Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

INAPPROPRIATE MEDICARE PART D PAYMENTS FOR SCHEDULE II DRUGS BILLED AS REFILLS

Daniel R. Levinson
Inspector General

September 2012
OEI-02-09-00605

EXECUTIVE SUMMARY: INAPPROPRIATE MEDICARE PART D PAYMENTS FOR SCHEDULE II DRUGS BILLED AS REFILLS
OEI-02-09-00605

WHY WE DID THIS STUDY

Schedule II drugs have the highest potential for abuse of any prescription drugs legally available in the United States. They include narcotics commonly used to relieve pain and stimulants. Federal law prohibits the refilling of prescriptions for them. In addition, Schedule II drugs cannot be dispensed without a prescription that contains the name, address, and signature of the prescriber.

HOW WE DID THIS STUDY

We based this study on an analysis of prescription drug event records. Sponsors submit these records to the Centers for Medicare & Medicaid Services (CMS) for each drug dispensed to beneficiaries enrolled in their plans. Each record contains information about the pharmacy, prescriber, and drug. We analyzed all of the records for refills of Schedule II drugs that were billed in 2009.

WHAT WE FOUND

Medicare Part D inappropriately paid $25 million for Schedule II drugs billed as refills in 2009. Sponsors should not have paid for any of these drugs because Federal law prohibits the refilling of Schedule II controlled substances. Some of these drugs may have been inaccurately billed. It is possible that some long-term-care pharmacies incorrectly billed these drugs as refills when they were partial fills. Partial fills occur when a pharmacist does not dispense all doses of the prescribed medication at one time. Several concerns exist, however, if partial fills are inaccurately billed as refills. Moreover, over 25,000 Schedule II refills had invalid prescribers. Lastly, three-quarters of Part D sponsors paid for Schedule II drugs billed as refills, indicating that many sponsors do not have adequate controls to prevent these refills.

WHAT WE RECOMMEND

We recommend that CMS: (1) issue guidance to sponsors to prevent billing of Schedule II refills and to ensure accurate billing of partial fills; (2) exclude Schedule II refills when calculating payments to sponsors; (3) monitor sponsors to ensure that they validate prescriber numbers for Schedule II drugs; and (4) follow up on sponsors, pharmacies, and prescribers with high numbers of refills. CMS concurred with our recommendation to monitor sponsors to ensure they validate prescriber numbers and partially concurred with the other three recommendations.

TABLE OF CONTENTS

OBJECTIVE

To determine the extent to which Medicare Part D paid for Schedule II drugs billed as refills in 2009.

BACKGROUND

Schedule II drugs have the highest potential for abuse of any prescription drugs legally available in the United States.[1] They include narcotics commonly used to relieve pain and stimulants. The Drug Enforcement Agency (DEA) regulates Schedule II drugs, and the Controlled Substance Act prohibits the refilling of prescriptions for them. In 2009, Medicare Part D paid $2.2 billion for Schedule II drugs.

Abuse of Schedule II and other prescription drugs is a serious problem. The Centers for Disease Control and Prevention (CDC) has characterized prescription drug abuse as an epidemic.[2] In fact, more deaths in 2007 were caused by prescription painkillers, including several Schedule II drugs, than by cocaine and heroin combined.[3]

In addition to causing public health concerns, Schedule II drugs have been at the center of several schemes to defraud the Medicare Part D program. Schemes involving Schedule II drugs include forged prescriptions and diversion through "unscrupulous pharmacists, doctors, and dentists."[4] In a recent case, two Los Angeles-based doctors were charged with health care fraud for knowingly prescribing Schedule II drugs to individuals who did not have a medical need for them. Over an 18-month period, Medicare Part D paid more than $2.7 million for the Schedule II drugs prescribed by these doctors.[5]

There have also been several recent DEA settlements related to the dispensing of Schedule II drugs. A long-term-care pharmacy recently

[1] 21 U.S.C. § 812. Also see 21 CFR § 1308.12 for a listing of drugs identified as Schedule II substances.

[2] CDC, Press Release, *Prescription Painkiller Overdoses at Epidemic Levels*, November 1, 2011. Accessed at http://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html on February 21, 2012.

[3] CDC, *Unintentional Drug Poisoning in the United States*, July 2010. Accessed at http://www.cdc.gov/HomeandRecreationalSafety/pdf/poison-issue-brief.pdf on July 12, 2011.

[4] DEA, *Drugs and Chemicals of Concern: Oxycodone*. Accessed at http://www.deadiversion.usdoj.gov/drugs_concern/oxycodone/summary.htm on September 27, 2011.

[5] Department of Justice (DOJ), *Grand Jury Indicts 14 in Los Angeles-Based OxyContin Ring That Allegedly Distributed Over 1 Million Pills of the Highly Addictive Painkiller*, October 13, 2011. Accessed at www.justice.gov/dea/pubs/states/newsrel/2011/la101311.html on February 22, 2012.

agreed to pay $50 million to resolve Government claims that the pharmacy had dispensed controlled substances without written prescriptions and did not properly document partial fills of controlled substances.[6] DEA also reached a settlement with a pharmaceutical distributor for failing to maintain adequate controls to prevent the diversion of controlled substances, specifically oxycodone.[7] In another case, a pharmacy benefits manager recently paid almost $3 million to settle claims that it did not have practices to prevent diversion of controlled substances and used invalid DEA numbers at its mail-order pharmacies.[8]

Schedule II Drugs

The Controlled Substances Act establishes five schedules of drugs that are considered controlled.[9] These schedules are based on medical use and the potential for abuse. The most restricted is Schedule I, which includes drugs that have a high potential for abuse and no currently accepted medical use in the United States. Schedule V is the least restricted.

Schedule II drugs have a high potential for abuse and may lead to severe psychological or physical dependence.[10] These drugs include narcotics and narcotic substances such as morphine, opium, oxycodone (OxyContin), meperidine (Demerol), and fentanyl (Sublimaze or Duragesic). They also include stimulants such as amphetamine (Dexedrine, Adderall) and methylphenidate (Ritalin).[11]

Schedule II drugs are subject to a number of restrictions under Federal law and regulations. Specifically, Federal law prohibits the refilling of prescriptions for Schedule II drugs.[12] In addition, Schedule II drugs cannot be dispensed without a prescription that contains the name,

---

[6] DEA, *Omnicare in $50 Million Settlement—Largest Controlled Substance Settlement in History*, May 11, 2012. Accessed at http://www.justice.gov/dea/pubs/states/newsrel/2012/det051112.html on May 15, 2012.

[7] DEA, *DEA Suspends for Two Years Pharmaceutical Wholesale Distributor's Ability to Sell Controlled Substances from Lakeland, Florida Facility*, May 15, 2012. Accessed at http://www.justice.gov/dea/pubs/pressrel/pr051512.html on May 24, 2012.

[8] U.S. Attorney's Office, Eastern District of Pennsylvania, "United States Settles With Express Scripts Over Diversion Of Controlled Substances And Use Of Improper DEA Numbers," May 15, 2012. Accessed at http://www.justice.gov/usao/pae/News/2012/May/esi_release.htm on May 22, 2012.

[9] 21 U.S.C. § 801 et seq.

[10] 21 U.S.C. § 812.

[11] DEA, *Pharmacist's Manual*, 2010, p. 5. Accessed at http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf on November 8, 2011.

[12] 21 U.S.C. § 829(a).

address, and signature of the prescriber.[13] DEA regulations further require that Schedule II drugs be prescribed by individual practitioners who are registered with DEA.[14]

DEA guidance states that prescribing practitioners and pharmacists are responsible for ensuring that Schedule II drugs are dispensed properly. The guidance states that the practitioner is responsible for ensuring that the prescription conforms to all Federal and State laws and regulations.[15] It further states that "a pharmacist who deliberately fills a questionable prescription may be prosecuted, along with the issuing practitioner, for knowingly and intentionally distributing controlled substances."[16]

In addition, Federal regulations limit the circumstances under which partial fills of Schedule II drugs are permissable.[17] Partial fills occur when a pharmacist does not dispense all doses of the prescribed medication at one time; instead, the pharmacist dispenses the drug over multiple fills. Partial fills of Schedule II drugs must be completed within 72 hours, unless the patient is in a long-term-care facility or terminally ill. Partial fills are not considered refills.[18]

Medicare Part D

Medicare Part D provides an optional prescription drug benefit to Medicare beneficiaries. The Centers for Medicare & Medicaid Services (CMS) contracts with private insurance companies, known as sponsors, to provide drug coverage to beneficiaries who choose to enroll. These sponsors contract with a network of pharmacies to dispense drugs to the

---

[13] In 2009, Schedule II drugs could not be dispensed without a written prescription except in emergency situations and when dispensed directly to the ultimate user by a practitioner other than a pharmacist. A paper prescription could be transmitted to the pharmacy by the practitioner or his or her agent via facsimile machine. 21 CFR § 1301.11. Also see DEA, *Practitioner's Manual Section V – Valid Prescription Requirements*, 2006. Accessed at http://www.deadiversion.usdoj.gov/pubs/manuals/pract/section5.htm on November 1, 2011. Beginning in 2010, practitioners were allowed to sign and transmit electronic prescriptions for controlled substances under certain circumstances. See 21 CFR § 1301.08.

[14] Practitioners must be authorized to prescribe controlled substances by the jurisdiction in which they are licensed to practice. DEA maintains a registry of all these practitioners and includes their assigned DEA numbers and information about which schedules of drugs each is allowed to prescribe. DEA registration grants practitioners Federal authority to handle controlled substances. See 21 CFR § 1301.11.

[15] DEA, *Pharmacist's Manual*, 2010, p. 29. Accessed at http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf on November 8, 2011.

[16] Ibid., p. 30.

[17] 21 CFR § 1306.13.

[18] Although Schedule II drugs cannot be refilled, practitioners may issue multiple prescriptions at one time, each authorizing a 90-day supply. 21 CFR § 1306.12.

beneficiaries enrolled in their plans. These pharmacies include, retail, long-term-care, specialty, and mail-order pharmacies, among others.[19]

Sponsors are required to safeguard Part D from fraud and abuse. CMS recommends that sponsors use claims processing edits to monitor their programs and to automatically deny payment, when appropriate.[20] Beginning in January 2012, CMS required sponsors to ensure that the prescriber identifiers on Prescription Drug Event (PDE) records are active and valid. They must also confirm that any controlled substances are consistent with the schedule of drugs that the provider is allowed to prescribe. To do this, sponsors must validate the DEA numbers on PDE records for Schedule II drugs or map the National Provider Identifiers (NPI) on the PDE records to the prescriber's DEA number and then confirm that the controlled substance is consistent with the prescriber's registration.[21] CMS also requires sponsors to have compliance plans that contain measures to detect, prevent, and correct fraud, waste, and abuse.[22] As part of these plans, CMS expects that sponsors will monitor their contractors and subcontractors, including their pharmacies.[23]

CMS contractors are also charged with safeguarding Part D. CMS contracts with two Medicare Drug Integrity Contractors (MEDIC) to help identify Part D vulnerabilities. One MEDIC's responsibilities include, among other things, detecting, preventing, and investigating potential fraud, waste, and abuse, as well as referring potential cases to law enforcement. The other MEDIC's responsibilities include performing special studies and providing technical assistance to CMS. Additionally, CMS contracts with a Recovery Audit Contractor (RAC) for Part D. Beginning in 2012, the RAC will review excluded prescribers, excluded pharmacies, and duplicate payments.

---

[19] A specialty pharmacy dispenses high-cost drugs to patients with chronic, complex illnesses.

[20] CMS, *Prescription Drug Benefit Manual Chapter 9 – Part D Program to Control Fraud, Waste, and Abuse*, § 50.2.6.3.1, April 2006. Accessed at http://www.cms.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf on January 12, 2012.

[21] CMS, *Prescription Drug Manual – Chapter 5: Benefits and Beneficiary Protections*, §§ 90.2 and 90.2.4, September 2011. Accessed at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf on May 8, 2012.

[22] 42 CFR § 423.504(b)(4)(vi).

[23] Part D regulations and CMS guidance refer to these contractors and subcontractors as first-tier and downstream entities. See 42 CFR § 423.501 and CMS, *Prescription Drug Benefit Manual Chapter 9 – Part D Program to Control Fraud, Waste, and Abuse, Part D Sponsors Accountability and Oversight – Section 40*, April 2006. Accessed at http://www.cms.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf on July 19, 2011.

Prescription Drug Event Records

Sponsors submit a PDE record to CMS for each prescription filled for their enrollees. CMS uses the records to administer the program and to calculate its payments to sponsors at the end of each year in a process known as reconciliation.

Each PDE record contains a unique identification number for the prescriber.[24] Most PDE records contain the prescriber's NPI, which CMS issues to each health care provider. CMS maintains a registry of all assigned NPIs, along with the name and address of the health care providers. If an NPI does not appear in the registry, it has not been assigned to a health care provider.

PDE records also include a field, called "Fill Number," that indicates whether a prescription is a refill. This field is one of several on the PDE record that is standard throughout the industry. Industry standards are set by the National Council for Prescription Drug Plans (NCPDP). NCPDP instructs pharmacies to enter "0" for new prescriptions, "1" for a first refill, and "2" for a second refill.[25]

Sponsors are required to provide certification of the accuracy, completion, and truthfulness of PDE data.[26] In addition, CMS takes steps to ensure the accuracy of the PDE records. CMS performs edits on the PDE records before it accepts them from sponsors. For example, CMS determines whether certain data are missing and whether certain values are within acceptable ranges. CMS considers values between 0 and 99 to be within an acceptable range for the Fill Number field.[27]

---

[24] PDE records allow four types of prescriber identification numbers: NPIs, DEA numbers, State license numbers, and Unique [Physician] Identification Numbers (UPIN). In May 2008, CMS issued guidance stating that plans and pharmacies "should make all reasonable efforts to obtain NPIs in the Prescriber ID field." See CMS, *Prescriber Identifier on Part D NCPDP Pharmacy Claims Transactions*, May 1, 2008. Accessed at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoNPIPrescriberID_050108v2.pdf. on June 6, 2012.

[25] Pursuant to the Health Insurance Portability and Accountability Act of 1996, the Secretary of Health and Human Services named the NCPDP Telecommunication Standards as the electronic transaction standards for retail pharmacies. These standards define a "Fill Number" of 0 to be the "original dispensing." NCPDP's Universal Claim Form Sample further defines Fill Number values of 1 and 2 as refills. See NCPDP, *Universal Claim Form Sample* and NCPDP, *Telecommunication Standard Implementation Guide Version D.0*, August 2010.

[26] 42 CFR § 423.505(k).

[27] CMS, *Medicare Part D Prescription Drug Event (PDE) Data Elements*, April 8, 2008. Accessed at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/downloads//PDEDataElements.pdf on April 12, 2012.

Related Work

Four recent Office of Inspector General (OIG) audits found that the sponsors did not have adequate controls to ensure the accuracy of the PDE data they submitted to CMS.[28] Three of these audits also found that the sponsors did not have adequate controls to prevent Schedule II refills. These reports recommended that the sponsors strengthen their controls and issue guidance to their pharmacies, clarifying Federal requirements.

Another OIG report found that approximately 228,000 PDE records for Schedule II drugs in 2007 did not contain valid prescriber identifiers.[29] CMS and sponsors performed edits on the prescriber identifier fields; however, these edits were insufficient.

METHODOLOGY

Data Collection and Analysis

This report is based on analysis of PDE records for all drugs paid for by Part D in 2009. In total, we identified 1.07 billion PDE records for Part D prescriptions filled between January 1 and December 31, 2009.

To identify the PDE records for Schedule II drugs, we matched the PDE records to First DataBank using the National Drug Code on the PDE records. First DataBank contains information about each drug, including its name; whether it is a controlled substance; and, if so, the schedule of the drug. We identified 20.1 million PDE records for Schedule II drugs billed by 61,472 pharmacies.[30] To identify the PDE records that were refills for Schedule II drugs, we looked at the Fill Number field on the PDE record. The first time a prescription is filled the Fill Number should be 0. Any value greater than 0 is considered a refill.

---

[28] OIG, *Review of Medicare Part D Prescription Drug Event Data for Schedule II Drugs at Health Net, Inc.*, A-09-10-02046, September 2011. OIG, *Review of Medicare Part D Prescription Drug Event Data for Schedule II Drugs at CVS Caremark Corporation*, A-09-11-02074, February 2012. OIG, *Review of Medicare Part D Prescription Drug Event Data for Schedule II Drugs at Hawaii Medical Services Association*, A-09-11-02028, December 2011. OIG, *Review of Medicare Part D Prescription Drug Event Data for Schedule II Drugs at United HealthCare Medicare & Retirement*, A-09-11-02023, July 2012.

[29] OIG, *Oversight of Prescriber Identifier Field in Prescription Drug Event Data for Schedule II Drugs*, A-14-09-00302, February 2011. Accessed at http://oig.hhs.gov/oas/reports/other/140900302.pdf on November 1, 2011. Another OIG report looked at the prescriber identifiers for PDE records billed in 2007. It found that Medicare Part D paid $1.2 billion for drugs with invalid prescriber identifiers. See OIG, *Invalid Prescriber Identifiers on Medicare Part D Claims*, OEI-03-09-00140, June 2010.

[30] To determine the total number of pharmacies, we used the NPI. If we were unable to identify the NPI for the pharmacy, we did not include the PDE record in our analysis. In total, we excluded less than 0.1 percent of all PDE records.

Next, we calculated the total number of Schedule II drugs billed to Medicare Part D in 2009. To calculate the cost of these refills, we summed the three fields that indicate the gross drug costs—the ingredient cost, dispensing fee, and sales tax. These fields include the amount paid by Part D sponsors, the Government, and by or on behalf of beneficiaries. In addition, we determined the most common Schedule II drugs that were refilled. For the purpose of this report, we considered drugs with the same name as the same drug, regardless of dosage or strength.

We then determined the total number of pharmacies that billed for refills of Schedule II drugs and the type of pharmacy, i.e., retail, long-term-care, or other type, that billed for each refill.[31] We used the NPI for each pharmacy and matched it to the NCPDP database to identify the type of pharmacy. We calculated the percentage and the average number of refills of Schedule II drugs that were billed by each type of pharmacy.

Next, we determined the total number of prescribers who were associated with Schedule II refills and whether the prescriber identifiers were valid.[32] To do this, we checked the NPI or DEA identification number on the PDE records against CMS and DEA files.[33] In October 2010, we obtained CMS's registry of active NPI numbers through its National Plan and Provider Enumeration System and accessed a file of active DEA registrants. We also obtained lists of inactive NPI numbers and retired DEA registration numbers. We compared the NPI and DEA prescriber identifiers on the PDE records to these registries. We considered a prescriber identifier to be invalid if it had never been assigned or if it had been deactivated or retired before January 1, 2009. We also considered a prescriber identifier to be invalid if it was assigned to a pharmacy, i.e., the pharmacy's NPI was listed as the prescriber.

Lastly, to identify the sponsors that paid for Schedule II refills, we matched the contract number on the PDE records with data from CMS's Health Plan Management System. We used this information to calculate the total number of Schedule II refills paid for by each sponsor.[34]

[31] We could not identify the pharmacy type for 2,585 refills.

[32] Prescribers can use multiple identifiers to prescribe drugs, such as a DEA number or an NPI. This analysis is based on the identifier on the PDE record. We did not aggregate all identification numbers for each individual prescriber.

[33] Less than 1 percent (0.92 percent) of refills were billed using other types of prescriber identifiers, such as UPINs and State license numbers. In these cases, we assumed the prescriber identifiers were valid.

[34] We identified two invalid sponsor identification numbers. We did not include these invalid numbers in our analysis of sponsors. In total, these two numbers accounted for 477 refills.

Limitations

This review is based on an analysis of PDE data; we did not review documentation from the pharmacies or prescribers to verify the data. We also did not independently verify the accuracy of the data from First DataBank or NCPDP.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

Medicare Part D inappropriately paid $25 million for Schedule II drugs billed as refills in 2009

In 2009, Medicare Part D inappropriately paid for 397,203 Schedule II drugs billed as refills. These drugs amounted to $24.6 million and accounted for 2 percent of all Schedule II drugs dispensed in 2009. [35] Sponsors should not have paid for any of these drugs because Federal law prohibits the refilling of Schedule II drugs. Schedule II drugs can be highly addictive and are commonly abused. Also, they are often diverted and resold for profit. CMS relies on sponsors to ensure that Part D does not pay for Schedule II refills.

Fentanyl and oxycodone-acetaminophen were the Schedule II drugs most commonly billed as refills. These two drugs accounted for more than half of all Schedule II refills. See Table 1. Fentanyl is a painkiller with effects similar to those of heroin, but hundreds of times more potent.[36] Oxycodone with acetaminophen is a commonly abused painkiller that provides a euphoric high.[37] According to DOJ, a 100-tablet bottle of 40-milligram OxyContin (the brand-name version of oxycodone) sells for approximately $2,000 to $4,000 on the street.[38]

[35] The total includes the amounts paid by Part D sponsors, the Government, and by or on behalf of beneficiaries.

[36] DEA, *Briefs and Backgrounds: Fentanyl*. Accessed at http://www.justice.gov/dea/concern/fentanyl.html#fentanyl on September 27, 2011.

[37] DEA, *Oxycodone*. Accessed at http://www.deadiversion.usdoj.gov/drugs_concern/oxycodone/oxycodone.pdf on June 6, 2012.

[38] DOJ, National Drug Intelligence Center, *OxyContin Diversion and Abuse*, January 2001. Accessed at http://www.justice.gov/ndic/pubs/651/abuse.htm on November 10, 2011.

Table 1: Refills of Schedule II Drugs Paid by Medicare Part D, 2009

Drug Name	Number of Refills	Percentage of All Schedule II Refills	Total Amount Paid
Fentanyl	123,102	31%	$11,624,163
Oxycodone-acetaminophen	80,202	20%	$852,634
Morphine sulphate	45,580	11%	$1,565,523
Oxycodone HCl	42,063	11%	$2,121,718
OxyContin	20,522	5%	$4,432,056
Methadone HCl	19,592	5%	$254,755
Oxycodone HCl-acetaminophen	14,034	4%	$698,090
Methadone insensol	14,020	4%	$230,683
Hydromorphine HCl	10,134	3%	$353,840
Endocet	6,911	2%	$339,387
Other drugs	21,043	5%	$2,098,310
Total	**397,203**	**100%***	**$24,571,159**

*Total does not equal 100 percent because of rounding.
Source: OIG analysis of Part D data, 2012.

Some of these drugs may have been inaccurately billed

A total of 12,356 pharmacies billed for refills of Schedule II drugs in 2009.[39] Six percent of these pharmacies were long-term-care pharmacies. These pharmacies billed for 75 percent of the Schedule II refills. In comparison, retail pharmacies billed for 17 percent of the Schedule II refills.[40] Long-term-care pharmacies billed for more refills on average than other types of pharmacies. On average, long-term-care pharmacies billed for 423 refills each, while retail pharmacies billed for 6 each.

It is possible that some long-term-care pharmacies incorrectly billed these drugs as refills when the drugs were actually dispensed as partial fills. Partial fills for Schedule II drugs are allowed for beneficiaries in long-term-care facilities when certain conditions are met. For example, if a physician prescribes a 28-day supply of a Schedule II drug, the pharmacy

[39] These pharmacies represent 20 percent of all pharmacies and 44 percent of long-term-care pharmacies that billed for Schedule II drugs in 2009.

[40] The remaining refills were billed by other types of pharmacies, which included mail-order, institutional, and home-infusion pharmacies.

does not have to dispense all 28 days at one time. Instead, it can dispense four 7-day supplies or two 14-day supplies.

The data from long-term-care pharmacies provide further evidence that these refills may have actually been partial fills. Notably, the Schedule II drugs billed as refills were often for shorter supplies than nonrefills of Schedule II drugs. For example, 82 percent of Schedule II drugs billed as refills were for less than a month's supply, while 42 percent of nonrefills were for less than a month's supply.

CMS officials noted that, according to their industry contacts, long-term-care pharmacies do not have a consistent approach to billing partial fills. They further explained that long-term-care pharmacies may bill partial fills differently depending upon the sponsor they are billing and the software they use.

Inaccurate billing of partial fills as refills raises several concerns. First, beneficiaries may be paying multiple copayments instead of one for these drugs. If the beneficiary receives the low-income cost-sharing subsidy, the Government pays these additional costs.[41] Second, incorrect billing affects the accuracy of PDE data. As noted earlier, four recent OIG audits found problems with the accuracy of PDE data.[42] These audits found that the sponsors did not have adequate controls to ensure the accuracy of the PDE data they submitted to CMS. Data accuracy is important because it is the basis on which sponsors are paid. Also, sponsors, CMS, and OIG use PDE data to detect and prevent fraud, waste, and abuse. Poor data can hinder these efforts.

Over 25,000 of the Schedule II drugs billed as refills had invalid prescribers

Medicare paid for 25,836 refills of Schedule II drugs that did not have valid prescriber information. As noted earlier, Schedule II drugs cannot be dispensed without a prescription that contains the name, address, and signature of the prescriber. These refills accounted for 7 percent of

[41] Most beneficiaries are responsible for paying certain costs, such as coinsurance, under Part D. However, certain low-income beneficiaries are eligible to receive assistance to pay some or all of these costs. The low-income cost-sharing subsidy refers to the Government's portion of cost-sharing payments for these beneficiaries.

[42] OIG, *Review of Medicare Part D Prescription Drug Event Data for Schedule II Drugs at Health Net, Inc.*, A-09-10-02046, September 2011. OIG, *Review of Medicare Part D Prescription Drug Event Data for Schedule II Drugs at CVS Caremark Corporation*, A-09-11-02074, February 2012. OIG, *Review of Medicare Part D Prescription Drug Event Data for Schedule II Drugs at Hawaii Medical Services Association*, A-09-11-02028, December 2011.

Schedule II refills billed. Medicare Part D paid a total of $1.4 million for these refills.

Specifically, 2,360 of the Schedule II refills billed had no prescriber number. Another 11,491 had numbers that had not been assigned to a provider, such as "AB0000000." The remaining 11,985 listed the identification numbers of pharmacies, not the numbers of individual prescribers.

Being able to identify the prescriber helps ensure that Schedule II drugs are prescribed and dispensed properly. When the prescriber number is unknown or invalid, it creates significant vulnerabilities and hinders efforts by sponsors, CMS, and OIG to safeguard the program. CMS has recently made several changes to ensure that prescriber numbers are valid. As of January 2012, CMS required sponsors to ensure that the prescriber identifiers on the PDE records are active and valid.

Overall, in 2009, 38,979 prescribers were associated with Schedule II drugs billed as refills. Most of these prescribers were associated with one or two refills each; however, a number were associated with hundreds of refills.

Three-quarters of Part D sponsors paid for Schedule II drugs billed as refills

In total, 270 Part D sponsors paid for at least one Schedule II drug in 2009. Of these, 194 paid for Schedule II drugs billed as refills. Each of these sponsors paid for between 1 and 81,576 refills. Twenty-four sponsors paid for more than 1,000 Schedule II refills each; three of these sponsors were responsible for almost half of all Schedule II refills billed.

These findings indicate that many sponsors do not have adequate controls to prevent refills of Schedule II drugs. As noted earlier, recent audits of three sponsors found that these sponsors did not have controls to prevent these refills.

CONCLUSION AND RECOMMENDATIONS

Federal law prohibits the refilling of Schedule II drugs. Despite this, Medicare Part D inappropriately paid $25 million for Schedule II drugs billed as refills in 2009. Some of these drugs may have been incorrectly billed. In addition, we found that numerous refills of Schedule II drugs had invalid prescribers, despite requirements that Schedule II drugs cannot be dispensed without a prescription that contains the name, address, and signature of the prescriber. Further, three-quarters of all sponsors paid for Schedule II drugs billed as refills, indicating that many sponsors do not have adequate controls to prevent these refills.

These findings raise a number of concerns. Under no circumstances should Medicare pay for refills of Schedule II drugs. Paying for such drugs raises public health concerns and may contribute to the diverting of controlled substances and their being resold on the street. The findings also raise questions about the accuracy of Part D data. Data accuracy is important because it is the basis on which sponsors are paid and CMS, OIG, and others use the data to detect and prevent fraud, waste, and abuse in Part D. Also, if some of these refills are actually partial fills and are not accurately billed as such, beneficiaries and the Government may be overpaying for copayments.

We recommend that CMS:

Issue Guidance to Sponsors To Prevent Billing of Schedule II Refills and To Ensure Accurate Billing of Partial Fills

CMS should work with sponsors and pharmacies to determine why many sponsors do not have controls to prevent refills and why certain pharmacies, particularly long-term-care pharmacies, are billing for Schedule II refills.

CMS should use this information to develop guidance to sponsors to prevent Schedule II refills and to ensure accurate billing of partial fills. The guidance should clarify what controls sponsors need to have and how to bill for partial fills, including how to bill for copayments so that beneficiaries are not overcharged and the Government does not overpay for these drugs.

Exclude Schedule II Refills When Calculating Payments to Sponsors

CMS should put edits in place to identify refills of Schedule II drugs submitted by sponsors. CMS should exclude these PDE records when calculating its final payments to sponsors at the end of each year.

Monitor Sponsors To Ensure That They Validate Prescriber Numbers for Schedule II Drugs

CMS has made a number of recent changes to ensure that prescriber identification numbers are valid. Beginning in 2012, sponsors must validate the prescriber number on the claim and confirm that the controlled substance is consistent with the schedule of drugs that the provider is allowed to prescribe. CMS should monitor sponsors closely to ensure that they are complying with the new requirements.

Follow Up on Sponsors and Pharmacies With High Numbers of Refills

In a separate memorandum, we will refer the sponsors and pharmacies with high numbers of Schedule II refills to CMS for appropriate action.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with one of our recommendations and partially concurred with the other three. In addition, CMS stated that it is highly likely that OIG is misinterpreting partial fills dispensed to patients in long-term-care facilities as refills of Schedule II drugs. In response, we note that this is not an issue of misinterpretation of the data; the data clearly show that these Schedule II drugs were billed as refills. We cannot assume that all drugs billed as refills by long-term-care pharmacies are partial fills, especially when the claims data offer no evidence to that effect. We further note that not all long-term-care pharmacies bill for Schedule II refills. As a result, we acknowledge in the report that some long-term-care pharmacies may be incorrectly billing these drugs as refills; however, under no circumstances should CMS pay for Schedule II drugs that are billed as refills.

CMS concurred with our recommendation to monitor sponsors to ensure that they validate prescriber numbers for Schedule II drugs. CMS stated that it began validating the format of the prescriber identifiers that are coded as NPIs and will exclude from payment reconciliation PDEs with invalid NPIs.

CMS partially concurred with our recommendation to issue guidance to sponsors to prevent billing of Schedule II refills and to ensure accurate billing of partial fills. CMS stated that it has already provided guidance regarding partial fills and will consider releasing further guidance with respect to copayments on partial fills, if it is determined to be necessary. CMS did not agree to work with individual sponsors and pharmacies to determine why sponsors do not have controls to prevent such refills; it will instead explore the use of PDE edits to prevent such billing practices.

CMS partially concurred with our recommendation to exclude Schedule II refills when calculating payments to sponsors. It agreed that edits should be in place to prevent billing of Schedule II drugs as refills and that it will explore modifying PDE edits to alert Part D sponsors to inappropriate refills of Schedule II drugs. CMS did not agree with excluding Schedule II drugs billed as refills when calculating payments to sponsors. It stated that it will cite the results of this report in guidance to plans and, as indicated above, will examine placing PDE edits to alert sponsors to inappropriate refills, which should eliminate any future reconciliation issues associated with the billing of Schedule II drugs as refills.

Lastly, CMS partially concurred with our recommendation to follow up with sponsors and pharmacies with high numbers of refills. CMS agreed

that it should follow up with industry through NCPDP to determine whether there is another acceptable use of the standard that could be used to distinguish legally dispensed partial fills of Schedule II drugs in long-term care from illegally dispensed refills. If there is, CMS will explore options for either encouraging or requiring the use of that alternative process to improve controls over fraud, waste, and abuse.

We support CMS's efforts to address these issues. For the full text of CMS's comments, see Appendix A.

APPENDIX A

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs

200 Independence Avenue SW
Washington, DC 20201

DATE: AUG 0 2 2012

TO: Daniel R. Levinson
Inspector General

FROM: Marilyn Tavenner /S/
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills" (OEI-02-09-00605)

Thank you for the opportunity to review and comment on this OIG draft report to determine the extent to which Medicare Part D paid for Schedule II drugs billed as refills in 2009. The Centers for Medicare & Medicaid Services (CMS) appreciates the OIG's concern for the potential fraud and abuse associated with Schedule II drugs. Nevertheless, CMS is concerned that the OIG's interpretation of prescription drug event (PDE) data does not support its finding that Medicare inappropriately paid for Schedule II drugs billed as refills. Given the known limitation of the National Council of Prescription Drug Program (NCPDP) electronic pharmacy billing standard (the HIPAA standard) for billing partial fills of Schedule II drugs appropriately dispensed to patients in long-term care facilities, it is highly likely that OIG is misinterpreting partial fills dispensed to long-term care facility residents as refills of Schedule II drugs.

In long-term care facilities, 21 C.F.R. 1306.13(b) allows for the partial filling of prescription Schedule II drugs in order to reduce the quantity of drugs on hand. However, the dispensing status field on the NCPDP electronic pharmacy billing standard may not be used to indicate this type of partial fill for Schedule II drugs. The standard limits the use of this field to situations where inventory shortages do not allow the full quantity to be dispensed. Use of this field in contravention of the standard would be a Health Insurance Portability and Accountability Act (HIPAA) violation. Consequently, pharmacies use the fill number field to distinguish multiple partial fills of Schedule II controlled substances in long-term care for billing purposes (to avoid rejection as a duplicate claim) and, therefore, the fill number cannot be relied upon to identify illegal refills.

The OIG reports that "refills" of Schedule II drugs were identified using the fill number field on the PDE record. The PDE data show that 75 percent of these claims in question were billed by long-term care pharmacies. As discussed above, we believe these claims more likely represent legally dispensed partial fills as opposed to illegal refills. The OIG also reports that retail pharmacies billed for 17 percent of the claims in question. Yet, we point out that these could still represent partial fills for patients in long-term care facilities. Although a national provider

identifier (NPI) maybe used to identify a retail pharmacy, many such pharmacies also service patients in long-term care and, consequently, appropriately dispense partial fills for Schedule II drugs to these patients. For these reasons, we do not believe that the OIG methodology using fill number and pharmacy NPIs reported on PDEs supports a finding that pharmacies illegally dispensed, or that Medicare inappropriately paid for $25 million in refills out of the total $2.2 billion in payments for Schedule II drugs in 2009.

OIG Recommendation

The CMS should issue guidance to sponsors to prevent billing of Schedule II refills and to ensure accurate billing of partial fills. CMS should work with sponsors and pharmacies to determine why many sponsors do not have controls to prevent refills and why certain pharmacies, particularly long-term care pharmacies, are billing for Schedule II refills. CMS should issue guidance to sponsors to prevent billing of Schedule II refills and to ensure accurate billing of partial fills.

CMS Response

The CMS partially concurs with the OIG's recommendation that CMS issue guidance to Part D sponsors to prevent billing of Schedule II refills and to ensure accurate billing of partial fills. CMS has already provided guidance regarding partial fills. In the "Prescription Drug Event Participation Guide – 2011 Regional IT Technical Assistance," CMS instructs that if plans accept partial and complete claims from pharmacies, plans should combine the partial and complete claims and report a single PDE summarizing both billing transactions. If a plan prematurely reports a PDE based on a partial fill only, the plan must adjust the PDE if the completion billing transaction is subsequently received. This guidance is used by the PDE submitters, typically the sponsor's contracted Pharmacy Benefit Manager (PBM). CMS recognizes, however, that this guidance may not be applicable for this issue and will consider releasing additional guidance with respect to copayments on partial fills if it is determined to be necessary.

The CMS also believes that outreach to the individual sponsors and pharmacies is not an efficient use of resources. As such, CMS does not concur with the OIG's recommendation that CMS work with the individual sponsors and pharmacies to determine the reason why sponsors do not have controls to prevent refills of Schedule II drugs and determine why pharmacies are refilling Schedule II drugs. CMS, instead, will explore the use of PDE edits to prevent such billing practices as described below.

OIG Recommendation

The CMS should exclude Schedule II refills when calculating payments to sponsors. CMS should put edits in place to identify refills of Schedule II drugs submitted by sponsors. CMS should exclude Schedule II refills when calculating payments to sponsors.

CMS Response

The CMS partially concurs with this recommendation. CMS concurs with the OIG that edits should be in place to prevent the billing of Schedule II drugs as refills and will explore modifying PDE edits to alert Part D sponsors to inappropriate refills of Schedule II drugs. However, there are technical issues that may prevent establishing a full reject edit. CMS has begun the process of developing code and examining the various technical issues that could limit our PDE editing.

The CMS does not concur with excluding Schedule II drugs billed as refills when calculating payments to sponsors. First, this OIG provides no proof that these PDEs should be rejected. As we have already stated, we believe these claims more likely represent legally dispensed partial fills as opposed to illegal refills, thus the plans payments were legitimate. Furthermore, the OIG assumes that its findings have reconciliation implications, but the report does not provide that evidence. Without a PDE analysis to determine reconciliation implications, CMS will not exclude Schedule II drugs billed as refills when calculating payments to sponsors. CMS will, however, cite the results of this report in guidance to plans requiring the submission of adjustment or deletion PDEs to be submitted when appropriate. Once that is done, reconciliation implications can be assessed. Moreover, as indicated above, CMS will examine placing PDE edits to alert part D sponsors to inappropriate refills of Schedule II drugs. This should eliminate any future reconciliation issues associated with the billing of Schedule II drugs as refills.

OIG Recommendation

The CMS should monitor sponsors to ensure they validate prescriber numbers for Schedule II drugs.

CMS Response

The CMS concurs with the OIG that sponsors submit valid prescriber numbers. In its recommendations, the OIG noted that CMS made recent changes to ensure that the prescriber identifiers are valid. The OIG recommends that CMS monitor the sponsors closely to ensure that they are complying with the requirements. On January 1, 2012, CMS began validating the format of the prescriber identifiers on the PDEs that are coded as National Provider Identifiers (NPI) and will exclude from payment reconciliation PDEs with invalid NPIs. CMS uses data from the National Plan & Provider Enumeration System (NPPES) for validation of the NPI and to verify that the NPI is valid on the date of service on the PDE. If sponsors submit invalid NPIs, the PDE will be rejected ensuring that sponsors comply with the NPI requirements.

OIG Recommendation

The CMS follow up on sponsors and pharmacies with high numbers of refills.

CMS Response

The CMS partially concurs with this recommendation. While we do not believe the OIG methodology supports a finding that pharmacies illegally dispensed, or that Medicare inappropriately paid for refills of Schedule II drugs, we agree that we should follow-up with industry through NCPDP to determine if there is another acceptable use of the standard that could be used to distinguish legally dispensed partial fills of Schedule II drugs in long-term care from illegally dispensed refills. If there is, we will explore our options for either encouraging or requiring the use of that alternative process to improve controls over fraud, waste and abuse.

Thank you for the opportunity to review and comment on the draft OIG report.

ACKNOWLEDGMENTS

This report was prepared under the direction of Jodi Nudelman, Regional Inspector General for Evaluation and Inspections in the New York regional office, and Nancy Harrison and Meridith Seife, Deputy Regional Inspectors 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 the report include Jenell Clarke and Jason Kwong; central office staff who contributed include Eddie Baker, Jr., Kevin Farber, Meghan Kearns, Debra Roush, and Rita Wurm.

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.