

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE PART D PAYMENTS
FOR BENEFICIARIES IN PART A
SKILLED NURSING FACILITY
STAYS IN 2006**



Daniel R. Levinson
Inspector General
June 2009
OEI-02-07-00230

Office of Inspector General

<http://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 nationwide 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 health care industry concerning the anti-kickback statute and other OIG enforcement authorities.



OBJECTIVE

To determine the extent to which Medicare Part D paid for drugs for beneficiaries in Part A skilled nursing facility (SNF) stays in 2006.

BACKGROUND

Medicare Part D provides outpatient prescription drug coverage for Medicare beneficiaries who enroll. Part D covers most prescription drugs; however, it excludes drugs that are covered under Medicare Parts A or B. Specifically, Part D excludes drugs for beneficiaries in Part A SNF stays if the drugs were for use in the facility or to facilitate the beneficiaries' discharge.

The Centers for Medicare & Medicaid Services (CMS) has identified duplicate payments by Medicare Parts A and D as a potential vulnerability. CMS further states that billing multiple payers (e.g., Parts A and D) for the same prescription is an example of pharmacy fraud, waste, and abuse.

This review determines the extent to which Medicare Part D paid for drugs for beneficiaries in Part A SNF stays in 2006.

FINDINGS

Medicare Part D paid for 1.2 million drugs, amounting to \$75 million, for beneficiaries in Part A SNF stays in 2006; the majority of these payments were most likely inappropriate. Sixty percent of the drugs Part D paid for while beneficiaries were in Part A SNF stays in 2006 were dispensed by long-term care pharmacies. Long-term care pharmacies dispense drugs for use in long-term care settings, including SNFs. These drugs were most likely dispensed for use in the facility during a Part A SNF stay and covered under Medicare Part A, rather than Part D. Therefore, Part D payments for these drugs, which amounted to \$41.3 million, were most likely inappropriate. Retail and other types of pharmacies dispensed the remaining 40 percent of drugs paid for by Part D for this population. If these drugs were for use in the facility or were to facilitate the beneficiaries' discharge, these Part D payments were also inappropriate.

Part D payments were widespread among SNFs and pharmacies.

Nearly every SNF and half of all pharmacies had beneficiaries who had a drug paid for by Part D during their Part A SNF stay. At the same

time, a small number of SNFs and pharmacies were responsible for a large percentage of these Part D payments. Notably, 160 SNFs accounted for 12 percent (\$8.6 million) of the payments and 30 pharmacies accounted for 18 percent (\$13 million) of all Part D payments for beneficiaries in Part A SNF stays.

RECOMMENDATIONS

Based on these findings, we recommend that CMS:

Ensure that Part D payments for drugs for beneficiaries in Part A SNF stays are appropriate. CMS should ensure that Part D does not pay for drugs that are covered under Parts A or B for beneficiaries in Part A SNF stays.

Specifically, we recommend that CMS take the following actions:

Provide additional guidance about when Parts A and D can pay for drugs for beneficiaries preparing for discharge. CMS should provide additional guidance to SNFs, pharmacies, and Part D sponsors that clarifies the circumstances under which Part D can pay for drugs before beneficiaries are discharged from Part A SNF stays. Specifically, CMS should clarify when Part A covers drugs by defining what is considered a “limited supply” and providing further guidance about when Part A should cover these drugs to facilitate discharge. It should also clarify when Part D may cover extended supplies of drugs for beneficiaries before they are discharged from Part A SNF stays.

Educate SNFs, pharmacies, and Part D sponsors that drugs covered under Parts A or B for beneficiaries in SNF stays are not eligible for payment under Part D. CMS should educate SNFs, pharmacies, and Part D sponsors that it is inappropriate for Part D to pay for drugs for beneficiaries in Part A SNF stays. CMS should consider holding open-door forums, developing factsheets, or using other methods to inform these entities about this issue.

Implement retrospective reviews to prevent inappropriate Part D payments for drugs for this population. CMS should implement routine reviews to ensure that inappropriate Part D payments do not occur. Further, CMS should conduct ongoing analysis and monitor trends in Part D payments for beneficiaries in Part A SNF stays.

Follow up with the SNFs and pharmacies that were responsible for a large percentage of Part D payments for beneficiaries in Part A SNF stays. CMS should consider tracking these entities to ensure that payments have

decreased. To help CMS address this issue, we will forward information in a separate memorandum about the SNFs and pharmacies that were responsible for a large percentage of the Part D payments.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with the three recommendations in our draft report. However, it raised several concerns about the report and in response we clarified the language in the report and added a recommendation.

In response to our recommendation to educate SNFs, pharmacies, and Part D sponsors, CMS noted that it had recently issued a memorandum to Part D sponsors reminding them of the exclusion of Part D payments for drugs covered under Medicare Part A stays. The memorandum also announced that effective 2009, Part D sponsors would receive lists twice annually of their institutional beneficiaries.

In response to our recommendation to implement retrospective reviews, CMS stated that it expects to better understand the most appropriate controls for prevention and detection of inappropriate Part D payments after it looks at the specific information the Office of Inspector General (OIG) provides about the SNFs and pharmacies that were responsible for the largest percentage of payments. CMS will also review feedback from sponsors about the value of the list of institutional beneficiaries, including those in SNFs.

In response to our recommendation to follow up with the SNFs and pharmacies that were responsible for a large percentage of the payments, CMS stated that it will investigate the allegations of duplicate payments upon receipt of OIG's data.

CMS also raised concerns about our methodology, stating that our draft report failed to consider contemporary pharmacy practice and as a result inflated the number of potential erroneous Part D payments. Specifically, CMS noted that current pharmacy practice allows patients to refill a prescription before their current supply is exhausted. CMS further noted that although Part A provides reimbursement for "a limited supply" to facilitate beneficiary discharge, beneficiaries must be permitted to have a full outpatient supply available to continue therapy once this limited supply is exhausted.

In response to CMS's comments, we recognize that there are circumstances in which drugs may be billed to Part D if they are not for

R E C O M M E N D A T I O N S

use in the facility or to facilitate the beneficiaries' discharge. Although it is unlikely that drugs dispensed by long-term care pharmacies meet these conditions, we modified the language in the report to address CMS's concerns. In addition, we note that it would be beneficial for CMS to provide additional guidance to SNFs, pharmacies, and Part D sponsors that clarifies the circumstances under which Parts A and D can pay for drugs for beneficiaries preparing for discharge. As a result, we added a recommendation to the report that CMS provide additional guidance on these issues. We also note that we will provide the information about the SNFs and pharmacies that were responsible for a large percentage of Part D payments in a separate memorandum.

▶ T A B L E O F C O N T E N T S

EXECUTIVE SUMMARY i

INTRODUCTION 1

FINDINGS..... 7

 Part D paid for 1.2 million drugs for beneficiaries in
 Part A SNF stays; the majority of payments were most likely
 inappropriate..... 7

 Part D payments were widespread among SNFs and
 pharmacies 9

RECOMMENDATIONS 11

 Agency Comments and Office of Inspector General Response 12

APPENDIXES 15

 A: Most Frequently Dispensed Drugs Paid for by Part D..... 15

 B: Drugs with the Highest Part D Expenditures 16

 C: Centers for Medicare & Medicaid Services Comments 17

ACKNOWLEDGMENTS 21

OBJECTIVE

To determine the extent to which Medicare Part D paid for drugs for beneficiaries in Part A skilled nursing facility (SNF) stays in 2006.

BACKGROUND

Medicare Part D provides outpatient prescription drug coverage for Medicare beneficiaries who enroll. Part D covers most prescription drugs; however, it excludes drugs that are covered under Medicare Parts A or B. Specifically, Part D excludes drugs for beneficiaries in Part A SNF stays. These drugs are covered under Part A, except for a few drugs that are covered under Part B.

The Centers for Medicare & Medicaid Services (CMS) has identified duplicate payments by Medicare Parts A and D as a potential vulnerability. According to CMS, “[w]ith the implementation of the prescription drug benefit, there is potential for inappropriate duplicate coverage between Parts A, B, and D drugs.”¹ CMS further states that billing multiple payers (e.g., Parts A and D) for the same prescription is an example of pharmacy fraud, waste, and abuse.²

This review determines the extent to which Medicare Part D paid for drugs for beneficiaries in Part A SNF stays in 2006 during the first year of the Part D benefit.

Medicare Part D Prescription Drug Program

CMS contracts with private entities, known as sponsors, to provide the Part D benefit. These sponsors may offer a stand-alone prescription drug plan or they can offer prescription drug coverage as part of a managed care plan, known as a Medicare Advantage Prescription Drug Plan.

Each Part D plan develops its own list of covered drugs, known as a formulary, which must meet certain standards. Each plan’s formulary must contain at least two drugs within each therapeutic category and pharmacologic class.³ It also must cover “all or substantially all” of the

¹ CMS, “Prescription Drug Benefit Manual,” ch. 9—Part D Program to Control Fraud, Waste and Abuse, § 70.2.4 Rev. 2 (April 25, 2006). Available online at http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf. Accessed on July 17, 2008.

² *Ibid.*, § 70.1.3.

³ 42 CFR § 423.120(b)(2)(i).

I N T R O D U C T I O N

drugs in six categories: immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes.⁴ Certain classes of drugs are excluded from coverage by Part D. These include benzodiazepines, barbiturates, weight management drugs, and over-the-counter drugs.⁵

In addition, Part D generally excludes from coverage drugs that are covered under Parts A or B. Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA):

A drug prescribed for a Part D eligible individual that would otherwise be a covered Part D drug under this part shall not be so considered if payment for such drug as so prescribed and dispensed or administered with respect to that individual is available (or would be available but for the application of a deductible) under Part A or B for the individual.⁶

CMS stated in the Part D final rule that this requirement means that an otherwise covered Part D drug is excluded from coverage under Part D if payment is available under Part A or Part B.⁷ CMS further clarified Part D coverage in a subsequent Part D rule issuance that “. . . if payment could be available under Part A or Part B to that individual for such drug, then it would not be covered under Part D.”⁸ Further, CMS has explained that “. . . if Medicare Part A is paying for the nursing home stay, an individual’s drug costs will in all likelihood be covered through Medicare Part A payment, and so the issue of Part D cost-sharing liability does not apply.”⁹

Medicare Part A Skilled Nursing Facility Coverage

Medicare Part A covers posthospital skilled nursing care for beneficiaries who meet certain conditions. To qualify for Part A SNF coverage, the beneficiary must first have a medically necessary inpatient hospital stay of at least 3 consecutive days.¹⁰ The beneficiary

⁴ CMS, “Prescription Drug Benefit Manual.” Available online at http://www.healthplus.org/uploadedFiles/PDFs/Medicare/PDBMChap6FormularyReqmnts_03.09.07.pdf. Accessed on December 3, 2008.

⁵ 42 U.S.C. § 1395w-102(e)(2)(A) (citing to 42 U.S.C. § 1396r-8(d)).

⁶ MMA, P.L. No. 108-173, Title I § 101(a)(e)(2)(B) (codified at 42 U.S.C. 1395w-102(e)(2)(B)).

⁷ 70 Fed. Reg. 4194, 4230 (Jan. 28, 2005).

⁸ 73 Fed. Reg. 20486, 20493 (Apr. 15, 2008).

⁹ 70 Fed. Reg. 4341, 4372 (Jan. 28, 2005).

¹⁰ 42 CFR § 409.30(a)(1).

must be admitted to a SNF within a specified time period (generally 30 days) of hospital discharge and must require skilled care for the condition for which he or she received inpatient hospital services.¹¹ SNF care provided under Medicare Part A is limited to a benefit period of 100 days and requires a copayment for days 21 through 100.¹²

Medicare pays SNFs prospectively for beneficiaries in Part A stays. These prospective payments cover most services supplied by the SNF, including nursing care and physical, occupational, and speech therapies.¹³ The payments also cover drugs and biologicals furnished by the facility for use in the facility for the care and treatment of beneficiaries.¹⁴ In addition, payments cover a limited supply of drugs for use outside the SNF if it is medically necessary to facilitate the beneficiary's departure from the facility and is required until he or she can obtain a continuing supply.¹⁵ Further, payments for drugs "are not limited to those routinely stocked by the facility but include those obtained for the patient from an outside source, such as a pharmacy in the community."¹⁶

Part A does not cover certain drugs that may be billed separately to Medicare Part B.¹⁷ For example, Part B covers various chemotherapy drugs.¹⁸

Provision of Prescription Drugs in SNFs

Nursing homes typically contract with long-term care pharmacies to provide drugs to their residents.¹⁹ These pharmacies provide specialized services, such as a comprehensive inventory of drugs

¹¹ 42 CFR § 409.30(b)(1).

¹² 42 CFR § 409.61(b); see also CMS, "Medicare General Information, Eligibility, and Entitlement," ch. 3—Deductibles, Coinsurance Amounts, and Payment Limitations, Rev. 41, Oct. 27, 2006, § 10.4.

¹³ 42 CFR §§ 413.335 and 409.20. For critical-access hospitals, Part A pays on a reasonable cost basis for SNF services furnished under a swing-bed agreement rather than through prospective payments. See 42 CFR § 413.114(a)(2).

¹⁴ 42 CFR § 409.25.

¹⁵ 42 CFR § 409.25(a)(2).

¹⁶ CMS, "Skilled Nursing Facility Manual," Pub-12, § 230.5, Drugs and Biologicals.

¹⁷ 42 CFR § 411.15(p)(2).

¹⁸ 68 Fed. Reg. 46060 (Aug. 4, 2003). Also see CMS, "Overview of SNF Consolidated Billing (CB)." Available online at http://www.cms.hhs.gov/SNFPPS/05_ConsolidatedBilling.asp#TopOfPage. Accessed on November 25, 2008.

¹⁹ 70 Fed. Reg. 4194, 4250 (Jan. 28, 2005).

commonly used in long-term care settings, specialized packaging, intravenous therapy medications, 7-day-a-week delivery, pharmacy on-call services, and emergency medications.²⁰

One long-term care pharmacy generally provides drugs to all residents in a nursing facility. For beneficiaries in Part A SNF stays, the SNF is responsible for reimbursing the pharmacy for the drugs covered under Part A. For beneficiaries who are covered by Part D and are not in Part A SNF stays, the beneficiary and/or the Part D sponsor is responsible for reimbursing the pharmacy.

Potential Vulnerabilities

If Part D pays for a drug that is covered by Part A, Medicare, in effect, pays twice for this drug and either the SNF or the pharmacy profits. Under Part A, Medicare pays SNFs prospectively to cover the costs of services and items, including drugs, provided to beneficiaries in Part A SNF stays. If the SNF receives the prospective payments for the beneficiary but does not reimburse the pharmacy for the drugs, the SNF profits. If the SNF reimburses the pharmacy for the drug and the pharmacy is also paid by Part D, the pharmacy profits.

Payment Controls

Part A data files are maintained separately from Part D data files. Currently, there is no system in place that combines the data from both programs to check for duplicate payments. Additionally, Part D sponsors are responsible for developing a program to control fraud, waste, and abuse but do not have access to Part A data. Further, the Medicare Drug Integrity Contractors (MEDIC) are responsible for conducting data analysis to identify fraud, waste, and abuse in the Part D program; however, they also lack access to Part A data.

METHODOLOGY

Scope

This study determines the extent to which Medicare Part D paid for drugs for beneficiaries in Part A SNF stays that began in 2006, the first year of the Part D benefit. Our analysis includes all drugs paid for by Medicare Part D for beneficiaries while they were in Part A SNF stays.

²⁰ CMS, "Long-Term Care Guidance, March 16, 2005." Available online at <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/LTCGuidance.pdf>. Accessed on July 31, 2007.

Identifying Part A Skilled Nursing Facility Stays

We used CMS's Medicare Provider Analysis and Review (MEDPAR) file to identify beneficiaries who had SNF stays that began in 2006. Each MEDPAR record represents a SNF stay from admission to discharge. We included only the days of each beneficiary's stay that were covered by Medicare. For each stay, we excluded the beneficiary's day of discharge from our analysis because SNFs are not reimbursed for the day that the beneficiary leaves the nursing home. The last day of the stay that was covered by Medicare is referred to as the day before discharge.

Identifying Drugs Paid for by Part D

We identified the drugs paid for by Part D for beneficiaries in Part A SNF stays using CMS's Prescription Drug Event (PDE) data. As a condition of payment, sponsors must submit a PDE record to CMS for each Part D covered drug dispensed.²¹ We used all final PDE events that were received by CMS as of August 1, 2007.

We identified the drugs paid for by Medicare Part D for beneficiaries in Part A SNF stays by matching the MEDPAR data to the PDE data using the beneficiaries' Health Insurance Claim Number. If the date of service on the drug event was the same as the start date or between the start date and the discharge date, then we included the event in our population.

We then merged the data with the National Council for Prescription Drug Program's database by pharmacy identification number. We used information from this database to determine the total number of pharmacies and to identify the types of pharmacies (e.g., long-term care, retail) that dispensed the drugs. We also obtained information about the types of drugs that were dispensed based on the National Drug Codes from First DataBank's National Drug Data File.²²

²¹ CMS, "Updated Instructions: Requirements for Submitting Prescription Drug Event Data," April 27, 2006. Available online at: <http://www.cms.hhs.gov/DrugCoverageClaimsData/Downloads/PDEGuidance.pdf>. Assessed on December 30, 2008.

²² This data file contains descriptive information about all medications approved by the Food and Drug Administration, plus information on commonly used over-the-counter drugs and alternative therapy agents.

Analysis of Drugs Paid for During Part A Skilled Nursing Facility Stays

We analyzed the merged file described above to determine the total amount paid by Part D for drugs while beneficiaries were in Part A SNF stays. This amount is based on the ingredient cost, the dispensing fee, and the sales tax from the PDE data for the drugs dispensed to these beneficiaries. It includes the amount paid by Part D sponsors, the amount paid by the Government, and the amount paid by or on behalf of beneficiaries. We also analyzed the file to determine the number of drugs paid for by Medicare Part D for these beneficiaries, the types of drugs that were most frequently dispensed,²³ and the drugs with the highest Part D expenditures. We analyzed the average drug costs based on the average cost per drug event in the PDE data. For the purposes of this study, we use the term “drugs” to refer to paid Part D claims, which are also known as Part D drug events.

Limitations

This study determines the extent to which Part D paid for drugs dispensed during beneficiaries’ Part A SNF stays. These payments are inappropriate if the drugs were dispensed for use in the facility or to facilitate the beneficiaries’ discharge because Medicare covers these drugs under Parts A or B. Based on the data, however, we could not determine whether the drugs met these criteria in all situations. This determination can only be made based on a review of the medical record, which was beyond the scope of this study. In addition, we cannot determine from the data whether the pharmacy or the SNF was profiting from any inappropriate payments. Lastly, our analysis of drug costs did not take into account the dosage of the drugs.

Standards

Our review was conducted in accordance with the “Quality Standards for Inspections” issued by the President’s Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

²³ For the purposes of this report, the date the drug was dispensed is based on the date of service on the drug claim, which is the date that the pharmacy filled the prescription.

► FINDINGS

Medicare Part D paid for 1.2 million drugs, amounting to \$75 million, for beneficiaries in Part A SNF stays in 2006; the majority of these payments were most likely inappropriate

Medicare Part D paid for 1.2 million drugs for beneficiaries while they were in Part A SNF stays in 2006.²⁴ This amounted to \$75 million in Part D payments, the majority of which were most

likely inappropriate.²⁵ Medicare Part D excludes drugs that are covered under Parts A or B. Part A (and in some cases Part B) covers drugs for beneficiaries in Part A SNF stays.²⁶

Sixty percent of the drugs for beneficiaries in Part A stays were dispensed by long-term care pharmacies; these payments were most likely inappropriate

As shown in Chart 1 on the next page, long-term care pharmacies dispensed 60 percent of the drugs Part D paid for while beneficiaries were in Part A SNF stays in 2006. Nearly one-third (31 percent) of these drugs were dispensed on the day of admission to the SNF.

Long-term care pharmacies dispense drugs for use in long-term care settings, including SNFs. These drugs generally have specialized labeling that is used exclusively in an institutional setting. These drugs were most likely dispensed for use in the facility during a Part A SNF stay and covered under Medicare Part A, rather than Part D. Therefore, Part D payments for these drugs, which amounted to \$41.3 million, were most likely inappropriate.

Retail and other types of pharmacies dispensed the remaining 40 percent of drugs paid for by Part D for beneficiaries in Part A SNF stays

Retail pharmacies dispensed 35 percent of the drugs for these beneficiaries for a total of \$27.3 million in Part D payments. Other pharmacies (including institutional, home infusion, and mail order)

²⁴ For the purposes of this study, we use the term “drugs” to refer to paid Part D claims, which are also known as Part D drug events.

²⁵ Part D payments are made by Part D sponsors, Medicare, and beneficiaries or by a third party on behalf of the beneficiary.

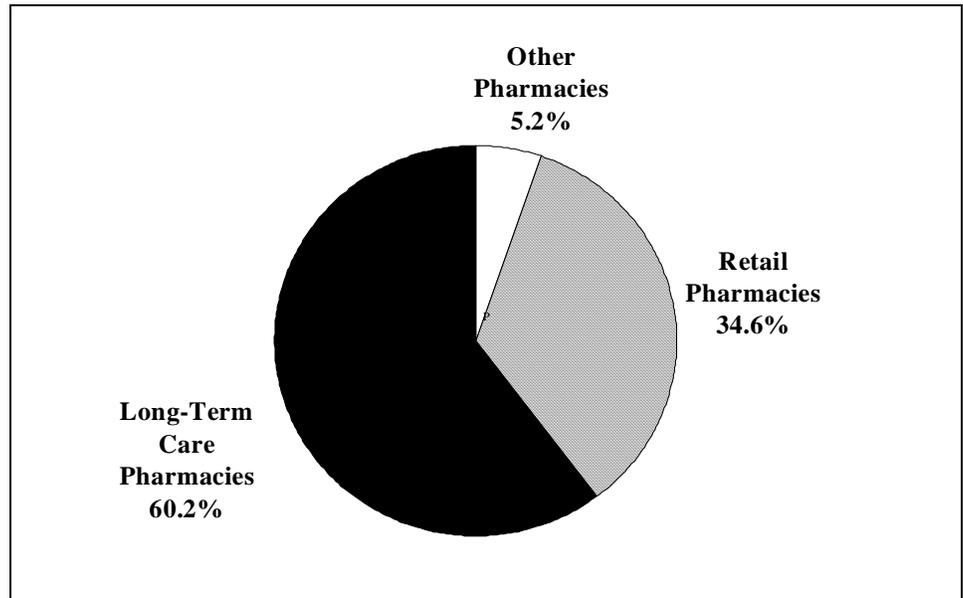
²⁶ 42 CFR § 409.25.

FINDINGS

dispensed the remaining 5 percent of the drugs, totaling \$6 million.²⁷ About 26 percent of drugs dispensed by retail pharmacies and 10 percent of drugs dispensed by other types of pharmacies were dispensed on the day before discharge.

As noted earlier, Part A not only covers drugs routinely stocked by the facility but also those obtained for the patient from an outside source, such as a pharmacy in the community.²⁸ If these drugs were obtained for use in the SNF, the Part D payments were inappropriate. Also, Part A covers a limited supply of drugs for use outside the SNF if it is medically necessary to facilitate a beneficiary's discharge. If these drugs were for this purpose, these Part D payments were also inappropriate.²⁹

Chart 1: Source of Drugs Paid by Part D for Beneficiary in Part A SNF Stays in 2006



Source: OIG analysis of CMS data, 2008.

²⁷ An institutional pharmacy is a pharmacy in a hospital (inpatient) used by the pharmacist for the compounding and delivery of medicinal preparations to be administered to the patient by nursing or other personnel. A home infusion pharmacy is a decentralized patient care organization that provides care to patients with acute or chronic conditions generally pertaining to drugs and biologics administered through catheters and/or needles in home and alternative sites.

²⁸ CMS, "Skilled Nursing Facility Manual," Pub. 12, § 230.5, Drugs and Biologicals.

²⁹ This determination can only be made based on a review of the medical record, which was beyond the scope of this study.

The drugs paid for by Part D varied; however, a relatively small number of drugs accounted for a large percentage of the Part D payments

Overall, Part D paid for 2,396 different types of drugs for beneficiaries in Part A SNF stays. On average, each type of drug was dispensed 513 times, ranging from 1 to 45,832 times. The average cost per drug was \$61 and costs ranged from \$0.01 to \$12,794. The median drug cost was \$24 and the most common cost per drug was about \$8. Of the 25 most frequently dispensed drugs, 13 were generic and 12 were brand-name drugs. Appendix A provides a list of the drugs most commonly paid for by Part D for beneficiaries in Part A SNF stays.

A relatively small number of drugs accounted for a large percentage of Part D payments for beneficiaries in Part A SNF stays. Specifically, 25 drugs accounted for 40 percent of the Part D payments for these beneficiaries. Twenty-three of the drugs were brand-name drugs, and two were generic. The average cost of these drugs was \$124 and the median cost was \$118. See Appendix B for a list of the 25 drugs.

Part D payments were widespread among SNFs and pharmacies

Nearly every SNF and half of all pharmacies had beneficiaries who had a drug paid for by Part D during their Part A SNF stay.

At the same time, a small number of SNFs and pharmacies were responsible for a large percentage of these Part D payments.

Nearly every SNF had beneficiaries in Part A SNF stays who received drugs paid for by Part D

Ninety-seven percent (16,009 of 16,525) of all SNFs had at least one beneficiary who had a drug paid for by Part D during a Part A SNF stay. Part D paid for an average of 77 drugs per facility for these beneficiaries. Part D payments for these drugs averaged \$4,659 per facility.

Although these payments were widespread, 160 SNFs accounted for 12 percent (\$8.6 million) of the Part D payments for beneficiaries in Part A SNF stays. Notably, one SNF had nearly \$270,000 in Part D payments for drugs for these beneficiaries.

About half of pharmacies received Part D payments for beneficiaries in Part A SNF stays

Forty-nine percent (36,171 of 73,398) of all pharmacies received Part D payments for beneficiaries in Part A SNF stays. These pharmacies

F I N D I N G S

dispensed an average of 34 drugs for these beneficiaries. On average, Medicare Part D payments totaled \$2,062 per pharmacy.

Compared to other types of pharmacies, long-term care pharmacies dispensed more drugs paid for by Part D per pharmacy for beneficiaries in Part A SNF stays. Long-term care pharmacies dispensed an average of 586 drugs paid for by Part D while beneficiaries were in Part A SNF stays. Part D payments for these drugs were, on average, \$32,711 per pharmacy and ranged from \$5 to over \$1 million. In contrast, retail pharmacies dispensed an average of 13 drugs, or \$830 per pharmacy. Other pharmacies dispensed an average of 31 drugs, or \$2,883 per pharmacy.

Although these payments were widespread among pharmacies, 30 pharmacies accounted for 18 percent (\$13 million) of all Part D payments for beneficiaries in Part A stays. Notably, 26 of these 30 pharmacies were long-term care pharmacies.



R E C O M M E N D A T I O N S

Based on our review, we found that Medicare Part D paid for 1.2 million drugs, amounting to \$75 million, for beneficiaries in Part A SNF stays in 2006. The majority of these payments were most likely inappropriate. Medicare Part D excludes drugs that are covered by Parts A or B. Part A (and in some cases Part B) covers drugs for beneficiaries in Part A SNF stays if the drugs were dispensed for use in the facility or to facilitate the beneficiaries' discharge.

Specifically, we found that 60 percent of the drugs for these beneficiaries were dispensed by long-term care pharmacies. Long-term care pharmacies dispense drugs for use in long-term care settings, including SNFs. These drugs were most likely dispensed for use in the facility during a Part A SNF stay. Therefore, Part D payments for these drugs, which amounted to \$41.3 million, were most likely inappropriate. The remaining drugs were dispensed by retail or other types of pharmacies. If these drugs were for use in the facility or were to facilitate the beneficiaries' discharge, these Part D payments were also inappropriate.

Lastly, we found that Part D payments for drugs for beneficiaries in Part A SNF stays were widespread among SNFs and pharmacies. Nearly every SNF and half of all pharmacies had beneficiaries who had a drug paid for by Part D during a Part A SNF stay. At the same time, a small number of SNFs and pharmacies were responsible for a large percentage of these Part D payments.

Based on these findings, we recommend that CMS:

Ensure That Part D Payments for Drugs for Beneficiaries in Part A SNF Stays Are Appropriate

CMS should ensure that Part D does not pay for drugs that are covered under Parts A or B for beneficiaries in Part A SNF stays.

Specifically, we recommend that CMS take the following actions:

Provide additional guidance about when Parts A and D can pay for drugs for beneficiaries preparing for discharge. CMS should provide additional guidance to SNFs, pharmacies, and Part D sponsors that clarifies the circumstances under which Part D can pay for drugs before beneficiaries are discharged from Part A SNF stays. Specifically, CMS should clarify when Part A covers drugs by defining what is considered

R E C O M M E N D A T I O N S

a “limited supply” and providing further guidance about when Part A should cover these drugs to facilitate discharge. It should also clarify when Part D may cover extended supplies of drugs for beneficiaries before they are discharged from Part A SNF stays.

Educate SNFs, pharmacies, and Part D sponsors that drugs covered under Parts A or B for beneficiaries in SNF stays are not eligible for payment under Part D. CMS should educate SNFs, pharmacies, and Part D sponsors that it is inappropriate for Part D to pay for drugs for beneficiaries in Part A SNF stays. CMS should consider holding open-door forums, developing factsheets, or using other methods to inform these entities about this issue.

Implement retrospective reviews to prevent inappropriate Part D payments for drugs for this population. CMS should implement routine reviews to ensure that inappropriate Part D payments do not occur. Further, CMS should conduct ongoing analysis and monitor trends in Part D payments for beneficiaries in Part A SNF stays. As noted earlier, Part D sponsors and the MEDICs do not currently have access to Part A data. CMS should consider providing the MEDICs and the sponsors access to Part A data to conduct ongoing analysis and to identify inappropriate Part D payments for this population.

Follow up with the SNFs and pharmacies that were responsible for a large percentage of Part D payments for beneficiaries in Part A SNF stays. CMS should consider tracking these entities to ensure that payments have decreased. To help CMS address this issue, we will forward in a separate memorandum information about the SNFs and pharmacies that were responsible for a large percentage of the Part D payments.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with the three recommendations in our draft report. However, it raised several concerns about the report and in response we clarified the language in the report and added a recommendation.

In response to our recommendation to educate SNFs, pharmacies, and Part D sponsors, CMS stated that it is committed to providing additional information about its programs. Among other things, CMS noted that it had recently issued a memorandum to Part D sponsors reminding them of the exclusion of Part D payments for drugs covered under Medicare Part A stays. The memorandum also announced that

R E C O M M E N D A T I O N S

effective 2009, Part D sponsors would receive lists twice annually of their institutionalized beneficiaries, including those in SNFs. CMS advised Part D sponsors that this information will provide them with a mechanism to identify beneficiaries for whom the sponsor may be most at risk for being billed inappropriately for Part D payment.

In response to our recommendation to implement retrospective reviews, CMS stated that although it concurs in general, it is currently unsure of the most appropriate strategy for implementing these reviews. CMS stated that it expects to better understand the most appropriate controls for prevention and detection of inappropriate Part D payments after it looks at the specific information OIG will provide about the SNFs and pharmacies that were responsible for the largest percentage of payments. CMS will also review feedback from sponsors about the value of the list of institutional beneficiaries, including those in SNFs. CMS stated that it will explore whether the most timely and effective strategy for review for potential duplicate Part D payments is at the Part D plan level, and if that is the case, it will provide additional guidance to sponsors.

In response to our recommendation to follow up with the SNFs and pharmacies that were responsible for a large percentage of the payments, CMS stated that it will investigate the allegations of duplicate payments upon receipt of OIG's data.

CMS also raised concerns about our methodology, stating that our draft report failed to consider contemporary pharmacy practice and as a result inflated the number of potential erroneous Part D payments. Specifically, CMS noted that current pharmacy practice allows patients to refill a prescription before their current supply is exhausted. CMS further noted that although Part A provides reimbursement for "a limited supply" to facilitate beneficiary discharge, beneficiaries must be permitted to have a full outpatient supply available to continue therapy once this limited supply is exhausted.

In response to CMS's comments, we recognize that there are circumstances in which drugs may be billed to Part D if they are not for use in the facility or to facilitate the beneficiaries' discharge. Although it is unlikely that drugs dispensed by long-term care pharmacies meet these conditions, we modified the language in the report to address CMS's concerns. In addition, we note that it would be beneficial for CMS to provide additional guidance to SNFs, pharmacies, and Part D sponsors that clarifies the circumstances under which Parts A and D

R E C O M M E N D A T I O N S

can pay for drugs for beneficiaries preparing for discharge. Currently, CMS guidance does not explicitly state what is considered a limited supply of drugs covered by Part A, nor does it state under which circumstances Part D can pay for drugs. As a result, we added a recommendation to the report that CMS provide additional guidance on these issues. We also note that we will provide the information about the SNFs and pharmacies that were responsible for a large percentage of Part D payments in a separate memorandum.

The full text of CMS's comments is provided in Appendix C.

▶ A P P E N D I X ~ A

Most Frequently Dispensed Drugs Paid for by Part D for Beneficiaries in Medicare Part A Skilled Nursing Facility Stays			
Rank	Drug Name	Generic or Brand Name	Number of Drugs Dispensed*
1	Furosemide	Generic	45,832
2	Warfarin sodium	Generic	27,890
3	Lisinopril	Generic	23,534
4	Metoprolol tartrate	Generic	23,116
5	Potassium chloride	Generic	21,215
6	Lovothyroxine sodium	Generic	20,872
7	Hydrocodone w/ acetaminophen	Generic	20,503
8	Norvasc	Brand name	18,087
9	Aricept	Brand name	16,434
10	Protonix	Brand name	15,840
11	Omeprazole	Generic	15,324
12	Levaquin	Brand name	15,181
13	Lexapro	Brand name	14,322
14	Lipitor	Brand name	13,759
15	Seroquel	Brand name	13,419
16	Prednisone	Generic	13,120
17	Prevacid	Brand name	12,755
18	Mirtazapine	Generic	11,970
19	Gabapentin	Generic	11,566
20	Plavix	Brand name	11,548
21	Risperdal	Brand name	11,453
22	Toprol XL	Brand name	11,100
23	Albuterol sulfate	Generic	10,602
24	Novolin R	Brand name	10,385
25	Isosorbide mononitrate	Generic	9,814
	Total		419,641

Source: Office of Inspector General analysis of Centers for Medicare & Medicaid Services data, 2006.

* Note: For the purposes of this study, we use the term “drugs” to refer to paid Part D claims.

▶ A P P E N D I X ~ B

Drugs With the Highest Medicare Part D Expenditures for Beneficiaries in Medicare Part A Skilled Nursing Facility Stays				
Rank	Drug Name	Generic or Brand Name	Total Part D Payments	Percentage of Part D Payments
1	Lovenox	Brand name	\$2,282,281	3.1%
2	Aricept	Brand name	\$2,137,327	2.9%
3	Seroquel	Brand name	\$1,783,011	2.4%
4	Risperdal	Brand name	\$1,749,444	2.3%
5	Zyprexa	Brand name	\$1,727,855	2.3%
6	Procrit	Brand name	\$1,607,826	2.2%
7	Protonix	Brand name	\$1,571,417	2.1%
8	Prevacid	Brand name	\$1,503,141	2.0%
9	Plavix	Brand name	\$1,314,817	1.8%
10	Lipitor	Brand name	\$1,170,750	1.6%
11	Levaquin	Brand name	\$1,133,232	1.5%
12	Advair Diskus	Brand name	\$982,316	1.3%
13	Namenda	Brand name	\$977,457	1.3%
14	Lexapro	Brand name	\$963,398	1.3%
15	Norvasc	Brand name	\$951,693	1.3%
16	Zyvox	Brand name	\$912,025	1.2%
17	Nexium	Brand name	\$892,506	1.2%
18	Fentanyl	Generic	\$845,852	1.1%
19	Thalomid	Brand name	\$825,989	1.1%
20	Coreg	Brand name	\$824,200	1.1%
21	Lantus	Brand name	\$709,699	1.0%
22	Ambien	Brand name	\$709,441	1.0%
23	Aranesp	Brand name	\$700,093	0.9%
24	Zocor	Brand name	\$683,840	0.9%
25	Omeprazole	Generic	\$625,870	0.8%
	Total		\$29,585,480	39.7%

Source: Office of Inspector General analysis of Centers for Medicare & Medicaid Services data, 2006.

Centers for Medicare & Medicaid Services Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

DATE: MAR 04 2009

TO: Daniel R. Levinson
Inspector General

FROM: *Charlene Frizzera*
Charlene Frizzera
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Medicare Part D Payments for Beneficiaries in Part A Skilled Nursing Facility Stays in 2006," (OEI-02-07-00230)

Thank you for the opportunity to review and comment on the OIG's draft report that examines the appropriateness of Part D plan payments for beneficiaries who resided in a Part A skilled nursing facility (SNF) stay during 2006. The Centers for Medicare & Medicaid Services (CMS) is committed to upholding the provision of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) that requires Part D sponsors to exclude from payment an otherwise covered Part D drug if payment is available under Part A or Part B. CMS takes seriously allegations of fraud, waste and abuse and will follow up, as appropriate, on any confirmed cases involving a Part D sponsor inappropriately paid under a Part A stay.

We acknowledge the real possibility of inappropriate Part D duplicate payments for beneficiaries under Part A stays, and as described below in detail, we have taken numerous steps to help plans identify inappropriate payments. However, we continue to believe that the underlying methodology utilized by the OIG seriously inflated the number of potential erroneous Part D payments. Specifically, the study methodology failed to consider contemporary pharmacy practice and the standard of care provided in skilled nursing facilities by using the prescription drug event date (PDE) dispensing date as equivalent to the patient administration date. As a result, any PDE dispensing date occurring within the period of a Part A stay is identified as an erroneous Part D duplicate payment. CMS believes that this conclusion is not appropriate in all cases.

Current pharmacy practice allows a patient to refill a prescription before their current supply is exhausted. For example, a patient receiving a 30 day supply of medication typically is permitted to obtain a refill on day 26 so that the individual will have a fresh supply on hand prior to exhausting the initial 30 days of medication. Similarly, for patients in a long-term care facility, medications are generally dispensed and delivered before the existing supply is exhausted (in some cases a number of days in advance) to ensure that there will be no gaps in therapy. Consequently, both long term care and retail pharmacies may appropriately bill Part D for

Page 2 – Daniel R. Levinson

medications dispensed and delivered near the end of a beneficiary's Part A stay because these medications are being dispensed for consumption after the Part A stay is exhausted. Nevertheless, in this report, drugs with a PDE dispensing date near the end of a beneficiary's Part A stay will appear as inappropriate, duplicate Part D payments. We recommend the OIG correct its methodology and re-report its findings considering this is common pharmacy practice for all patients, not just for people with Medicare.

It is important to emphasize that there are legitimate level of care transitions that necessitate the dispensing of Part D drugs before a patient is discharged from a Part A facility. While Part A does provide reimbursement for "a limited supply" to facilitate beneficiary discharge, beneficiaries must be permitted to have a full outpatient supply available to continue therapy once this limited supply is exhausted.¹ This is particularly true for beneficiaries using mail-order pharmacy, home infusion therapy, or residing in rural areas where obtaining a continuing supply of drug may involve certain delays. Thus, the current standard of care promotes caregivers receiving outpatient Part D prescriptions in advance of discharge from a Part A stay.

In addition, CMS is very concerned that the current draft report may undercut the beneficiary protections of CMS' existing transition policy. Access to Part D drugs during level of care changes is absolutely necessary to maintaining high quality prescription drug coverage and in preventing any interruptions in drug therapy. Delays in accessing Part D drugs may hinder discharge from a long-term care facility. Therefore, the OIG should articulate caution in its final report about the conclusions so as to not impede access to transition supplies for some of Medicare's most vulnerable beneficiaries. Moreover, given that the report relies on 2006 data that may reflect initial start up issues, the OIG should frame the final report in such a way as to ensure that Part D sponsors do not become overly cautious in providing Part D drugs related to discharge from a Part A stay.

The OIG recommend CMS ensure that Part D payments for drugs for beneficiaries in Part A SNF stays are appropriate. Specifically, the OIG recommend CMS take the following actions:

OIG Recommendation

Educate SNFs, pharmacies, and Part D sponsors that drugs covered under Parts A or B for beneficiaries in SNF stays are not eligible for payment under Part D.

CMS Response

The CMS concurs with this recommendation and is firmly committed to providing additional information about our programs. Since the inception of the Part D program, CMS has worked tirelessly to provide education to all of our partners regarding the interface of drug coverage under Medicare Parts A, B, and D. In the 2005 Part D final rule, CMS provided an extensive discussion on the relationship of drug reimbursement of Medicare Part A, B, and D. This message was reinforced in hundreds of outreach events specifically targeted at LTC facilities, pharmacies, and pharmacists. Furthermore, CMS conducted numerous pharmacy open door forums between 2005 and 2008 that included information regarding payment for drugs under

¹ Medicare Benefit Policy Manual, Chapter 1, Section 30.2, Drugs for Use Outside the Hospital.

Page 3 – Daniel R. Levinson

various Medicare programs and addressed the exclusion of Part D drug reimbursement when payment was available under Medicare Parts A and B.

Our educational effort continues today. Recently, the CMS Office of External Affairs revised an educational tool entitled, "Medicare Drug Coverage under Part A, Part B, and Part D." This tool provides extensive information on the relationship of drug reimbursement under various Medicare Programs and is available for use by the pharmacy and long term care community. We have also posted in-depth information about Medicare payment on our Long Term Care Pharmacy website.²

In addition, following the OIG's exit conference, in a November 2008 memorandum, we reminded Part D sponsors of the exclusion of Part D payment for drugs covered under Medicare Part A stays.³ This memorandum also announced that effective 2009, Part D sponsors would receive lists twice annually of their institutional enrollees, including the names and addresses of the particular LTC facilities and any applicable indicators of Part A stays from most recent available MDS data. We advised Part D sponsors that this information would assist them in preventing Part D payment for drugs covered under Medicare Part A stays. The Part A indicator will provide Part D sponsors with a mechanism to identify beneficiaries for which the sponsor may be most at risk for being billed inappropriately for Part D payment.

As educational opportunities present themselves, CMS will continue to provide information on the relationship and reimbursement for drugs under Medicare Parts A, B and D. Moreover, we continue to enhance our relationships with the various pharmacy and long term care associations and plan to reinforce the message regarding the exclusion of payment for Part D drugs for beneficiaries under a Part A stay.

OIG Recommendation

Implement retrospective reviews to prevent inappropriate Part D payments for drugs for this population.

CMS Response

The CMS concurs with this recommendation in general; however, we are currently unsure of the most appropriate strategy for implementing a retrospective review process. We look forward to receiving the OIG specific information about the SNFs and pharmacies that were responsible for a large percentage of the Part D payments under review. After we have looked into this information and receive feedback from sponsors on the value of sending out the biannual list of institutional enrollees, we expect to better understand the factors underlying this type of error, as well as the most appropriate controls for prevention and detection. We will explore whether the most timely and effective strategy for review for potential duplicate Part D payments is at the Part D plan level. For example, this review could be a component of the Part D sponsor's retrospective drug utilization review system required under 42 CFR 423.153(c)(3). Should our analysis determine that this is the most appropriate place for this review, we will provide

² http://www.cms.hhs.gov/Pharmacy/04_ltc.asp#TopOfPage

³ http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/MemoLTCContracting_11.25.08.pdf

Page 4 – Daniel R. Levinson

additional guidance to Part D sponsors in the annual Call Letter and ultimately in Chapter 7 of the Medicare Prescription Drug Benefit Manual, section 20.3, Retrospective Drug Utilization Review.

OIG Recommendation

Follow up with the SNFs and pharmacies that were responsible for a large percentage of Part D payments for beneficiaries in Part A SNF stays.

CMS Response

The CMS concurs with this recommendation and will investigate the allegations of duplicate payments upon receipt of the OIG's supplemental data. We take very seriously the allegations about Part D sponsors and will implement corrective action upon confirmation of inappropriate payments.

Thank you for your efforts to study this matter. CMS is serious about enforcing Part D Sponsors' adherence to CMS requirements. To the extent that sponsors are not in compliance with Part D program requirements, CMS will investigate and take action where necessary.



A C K N O W L E D G M E N T S

This report was prepared under the direction of Jodi Nudelman, Regional Inspector General for Evaluation and Inspections in the New York regional office, and Meridith Seife, Deputy Regional Inspector General.

Miriam Anderson served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the New York regional office who contributed to this report include Taryn Eckstein, Michelle McInnis, and David Rudich. Other regional and central office staff who contributed include Eddie Baker and Sandy Khoury.