's terminal illness. For example, a hospice beneficiary could fall and break her hip and get a prescription analgesic that was unrelated to her terminal illness. Medicare Part D should pay for this drug because it is not related to the beneficiary's terminal illness. However, the prescription drugs in the four common categories, when prescribed for hospice beneficiaries, are used primarily for palliative care. Thus, hospice organizations should generally pay for these drugs because the hospice per diem payments are intended to cover their costs.

With help from CMS, NHPCO, and hospice officials, we identified 16 American Hospital Formulary Service (AHFS) drug classifications that could contain prescription drugs used to treat common end-of-life symptoms.³ With assistance from CMS, we reviewed each prescription drug in the 16 classifications and identified 469 prescription analgesic, antinausea, laxative, and antianxiety drugs used to treat these symptoms.

We identified approximately 1.1 million beneficiaries who had Medicare Part A hospice claims with dates of service that started and ended during CY 2009.⁴ Of these beneficiaries, 437,121 had approximately 2.8 million Medicare Part D PDE records that corresponded to the 469 prescription drugs during the year. To determine which prescription drugs should have been covered under the per diem payments made to hospice organizations, we included only those Medicare Part D PDE records with fill dates during the beneficiaries' hospice dates of service.

Additionally, for the 1.1 million beneficiaries, we selected 2 hospice diagnoses for more specific analyses: chronic obstructive pulmonary disease (COPD) and amyotrophic lateral sclerosis (ALS). We selected COPD because we noted numerous prescriptions for inhalers in the Medicare Part D PDE records and because it was one of the more common diagnoses in the CY 2009

² Chemotherapy drugs are included in the analgesic category. They are used palliatively for hospice patients to shrink tumors, thereby alleviating pain.

³ The AHFS classification categorizes drugs with similar pharmacologic, therapeutic, and/or chemical characteristics into a four-tier hierarchy.

⁴ While these beneficiaries could have received hospice care before or after CY 2009, we included only CY 2009 claims for hospice services.

hospice claims. We selected ALS because only one drug is used for its treatment. Based on our research of the diagnoses and discussions with CMS officials, we identified 8 AHFS drug classifications that included 54 drugs prescribed for COPD and 1 AHFS drug classification for the 1 drug prescribed for ALS. CMS officials said that Part D should not pay for these drugs prescribed for hospice beneficiaries who have a principal diagnosis of COPD or ALS.

During the year, almost 30,000 hospice beneficiaries with a principal diagnosis of COPD had approximately 246,000 Medicare Part D PDE records that corresponded to the 54 COPD drugs.⁵ Additionally, more than 500 hospice beneficiaries with a principal diagnosis of ALS had approximately 2,200 Part D PDE records that corresponded to the 1 ALS drug.⁶ Again, to determine which prescription drugs should have been covered under the per diem payments made to hospice organizations, we then included only those Part D PDE records with fill dates during the beneficiaries' hospice dates of service.

We also spoke with the Medicare Part D sponsors for five plans regarding their procedures for identifying prescription drugs that hospice organizations should provide.

We assessed the reliability of STARS data by electronically testing required data elements and by checking the basic reasonableness of the data against another source. We determined that these data are sufficiently reliable for the purposes of this report.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

FINDINGS AND RECOMMENDATIONS

During CY 2009, Medicare Part D paid for prescription analgesic, antinausea, laxative, and antianxiety drugs, as well as prescription drugs used to treat COPD and ALS, that likely should have been covered under the per diem payments made to hospice organizations. As a result, the Medicare program could be paying twice for prescription drugs for hospice beneficiaries: once under the Medicare Part A hospice per diem payments and again under Medicare Part D. Hospice beneficiaries could also be unnecessarily paying copayments for prescription drugs under Part D.

We identified 198,543 hospice beneficiaries who received 677,022 prescription drugs through the Medicare Part D program that potentially should have been covered under the per diem payments made to hospice organizations. Part D paid pharmacies \$33,638,137 for these prescription drugs, and beneficiaries paid \$3,835,557 in copayments. We contacted the Part D

⁵ We obtained the Medicare Part D PDE records related to COPD beneficiaries from the STARS on November 10, 2010.

⁶ We obtained the Medicare Part D PDE records related to ALS beneficiaries from the STARS on November 10, 2010.

sponsors for five plans and found that, during our audit period, they did not have procedures to identify prescription drugs that should have been covered under the per diem payments.

We present our findings for prescription analgesic, antinausea, laxative, and antianxiety drugs first, followed by our findings for prescription drugs used to treat COPD and ALS.

FEDERAL REQUIREMENTS

Pursuant to 42 CFR § 418.202(f), covered hospice services include drugs and biologicals “used primarily for the relief of pain and symptom control related to the individual’s terminal illness” Thus, when explaining the “relationship between the requirement that hospices must provide drugs for patients and the Medicare Part D benefit” in the preamble to CMS’s final rule revising the hospice conditions of participation, CMS stated that:

Hospices are required by section 1861(dd)(1)(E) of the Act to furnish all drugs and supplies related to the terminal illness and related conditions. 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 [73 Fed. Reg. 32088, 32145 (June 5, 2008)].

Accordingly, in the final rule, CMS included a condition of participation at 42 CFR § 418.106 stating 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.”

MEDICARE PART D AND BENEFICIARIES PAID MORE THAN \$30 MILLION FOR DRUGS IN FOUR COMMON CATEGORIES THAT POTENTIALLY SHOULD HAVE BEEN COVERED UNDER MEDICARE PART A

During CY 2009, Medicare Part D paid pharmacies \$26,980,792 and beneficiaries paid \$3,092,554 in copayments for prescription analgesic, antinausea, laxative, and antianxiety drugs that potentially should have been covered under the per diem payments made to hospice organizations. We identified 186,156 hospice beneficiaries who received 623,509 prescription drugs in the 4 common categories.

The table on the next page shows the number of Medicare Part D PDE records and the total amount of payments associated with each of the four common prescription drug categories.

**Number of Medicare Part D Prescription Drug Event Records and Amounts Paid
by Medicare Part D and Beneficiaries**

Drug Category	Number of Medicare Part D Prescription Drug Event Records	Amount of Medicare Part D Payments	Amount of Beneficiary Copayments
Analgesics ⁷	428,084	\$21,904,799	\$2,348,515
Antinausea	95,137	2,908,456	409,606
Laxatives	76,404	1,888,267	252,688
Antianxiety	23,884	279,270	81,745
Total	623,509	\$26,980,792	\$3,092,554

MEDICARE PART D AND BENEFICIARIES PAID MORE THAN \$7 MILLION FOR DIAGNOSIS-SPECIFIC DRUGS THAT SHOULD HAVE BEEN COVERED UNDER MEDICARE PART A

We analyzed three categories of prescription drugs used to treat COPD: inhaled drugs, drugs used to treat complications from COPD, and drugs used for people with a genetic predisposition to COPD. During CY 2009, Medicare Part D paid pharmacies \$6,085,347 and beneficiaries paid \$693,432 in copayments for prescription drugs in these categories that should have been covered under the per diem payments made to hospice organizations. We identified 12,169 beneficiaries who had been admitted to hospice care for COPD and who had received 52,861 prescription drugs in the 3 categories.

We analyzed one prescription drug used to treat ALS. During CY 2009, Medicare Part D paid pharmacies \$571,998 for this prescription drug and beneficiaries paid \$49,571 in copayments that should have been covered under the per diem payments made to hospice organizations. We identified 218 beneficiaries who had been admitted to hospice care for ALS and who had received 652 prescriptions of the drug.

SOME SPONSORS DID NOT HAVE PROCEDURES TO IDENTIFY DRUGS PAID BY MEDICARE PART D THAT POTENTIALLY SHOULD HAVE BEEN COVERED UNDER MEDICARE PART A

We contacted the sponsors for five Medicare Part D plans. These sponsors submitted more than 40 percent of the Medicare Part D PDE records in the four common prescription drug categories that potentially should have been covered under the per diem payments made to hospice organizations. According to sponsor officials, they did not have procedures during our audit period to identify prescription drugs that hospice organizations should have provided. However, two of the sponsors said that they were conducting postpayment reviews to (1) identify hospice beneficiaries through the beneficiary data that CMS provides and (2) determine whether certain prescription drugs should have been covered under the per diem payments. One of the sponsors started postpayment reviews of prescription analgesics in CY 2010; the other sponsor started

⁷ This total includes 14,519 prescriptions for chemotherapy drugs that potentially should have been provided under the Medicare Part A hospice benefit. Medicare Part D paid pharmacies \$6,940,295 for these prescription drugs, and beneficiaries paid \$843,164 in copayments.

postpayment reviews of palliative drug prescriptions in CY 2011. Further, one of these sponsors is planning to implement a program under which pharmacists will be alerted when an analgesic drug prescription is being submitted for a hospice beneficiary. The pharmacist could then inform the individual submitting the prescription that it might be covered by the beneficiary's hospice organization.

CONCLUSION

The Medicare program could be paying twice for prescription drugs for hospice beneficiaries: once under the Medicare Part A hospice per diem payments and again under Medicare Part D. Hospice beneficiaries could also be unnecessarily paying copayments for prescription drugs under Part D. CMS sends beneficiary data monthly to all Part D sponsors and has informed them that they may be paying for drugs that should be covered under the per diem payments made to hospice organizations. The sponsors we contacted did not consistently use the beneficiary data to determine whether prescription drugs were related to hospice care and should have been covered under the per diem payments. Additionally, PDE records submitted to CMS did not indicate whether prescriptions were related to hospice care.

RECOMMENDATIONS

We recommend 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.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

CMS concurred with two of our three recommendations. CMS did not concur with our second recommendation that it 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. CMS stated that it would need conclusive evidence that there is such an issue before making payment adjustments and that implementing our methodology for an ongoing oversight program would be difficult and costly. CMS indicated that, despite our developing and implementing an elaborate research methodology, we were unable to definitively determine that duplicate payments were made. However, CMS stated that it would consider whether it is possible to develop a cost-effective methodology that will yield conclusive findings suitable to make Part D plan payment adjustments. CMS's comments are included in their entirety as the Appendix.

OFFICE OF INSPECTOR GENERAL RESPONSE

In our second recommendation, we did not recommend that CMS make payment adjustments or implement our methodology. We were suggesting that, because of the potential cost savings to Medicare, CMS do more to address this issue. Our methodology was complex, but CMS and hospice industry officials endorsed it and assisted us in its development. Our prior audit work, in which we worked with hospice medical and pharmacy staff, proved that duplicate payments were made. This audit shows that duplicate payments are potentially being made on a national level and that the issue warrants CMS's increased attention.

APPENDIX

APPENDIX: CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS



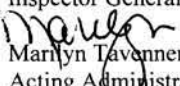
DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: MAY 03 2012

TO: Daniel R. Levinson
Inspector General

FROM: 
Marilyn Tavenner
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: *Medicare Could Be Paying Twice for Prescription Drugs for Beneficiaries in Hospice* (A-06-10-00059)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General (OIG) draft report entitled, "*Medicare Could Be Paying Twice for Prescription Drugs for Beneficiaries in Hospice*." The purpose of this report was to determine whether Medicare Part D paid for prescription drugs that likely should have been covered under the per diem payments made to hospice organizations.

Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 amended Title XVIII of the Social Security Act (the Act) by establishing the Medicare Part D prescription drug benefit. Under Part D, which began January 1, 2006, individuals entitled to benefits under Medicare Part A or enrolled in Medicare Part B may obtain drug coverage. CMS contracts with prescription drug plans and Medicare Advantage plans to offer prescription drug benefits to eligible individuals under Medicare Part D. Every time a beneficiary fills a prescription covered under Part D, the sponsor must submit prescription drug event (PDE) data, including drug cost and payment information to CMS.

Hospice programs, as specified in section 1861(dd) of the Act and in Federal regulations at Part 418, must provide individuals under hospice care with drugs and biologicals related to the palliation and symptom management of the terminal illness as defined in the hospice plan of care. The only drugs covered by the hospice program are those used primarily for relief of pain and symptom control related to the individual's terminal illness. However, because hospice care is a Medicare Part A benefit, the drugs provided by the hospice and covered under the Medicare per diem payment to the hospice program are not covered under Part D.

In the last couple of years, CMS has taken action to prevent Part D payment for drugs that should be the responsibility of the Medicare hospice provider. This included issuing 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. Subsequently, in the 2012 Call Letter, issued in April 2011, we clarified that all Part D

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sponsors currently had the ability to identify any Medicare enrollees who have elected hospice. We noted that CMS sends beneficiary-level hospice data to all Part D sponsors on daily transaction reply reports (TRR) sent at the time of the beneficiary's enrollment and subsequently whenever the hospice information changes. The TRRs include a hospice indicator, a hospice start date and, if applicable, hospice termination date. We indicated that sponsors need to ensure their claims processor is notified of an enrollee's hospice election and that processes are in place that can prevent Part D payment for hospice drugs. This requirement was effective with the 2012 contract year.

In the 2012 Call Letter, we noted that we had received requests for further guidance regarding how sponsors should identify hospice drugs and questioning whether sponsors should establish a point-of-sale prior authorization edit or to pay the claim at point-of-sale and make a retrospective Part A vs. Part D payment determination. Given our concerns that Medicare Part D enrollees' access to Part D drugs is not inappropriately restricted, we suggested that unless the plan has information available at point-of-sale to determine payment responsibility, sponsors should pay 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.

Technical Comment

Although the OIG notes in the draft report that prescriptions for drugs in the four categories of drugs typically used for the treatment of hospice patients' symptoms also may be prescribed for uses unrelated to the individual's terminal illness, other complexities affecting the determination of payment responsibility are not addressed. The majority of hospice patients receive their care at home and thus use retail or mail order pharmacies. Since the prescription does not contain a diagnosis, the pharmacy does not know the diagnosis, and while the Part D sponsor knows and can inform the pharmacy of the individual's hospice election, unless the drug was previously established as a hospice-related drug, follow-up is necessary to determine whether the hospice or Part D has payment responsibility.

We appreciate the OIG's efforts in working with CMS in identifying vulnerabilities in the Medicare program. Our response to each of the OIG recommendations follows.

OIG Recommendation

The OIG recommends CMS educate sponsors, hospices, and pharmacies that it is inappropriate for Medicare Part D to pay for drugs related to hospice beneficiaries' terminal illnesses.

CMS Response

CMS concurs with this recommendation. CMS agrees with the OIG's goal to prevent Part D payment for drugs that are related to a hospice patient's terminal illness and, therefore, included in the Medicare per diem payments to the hospice. CMS will remind Part D sponsors and hospice organizations of their payment responsibilities and will communicate through Part D sponsors to pharmacies regarding their role in efforts to ensure Medicare hospice drugs are not billed to Part D.

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OIG Recommendation

OIG recommends CMS 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.

CMS Response

We do not concur with the OIG's recommendation. We agree that it is possible Part D may have paid for drugs that were already covered under the per diem payments made to hospice organizations, but we would need conclusive evidence that such an issue exists before making payment adjustments. Despite developing and implementing an elaborate research methodology, OIG was not able to definitively determine that duplicate payments were made. Given the complexity of OIG's methodology, it would be difficult and costly for CMS to implement this methodology for an on-going oversight program, especially considering that the results would not be sufficiently conclusive to be actionable. However, CMS will examine the issue further by considering whether it is possible to develop a cost-effective methodology that will yield conclusive findings suitable to make Part D plan payment adjustments.

OIG Recommendation

The OIG recommends CMS require sponsors to develop controls that prevent Part D from paying for drugs that are already covered in the per diem payments.

CMS Response

CMS concurs with this recommendation. As we have stated earlier, CMS already issued guidance to prevent Part D payment for drugs that should be the responsibility of the Medicare hospice provider. Specifically, we indicated that sponsors need to ensure their claims processor is notified of an enrollee's hospice election and that processes are in place to prevent Part D payment for hospice drugs. This requirement was effective with the 2012 contract year.

Again, we appreciate the opportunity to comment on this draft report and look forward to working with OIG on this and other issues.