Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE PART D IS STILL PAYING MILLIONS FOR DRUGS ALREADY PAID FOR UNDER THE PART A HOSPICE BENEFIT

Inquiries about this report may be addressed to the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

Joanne M. Chiedi
Acting Inspector General

August 2019
A-06-17-08004

Office of Inspector General

https://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nation-wide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the healthcare industry concerning the anti-kickback statute and other OIG enforcement authorities.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC
at https://oig.hhs.gov

Section 8M of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site.

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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.

Report in Brief
Date: August 2019
Report No. A-06-17-08004

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

Medicare Part D Is Still Paying Millions for Drugs Already Paid for Under the Part A Hospice Benefit

Why OIG Did This Review

In 2012, we issued a report to the Centers for Medicare & Medicaid Services (CMS) indicating that during 2009, Medicare Part D paid for prescription drugs that likely should have been paid for by hospice organizations under the Medicare Part A hospice benefit. We matched Part A and Part D data to identify occurrences when Part D paid for drugs for beneficiaries who were receiving hospice care at the same time. We conducted this audit to follow up and expand on the previous audit.

Our objective was to determine whether the Medicare Part D program paid for drugs during 2016 that should have been paid for by hospice organizations under the Medicare Part A hospice benefit.

How OIG Did This Review

Our audit covered $422.7 million in Part D total costs for prescriptions filled while beneficiaries were receiving hospice care.

We selected a stratified random sample of 200 Part D records and contacted hospice organizations to find out if they should have paid for the drugs.

What OIG Found

Medicare Part D paid for drugs during 2016 that hospices should have paid for under the Medicare Part A hospice benefit. On the basis of our sample results, we estimated that the Part D total cost was $160.8 million for drugs that hospice organizations should have paid for. Additionally, although hospices told us they should not have paid for the drugs associated with the remaining $261.9 million of the $422.7 million total cost, a review of CMS communications with hospices and sponsors between 2012 and 2016 indicates otherwise—hospice organizations or hospice beneficiaries likely should have paid for many of these drugs, not Part D.

What OIG Recommends and CMS Comments

CMS must do more to avoid paying twice for the same drugs. As we have previously recommended, CMS should work directly with hospices to ensure that they are providing drugs covered under the hospice benefit. In addition, we recommend that CMS should develop and execute a strategy to ensure that Part D does not pay for drugs that should be covered by the Part A hospice benefit, which would save at least an estimated $160.8 million a year in Part D total cost, with potentially much higher annual savings associated with the drugs that hospices said they were not responsible for providing. This should include working with Part D sponsors and seeking whatever authorities are necessary to develop proper controls.

In written comments on our draft report, CMS stated that its current efforts will address the issue and help ensure there is no disruption in beneficiary access, indicating that it will continue to engage in meaningful activities to reduce duplicate payment in this area, such as ensuring hospice providers are proactively educating beneficiaries on covered services and items (including drugs) and Part D drug plan sponsors are appropriately applying prior authorization criteria and coordinating with hospice providers on drug coverage issues.

Although we acknowledge CMS's efforts after our 2012 report, we disagree that they will adequately address the issue because the duplicate payments persist. We continue to recommend that CMS develop controls to stop the duplicate hospice drug payments.

TABLE OF CONTENTS

INTRODUCTION

WHY WE DID THIS REVIEW

In June 2012, we issued a report to the Centers for Medicare & Medicaid Services (CMS) indicating that during 2009, Medicare Part D paid $33.6 million and hospice beneficiaries paid $3.8 million for prescription drugs (drugs) that likely should have been paid for by hospice organizations.[1] That work was focused on four categories of drugs commonly prescribed to beneficiaries at the end of their lives (analgesic, anti-nausea, laxative, and anti-anxiety drugs)[2] and disease-specific drugs for two diseases—chronic obstructive pulmonary disease (COPD) and amyotrophic lateral sclerosis. We identified instances in which Part D paid for these drugs for beneficiaries who were receiving hospice care at the same time. We did not contact hospice providers to verify whether they should have paid for the drugs.

We conducted this audit to follow up and expand on the previous audit by contacting hospices to find out whether they should have provided and paid for drugs that Part D paid for and to determine the magnitude of any problem.

OBJECTIVE

Our objective was to determine whether the Part D program paid for drugs during 2016 that should have been paid for by hospice organizations under the Part A hospice benefit.

BACKGROUND

Medicare Part A 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 providing physical and emotional comfort. Hospice care may be provided to individuals 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, an individual must be entitled to Part A and be certified as terminally ill (i.e., have a medical prognosis that life expectancy is 6 months or less if the illness runs its normal course). CMS implemented the hospice benefit through regulation in a final rule that went into effect on November 1, 1983.[3]

---

[1] *Medicare Could Be Paying Twice for Prescription Drugs for Beneficiaries in Hospice* (A-06-10-00059), issued June 28, 2012.

[2] For the purposes of this report, we will refer to these four categories of drugs as common end-of-life drugs.

[3] 48 Fed. Reg. 56008 (Dec. 16, 1983).

CMS makes a per diem payment to a hospice organization for each day that a beneficiary is in hospice care, regardless of the number of services provided. Drugs used primarily for symptom control and the relief of pain related to the beneficiary's terminal illness and related conditions are covered under the hospice benefit, and the cost of providing these drugs is included in the per diem rate.

Medicare conditions of participation[4] require hospices to conduct a patient-specific comprehensive assessment that identifies the patient's need for hospice care and services, including a review of all of the patient's prescription and over-the-counter drugs, herbal remedies, and other alternative treatments that could affect drug therapy. Before hospice care is provided, the hospice must develop a written plan of care that specifies the services necessary to meet the patient's needs as identified in the comprehensive assessment. The plan must also be periodically reviewed and updated. Drugs necessary to meet the patient's needs are included in the plan of care. Some drugs that were used before hospice care started are continued as part of the hospice plan of care. Other drugs are discontinued because they are no longer effective or may cause additional negative symptoms in the patient, or both.

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 (the Act) by establishing the Part D voluntary prescription drug benefit. Under Part D, which went into effect on January 1, 2006, individuals who are entitled to benefits under Part A or are enrolled in Part B may obtain voluntary coverage for outpatient prescription drugs.

Prescription drug coverage is offered by non-governmental 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 drugs to enrolled beneficiaries and pay the pharmacies when they dispense drugs to the beneficiaries.

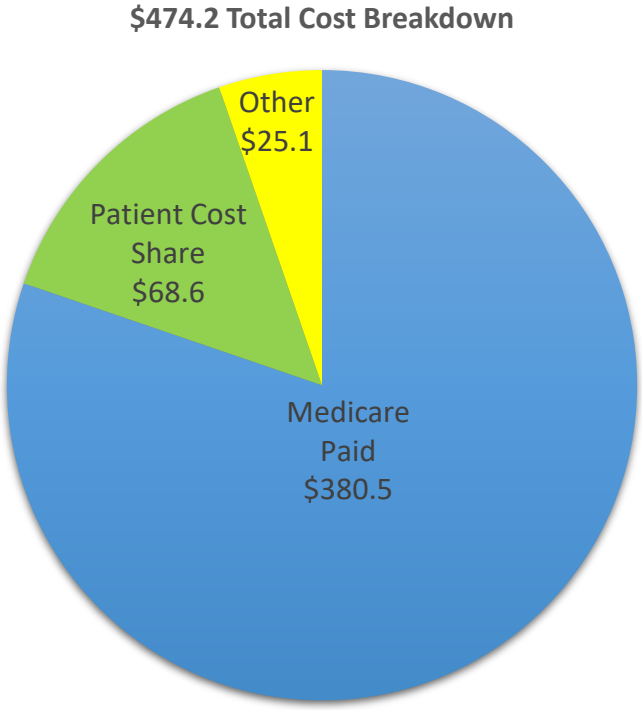
Beneficiaries enrolled in a Part D prescription drug plan are responsible for copayments for the drugs they receive. When these beneficiaries fill covered prescriptions under Part D, sponsors must submit prescription drug event (PDE) data to CMS. PDE data include drug cost and payment information that 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.

Part D should not pay for drugs if they are covered under the Part A hospice benefit. In its proposed rule addressing the fiscal year (FY) 2019 hospice wage index and payment rate

[4] Conditions that a hospice organization must meet to participate in Medicare.

update, CMS reported that the gross total drug cost (total cost) for Part D drugs received by hospice beneficiaries during FY 2017 was $474.2 million.[5] CMS stated that the portion of the total cost that Medicare paid for is about $380.5 million.[6] Medicare payments for Part D drugs provided to hospice beneficiaries increased from $325.5 million in 2011 to $380.5 million in FY 2017. CMS also stated that the beneficiary cost-sharing amount was approximately $68.6 million during FY 2017.[7] CMS did not indicate how much of the Medicare payment and beneficiary cost-sharing amounts should have been paid for by hospice organizations. Figure 1 shows CMS's breakdown of the FY 2017 Part D costs.

Figure 1: Part D Drug Costs for Drugs That Hospice Beneficiaries Received During FY 2017 (in Millions)



[5] 83 Fed. Reg. 20934, 20947 (May 8, 2018).

[6] CMS adds two PDE fields to calculate the Medicare paid amount: the covered drug plan paid amount and the low-income cost-sharing subsidy amount.

[7] CMS adds three PDE fields to calculate the beneficiary cost-sharing amount: the patient pay amount, the patient liability reduction due to other payer amount, and the other true out-of-pocket amount.

Previous OIG Work Concerning Hospice-Covered Drugs

In our 2012 report to CMS, we recommended, among other things, that 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 did not concur with the recommendation, indicating that it would need conclusive evidence that the issue exists before making payment adjustments, and that it would be difficult and costly to implement OIG's methodology for an ongoing oversight program. CMS stated that, despite developing and implementing an elaborate research methodology, OIG was not able to definitively determine that duplicate payments were made.

In an OIG Portfolio about vulnerabilities in the hospice program published in July 2018,[8] we recommended that CMS develop and execute a strategy to work with hospices to ensure that they provide drugs covered under the hospice benefit as necessary and that the cost of drugs covered under the benefit would not be inappropriately shifted to Part D. CMS did not concur with this recommendation, noting that it had directed certain sponsors to conduct audits for payments made for beneficiaries who are enrolled in hospice care to ensure that payments are made appropriately.

CMS Communications Regarding Hospice-Covered Drugs

Between our 2012 report and our 2016 audit period, CMS communicated its views regarding hospice-covered drugs through various formats, including call letters,[9] memorandums to all sponsors and hospice providers, and annual proposed and final rules to update the hospice payment rate and wage index. The following is a summary of the information that CMS communicated.

Hospices Should Provide Virtually All Care, Including Drugs

The Act and Federal regulations specify that hospices are responsible for covering all drugs for the palliation and management of a beneficiary's terminal illness and related conditions. CMS frequently stated that in its 1983 final rule implementing the hospice benefit, it interpreted related conditions broadly, indicating that hospices were required to cover virtually all care that terminally ill patients need.

In the proposed rule addressing the FY 2015 hospice wage index and payment rate update, CMS solicited comments on definitions of terminal illness and related conditions for further

[8] *Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: An OIG Portfolio* (OEI-02-16-00570).

[9] Call letters contain information that Part D sponsors need to consider when preparing their bids to participate in Part D.

discussion and consideration for potential future rulemaking.[10] CMS intended the definitions to strengthen and clarify the concepts of holistic and comprehensive hospice care. CMS stated that many health problems are brought on by underlying conditions because bodily systems are interdependent; it is often not a single diagnosis that represents the terminal prognosis of the patient but the combined effect of several conditions.

CMS noted that commenters to prior years' proposed rules believed that longstanding, preexisting conditions should not be considered related to a patient's terminal illness or related conditions, and that chronic, stable conditions play little or no role in a patient's terminal illness or related conditions. CMS explained that it believes these conditions are included in the hospice bundle of services, and that the original implementing regulations of the Medicare hospice benefit articulate a set of requirements that do not distinguish between preexisting, chronic, or controlled conditions. CMS also stated that prior commenters asserted that comorbidities and the maintenance of comorbidities are not related to the terminal illness or related conditions, and that these types of conditions should not be included in the bundle of services covered by hospice care. CMS responded to these prior commenters as follows:

> We have recognized throughout the federal regulations at [42 CFR] § 418 that the total person is to be assessed, including acute and chronic conditions, as well as controlled and uncontrolled conditions, in determining an individual's terminal prognosis. All body systems are interrelated; all conditions, active or not, have the potential to affect the total individual. The presence of comorbidities is recognized as potentially contributing to the overall status of an individual and should be considered when determining the terminal prognosis.

CMS did not include the broad definitions of terminal illness and related conditions in the FY 2015 final rule and has not included them in subsequent final rules.

Hospice Beneficiaries May Be Liable for the Cost of Some Drugs

In a memorandum to all Part D sponsors and hospice providers in March 2014, CMS stated that there may be instances in which a hospice beneficiary pays for a drug (and not the hospice organization or Part D).[11] CMS specified that when it is determined that a drug is no longer an effective treatment for the beneficiary or causes additional negative symptoms, the drug should not be covered under hospice benefits because it would be unreasonable or unnecessary for palliation or symptom management. If a beneficiary chooses to continue to fill these prescriptions, the financial responsibility falls to the beneficiary and Part D should not cover them. Additionally, Part D should not pay for drugs in instances in which a beneficiary requests a drug that is not on the hospice's formulary and refuses to try a formulary equivalent.

[10] 79 Fed. Reg. 26538, 26554-26555, (May 8, 2014).

[11] CMS, *Part D Payment for Drugs for Beneficiaries Enrolled in Hospice—Final 2014 Guidance*, March 10, 2014.

Controls To Stop Part D Payments of Hospice-Covered Drugs

In April 2013, CMS stated that Part D sponsors are required to ensure that Part D does not pay for drugs that may be covered under the Part A per diem payment to a hospice program.[12] CMS strongly encouraged sponsors in that announcement to place beneficiary-level prior authorization[13] requirements on only the common end-of-life drugs but commented that it also permitted "sponsors to use other approaches, such as pay-and-chase, to resolve payment responsibility" between Part D and hospices.

In a March 2014 memorandum to all Part D sponsors and hospice providers, CMS reiterated that drugs covered under Part A per diem payments are excluded from coverage under Part D, and that it expects Part D coverage for a hospice beneficiary's drugs to occur only under unusual and exceptional circumstances.[14] CMS stated that, effective May 1, 2014, sponsors should place prior authorization requirements on all drugs for beneficiaries who have elected hospice. However, in a followup memorandum in July 2014, CMS rescinded this guidance on the basis of its conversations with stakeholders about the impact of the policy on beneficiary access to drugs and the operational challenges that it posed to sponsors and hospices.[15] CMS again encouraged prior authorization on only common end-of-life drugs and stated that sponsors were not expected to place prior authorizations on other categories of drugs or take special measures beyond their normal compliance and utilization review activities. CMS also circulated a form that could be used to help coordination between sponsors, hospices, and prescribers.

In the final rule addressing the FY 2015 hospice wage index and payment rate update, CMS stated that in formulating changes to help coordinate payment between sponsors and hospices, it became aware that the regulatory requirement for coordination was narrower than the requirement specified in the Act. CMS further stated, "The regulation does not include the requirement for Part D sponsors to coordinate with providers of drugs covered under Part A, such as hospices, since those drugs prescribed, dispensed, or administered under Part A are excluded from the definition of a covered Part D drug."[16] CMS also commented that it was considering amending the Part D regulations at 42 CFR § 423.464(f) to align the definition of other prescription drug coverage with the Act that would, in effect, require sponsors to

[12] *Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 1, 2013.

[13] Prior authorization means that once a beneficiary has elected hospice, a pharmacy would not fill a prescription for Part D payment until it can contact the beneficiary or prescriber to determine whether the hospice provider should cover the drug.

[14] *Part D Payment for Drugs for Beneficiaries Enrolled in Hospice—Final 2014 Guidance*, March 10, 2014.

[15] *Part D Payment for Drugs for Beneficiaries Enrolled in Medicare Hospice,* July 18, 2014.

[16] 79 Fed. Reg. 50452, 50497 (Aug. 22, 2014).

coordinate with providers of drugs covered under Part A such as hospices. The amendment has not occurred.

Additionally, in discussing its rationale for the proposed rules to facilitate the coordination of payment between sponsors and hospices in the same FY 2015 final rule, CMS stated that "Our previous understanding was that hospice coverage of drugs was very broad and very inclusive. Therefore, Part D payment for drugs furnished to hospice beneficiaries would be rare and the need for controls was not critical."[17]

HOW WE CONDUCTED THIS REVIEW

Our audit covered $422,693,830 in Part D total cost for 6,689,255 PDE records for beneficiaries while they were receiving hospice care in 2016.[18] We selected a stratified random sample of 200 PDE records and contacted the hospices that provided care to the beneficiaries who received the prescription drugs to find out whether the hospices should have paid for the drugs. The Part D total cost for our sample items was $397,121.

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 objectives.

Appendix A contains the details of our audit scope and methodology. Appendix B contains our statistical sampling methodology. Appendix C contains our sample results and estimates.

FINDINGS

Part D paid for drugs during 2016 that hospices should have paid for under the Part A hospice benefit. Hospices told us that they should have paid for the drugs associated with 86 of the 200 Part D records that we sampled.[19] As a result, the Medicare program paid twice for these drugs—once under the Part A hospice benefit and again under Part D. On the basis of our sample results, we estimated that the Part D total cost was $160.8 million for drugs that hospice organizations should have paid for under Part A. Additionally, although hospices told us that they should not have paid for 108 of the sampled Part D drugs associated with the

[17] 79 Fed. Reg. 50452, 50497 (Aug. 22, 2014).

[18] The total cost amount excludes vaccines, prescriptions that were filled on the first or last day of hospice care, and prescriptions with a total drug cost of $0.19 or less.

[19] Of the 200 sample items, hospices told us they should not have paid for 108 and they should have paid for 86. We did not receive responses for the remaining six sample items because the hospices had gone out of business. We counted the six items as non-errors for our estimates.

remaining $261.9 million of the $422.7 million total cost, a review of CMS communications with hospices and sponsors between 2012 and 2016 suggests otherwise—hospice organizations or hospice beneficiaries, not Part D, should have paid for many of these drugs. CMS has not developed or required controls to ensure that Part D is not paying for hospice-covered drugs.

FEDERAL REQUIREMENTS

Hospices should pay for all drugs used to treat a beneficiary's terminal illness and related conditions. Part D should not pay for drugs if they are covered under the Part A hospice benefit.

The hospice conditions of participation state that "drugs and biologicals related to the palliation and management of the terminal illness and related conditions . . . must be provided by the hospice while the patient is under hospice care" (42 CFR § 418.106). Thus, when explaining the "relationship between the requirement that hospices must provide drugs for patients and the Medicare Part D benefit" in its final rule revising the hospice conditions of participation, CMS states:

> 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.[20]

PART D PAID FOR DRUGS THAT HOSPICES SHOULD HAVE PAID FOR UNDER THE PART A HOSPICE BENEFIT

Hospice organizations told us that they should have paid for 86 of the 200 drugs related to the PDE records that we sampled, totaling $113,529 of the $397,121 Part D total cost in our sample.[21] We estimated that the Part D total cost for the drugs that hospices should have paid for during 2016 was $160.8 million. Table 1 on the following page shows the breakdown of the errors and dollars using CMS definitions of Total Cost, Medicare Share, and Beneficiary Cost Share. The results are presented in three categories—common end-of-life drugs, chemotherapy, and everything else (e.g., disease-specific drugs, maintenance drugs). See Appendices B and C for our statistical sampling methodology and the results of our sample in more detail.

[20] 73 Fed. Reg. 32088, 32145 (June 5, 2008).

[21] Drugs for which hospices told us they should have paid for are referred to as "errors" in this report.

Table 1: Errors Summarized by Total Cost, Medicare Share, and Beneficiary Cost Share

Stratification Category	Number Sampled	Total Errors	Total Cost of Errors	Estimated Part D Total Cost	Estimated Medicare Share	Estimated Beneficiary Cost Share
Common End-of-Life Drugs	30	25	$6,676	$6,769,384	$6,117,175	$692,739
Chemotherapy	30	6	26,044	2,371,509	2,345,347	26,163
Everything Else	140	55	80,809	151,663,853	129,867,249	20,659,278
Total	**200**	**86**	**$113,529**	**$160,804,746**	**$138,329,771**	**$21,378,180**

In our previous report, we determined that 100 percent of the common end-of-life drugs used by hospice beneficiaries during 2009, totaling just over $20 million in Part D total cost, should have been paid for by hospices.[22] After we issued that report, CMS strongly encouraged but did not require sponsors to have beneficiary-level prior authorization processes on common end-of-life drugs for beneficiaries who elect hospice care.

As Table 1 shows, the estimated Part D total cost for common end-of-life drugs was $6.8 million during 2016. Even though the 2016 error rate remained high at 83 percent (25 errors out of 30 sample items), the population of 2016 potential errors was significantly less than in 2009. During 2009, there were roughly 609,000 PDE records for common end-of-life drugs, totaling just over $20 million in total cost, but during 2016 the amounts were reduced to roughly 214,000 PDE records totaling $8.8 million in total cost. Prior authorization processes appear to have reduced Part D program spending for common end-of-life drugs.

The Part D total cost for chemotherapy drugs doubled from $6.9 million in 2009 to $13.8 million in 2016. We concluded that 100 percent of chemotherapy drugs should have been paid for by hospices in our 2012 report because industry representatives told us the drugs were most likely used to shrink tumors for palliative purposes. For this audit, hospices told us they should have provided and paid for 6 of the 30 sampled items, indicating that 20 percent—rather than 100 percent—of chemotherapy drugs were used for palliative purposes.[23] Accordingly, we estimated that the Part D total cost for chemotherapy drugs used for palliative purposes in 2016 was $2.4 million (17 percent of Part D spending for chemotherapy drugs).

We did not include the Everything Else category in our previous audit. The Part D total cost for drugs in this category during 2016 was $400.1 million. Drugs in this group included disease-specific drugs associated with a beneficiary's primary hospice diagnosis (e.g., Alzheimer's,

[22] In the 2012 report (A-06-10-00059), we included chemotherapy drugs in the analgesic category with the belief that they were prescribed to shrink tumors and help control pain. The total amount of duplicate payments for common end-of-life drugs including chemotherapy drugs was $26,980,792, comprising $20,040,497 for common end-of-life drugs and $6,940,295 for chemotherapy drugs.

[23] The remaining 80 percent of chemotherapy drugs were potentially provided for curative purposes. If so, the individuals should not have been receiving hospice care.

COPD, congestive heart failure, HIV), as well as drugs used for secondary diagnoses and comorbidities and for maintenance drugs for preexisting conditions. Hospices told us that they should have paid for the drugs associated with 55 of 140 sampled PDE records. We estimated that the Part D total cost for drugs in the Everything Else category that should have been paid for by hospices in 2016 was $151.7 million.

For 27 of the 86 errors, the hospices either did not provide a reason or told us they could not determine a reason they did not pay for the drugs. Table 2 shows the reasons the hospices gave for the remaining 59 errors. (Some errors had more than one reason.)

Table 2: Hospice Reasons for Not Providing Drugs

Reasons	Number of Errors
The hospice had no knowledge that the medication was prescribed by an outside physician, filled by an outside pharmacy, or both.	36
The hospice had no knowledge that the medication was ordered by nursing home staff and filled by an outside pharmacy.	13
The hospice miscoded the drug as non-covered.	11
The drug was dispensed close to the hospice admission, so the hospice election was not yet processed in the Part D sponsor's system.	7
The pharmacy that dispensed the drug was aware of the patient's hospice election but billed Part D in error.	6
The hospice thought a third party was paying or they would have covered the prescription.	1

For the majority of errors, the hospices stated that they had no knowledge that a prescription was filled by an outside pharmacy (a pharmacy not typically used by the hospice). CMS officials told us that hospice staff must be sure they are communicating with the patient and patient's family and should know every drug the patient is taking, that not knowing which drugs a patient is taking is a direct violation of the conditions of participation, and that patient harm could occur if the staff responsible for a patient's health do not know what drugs the patient is taking.

CMS COMMUNICATIONS INDICATE THAT HOSPICES SHOULD HAVE PAID FOR MANY OF THE DRUGS ASSOCIATED WITH THE REMAINING PRESCRIPTION DRUG EVENT RECORDS

Hospice organizations told us that they should not have paid for 108 of the drugs associated with the sampled PDE records. A review of the documentation that hospices sent us, in light of CMS communications to hospices and sponsors between our last report and 2016 (audit period for this review), indicates that the hospice organizations or the hospice beneficiaries should have paid for many of the drugs associated with the sampled PDE records. Accordingly, the remaining $261.9 million in Part D total cost likely should have been paid by the hospice

organizations or hospice beneficiaries. Of this total, we estimated that the Medicare share was $210.8 million and the beneficiary cost share was $28.6 million.

Hospice Organizations Should Have Paid for Drugs Used To Treat Secondary Diagnoses, Comorbidities, and Preexisting Conditions

Hospices are required to furnish all drugs and biologicals used for the relief of pain and symptom control related to an individual's terminal illness and related conditions. In the proposed rule addressing the FY 2015 hospice wage index and payment rate update, CMS sought feedback on broad definitions of "terminal illness" and "related conditions" that were designed to strengthen and clarify the concepts of holistic and comprehensive hospice care. The proposed definitions were not incorporated into the final rule, which allows hospices to interpret the terms more narrowly to decrease their drug costs. CMS has repeatedly communicated, however, that hospices should provide virtually all care, including drugs, to their Medicare patients.

Following are concepts that CMS communicated to hospices and sponsors and examples from the 108 sample items that illustrate why, in light of CMS's communications, the drugs likely should have been covered by hospice.

Secondary Diagnoses

CMS stated that many health problems are brought on by underlying conditions because bodily systems are interdependent; it is often not a single diagnosis that represents the terminal prognosis but the combined effect of several conditions:

- For one sample item, the Part D total cost was $592 for a drug that is used to treat Parkinson's disease. The hospice medical director documented that Alzheimer's disease was the primary hospice diagnosis and Parkinson's disease a secondary diagnosis. A hospice official responded to our audit that the hospice was not responsible for the drug used for Parkinson's disease because it is not used to treat the primary hospice diagnosis.

- For one sample item, the Part D total cost was $1,407 for a drug that was used to help control HIV infection. The hospice physician documented that a terminal diagnosis was latent syphilis but unspecified as early or late. The hospice physician also documented that a secondary diagnosis was HIV. A hospice official responded to our audit that the hospice should not have paid for the HIV drug because its policy was to cover only drugs related to the terminal diagnosis.

Comorbidities

CMS also stated that the presence of comorbidities is recognized as potentially contributing to the overall status of an individual and should be considered when determining the terminal prognosis:

- For one sample item, the Part D total cost was $1,471 for a drug that is used to help control HIV infection. The hospice physician's terminal diagnosis was heart failure, and the physician narrative stated that the patient had a "major comorbidity" of HIV. A hospice official responded to our audit that the hospice did not pay for the drug to help control HIV infection because it was not related to heart failure.

Preexisting Conditions

CMS stated that longstanding, preexisting conditions are included in the hospice bundle of services, and that the original implementing regulations for hospice articulate a set of requirements that do not distinguish between preexisting, chronic, or controlled conditions:

- For 19 sample items, Part D paid from $84 to $1,302 for diabetic therapy drugs. The hospice officials told us that the hospices did not pay for these drugs because they were for preexisting conditions and unrelated to the terminal diagnoses.

Hospice Beneficiaries May Have Been Liable for the Cost of the Drugs

CMS stated that a hospice beneficiary should pay for drugs when the beneficiary (1) chooses to continue a drug that the hospice determined is no longer effective in the intended treatment, may be causing additional negative symptoms, or both or (2) requests a drug that is not on the hospice formulary and refuses to try a formulary-equivalent drug. Neither Part D nor the hospice should pay for a drug when one of these conditions occurs:

- For one sample item, the Part D total cost was $349 for a drug that was used to treat Alzheimer's disease. According to a note by the hospice's medical director, the hospice did not cover the drug because it was no longer beneficial to the patient or the risk to the patient outweighed the benefit. The patient's care plan showed that the patient was going to continue the drug at her own expense.

CONCLUSION

In the proposed rule addressing the FY 2019 hospice wage index and payment rate update, CMS expressed its opinion that hospices were not providing the broad range of drugs that they should have:

> [W]e remain concerned that common palliative and other disease-specific drugs for hospice beneficiaries that are covered under the Part A Medicare hospice

> benefit are instead being covered and paid for through Part D. . . . we believe Medicare could be paying twice for drugs that are already covered under the hospice per diem payment by also paying for them under Part D. . . . The comprehensive nature of services covered under the Medicare hospice benefit is structured such that hospice beneficiaries should not have to routinely seek items, services, and/or medications beyond those provided by hospice.[24]

Regarding potential changes in the Part A hospice benefit, CMS sought feedback on broad definitions of terminal illness and related conditions to help clarify the hospices' responsibility to provide virtually all care, including drugs, to their patients but never included the definitions in final rules. In the OIG Portfolio about vulnerabilities in the hospice program, we recommended that CMS develop and execute a strategy to work directly with hospices to ensure that they provide drugs covered under the hospice benefit as necessary and that the cost of drugs covered under the benefit is not inappropriately shifted to Part D. CMS did not concur with this recommendation, noting that CMS had directed certain sponsors to conduct audits for payments made for beneficiaries who are enrolled in hospice care to ensure that payments are made appropriately.

Concerning potential changes to Part D, CMS has suggested that sponsors put in preauthorization controls only for the common end-of-life drugs and communicated its views to sponsors that hospices are responsible for providing virtually all care to hospice beneficiaries, even indicating that Part D payment for drugs would be rare once an individual elects hospice care. The Part D total cost associated with common end-of-life drugs appears to have decreased due to prior authorization processes, but the majority of the Part D total cost for hospice beneficiaries was for drugs that are not designated as common end-of-life drugs. Additionally, CMS considered amending the Part D regulations at 42 CFR § 423.464(f) to align the definition of other prescription drug coverage with the Act to, in effect, require sponsors to coordinate with providers of drugs covered under Part A such as hospices, but this amendment has not occurred.

During 2016, Part D paid $422.7 million for drugs associated with 6.7 million PDE records for beneficiaries who were receiving hospice care. On the basis of our sample of 200 PDE records, we estimated that hospice organizations should have provided and paid for drugs totaling $160.8 million in Part D total cost. The drugs were essentially paid for twice: once through the per diem payments made to Part A hospice organizations and once through Part D. Additionally, hospices or hospice beneficiaries likely should have paid for the remaining $261.9 million in Part D total cost.

[24] 83 Fed. Reg. 20934, 20947 (May 8, 2018).

RECOMMENDATION

CMS must do more to avoid paying twice for the same drugs. As OIG has previously recommended, CMS should work directly with hospices to ensure that they are providing drugs covered under the hospice benefit. In addition, we recommend that CMS should develop and execute a strategy to ensure that Part D does not pay for drugs that should be covered by the Part A hospice benefit, which would save at least an estimated $160.8 million a year in Part D total cost, with potentially much higher annual savings associated with the drugs that hospices said they were not responsible for providing. This strategy should include working with Part D sponsors and seeking whatever authorities are necessary to develop proper controls.

CMS COMMENTS

In written comments on our draft report, CMS responded to our recommendation as follows:

> While CMS agrees with the importance to avoid duplicate payments to Medicare Part D drug plan sponsors and hospices, we maintain that CMS's current efforts will address the issue and help ensure there is no disruption in beneficiary access. As such, CMS will continue to engage in meaningful activities to reduce duplicate payment in this area, such as ensuring hospice providers are proactively educating beneficiaries on covered services and items (including drugs) and Part D drug plan sponsors are appropriately applying prior authorization criteria and coordinating with hospice providers on drug coverage issues.

CMS's comments are included in their entirety as Appendix D.

OFFICE OF INSPECTOR GENERAL RESPONSE

Although we acknowledge CMS's current efforts, we disagree that these efforts will address the issue of duplicate payments for hospice-covered drugs without a strategy that includes controls to identify and stop duplicate payments. Specifically, in 2012 we reported that duplicate payments occurred during 2009. In this current report, we identified millions of dollars in duplicate payments that still occurred in 2016 despite previous recommendations. Therefore, it appears that CMS's activities to reduce duplicate payments in this area have not been effective. We continue to recommend that CMS develop a strategy to stop the duplicate hospice drug payments that includes working with Part D sponsors and seeking whatever authorities are necessary to develop proper controls.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered $422,693,830 in Part D total cost for 6,689,255 PDE records for beneficiaries while they were receiving hospice care in 2016. The total cost amount excludes vaccines, prescriptions that were filled on the first or last day of hospice care, and prescriptions with a total cost of $0.19 or less. We selected a stratified random sample of 200 PDE records and contacted the hospices that provided care to the beneficiary who received the prescription drug. The Part D total cost for our sample items was $397,121.

We conducted our fieldwork from September 2017 through September 2018.

Methodology

To accomplish our objective, we:

- reviewed Federal laws, regulations, and CMS guidance;
- gained an understanding of the hospice and Part D payment requirements;
- obtained paid hospice claims with dates of service during 2016;
- obtained, for beneficiaries who received Part A hospice care during 2016, PDE records with prescription fill dates that occurred during hospice claim dates, except for the first and last day of a beneficiary's hospice care period;
- selected for review a stratified random sample of 200 PDE records;
- requested the hospice providers that provided care to the beneficiaries associated with the 200 PDE records to assess whether they should have paid for the Part D prescription(s), and analyzed their responses;
- used OIG-Office of Audit Services (OIG-OAS) statistical software to estimate the error amount, as well as the amounts in the PDE fields that comprise CMS's definition of Medicare share (covered drug plan paid amount and low-income cost-sharing subsidy amount) and beneficiary cost share (patient pay amount, other true out-of-pocket amount, and patient liability reduction due to other payer amount) for the errors and non-errors; and
- discussed our results with CMS officials.

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 objectives.

APPENDIX B: STATISTICAL SAMPLING METHODOLOGY

TARGET POPULATION

The population consisted of Part D PDE records for hospice beneficiaries when the drug was paid and dispensed during Part A hospice care in calendar year 2016.

SAMPLING FRAME

We obtained a data file that contained 6,701,804 Part D PDE records totaling $422,695,926 in total cost, excluding PDE records that were associated with vaccines or dispensed on the first or last day of a hospice-care period. We then removed PDE records with a total cost of $0.19 or less. The resulting sampling frame contained 6,689,255 Part D PDE records totaling $422,693,830.

SAMPLE UNIT

The sample unit was a paid PDE record.

SAMPLE DESIGN AND SAMPLE SIZE

We selected a stratified random sample of 200 PDE records containing 12 strata, as follows:

Table 3: Sample Strata

Stratum Number	Stratum Title	Strata Bounds (Total Drug Cost)	Number of Paid Claims	Total Drug Costs	Sample size
1	Chemotherapy	< $800	10,322	$365,319.99	10
2	Chemotherapy	≥ $800	1,610	13,465,245.56	20
3	Common End-of-Life Drugs	< $600	213,313	7,081,067.42	20
4	Common End-of-Life Drugs	≥ $600	851	1,701,941.37	10
5	Everything Else	< $25	4,598,187	45,186,598.33	15
6	Everything Else	$25 to $99.99	986,929	47,264,996.30	15
7	Everything Else	$100 to $219.99	385,390	60,103,781.02	20
8	Everything Else	$220 to $349.99	272,218	76,450,927.66	20
9	Everything Else	$350 to $499.99	130,404	51,181,187.56	20
10	Everything Else	$500 to $1,299.99	71,923	53,170,104.62	20
11	Everything Else	$1,300 to $6,999.99	15,636	38,013,264.70	15
12	Everything Else	≥ $7,000	2,472	28,709,395.95	15
Total			**6,689,255**	**$422,693,830.48**	**200**

SOURCE OF RANDOM NUMBERS

The random numbers were generated by the Region VI Statistical Specialist using the OIG-OAS statistical software.

METHOD OF SELECTING SAMPLE ITEMS

We consecutively numbered the PDE records within each stratum. After generating the random numbers for each stratum, we selected the corresponding sample units.

ESTIMATION METHODOLOGY

We used the OIG-OAS statistical software to estimate the dollar value of drugs that were paid for in error because the hospices told us they should have provided and paid for the drugs. We calculated separate dollar estimates for the cost savings to Medicare and the cost savings for beneficiaries for drugs associated with PDE records that were paid in error, as well as PDE records that the hospices indicated they should not have provided. We also used this program to calculate the corresponding lower and upper limits at the 90-percent confidence levels.

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Table 4: Sample Results

Stratum	Frame Size	Value of Frame	Sample Size	Total Value of Sample	Sample Items in Error	Sample Items At-Risk
1	10,322	$365,319.99	10	$402.54	3	7
2	1,610	13,465,245.56	20	166,192.11	3	17
3	213,313	7,081,067.42	20	598.68	18	2
4	851	1,701,941.37	10	12,109.52	7	3
5	4,598,187	45,186,598.33	15	155.24	8	7
6	986,929	47,264,996.30	15	735.45	9	6
7	385,390	60,103,781.02	20	3,015.07	12	8
8	272,218	76,450,927.66	20	5,999.29	3	17
9	130,404	51,181,187.56	20	7,774.08	5	15
10	71,923	53,170,104.62	20	14,524.87	7	13
11	15,636	38,013,264.70	15	28,467.49	4	11
12	2,472	28,709,395.95	15	157,146.63	7	8
Total	**6,689,255**	**$422,693,830.48**	**200**	**$397,120.97**	**86**	**114**

Table 5: Statistical Estimates

Limits calculated at the 90-percent confidence level

Estimate Description	Lower Limit	Point Estimate	Upper Limit
Part D Total Cost of Errors	$132,093,515	$160,804,746	$189,515,980
Medicare Share of Errors	111,598,275	138,329,771	165,061,266
Beneficiary Cost Share of Errors	13,190,023	21,378,180	29,566,336
Medicare Share of At-Risk PDE	182,432,451	210,821,611	$239,210,771
Beneficiary Cost Share of At-Risk PDE	17,593,663	28,579,240	39,564,817

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: JUN - 3 2019

TO: Daniel R. Levinson
Inspector General

FROM: Seema Verma
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Medicare Part D is Still Paying Millions for Drugs Already Paid for Under the Part A Hospice Benefit (A-06-17-08004)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report. CMS appreciates the OIG's ongoing work to examine the issue of potential duplicate payments for prescription drugs dispensed to Medicare beneficiaries who elect Part A hospice for their end-of-life care and have Part D outpatient prescription drug coverage.[1]

CMS continues to work to strengthen Medicare and avoid duplicate payments to Medicare Part D drug plan sponsors and hospices. CMS expects hospices, Medicare Part D drug plan sponsors, pharmacists, and prescribers to communicate so that hospice beneficiaries and caregivers are provided complete and accurate information regarding their hospice benefit under Medicare, as well as their rights, responsibilities, and financial liability to ensure they are empowered to make informed treatment decisions that align with their personal needs, preferences, and goals. In recent years, CMS has engaged in multiple activities to reduce duplicate payment, such as working with Part D drug plan sponsors to support sponsor-directed audits and implement appropriate, informed prior authorization.[2] CMS continues to consider other meaningful ways to address non-hospice healthcare utilization that occurs during a hospice episode of care.[3]

---

[1] In Medicare, Part D outpatient prescription drug claims for hospice beneficiaries accounted for one-quarter of one percent of total Part D outpatient drug spending in 2016.

[2] CMS agreed with the OIG in a report from 2012 that further education and controls were needed to avoid potential duplicate payments for beneficiaries who elect both Part A hospice care and Part D drug coverage. As a result, CMS created a voluntary, standardized form and guide, with industry input, to inform a Part D prior authorization (PA) process for four common hospice drug categories (analgesics, antinausea, anti-anxiety, and laxatives). As a result, the percentage of beneficiaries enrolled in hospice who received medications in these categories through Part D plans in 2016 was seventy five percent less than in 2013, without a negative effect on beneficiary satisfaction. In 2014, efforts to establish a PA process for drugs beyond the four common hospice drug categories caused significant disruption in beneficiary access and CMS discontinued that policy.

[3] CMS recently published a proposed rule (CMS-1714-P) that would require modifications to how hospices notify beneficiaries if there are services, items, or drugs that are not related to the treatment of a beneficiary's terminal condition and therefore not covered by the hospice. CMS believes making the proposed modification a condition for payment will help to ensure that hospices are diligent in providing this information to both Medicare hospice beneficiaries and other payers like Part D sponsors. The proposed rule may be accessed via the Hospice Center on cms.gov at: https://www.cms.gov/center/provider-type/hospice-center.html.

CMS appreciates the work OIG has conducted to enable CMS to further examine the issue of potential duplicate payments for prescription drugs dispensed to Medicare beneficiaries in hospice, and we will continue to take the OIG's findings into account as we work to reduce duplicative payments.

OIG's recommendation and CMS's response is below.

OIG Recommendation

CMS should work directly with hospices to ensure that they are providing drugs covered under the hospice benefit. In addition, we recommend that CMS develop and execute a strategy to ensure that Part D does not pay for drugs that should be covered by the Part A hospice benefit, which would save at least an estimated $160.8 million a year in Part D total cost, with potentially higher annual savings associated with the drugs that hospices said they were not responsible for providing. This strategy should include working with Part D sponsors and seeking whatever authorities are necessary to develop proper controls.

CMS Response

While CMS agrees with the importance to avoid duplicate payments to Medicare Part D drug plan sponsors and hospices, we maintain that CMS's current efforts will address the issue and help ensure there is no disruption in beneficiary access. As such, CMS will continue to engage in meaningful activities to reduce duplicate payment in this area, such as ensuring hospice providers are proactively educating beneficiaries on covered services and items (including drugs) and Part D drug plan sponsors are appropriately applying prior authorization criteria and coordinating with hospice providers on drug coverage issues.