Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

RETAIL PHARMACIES WITH QUESTIONABLE PART D BILLING

Daniel R. Levinson
Inspector General

May 2012
OEI-02-09-00600

EXECUTIVE SUMMARY: RETAIL PHARMACIES WITH QUESTIONABLE PART D BILLING
OEI-02-09-00600

WHY WE DID THIS STUDY

Under the Medicare Part D program, the Centers for Medicare & Medicaid Services (CMS) contracts with private insurance companies, known as sponsors, to provide prescription drug coverage to beneficiaries who choose to enroll. In the 6 years since Part D began, the Office of Inspector General (OIG) has issued several reports that found that Part D had limited safeguards in place.

HOW WE DID THIS STUDY

We based this study on an analysis of prescription drug event records. Sponsors submit these records to CMS for each prescription dispensed to beneficiaries enrolled in their plans. Each record contains information about the pharmacy, prescriber, beneficiary, and drug. We analyzed all of the records for prescriptions billed by retail pharmacies in 2009. We developed eight measures to describe Part D billing and to identify pharmacies with questionable billing.

WHAT WE FOUND

Retail pharmacies each billed Part D an average of nearly $1 million for prescriptions in 2009. Over 2,600 of these pharmacies had questionable billing. These pharmacies had extremely high billing for at least one of the eight measures we developed. For example, many pharmacies billed extremely high dollar amounts or numbers of prescriptions per beneficiary or per prescriber. This could mean that a pharmacy is billing for drugs that are not medically necessary or were never provided to the beneficiary. Although some of this billing may be legitimate, pharmacies that bill for extremely high amounts warrant further scrutiny. The Miami, Los Angeles, and Detroit areas were the most likely to have pharmacies with questionable billing.

WHAT WE RECOMMEND

Together, the findings of this report and prior OIG reports call for a strong response to improve Part D oversight. Therefore, we recommend that CMS: (1) strengthen the Medicare Drug Integrity Contractor's monitoring of pharmacies and ability to identify pharmacies for further review, (2) provide additional guidance to sponsors on monitoring pharmacy billing, (3) require sponsors to refer potential fraud and abuse incidents that may warrant further investigation, (4) develop risk scores for pharmacies, (5) further strengthen its compliance plan audits, and (6) follow up on the pharmacies identified as having questionable billing. CMS concurred with four of the recommendations and partially concurred with the other two.

TABLE OF CONTENTS

OBJECTIVES

1. To describe Part D billing by retail pharmacies in 2009.
2. To identify retail pharmacies with questionable Part D billing in 2009.

BACKGROUND

The Medicare Part D program provides an optional prescription drug benefit to Medicare beneficiaries.[1] 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 in the program. In 2010, approximately 35 million beneficiaries were enrolled.[2]

In the 6 years since Part D began, the Office of Inspector General (OIG) and others have raised concerns about Part D billing. In several reports, OIG found that the program has limited safeguards in place and is vulnerable to fraud, waste, and abuse.[3]

Additionally, recent investigative cases have illustrated a variety of alleged fraud schemes by pharmacies. For example, a pharmacist who owned 26 pharmacies was charged with health care fraud and drug diversion. The owner allegedly paid physicians to write prescriptions that were medically unnecessary and to direct patients to fill them at his pharmacies. The pharmacies purportedly billed $37.7 million to Medicare.[4] In another case, the owners of two pharmacies were charged with fraudulently billing Part D for $3 million for drugs that were never purchased by their pharmacies or dispensed to beneficiaries.[5]

Concerns about program vulnerabilities have been further heightened by the growing prescription drug abuse problem in the Nation. The number

[1] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173.

[2] The Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, *2011 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medicare Insurance Trust Funds*, p. 9. Accessed at https://www.cms.gov/ReportsTrustFunds/downloads/tr2011.pdf on June 28, 2011.

[3] Examples include OIG, *Medicare Drug Plan Sponsors' Identification of Potential Fraud and Abuse*, OEI-03-07-00380, October 2008; and OIG, *Medicare Drug Integrity Contractors' Identification of Potential Part D Fraud and Abuse*, OEI-03-08-00420, October 2009.

[4] United States Attorney's Office, Eastern District of Michigan, *Twenty-six Indicted in Drug Distribution Investigation That Led to Uncovering Massive Health Care Fraud*, August 2, 2011. Accessed at http://www.justice.gov/usao/mie/news/2011/2011_8_2_bpatel.html on August 4, 2011.

[5] Department of Justice, *Two Brooklyn, New York Pharmacists Charged in $3 Million Health Care Fraud Scheme*, July 26, 2011. Accessed at http://www.justice.gov/opa/pr/2011/July/11-crm-970.html on November 14, 2011.

of accidental deaths caused by prescription painkillers each year has increased substantially since 2000.[6] In 2007, more people died from overdoses of prescription painkillers, such as oxycodone, than from cocaine and heroin combined.[7]

Despite these concerns, little information is currently available about Part D billing. There are no data about how pharmacies typically bill Part D, or about questionable billing. Identifying these data is an important first step in detecting potential fraud, waste, and abuse.

This study provides a first look at Part D billing by pharmacies nationwide. It is part of the Health Care Fraud Prevention and Enforcement Action Team Initiative (HEAT), which focuses on detecting health care fraud through innovative data analysis and enhanced cooperation between the Department of Justice, OIG, and CMS.[8]

Medicare Part D

Medicare beneficiaries who choose to participate in the Part D program enroll in one of many plans offered by Part D sponsors. The sponsors may contract directly with pharmacies or they may contract with third-party entities, such as pharmacy benefit managers (PBM), which contract with pharmacies on the sponsors' behalf.[9] Pharmacies include retail, long-term-care, and mail-order; they may be independently owned or part of a chain. Retail pharmacies are the most common type of pharmacy participating in Part D. Currently, almost all retail pharmacies in the Nation participate in Part D.[10]

Types of Part D Fraud and Abuse

CMS has identified a number of potential pharmacy fraud schemes.[11] Many of these schemes include inappropriate billing practices, such as billing for nonexistent prescriptions, billing for brand-name drugs when

---

[6] Centers for Disease Control and Prevention (CDC), Office of the Director, *Public Health Grand Rounds*, February 17, 2011, p. 10. Accessed at http://www.cdc.gov/about/grand-rounds/archives/2011/pdfs/PHGRRx17Feb2011.pdf on July 12, 2011.

[7] 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.

[8] U.S. Department of Health and Human Services and U.S. Department of Justice, *HEAT Task Force Success*. Accessed at http://www.stopmedicarefraud.gov/heattaskforce/index.html on January 11, 2011.

[9] PBMs can provide a number of other services to sponsors, including processing prescription drug claims and managing formularies.

[10] OIG, *Retail Pharmacy Participation in Medicare Part D Prescription Drug Plans in 2006*, OEI-05-06-00320, June 2007.

[11] CMS, *Prescription Drug Benefit Manual Chapter 9 – Part D Program to Control Fraud, Waste, and Abuse*, April 2006. Accessed at http://www.cms.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf on June 28, 2011.

generics were dispensed, and billing for prescriptions that were never picked up. Other schemes include drug diversion and kickbacks. Drug diversion occurs when a pharmacy dispenses a prescription drug for inappropriate or illegal purposes. A kickback occurs when a pharmacy pays a prescriber to write or a beneficiary to fill an unnecessary prescription that is billed to Medicare.

These schemes have often involved Schedule II or III controlled substances. Schedule II drugs have a high potential for abuse and may lead to severe psychological or physical dependence if abused.[12] They include drugs such as oxycodone and morphine. Federal law prohibits the refilling of prescriptions for Schedule II drugs. Schedule III drugs also have potential for abuse and include anabolic steroids, codeine with hydrocodone, and barbiturates.

Detecting and Deterring Fraud and Abuse

CMS relies on sponsors to help safeguard the Part D program from fraud and abuse. CMS requires sponsors to have compliance plans that contain measures to detect, prevent, and correct fraud, waste, and abuse.[13] As part of these plans, CMS expects that sponsors will monitor their contractors and subcontractors, including pharmacies.[14] CMS also recommends that sponsors use data analysis to detect and prevent fraud, waste, and abuse.[15] Specifically, sponsors should use data analysis to recognize unusual trends and identify problem areas and to target their audits of contractors and subcontractors, including pharmacies.

Additionally, CMS contracts with two Medicare Drug Integrity Contractors (MEDIC) to help identify vulnerabilities in the Part D program. 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

---

[12] These are drugs regulated by the Controlled Substances Act, which established five schedules based on the medical use and the potential for abuse. The most restrictive is Schedule I, which includes drugs that have no currently accepted medical use and a high potential for abuse. Schedule V is the least restrictive. See 21 U.S.C. §§ 801-971.

[13] 42 CFR § 423.504(b)(4)(vi).

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

[15] CMS, *Prescription Drug Benefit Manual Chapter 9 – Part D Program to Control Fraud, Waste and Abuse § 50.2.6.2*, April 2006. Accessed at http://www.cms.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf on July 19, 2011.

MEDIC's responsibilities include performing special studies and providing technical assistance to CMS.

CMS is responsible for overseeing the sponsors and MEDICs. CMS conducts onsite audits of sponsors' compliance plans to assess the effectiveness of their fraud and abuse programs. CMS evaluates MEDICs' performance annually.

Related Work

In a 2008 report, OIG found that in the first 6 months of 2007, 24 of the 86 sponsors did not identify any potential fraud and abuse incidents.[16] Of the incidents that were reported, inappropriate billing, such as submitting claims for drugs that were not provided, was the most common. OIG recommended that CMS determine why certain sponsors had identified especially high or low volumes of potential fraud and abuse incidents and determine whether sponsors were initiating inquiries and corrective actions, as required. CMS concurred with these two recommendations.

In another 2008 report, OIG found that although CMS relied partly on audits to oversee sponsors' compliance plans, CMS had conducted only one such audit in 2007.[17] OIG recommended that CMS conduct routine audits of sponsors' compliance plans to verify that they meet all Federal requirements. CMS concurred with this recommendation and stated that it would begin compliance plan audits in 2007 and that sponsors would be accountable for meeting all requirements.

In 2009, OIG issued a report that highlighted vulnerabilities in the MEDICs' ability to identify Part D fraud and abuse.[18] Specifically, the report found that the MEDICs did not typically use proactive data analysis, such as identifying pharmacies that billed the highest Part D amounts, to detect potential fraud and abuse. The report also found that the MEDICs may not be aware of some potential fraud and abuse incidents because sponsors are not required to refer them to the MEDICs. OIG recommended that CMS ensure that the MEDICs have access to accurate and comprehensive data and require sponsors to report all incidents that are referred to law enforcement to MEDICs as well. CMS concurred with these recommendations, but stated that it did not have the regulatory basis to require sponsors to report such incidents.

---

[16] OIG, *Medicare Drug Plan Sponsors' Identification of Potential Fraud and Abuse*, OEI-03-07-00380, October 2008.

[17] OIG, *Oversight of Prescription Plan Sponsors' Compliance Plans*, OEI 03-08-00230, October 2008.

[18] OIG, *Medicare Drug Integrity Contractors' Identification of Potential Part D Fraud and Abuse*, OEI-03-08-00420, October 2009.

METHODOLOGY

This study is based on an analysis of prescription drug event (PDE) records for all Part D drugs billed by retail pharmacies in 2009. We matched these records to data from the National Council of Prescription Drug Programs (NCPDP) and First DataBank to obtain descriptive information about the pharmacies and drugs, respectively.

PDE Data

We first identified all PDE records with dates of service from January 1 to December 31, 2009, for covered Part D drugs.[19] In total, we identified 1.07 billion PDE records. Sponsors submit a record, called a PDE, to CMS for each prescription dispensed to beneficiaries enrolled in their plans. Each PDE record contains information about the drug and beneficiary, as well as identification numbers for the pharmacy and prescriber.

To determine which PDE records were billed by retail pharmacies, we used the National Provider Identifier (NPI) for each pharmacy and matched the PDE records to the NCPDP database. [20] This database contains descriptive information about each pharmacy, including its address, the type of pharmacy (e.g., retail), and ownership status (e.g., chain).[21] We identified 59,307 retail pharmacies that billed a total of 873.3 million PDE records.[22] These records represented 82 percent of all PDE records and 90 percent (59,307 of 65,888) of all pharmacies that billed Part D in 2009. Other types of pharmacies billed the remaining 196.2 million records. They included long-term-care pharmacies, mail-order pharmacies, and home infusion pharmacies. We excluded these pharmacies from our analysis because they offer different services and, therefore, may have billing patterns that are different from those of retail pharmacies.

[19] We used 2009 data because they were the most current full year of data available when we started the review.

[20] For almost all PDE records, the NPI of the pharmacy was included on the PDE record either by the sponsor or by CMS. We excluded 0.1 percent of the PDE records from our analysis because the NPI was missing, we could not determine whether the pharmacy that submitted the record was a retail pharmacy, or the pharmacy had multiple locations in the NCPDP.

[21] For the purposes of the report, we used the definitions of retail, chain, and independent pharmacies from the NCPDP. Accordingly, retail pharmacies are those in which the pharmacists store, prepare, and dispense prescription drugs for local patient populations. Chain pharmacies are part of a group of four or more pharmacies under common ownership. Independent pharmacies are one to three pharmacies under common ownership. We included franchise pharmacies with independent pharmacies because they are independently owned.

[22] We did not include 272 retail pharmacies that were alternate dispensing sites or Government pharmacies because they do not typically serve the public.

Using the National Drug Code on the PDE record, we matched the 873.3 million PDE records to data from First DataBank. First DataBank contains information about each drug, such as the drug name and whether the drug is brand name or generic.[23] It also indicates whether a drug is a controlled substance and, if so, which schedule the drug is on (Schedule II or III). For the purposes of this study, we use the term "prescription" to mean one PDE record.

Measures of Pharmacy Billing

We calculated the total dollar amount and total number of prescriptions billed to Part D by retail pharmacies in 2009. [24] We also calculated the total number of beneficiaries who received Part D drugs from retail pharmacies in 2009 and the total number of prescribers who ordered these drugs.[25] We then calculated the number of different types of drugs billed by retail pharmacies. For this analysis, we considered a type of drug to include all drugs with the same name, regardless of dosage or strength.

Next, we developed eight measures to describe Part D billing and identify pharmacies with questionable billing. We developed these measures based on the results of past OIG analysis and fraud investigations of pharmacies, as well as input from CMS and contractor staff.

The eight measures are:

(1) average amount billed per beneficiary,

(2) average number of prescriptions per beneficiary,

(3) average amount billed per prescriber,

(4) average number of prescriptions per prescriber,

(5) percentage of prescriptions that were for Schedule II drugs,

(6) percentage of prescriptions that were for Schedule III drugs,

(7) percentage of prescriptions that were for brand-name drugs, and

---

[23] First DataBank determines whether a drug is brand name or generic based on the drug's name.

[24] To calculate the total Part D amount billed, we summed three fields on the PDE records that represent the total gross drug costs: ingredient cost, dispensing fee, and sales tax.

[25] To calculate the total number of beneficiaries, we identified the Health Insurance Claim Number (HICN) associated with each PDE record. To calculate the total number of prescribers, we identified the NPI for the prescriber on each PDE record. Because the PDE record can contain different types of identification numbers, such as an NPI or a Drug Enforcement Administration (DEA) number, we used a crosswalk developed by OIG analysts to identify the NPI associated with each prescriber identification number. We were able to identify the NPIs for 97 percent of the PDE records. For the remaining 3 percent, we used the alternative prescriber identification numbers included on the PDE records.

(8) percentage of prescriptions that were refills.[26]

We calculated these eight measures for each pharmacy. We then analyzed the distribution of all pharmacies for each measure and calculated the national averages for retail pharmacies.[27]

Identification of Pharmacies With Questionable Billing

For each measure discussed above, we set a threshold that indicated a pharmacy had billed an extremely high amount.[28] We used a standard technique for identifying outliers, known as the Tukey method.[29] Using this method, we set the threshold for each measure at the 75th percentile plus three times the interquartile range.[30] Values that exceeded these thresholds are extreme outliers. We considered all pharmacies that exceeded one or more of these thresholds to have questionable billing.

Lastly, we determined whether the pharmacies with questionable billing shared certain characteristics. Specifically, we determined the proportion of pharmacies with questionable billing that were independent and the proportion that were part of a chain. We also determined whether the pharmacies with questionable billing were concentrated in certain metropolitan areas. To do this, we identified each pharmacy's Core Base Statistical Area (CBSA) based on the pharmacy's address. A CBSA is a region around an urban center that has at least 10,000 people.[31] CBSAs include the entire metropolitan area, not just the urban center. For example, the New York metropolitan area includes counties in New York and New Jersey. We focused our analysis on the 52 CBSAs that had at least 250 pharmacies because we wanted to concentrate on large metropolitan areas. These 52 CBSAs included 47 percent of all retail pharmacies nationwide that billed Part D in 2009. We then determined the

---

[26] Each PDE record indicates whether the drug is a refill.

[27] The average number of prescriptions per beneficiary represents the average number of prescriptions one pharmacy billed per beneficiary. It does not represent the average number of prescriptions that each beneficiary received because beneficiaries can go to multiple pharmacies.

[28] We focused our analysis of questionable billing on pharmacies that billed for at least 100 PDE records and were paid at least $100,000 for Part D drugs in 2009. In total, 3,344 retail pharmacies did not meet these criteria. We also identified 163 retail pharmacies that reported providing some specialty pharmacy services. Specialty pharmacies generally dispense high-cost drugs to patients with chronic, complex illnesses. Because we could not determine whether differences in their billing were due to their specialty services, we excluded them from this analysis. A total of 55,963 pharmacies and 870.9 million PDE records were included in this analysis.

[29] See J.W. Tukey, *Exploratory Data Analysis*. Addison-Wesley, 1977.

[30] The interquartile range is calculated by subtracting the value at the 25th percentile from the value at the 75th percentile.

[31] U.S. Census Bureau, *Metropolitan and Micropolitan Statistical Areas*. Accessed at http://www.census.gov/population/www/metroareas/aboutmetro.html on March 3, 2011.

proportion of pharmacies in each CBSA that had questionable billing and identified the CBSAs with the highest proportions. For these areas, we also calculated the percentage of pharmacies with questionable billing that billed extremely high numbers or amounts for each measure. We also determined the types of drugs these pharmacies billed most frequently.

Limitations

We did not independently verify the accuracy of the PDE records or the data from the NCPDP or First DataBank. We based our analysis on the pharmacy type that each pharmacy reported in the NCPDP. As a result, our analysis of questionable billing may contain pharmacies that neglected to report providing specialty services. Providing such services may make a pharmacy more likely to exceed certain billing thresholds.

We designed this study to identify pharmacies that warrant further scrutiny. None of the measures we analyzed confirm that a particular pharmacy is engaging in fraudulent or abusive practices. Some pharmacies may be billing extremely high amounts for legitimate reasons. For example, a pharmacy located in a rural area with few physicians may bill for an extremely high average number of prescriptions per prescriber. Alternatively, a pharmacy located next to a pain clinic may bill for an extremely high percentage of Schedule II or III drugs.

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

Retail pharmacies each billed Part D an average of nearly $1 million for prescriptions in 2009

In total, 59,307 retail pharmacies billed Medicare Part D in 2009. These pharmacies billed Part D for a total of 873.3 million prescriptions for 24.4 million beneficiaries.[32] Part D paid $56.9 billion for these prescriptions.[33]

On average, retail pharmacies billed almost $1 million each for Part D prescriptions in 2009. Half of them billed more than $750,000, while 10 percent billed more than $1.8 million. In total, retail pharmacies billed for 3,804 different types of drugs; however, some drugs were more common than others. Twenty drugs accounted for one-third of all Part D prescriptions billed. See Appendix A for more information about these drugs.

Two-thirds of the retail pharmacies that billed Part D were chain pharmacies, while one-third were independent pharmacies. In all, 39,401 chain pharmacies and 19,906 independent pharmacies billed Part D in 2009.

Retail pharmacies billed about $1,500 per beneficiary and $1,800 per prescriber, on average

As shown in Table 1, retail pharmacies billed an average of $1,576 for each beneficiary they served. On average, they served 648 beneficiaries and billed for 24 prescriptions per beneficiary. Additionally, most (90 percent) pharmacies billed for fewer than 38 prescriptions per beneficiary.

Also, as shown in Table 1, retail pharmacies billed an average of $1,818 per prescriber. They had an average of 587 prescribers and billed for an average of 28 prescriptions per prescriber. Additionally, most pharmacies billed for fewer than 54 prescriptions per prescriber.

Schedule II and III drugs were a relatively small percentage of the prescriptions billed

On average, 2 percent of each pharmacy's Part D prescriptions were for Schedule II drugs. Schedule II drugs have a high potential for abuse and may lead to severe psychological or physical addiction. The most common Schedule II drugs billed were all painkillers and included

[32] For the purposes of this report, we use the term "prescription" to mean one PDE record.

[33] This includes the amount paid by sponsors, the Government, and by, or on behalf of, beneficiaries.

oxycodone-aceteminophen, oxycodone hydrochloride, morphine sulfate, and fentanyl.

On average, 3 percent of each pharmacy's Part D prescriptions were Schedule III drugs. Schedule III drugs also have potential for abuse. The most common drugs billed were hydrocodone-acetaminophen, acetaminophen-codeine, hydrocodone bitartrate-ibuprofen, and AndroGel. See Appendix B for the most common Schedule II and III drugs billed to Part D.

Table 1: Distribution of Part D Billing by Retail Pharmacies, 2009

	National Average for Retail Pharmacies	10th Percentile*	50th Percentile	90th Percentile
Average Amount Billed per Beneficiary	$1,576	$799	$1,390	$2,333
Average Number of Prescriptions per Beneficiary	24	13	22	38
Average Amount Billed per Prescriber	$1,818	$650	$1,335	$3,232
Average Number of Prescriptions per Prescriber	28	10	21	54
Percentage of Schedule II Drugs	2.2%	0.3%	1.7%	4.2%
Percentage of Schedule III Drugs	3.1%	1.0%	2.8%	5.3%
Percentage of Brand-Name Drugs	30.9%	24.9%	30.0%	37.9%
Percentage of Refills	55.4%	40.7%	57.9%	66.8%

*The 10th percentile indicates that 10 percent of all pharmacies fell below this value. The 50th percentile (also known as the median) indicates that half of all pharmacies fell below this value. The 90th percentile indicates that 90 percent of all pharmacies fell below this value.
Note: For the purposes of this report, we considered a prescription to be one PDE record.
Source: OIG analysis of Part D data, 2011.

Brand-name drugs and refills were common

On average, almost one-third of the prescriptions pharmacies billed for were for brand-name drugs. Brand-name drugs are typically more costly than generics. Lipitor, Plavix, Nexium, and Diovan were the most common brand-name drugs in 2009. For most pharmacies, 38 percent or less of their prescriptions was for brand-name drugs. At the same time, refills accounted for 55 percent of the prescriptions billed by retail pharmacies, on average. The remaining were new prescriptions, not refills.

Over 2,600 retail pharmacies had questionable billing

In total, 2,637 retail pharmacies had questionable Part D billing. Each of these pharmacies exceeded the threshold that indicated extremely high billing for at least one of the eight measures we developed. See Table 2 for these thresholds. These pharmacies represented 4 percent of all retail pharmacies nationwide. Together, they billed $5.6 billion to Part D in 2009. While some of this billing may be legitimate, all pharmacies that bill for such extremely high amounts warrant further scrutiny.

More than one-third of the pharmacies with questionable billing exceeded the thresholds for multiple measures. Specifically, 949 pharmacies did so for 2 or more measures; 54 did so for 4 or more measures. See Appendix C.

Table 2: Number of Pharmacies That Billed Extremely High Amounts by Measure, 2009

	National Average for Retail Pharmacies	Threshold for Extremely High Amounts	Number of Pharmacies That Billed Extremely High Amounts
Average Amount Billed per Beneficiary	$1,576	$4,050	778
Average Number of Prescriptions per Beneficiary	24	66	133
Average Amount Billed per Prescriber	$1,818	$5,977	850
Average Number of Prescriptions per Prescriber	28	102	559
Percentage of Schedule II Drugs	2.2%	8.1%	871
Percentage of Schedule III Drugs	3.1%	10.1%	276
Percentage of Brand-Name Drugs	30.9%	51.5%	439
Percentage of Refills	55.4%	99.1%	6
Total Number of Pharmacies			**2,637***

*A number of pharmacies exceeded multiple thresholds. As a result, the sum does not equal 2,637.
Note: For the purposes of this report, we considered a prescription to be one PDE record.
Source: OIG analysis of Part D data, 2011.

Almost 800 pharmacies billed extremely high dollar amounts per beneficiary; a smaller number billed for an extremely high number of prescriptions per beneficiary

Although some of this billing may be legitimate, billing high dollar amounts per beneficiary or for a high number of prescriptions per beneficiary could mean that a pharmacy is billing for drugs that were not medically necessary or were never provided to the beneficiary.

As shown in Table 2, 778 pharmacies billed extremely high dollar amounts, each with an average of at least $4,050 per beneficiary. This

amount was 2½ times the national average of $1,576 per beneficiary. In one case, a pharmacy billed an average of $23,145 for each beneficiary it served.

One hundred and thirty-three pharmacies billed for an extremely high number of prescriptions per beneficiary, each with an average of at least 66 prescriptions per beneficiary. Again, this number is more than 2½ times the national average of 24. More than half of these pharmacies billed for more than 300 prescriptions for at least 1 beneficiary. One of these pharmacies billed for 946 prescriptions for a single beneficiary in 1 year.

Eight hundred and fifty pharmacies billed extremely high dollar amounts per prescriber, while 559 billed for an extremely high number of prescriptions per prescriber

Billing high dollar amounts per prescriber or billing for a high number of prescriptions per prescriber may indicate that a pharmacy has relationships with certain prescribers. Although in some cases they may be legitimate, these relationships are a concern because the pharmacy and prescriber may be working together to bill for drugs that were not medically necessary or were never provided to the beneficiary.

The 850 pharmacies that billed extremely high dollar amounts per prescriber each averaged at least $5,977 per prescriber. This amount was about three times the national average of $1,818. Some of these pharmacies billed considerably more per prescriber on average. For example, five of these pharmacies each billed more than $90,000 per prescriber.

Additionally, 559 pharmacies billed for an extremely high number of prescriptions per prescriber; each averaged at least 102 prescriptions per prescriber. This number was about 3½ times the national average of 28 prescriptions per prescriber.

For many of these 559 pharmacies, a large percentage of the prescriptions were ordered by just a few prescribers. At one third of these pharmacies, one or two prescribers ordered more than half of the prescriptions. At 1 pharmacy, a single prescriber ordered 46,868 prescriptions. In another case, a single prescriber ordered 85 percent of the 20,186 prescriptions billed by 1 pharmacy during the year.

Over 1,000 pharmacies billed for an extremely high percentage of Schedule II or III drugs, which have potential for addiction and abuse

Schedule II and III drugs have a high risk for abuse. Although there may be valid reasons why some pharmacies bill for high percentages of

Schedule II and III drugs, all of these pharmacies warrant further scrutiny. Billing for a high percentage of these drugs may indicate that a pharmacy is billing for medically unnecessary drugs, which may be used inappropriately or diverted and resold for a profit. Misuse of these drugs has serious human and financial costs.

A total of 1,067 retail pharmacies billed for Schedule II or III drugs for an extremely high percentage of their prescriptions. Specifically, 871 pharmacies billed for a high percentage of Schedule II drugs. At least 8 percent of each of these pharmacies' Part D prescriptions were for Schedule II drugs. This was four times the national average of 2 percent. The most common Schedule II drugs among these 871 pharmacies were oxycodone hydrochloride, OxyContin, morphine sulfate, and Endocet. Several pharmacies billed over half their prescriptions as Schedule II drugs. Notably, about 75 percent of one pharmacy's prescriptions were billed as Schedule II drugs, and most of these prescriptions were ordered by one physician.

In addition, 276 pharmacies billed for Schedule III drugs for a high percentage of their prescriptions. More than 10 percent of each of these pharmacies' prescriptions were Schedule III drugs. This was more than three times the national average of 3 percent. The most common Schedule III drugs among these pharmacies were hydrocodone-acetaminophen, acetaminophen-codeine, Suboxone, and Lortab. In one case, almost one-third of the pharmacy's prescriptions were for Schedule III drugs. Eighty pharmacies had an extremely high percentage of prescriptions for both Schedule II and III drugs.

Over 400 pharmacies billed for an extremely high percentage of brand-name drugs, while a few pharmacies billed for an extremely high percentage of refills

Billing for a high percentage of brand-name drugs may indicate that a pharmacy is billing for brand names but dispensing generics or is billing for prescriptions never dispensed. A high percentage of refills could mean that a pharmacy is automatically billing for refills even when beneficiaries have not requested them or is billing for prescriptions that beneficiaries never picked up.

A total of 439 pharmacies billed for brand-name drugs for an extremely high percentage of their prescriptions. More than half of each of these pharmacies' prescriptions were for brand-name drugs, compared to the national average of 31 percent. The most common brand-name drugs billed by these pharmacies were Lipitor, Plavix, and Nexium. For one pharmacy, 99 percent of its prescriptions were for brand-name drugs.

Additionally, six pharmacies billed for an extremely high percentage of refills. More than 99 percent of each of these pharmacies' prescriptions for Part D drugs were refills, compared to the national average of 55 percent. One of these pharmacies billed for 5,297 prescriptions, all of which were refills.

Examples of Questionable Part D Billing

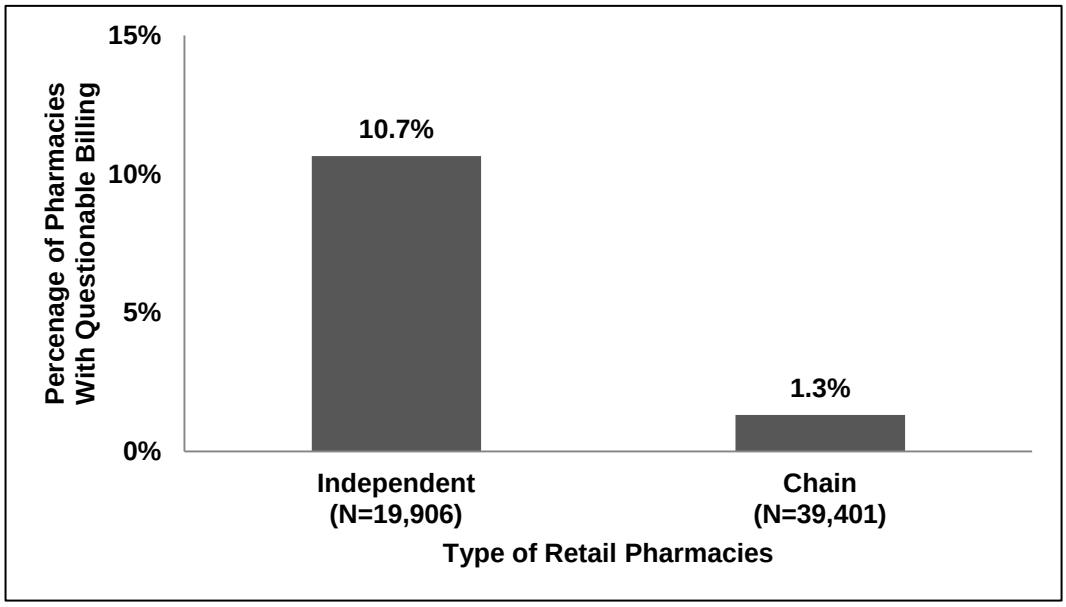
- One suburban pharmacy had particularly concerning billing. It billed more than $8.4 million to Part D in 2009, which is nine times the national average. Also, it billed for an average of 116 prescriptions per beneficiary and 132 prescriptions per prescriber. These are both almost five times the national average.
- One midwestern pharmacy billed for over 1,000 prescriptions each for 2 beneficiaries. One physician ordered almost all the prescriptions for one of these beneficiaries.
- A third pharmacy billed an average of $132,845 per prescriber, which is 73 times the national average. Virtually all of these prescriptions were for brand-name drugs.

Independent pharmacies were eight times more likely than chains to have questionable billing

Independent pharmacies were far more likely than chain pharmacies to have extremely high billing on one of more of the eight measures. As shown in Figure 1, almost 11 percent of independent pharmacies had questionable billing, compared to just over 1 percent of chain pharmacies.

Although independent pharmacies made up 34 percent of all retail pharmacies that billed Part D, they accounted for 80 percent of the pharmacies with questionable billing. Of the 2,637 pharmacies with questionable billing, 2,120 were independent.

Figure 1: Percentage of Independent and Chain Pharmacies With Questionable Billing, 2009



Source: OIG analysis of Part D data, 2011.

The Miami, Los Angeles, and Detroit areas were the most likely to have pharmacies with questionable billing

Certain metropolitan areas had a higher percentage of pharmacies with questionable billing than the Nation, which had 4 percent. The percentage of pharmacies with extremely high billing on one or more of the eight measures was four times higher in the Miami area than in the Nation as a whole. The percentages in the Los Angeles area and the Detroit area were about 2½ times the national percentage. Percentages in other metropolitan areas, including New York, Baltimore, and Tampa, were about two times the national percentage. See Figure 2.

Together, these six metropolitan areas accounted for almost 28 percent of all pharmacies with questionable billing in 2009. Ninety-three percent of the pharmacies with questionable billing in these six areas were independent pharmacies.

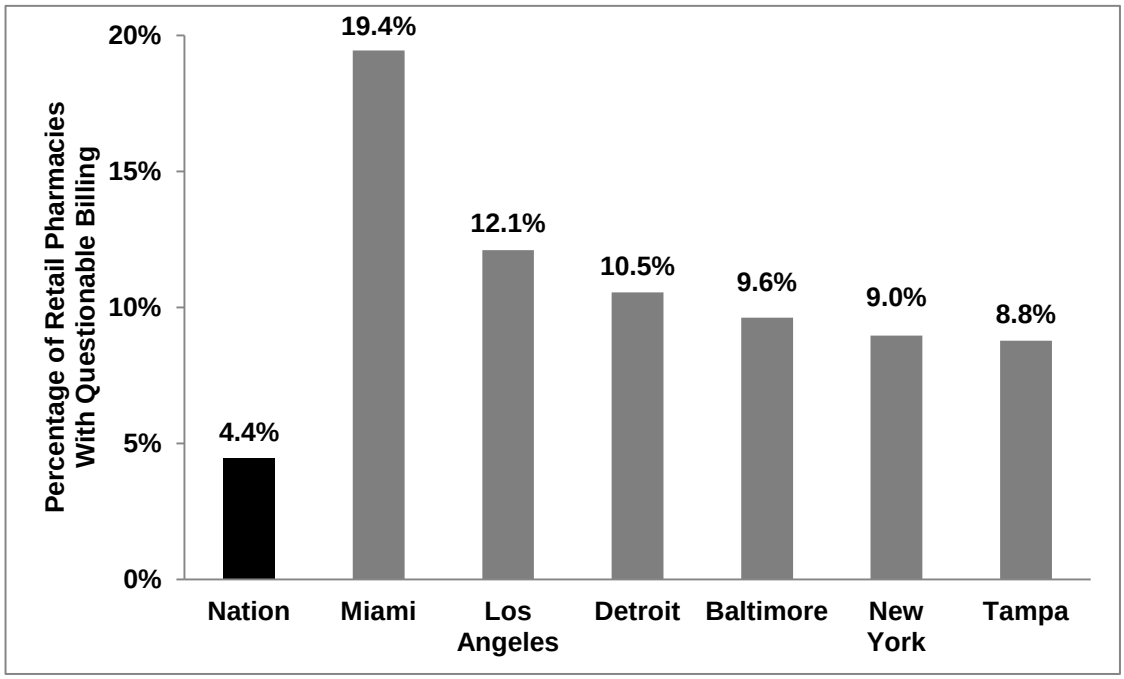
Miami. Nineteen percent of Miami area pharmacies had questionable billing in 2009. This is more than four times the percentage of pharmacies with questionable billing in the Nation as a whole.

Three-quarters of the pharmacies with questionable billing in the Miami area billed extremely high amounts per beneficiary. Some of these pharmacies billed exorbitant amounts. For example, 10 pharmacies billed an average of $8,000 or more per beneficiary, which is five times the national average per beneficiary. See Appendix D for more information

about the pharmacies with extremely high billing in the Miami area and the other metropolitan areas.

Brand-name drugs made up an extremely high percentage of prescriptions in 40 percent of the Miami area pharmacies with questionable billing. These pharmacies also billed for certain brand-name drugs at a much higher rate than pharmacies nationally. For example, they billed for Sure Comfort brand insulin needles 50 times more often than pharmacies nationwide. They also billed for Prevacid, a brand-name drug used to treat acid reflux, five times more often than pharmacies nationwide.

Figure 2: Percentage of Pharmacies in Each Area With Questionable Billing, 2009



Source: OIG analysis of Part D data, 2011.

Los Angeles. Twelve percent of Los Angeles area pharmacies had questionable billing in 2009, which is over 2½ times the percentage of pharmacies with questionable billing in the Nation as a whole.

Most commonly, pharmacies billed for extremely high percentages of brand-name drugs; over half of the pharmacies with questionable billing in the Los Angeles area did this. Like pharmacies in the Miami area, these pharmacies billed for certain brand-name drugs at a much higher rate than pharmacies in the Nation as a whole. For example, they billed for Celebrex, a brand-name drug used to treat arthritis, three times more often than pharmacies nationwide.

In addition, almost half the pharmacies with questionable billing in the Los Angeles area billed for extremely high dollar amounts per prescriber. In fact, three pharmacies billed an average of more than $20,000 per prescriber.

Detroit. Almost 11 percent of the pharmacies in the Detroit area had questionable billing in 2009. This is almost 2½ times the percentage of pharmacies with questionable billing in the Nation as a whole.

Schedule III drugs were the biggest problem in the Detroit area. Over 60 percent of pharmacies with questionable billing billed for an extremely high percentage of Schedule III drugs. Hydocodone acetaminophen, an addictive painkiller, was the most common Schedule III drug billed by these pharmacies.

New York. Nine percent of the pharmacies in the New York area had questionable billing in 2009, which is twice the percentage of pharmacies with questionable billing in the Nation as a whole. By far, the two most common problems in the area were billing for high dollar amounts per beneficiary and billing for a high percentage of brand-name drugs.

Seventy percent of the pharmacies with questionable billing in the New York area billed for extremely high average dollar amounts per beneficiary. Eight of these each billed an average of at least $10,000 per beneficiary.

Sixty-three percent of the area's pharmacies with questionable billing billed for extremely high percentages of brand-name drugs. In fact, more than one-third of all pharmacies in the Nation that billed for brand-name drugs for an extremely high percentage of their prescriptions were in the New York area. The three most common drugs they billed for were Plavix, Lipitor, and Nexium, which were the drugs most commonly billed for in the Nation as a whole. However, they also billed for an unusually high percentage of the Lidoderm patch, a local anesthetic (numbing medication) used to relieve postshingles pain.

Baltimore and Tampa. Like New York, both the Baltimore and Tampa areas had twice the percentage of pharmacies with questionable billing as the Nation as a whole.

Baltimore and Tampa both had a problem with Schedule II drugs. Over 80 percent of the pharmacies with questionable billing in each area billed for extremely high percentages of Schedule II drugs. For Tampa pharmacies with questionable billing, the most common drug was oxycodone hydrochloride, a narcotic painkiller that is frequently abused

for its euphoric effects.[34] It accounted for almost 4 percent of the prescriptions billed by these pharmacies. This is 15 times higher than the percentage billed nationally, which is less than 1 percent. Oxycodone hydrochloride was also among the most common drugs billed by pharmacies in the Baltimore area.

[34] See DEA, *Drugs and Chemicals of Concern: Oxycodone*, October 2000. Accessed at http://www.deadiversion.usdoj.gov/drugs_concern/oxycodone/summary.htm on October 19, 2011. Oxycodone is often used to alleviate or prevent the onset of opiate withdrawal by street users of heroin and methadone. Products with large amounts of oxycodone are highly attractive to opioid abusers.

CONCLUSION AND RECOMMENDATIONS

Thousands of pharmacies nationwide have questionable billing. While some pharmacies may be billing extremely high amounts for legitimate reasons, all warrant further scrutiny. Specifically, we found that many pharmacies billed for extremely high dollar amounts or numbers of prescriptions per beneficiary or per prescriber. Many also billed for extremely high amounts of Schedule II or III controlled substances, brand-name drugs, or refills. In addition, these pharmacies were more likely to be independent and to be in certain metropolitan areas, such as Miami, Los Angeles, and Detroit.

Our findings further indicate vulnerabilities in the oversight of the Part D program. Prior OIG reports have also found evidence of these vulnerabilities. For example, a 2009 OIG review revealed that the MEDICs may not be aware of some potential fraud and abuse incidents because sponsors are not required to refer these incidents to the MEDICs. Another report found that more than one-quarter of stand-alone Part D plan sponsors did not identify any potential fraud and abuse in 2007, even though CMS requires sponsors to have programs to detect, correct, and prevent fraud and abuse. A subsequent OIG report found that CMS's oversight of sponsors' compliance plans was extremely limited.

Together, these findings call for a strong response to improve Part D oversight. OIG is committed to continuing to conduct investigations and audits of pharmacies with questionable billing and to monitor pharmacy billing. CMS must also use all of the tools at its disposal to more effectively identify and fight fraud, waste, and abuse in Part D.

Therefore, we recommend that CMS:

Strengthen the MEDIC's Monitoring of Pharmacies and Ability To Identify Pharmacies for Further Review

One of the MEDICs is responsible for detecting, preventing, and investigating potential fraud, waste, and abuse. CMS should ensure that this MEDIC does more to systematically monitor pharmacies and to identify those with questionable billing. On an ongoing basis, the MEDIC should monitor pharmacy billing and identify those that need further review. It should use the measures presented in this report, as well as others it deems appropriate. It should also focus on independent pharmacies and those in the metropolitan areas we identified as having high percentages of pharmacies with questionable billing.

Provide Additional Guidance to Sponsors on Monitoring Pharmacy Billing

Part D sponsors are responsible for monitoring and auditing pharmacies, which are critical steps in fighting fraud, waste, and abuse. CMS should update its Part D manual or issue guidance reminding sponsors of the importance of conducting pharmacy-level data analysis. As part of this effort, CMS should solicit input from sponsors and the MEDIC on other ways to effectively monitor pharmacy billing and include this information in the updated guidance. CMS should also recommend that sponsors routinely generate and review reports on pharmacy billing to identify pharmacies for further review.

Require Sponsors To Refer Potential Fraud and Abuse Incidents That May Warrant Further Investigation

As we have previously recommended for Medicare Advantage organizations, CMS should require all Part D sponsors to report incidents of potential fraud and abuse that may warrant further investigation to CMS or other appropriate entities.[35] If necessary, CMS should seek statutory authority to implement this change. Current regulations stipulate that Part D sponsors should have procedures to voluntarily report this information. Because sponsors are on the front line of detecting fraud, waste, and abuse in Part D, a significant vulnerability exists when sponsors are not required to report this information.

Develop Risk Scores for Pharmacies

As it does for other parts of Medicare through its National Fraud Prevention Program, CMS should analyze billing data to detect pharmacies with a high risk for fraud. To do this, CMS should work with the MEDICs and sponsors to develop measures of pharmacy risk and assign each pharmacy a risk level, such as high, moderate, or low. CMS should provide this information to sponsors routinely so that they can use it to target pharmacies for audits and further review.

Further Strengthen Its Compliance Plan Audits

CMS is responsible for conducting onsite audits of sponsors' compliance plans to assess the effectiveness of their fraud and abuse programs. CMS has recently improved its audit process. As it continues these efforts, CMS should ensure that its audits include an in-depth review of how sponsors monitor and oversee pharmacies. As part of these audits, CMS should review the extent to which sponsors are effectively using data analysis to detect aberrant billing patterns. CMS should also review what

[35] OIG, *Medicare Advantage Organizations' Identification of Potential Fraud and Abuse (OEI-03-10-00310)*, February 2012.

actions sponsors take when they identify aberrant patterns and potential fraud, waste, and abuse.

Follow Up On the Pharmacies Identified as Having Questionable Billing

In a separate memorandum, we will refer the pharmacies with questionable billing to CMS for appropriate action.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its comments on the draft report, CMS concurred with four of the recommendations and partially concurred with the other two. CMS concurred with our first recommendation, to strengthen the MEDIC's monitoring of pharmacies and ability to identify pharmacies for further review. Specifically, CMS stated that it and the MEDIC will continue to refine the MEDIC's data analysis based on emerging trends and best available data. CMS also concurred with our second recommendation, to provide additional guidance to sponsors on monitoring pharmacy billing, stating that it has already issued guidance and will issue additional guidance in the 2013 Parts C and D Call Letter. In addition, CMS concurred with our fifth recommendation, to further strengthen compliance plan audits. It stated that it will continue to insist that an effective compliance program include the use of data analysis to detect potential fraud, waste, and abuse. Finally, CMS concurred with our sixth recommendation, to follow up on the pharmacies identified as having questionable billing, stating that the MEDIC will review the cases referred by OIG and conduct peer-to-peer comparisons and other analysis.

CMS partially concurred with our third recommendation, to require sponsors to refer potential fraud and abuse incidents that may warrant further investigations and stated that it will explore this option. CMS also concurred in part with our fourth recommendation, to develop risk scores for pharmacies. It stated that it will consider developing a risk assessment for pharmacies and sharing this information with sponsors. OIG supports CMS's efforts to explore requiring sponsors to report potential fraud and to develop pharmacy risk scores.

The full text of CMS's comments is provided in Appendix E. We made minor changes to the report based on technical comments.

APPENDIX A

Most Common Drugs Billed to Medicare Part D by Retail Pharmacies, 2009

Rank	Drug	Common Treatment	Number of Prescriptions Billed	Percentage of All Prescriptions Billed
1	Simvastatin	High cholesterol	28,099,312	3.2%
2	Lisinopril	High blood pressure	24,642,289	2.8%
3	Hydrocodone-acetaminophen	Pain	23,006,544	2.6%
4	Amlodipine besylate	High blood pressure	19,086,682	2.2%
5	Levothyroxine sodium	Hypothyroidism	19,068,278	2.2%
6	Furosemide	Swelling and fluid retention	18,183,668	2.1%
7	Omeprazole	Gastroesophageal reflux disease	16,562,103	1.9%
8	Metoprolol tartrate	High blood pressure	14,866,523	1.7%
9	Metformin HCl	Type 2 diabetes	14,331,451	1.6%
10	Hydrochlorothiazide	High blood pressure	14,011,233	1.6%
11	Lipitor*	High cholesterol/heart disease	13,849,439	1.6%
12	Atenolol	High blood pressure	13,045,879	1.5%
13	Plavix*	Heart disease	12,767,221	1.5%
14	Warfarin sodium	Blood clots	10,438,471	1.2%
15	Metoprolol succinate	High blood pressure	9,537,572	1.1%
16	Alendronate sodium	Osteoporosis	9,228,818	1.1%
17	Gabapentin	Seizures	8,839,510	1.0%
18	Zolpidem tartrate	Insomnia	8,037,495	0.9%
19	Potassium chloride	Potassium deficiency	7,697,500	0.9%
20	Nexium*	Gastroesophageal reflux disease	7,259,495	0.8%
Total			**292,559,483**	**33.5%**

***** Indicates that this is a brand-name drug.
Note: For more information on the common use for each drug, see National Institutes of Health, National Center for Biotechnology Information Pub Med Health, *Drugs and Supplements*. Accessed at http://www.ncbi.nlm.nih.gov/pubmedhealth on July 12, 2011.
Source: Office of Inspector General analysis of Part D data, 2011.

APPENDIX B

Most Common Schedule II Drugs Billed to Medicare Part D by Retail Pharmacies, 2009

Rank	Drug	Common Treatment	Number of Prescriptions Billed	Percentage of All Schedule II Prescriptions Billed
1	Oxycodone-acetaminophen	Pain	3,560,637	21.1%
2	Oxycodone HCl	Pain	2,065,483	12.3%
3	Morphine sulfate	Pain	2,038,891	12.1%
4	Fentanyl	Pain	1,756,646	10.4%
5	OxyContin*	Pain	1,358,823	8.1%
6	Oxycodone HCl-acetaminophen	Pain	1,252,833	7.4%
7	Endocet*	Pain	1,166,799	6.9%
8	Methadone HCl	Pain	1,143,404	6.8%
9	Hydromorphone HCl	Pain	564,687	3.4%
10	Amphetamine salt combo	Attention deficit hyperactivity disorder	310,460	1.8%
Total			**15,218,663**	**90.4%**

* Indicates that this is a brand-name drug.
Source: Office of Inspector General analysis of Part D data, 2011.

Most Common Schedule III Drugs Billed to Medicare Part D by Retail Pharmacies, 2009

Rank	Drug	Common Treatment	Number of Prescriptions Billed	Percentage of All Schedule III Prescriptions Billed
1	Hydrocodone-acetaminophen	Pain	23,006,544	86.9%
2	Acetaminophen-codeine	Pain	2,215,838	8.4%
3	Hydrocodone BIT-ibuprofen	Pain	220,915	0.8%
4	AndroGel*	Low testosterone	213,796	0.8%
5	Suboxone*	Opioid dependence	198,129	0.7%
6	Testosterone cypionate	Low testosterone	114,081	0.4%
7	Butalbital compound-codeine	Tension headache	63,229	0.2%
8	Butalbital-caff-APAP-codeine	Tension headache	59,242	0.2%
9	Testim*	Low testosterone	58,533	0.2%
10	Dronabinol	Nausea and vomiting	57,003	0.2%
Total			**15,218,663**	**90.4%**

* Indicates that this is a brand-name drug.
Source: Office of Inspector General analysis of Part D data, 2011.

APPENDIX C

Number of Pharmacies That Billed Extremely High Amounts by Number of Measures, 2009

Number of Measures	Number of Pharmacies That Billed Extremely High Amounts
1	1,688
2	685
3	210
4	46
5	8
Total	**2,637**

Source: Office of Inspector General analysis of Part D data, 2011.

APPENDIX D

Percentage of Pharmacies With Questionable Billing in Each Area That Exceeded the Threshold, 2009

Measures	Miami (N=119)	Los Angeles (N=197)	Detroit (N=52)	New York (N=256)	Baltimore (N=51)	Tampa (N=56)
Average Amount Billed per Beneficiary	76%	43%	31%	70%	18%	9%
Average Number of Prescriptions per Beneficiary	21%	16%	6%	9%	2%	2%
Average Amount Billed per Prescriber	20%	48%	19%	8%	8%	9%
Average Number of Prescriptions per Prescriber	7%	22%	4%	2%	4%	7%
Percentage of Schedule II Drugs	6%	5%	6%	5%	82%	86%
Percentage of Schedule III Drugs	0%	8%	62%	0%	0%	0%
Percentage of Brand-Name Drugs	40%	53%	6%	63%	0%	2%
Percentage of Refills	0%	0%	0%	0%	0%	2%

Note: We considered a pharmacy to have questionable billing if it exceeded the threshold on one or more of the eight measures. This table shows the percentage of pharmacies with questionable billing that exceeded the threshold for a particular measure. For example, 76 percent of the pharmacies in Miami that had questionable billing exceeded the threshold for average amount billed per beneficiary. See Table 2 for the national averages and the thresholds for each measure.
Source: Office of Inspector General analysis of Part D data, 2011.

APPENDIX E

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: MAR 2 1 2012

TO: Daniel R. Levinson
Inspector General

FROM: Marilyn Tavenner /S/
Acting Administrator

SUBJECT: Office of Inspector General Draft Report: "Retail Pharmacies with Questionable Part D Billing" (OEI-02-09-00600)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General (OIG) draft report entitled, "Retail Pharmacies with Questionable Part D Billing." This study provided a look at Part D billing by pharmacies nationwide. It is a part of the Health Care Fraud Prevention and Enforcement Action Team Initiative, which focuses on detecting health care fraud through the use of innovative data analysis and enhanced cooperation among the Department of Justice (DOJ), OIG, and CMS.

The CMS concurs in large part with OIG's recommendations. In fact, CMS already has in place actions that address a number of OIG's recommendations. For example, CMS will continue to monitor pharmacy-related projects conducted by the Medicare drug integrity contractor (MEDIC), enhance its relationship with plan sponsors, and provide guidance on the regulatory requirements regarding Prescription Drug Plan (PDP) sponsors' and Medicare Advantage (MA) organizations' obligations to prevent, detect, and correct Parts C and D program noncompliance and fraud, waste, and abuse. We believe it is important to note that OIG report identified what appeared to be questionable billing based on its own data analysis but did not determine any actual fraud committed by the pharmacies.

The CMS appreciates OIG's efforts in developing this study and will consider using select aspects of OIG's methodology in our own ongoing data analysis. In particular, we will work with our MEDIC to assess the underlying reasons for the questionable billing OIG has identified. We will assess whether the indicators developed for the study point to actionable items, as well as determine if the results might be improved by the application of certain adjustment factors the MEDIC has applied in previous data analyses.

We appreciate OIG's efforts in working with CMS to help identify retail pharmacies with questionable Part D billing. Our response to each of the OIG recommendations follows.

OIG Recommendation 1

The CMS should strengthen MEDIC's monitoring of pharmacies and ability to identify pharmacies for further review.

CMS Response

The CMS concurs with this recommendation. The MEDIC currently does this type of analysis. The MEDIC has conducted and continues to conduct a number of significant pharmacy-related projects. Each project the MEDIC conducts focuses not only on beneficiaries, prescribers, and drugs, but includes analyses at the pharmacy level to detect anomalies, trends, patterns, and spikes. CMS and the MEDIC will continue to refine data analyses based on emerging trends and best available data.

The CMS will consider the methodology used by OIG and explore approaches that could strengthen that methodology. As indicated in OIG's report, the analysis of questionable billing may contain pharmacies that neglected to report providing specialty services. Providing such services may make a pharmacy more likely to exceed certain billing thresholds. In addition, OIG was not able to confirm that a particular pharmacy is engaging in fraudulent or abusive practices. Some pharmacies may be billing extremely high amounts for legitimate reasons. For example, pharmacies located near pain clinics, hospitals, and other providers are likely to have very different billing patterns than a pharmacy located in a predominately residential area.

OIG Recommendation 2

The CMS should provide additional guidance to sponsors on monitoring pharmacy billing.

CMS Response

The CMS concurs with this recommendation. CMS agrees that Part D sponsors can do more to prevent fraud, waste, and abuse in the Medicare program. CMS has already provided Part D sponsors with additional guidance to strengthen drug utilization review requirements and clarifying processes around fraud detection and reporting. We will issue additional guidance in the 2013 Parts C and D Call Letter.

OIG Recommendation 3

The CMS should require sponsors to refer potential fraud and abuse incidents that may warrant further investigation.

CMS Response

The CMS partially concurs with this recommendation. CMS regulations do not currently require self-reporting of potential fraud and abuse incidents. CMS will explore the option of placing additional burden on plan sponsors versus the value of the information to be gained in collecting such data. Through guidance and education, CMS will continue to encourage plan sponsors to voluntarily refer potential fraud and abuse incidents that may warrant further investigation.

The plan sponsors have reported possible fraud cases to the MEDIC and will continue to do so. CMS has continuously strived to establish and enhance its relationship with plan sponsors. This relationship is founded in part on a mutual interest in combating fraud, waste, and abuse, which victimize the public and private sectors alike. To that end, CMS is committed to collaborating with plan sponsors to implement programs to prevent and detect fraud, waste, and abuse. Additionally, CMS is working collaboratively with law enforcement partners, including OIG and DOJ, to actively pursue a variety of avenues to partner with the private sector, including private payers such as plan sponsors, in areas such as data sharing and other mutually beneficial anti-fraud activities.

OIG Recommendation 4

The CMS should develop risk scores for pharmacies.

CMS Response

The CMS concurs in part with this recommendation. The MEDIC currently identifies pharmacies that present a fraud risk. CMS will consider developing a high, medium, and low risk assessment for pharmacies and sharing that information with sponsors, as appropriate.

OIG Recommendation 5

The CMS should further strengthen its compliance plan audits.

CMS Response

The CMS concurs with this recommendation. CMS' compliance program audits currently include a review of whether the sponsor uses data analysis effectively to detect aberrant patterns. CMS will continue to insist that an effective compliance program must include the use of data analysis for the detection of potential fraud, waste, and abuse.

OIG Recommendation 6

The CMS should follow up on the pharmacies identified as having questionable billing.

CMS Response

The CMS concurs with this recommendation. Although OIG's study did not focus on MEDIC actions and the findings did not include a crosscheck of MEDIC investigations, CMS agrees to have the NBI MEDIC continue to initiate investigations, as appropriate. The MEDIC continues to conduct several pharmacy-related projects. The MEDIC will review the cases referred by OIG and conduct peer-to-peer comparisons and other comparative analysis, such as pharmacy claim volume analysis that uses pattern recognition algorithms to analyze abnormal pharmacy prescription volume distributions.

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

Attachment

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 this report include Jenell Clarke, Jason Kwong, and David Rudich; central office staff who contributed include Eddie Baker Jr., Kevin Farber, Rob Gibbons, 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.