Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE INAPPROPRIATELY PAID FOR DRUGS ORDERED BY INDIVIDUALS WITHOUT PRESCRIBING AUTHORITY



Daniel R. Levinson Inspector General

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WHY WE DID THIS STUDY

Under Medicare Part D, 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 recent years, prescription drug abuse has emerged as a serious and growing problem. The Centers for Disease Control and Prevention has characterized prescription drug abuse as an epidemic. With the rise in prescription drug abuse, concerns about Medicare fraud, particularly prescriber fraud, have increased.

HOW WE DID THIS STUDY

We based this study on an analysis of all Prescription Drug Event records from 2009. Sponsors submit these records to CMS for each drug dispensed to beneficiaries enrolled in their plans. We matched each record to the National Plan and Provider Enumeration System to determine the prescriber type, such as physician or dentist. We selected 14 types that clearly did not have the authority to prescribe and identified the drugs they prescribed nationwide. We also identified 7 other types for a more in-depth review in the 10 States with the highest Part D payments.

WHAT WE FOUND

Nationwide, Part D inappropriately paid for drugs ordered by individuals who clearly did not have the authority to prescribe, such as massage therapists, athletic trainers, home contractors, interpreters, and transportation companies. This raises concerns about the appropriateness of Part D payments and about patient safety. In 10 States, Part D also inappropriately paid for drugs ordered by other individuals without the authority to prescribe, such as counselors, social workers, and chiropractors. Tens of thousands of these drugs were controlled substances. These drugs are of particular concern because they have potential for abuse.

WHAT WE RECOMMEND

Our findings show the need for increased oversight of prescribers. We recommend that CMS: (1) require sponsors to verify that prescribers have the authority to prescribe drugs, (2) increase the Medicare Drug Integrity Contractor's monitoring of prescribers, (3) ensure that Medicare does not pay for prescriptions from individuals without prescribing authority, and (4) follow up on the individuals without prescribing authority who ordered prescriptions. CMS concurred with all four recommendations.

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OBJECTIVE

To determine whether Medicare Part D paid for drugs ordered by individuals who did not have the authority to prescribe.

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 2011, 36 million beneficiaries were enrolled in Part D.²

Prescription drug abuse is a serious and growing problem. The Centers for Disease Control and Prevention (CDC) has characterized prescription drug abuse as an epidemic.³ In 2010, approximately 7 million people in the United States were misusing prescription drugs.⁴ Moreover, overdoses of prescription painkillers—called opioids—are among the leading causes of accidental death in the United States.⁵

With the rise in prescription drug abuse, concerns about Medicare fraud, particularly prescriber fraud, have increased. A number of recent fraud cases have focused on prescribers. In one case, a physician knowingly allowed nonmedical personnel to prescribe commonly abused painkillers, such as oxycodone, morphine, and hydrocodone, to Medicare patients.⁶ In a similar case, a physician assistant used prescriptions that were signed in advance by a physician to inappropriately prescribe drugs to Medicare

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, 2012 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medicare Insurance Trust Funds*, p. 164. Accessed at <u>http://www.cms.gov/Research-Statistics-Data-and-</u> <u>Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2012.pdf</u> on July 6, 2012.

³ 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.

⁴ National Institute on Drug Abuse, *Topics in Brief: Prescription Drug Abuse*, December 2011. Accessed at <u>http://www.drugabuse.gov/publications/topics-in-brief/prescription-drug-abuse</u> on September 18, 2012.

⁵ CDC, Unintentional Drug Poisonings in the United States, July 2010.

⁶ Federal Bureau of Investigation, *Palmetto Physician Pleads Guilty To Illegal Prescription Drug and Medicare Fraud Conspiracies*, March 18, 2010. Accessed at <u>http://www.fbi.gov/tampa/press-releases/2010/ta031810.htm</u> on July 2, 2012.

beneficiaries.⁷ In another case, a chiropractor was charged with illegally dispensing and distributing prescription drugs.⁸

This report is part of a larger body of work examining Part D billing. Another report identified pharmacies with questionable billing in 2009.⁹ A third report identified inappropriate Part D payments for Schedule II refills.¹⁰ A fourth report determines the extent to which general-care physicians have questionable prescribing patterns.¹¹ All four reports are 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 among the Department of Justice (DOJ), OIG, and CMS.¹²

Prescription Drugs

Medicare Part D covers prescription drugs that meet certain requirements and are used for medically accepted indications.¹³ CMS considers a drug to be "prescription" if the Food and Drug Administration has determined it must be labeled "**R** only," which means it cannot be dispensed without a prescription from a practitioner who is licensed to prescribe such drugs.¹⁴ The types of practitioners that are licensed to prescribe drugs are determined by State law.

The Drug Enforcement Administration (DEA) regulates certain drugs that have potential for abuse and dependence, called controlled substances.¹⁵

⁷ Attorney General of Texas, *A Dallas Man Pleads Guilty to Health Care Fraud in State and Federal Probe*, July 18, 2012. Accessed at

https://www.oag.state.tx.us/oagNews/release.php?id=4091 on July 23, 2012.

⁸ Department of Justice (DOJ), *Former Daytona Beach Chiropractor Charged With Illegally Dispensing Prescription Drugs and Health Care Fraud*. Accessed at <u>http://www.justice.gov/usao/flm/press/2012/may/20120518_Wagner.html</u> on May 22, 2012.

⁹ Office of Inspector General (OIG), *Retail Pharmacies With Questionable Part D Billing*, OEI-02-09-00600, May 2012.

¹⁰ OIG, Inappropriate Part D Payments for Schedule II Drugs Billed as Refills, OEI-02-09-00605, September 2012.

¹¹ OIG, Prescribers with Questionable Patterns in Medicare Part D, OEI-02-09-00603, June 2013.

¹² U.S. Department of Health and Human Services and DOJ, *HEAT Task Force Success*. Accessed at <u>http://www.stopmedicarefraud.gov/heattaskforce/index.html</u> on January 11, 2011.

¹³ For more information, see 42 U.S.C. § 1860D-2(e) and CMS, *Medicare Prescription Drug Benefit Manual, Chapter 6, Part D Drugs and Drug Formulary Requirements,* February 2010.

 ¹⁴ CMS, Medicare Prescription Drug Benefit Manual, Chapter 6, Part D Drugs and Drug Formulary Requirements, § 10, February 2010. Also see 21 U.S.C. § 353(b)(1).
¹⁵ 21 U.S.C. § 801 et seq. Also see DEA, Office of Diversion Control, Controlled Substance Schedule. Accessed at

http://www.deadiversion.usdoi.gov/schedules/index.html#define on November 13, 2012.

These drugs are divided into five schedules. Schedule II drugs have the highest potential for abuse of any prescription drugs legally available in the United States.¹⁶ They include stimulants and narcotics commonly used to relieve pain, such as oxycodone and morphine. Drugs on Schedules III through V also have a potential for abuse and psychological or physical dependence. The DEA requires all practitioners who handle controlled substances to register with the agency.¹⁷ It assigns each registrant a DEA number and maintains a database with information about each registrant, such as name, address, degree, and the drug schedules each is permitted to handle.

Part D Oversight

CMS relies on sponsors to help safeguard Part D from fraud and abuse. CMS requires sponsors to have compliance plans that contain measures to detect, prevent, and correct fraud, waste, and abuse.¹⁸ CMS recommends that sponsors use data analysis as part of these plans.¹⁹ Specifically, it recommends that sponsors develop indicators and establish baseline data so that they can recognize abnormalities and changes in prescribing patterns.

In addition, CMS contracts with a Medicare Drug Integrity Contractor (MEDIC) to detect and prevent fraud, waste, and abuse. Its responsibilities include identifying and investigating potential fraud and abuse, referring cases, and fulfilling requests for information from law enforcement.²⁰ The MEDIC is required to identify potential fraud and abuse through external sources, such as tips, as well as proactive methods, such as data analysis.²¹

CMS is responsible for the oversight of the sponsors and the MEDIC. CMS conducts a number of audits for sponsors, including onsite audits of their compliance plans.²² During these audits, CMS assesses the

¹⁶ Schedule I drugs currently have no accepted medical use in the United States. They include drugs such as heroin.

¹⁷ DEA registration grants prescribers Federal authority to handle certain schedules of controlled substances. See 21 CFR § 1301.11.

¹⁸ 42 CFR § 423.504(b)(4)(vi).

¹⁹ CMS, Prescription Drug Benefit Manual Chapter 9, Compliance Program Guidelines § 50.6.9, July 2012. Accessed at <u>http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter9.pdf</u> on September 12, 2012.

²⁰ CMS, *MEDIC Statement of Work*, July 2009.

²¹ For more information on the responsibilities of the MEDIC, see OIG, *MEDIC Benefit Integrity Activities in Medicare Parts C and D*, OEI-03-11-00310, January 2013.

²² For more information on audits by CMS, see OIG, *Audits of Medicare Prescription* Drug Plan Sponsors, OEI-03-09-00330, December 2011.

effectiveness of sponsors' fraud and abuse programs. CMS evaluates the MEDIC's performance annually.

Prescription Drug Event Data

Sponsors submit a Prescription Drug Event (PDE) record to CMS for each prescription filled for their enrollees. CMS uses the PDE 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 information about the drug and beneficiary. It also includes identification numbers for the prescriber and pharmacy, which are typically National Provider Identifiers (NPI).²³

Sponsors are required to certify the accuracy, completeness, and truthfulness of their PDE data.²⁴ Beginning in January 2012, they are also required to ensure that the prescriber identifiers on the PDE records are active and valid, meaning that they are currently assigned to a health care provider.²⁵ NPIs are assigned to many types of health care providers. Having an NPI does not mean that an individual has the authority to prescribe drugs. CMS does not specifically require sponsors to verify that drugs are ordered by individuals who have the authority to prescribe.

Prescriber Information

CMS maintains a registry of all the NPIs it assigns in its National Plan and Provider Enumeration System (NPPES) database.²⁶ To receive an NPI, providers report certain identifying information such as their names, addresses, and professional credentials, such as M.D. or R.N. Providers also indicate whether they are individuals or organizations, such as a hospital, clinic, or group practice.

Providers must also select a taxonomy code that provides information about their primary specialty.²⁷ The taxonomy code indicates a provider's

²⁷ CMS, National Plan and Provider Enumeration System (NPPES) Data Elements Data Dissemination: Information for Providers, June 20, 2007.

²³ PDE records allow four types of prescriber identification numbers: NPIs, DEA numbers, State license numbers, and Unique [Physician] Identification Numbers (UPIN). See CMS, *Prescriber Identifier on Part D NCPDP Pharmacy Claims Transactions*, May 1, 2009. Accessed at <u>https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoNPIPrescriberID_050108v2.pdf</u> on December 5, 2012.

^{24 42} CFR § 423.505(k).

²⁵ Sponsors must also confirm that any controlled substance is within the prescriber's scope of practice to prescribe. CMS, *Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 4, 2011.

²⁶ The Health Insurance Portability and Accountability Act of 1996 (HIPAA) required the development of a standard unique health care system identifier for each provider. Providers that are subject to HIPAA must have an NPI. This includes all providers that bill Medicare.

type and specialty, if any. For example, it may indicate that a prescriber is a family-medicine physician specializing in geriatric medicine.

Providers must ensure that information in the NPPES database, including the taxonomy, is updated and accurate. When applying for an NPI, providers certify that the information is correct and that they agree to provide notification within 30 days of any changes.²⁸

Related Work

A recent OIG report found that 2,637 retail pharmacies had questionable billing in 2009.²⁹ 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, which could mean that a pharmacy is billing for drugs that are not medically necessary or were never provided. Among other things, the report recommended that CMS strengthen its monitoring of pharmacies, provide additional guidance to sponsors on monitoring pharmacy billing, and further strengthen its compliance plan audits. CMS concurred with these recommendations.

Another recent OIG report found that Medicare Part D inappropriately paid \$25 million for Schedule II drugs billed as refills in 2009.³⁰ Sponsors should not have paid for any of these drugs because Federal law prohibits the refilling of Schedule II controlled substances without a valid prescription.³¹ Also, 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. Among other things, the report recommended that CMS issue guidance to sponsors to prevent billing of Schedule II refills and to exclude Schedule II refills when calculating payments to sponsors.

Another OIG report found that Medicare Part D paid \$1.2 billion in 2007 for drugs with invalid prescriber identifiers, which had either never been assigned or had been retired.³² The report recommended that CMS conduct periodic reviews to ensure the validity of prescriber identifiers

²⁸ CMS, National Provider Identifier (NPI) Application/Update Form, November 2008. Accessed at <u>https://www.cms.gov/Medicare/CMS-Forms/CMS-</u>

Forms/Downloads/CMS10114.pdf on June 5, 2012.

²⁹ OIG, *Retail Pharmacies With Questionable Part D Billing*, OEI-02-09-00600, May 2012.

³⁰ OIG, Inappropriate Part D Payments for Schedule II Drugs Billed as Refills, OEI-02-09-00605, September 2012.

 ³¹ Federal law permits partial refills under certain circumstances. It is possible some of these drugs may have been inaccurately billed as refills when they were partial fills.
³² OIG, *Invalid Prescriber Identifiers on Medicare Part D Claims*, OEI-03-09-00140, June 2010.

and require Part D plans to institute procedures to identify and review records containing invalid prescriber identifiers.

Finally, another OIG report found barriers to the MEDIC's benefit integrity efforts.³³ These barriers included problems in sharing of information and recovering inappropriate payments. The report also found that only a small percentage of the MEDIC's investigations and case referrals resulted from proactive data analysis. In the 1-year study period, the MEDIC initiated just 209 Part D investigations from proactive methods, such as data analysis.

METHODOLOGY

We based this study on an analysis of all PDE records from 2009, which we collected to undertake this study and other studies.³⁴ We matched these records to the NPPES database to obtain descriptive information about the prescribers.

PDE Data

We identified all PDE records for covered Part D drugs with dates of service from January 1 to December 31, 2009.³⁵ We identified 1.07 billion PDE records.³⁶

For each PDE record, we identified the identification number of the prescriber, which was generally an NPI. For records that used other types of prescriber identification numbers, we used a "crosswalk" developed by OIG analysts to identify the prescriber's NPI.³⁷

Using the NPI, we determined which PDE records were prescribed by individuals, as opposed to organizations. We focused our review on individual prescribers because organizations may be associated with multiple prescribers. We identified 1,102,275 individual prescribers who were associated with 1.03 billion PDE records.³⁸ These records represent

³⁶ The exact number of PDE records was 1,070,149,994.

³⁷ To develop this crosswalk, we used information from the Services Tracking, Analysis, and Reporting System, the DEA database, and the NPPES. We did not include 214,042 PDE records in our review because they did not have prescriber identification

214,042 PDE records in our review because they did not have prescriber identification numbers.

³⁸ The exact number of PDE records was 1,026,983,870.

³³ OIG, *MEDIC Benefit Integrity Activities in Medicare Parts C and D*, OEI-03-11-00310, January 2013.

³⁴ These studies include: Retail Pharmacies With Questionable Part D Billing (OEI-02-09-00600); Inappropriate Part D Payments for Schedule II Drugs Billed as Refills (OEI-02-09-00605); and Prescribers with Questionable Patterns in Medicare Part D (OEI-02-09-00603).

³⁵ This excludes any over-the-counter medications that sponsors provide as part of a utilization management program. These medications are not considered covered Part D drugs.

96 percent of all PDE records and totaled \$71 billion in Medicare payments.³⁹ All of these records contained NPIs that were assigned to providers. Having an NPI, however, does not mean that a provider has the authority to prescribe.

Analysis

To determine the prescriber type, such as a physician or dentist, we matched the NPI for each individual prescriber to the NPPES. We used the taxonomy code reported by each prescriber in the NPPES and grouped these codes into categories of prescriber types.⁴⁰

We reviewed the prescriber types of all Part D prescribers nationwide. We selected 14 prescriber types, such as contractors or veterinarians, that clearly did not have prescribing authority. We identified all of the PDE records for these prescriber types in all 50 States, the District of Columbia, and the Territories.⁴¹

We then conducted a more in-depth analysis of 10 States. To do this, we identified the 10 States with the highest Part D payments in 2009: California, Florida, New York, Texas, Pennsylvania, Ohio, Illinois, North Carolina, Michigan, and New Jersey.⁴² These States accounted for 53 percent of all Medicare Part D payments in 2009.⁴³ We selected seven prescriber types that we suspected did not have the authority to prescribe in these States. Attorneys from the Office of Counsel to the Inspector General reviewed State laws and confirmed that none of these 7 prescriber types had the authority to prescribe in these States. We then identified all of the PDE records for the 7 prescriber types in the 10 States.

We took several steps to verify that the individuals identified nationwide and in the 10 States did not report any other information in the NPPES that suggested they had the authority to prescribe. First, we reviewed all the information that these individuals reported in the additional taxonomy fields in the NPPES.⁴⁴ Second, we reviewed the information they reported in the credential field in the NPPES. We also determined whether any of

³⁹ The exact amount was \$70,657,705,438. We used three fields on the PDE records to calculate Part D payments: the ingredient cost, dispensing fee, and sales tax.

⁴⁰ We grouped codes based on the prescribers' scope of practice or services. For example, we grouped all of the counselors together and all of the non-advanced practice nurses together, including Registered Nurses and Licensed Practical Nurses.

⁴¹ For the purposes of this review, we refer to the District of Columbia and the Territories as States.

⁴² We calculated Part D payments for each State based on the prescribers' ZIP Codes.

⁴³ Medicare Part D payments in these 10 States amounted to \$37,715,549,212 in 2009.

⁴⁴ Providers may report up to 14 other taxonomies, in addition to their primary taxonomy. We reviewed all of the taxonomy codes these prescribers reported.

these individuals had a DEA number.⁴⁵ We assumed that individuals who reported any information suggesting that they were physicians, advance practice nurses, physician assistants, dentists, podiatrists, or optometrists or had a DEA number had the authority to prescribe and therefore excluded them from our analysis. For example, if a prescriber reported that he was an interpreter, but included "M.D." in the credential field, we assumed that he was a physician and excluded him from our analysis.

We then analyzed the PDE data for the 14 prescriber types we identified nationwide.⁴⁶ For these prescriber types, we calculated the total number of prescriptions and the amount Medicare paid for these prescriptions in all States.⁴⁷ For the purposes of this study, we use the term "prescription" to mean one PDE record.

We also analyzed the PDE data for the 7 prescriber types in the 10 States and calculated the total number of prescriptions these prescribers ordered and the amount Medicare paid for these prescriptions. We did this analysis by prescriber type and by State.

Finally, we calculated the total number of prescriptions for controlled substances ordered by the 14 prescriber types nationwide and the 7 prescriber types in the 10 States. To do this, we matched the National Drug Code on the PDE record to data from First DataBank. First DataBank indicates whether a drug is a controlled substance and, if so, which schedule the drug is on. We used this information to calculate the total number of prescriptions for controlled substances—Schedules II through IV—ordered by these prescriber types.⁴⁸

Limitations

This report does not review all prescriber types without the authority to prescribe. It looks at selected types that clearly do not have authority

⁴⁵ We used a crosswalk developed by OIG analysts that linked the NPIs to DEA numbers. This is a conservative approach. Not every prescriber with a DEA number has the authority to prescribe controlled substances. In some cases, mid-level practitioners have the right to only administer or dispense the drugs. DEA, Office Diversion Control, *Mid-Level Practitioners Authorization by State*, accessed at http://www.deadiversion.usdoj.gov/drugreg/practioners/index.html on August 8, 2012.

<u>Intp://www.deadiversion.dsdoj.gov/drugreg/practioners/index.intin</u> on August 8, 2012.

⁴⁶ We excluded PDE records for specific insulin brands that did not require a prescription. We identified these brands of insulin using the Food and Drug Administration drug labels. We also excluded medical supplies associated with the delivery of insulin, such as syringes, needles, and alcohol swabs, which are covered by Part D but do not require a prescription.

⁴⁷ To calculate the total amount Medicare paid, we summed three fields on the PDE records that represent the total gross drug costs: ingredient cost, dispensing fee, and sales tax.

⁴⁸ We were unable to match 105 PDE records to First Databank. As a result, we could not determine whether they were controlled substances.

nationwide and selected types that do not have the authority to prescribe in the 10 States.

In addition, 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 the NPPES.

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

Nationwide, Part D inappropriately paid for drugs ordered by individuals who clearly did not have the authority to prescribe, such as massage therapists and athletic trainers

Medicare should never pay for drugs ordered by individuals who do not have the authority to prescribe. To be covered under Medicare Part D, drugs must be prescribed in accordance with State law, which specifies the types of health care providers that have the authority to prescribe drugs in the State. Although these health care providers can vary by State, some types clearly do not have the authority to prescribe in any State. If drugs are being ordered for Medicare beneficiaries by individuals who do not have the authority to prescribe, it raises concerns about the appropriateness of Part D payments and about patient safety.

A review of Part D payments nationwide showed that Medicare inappropriately paid for 72,552 prescriptions ordered by 14 prescriber types that clearly do not have the authority to prescribe in any State. We selected these 14 prescriber types for review; they do not represent all types without the authority to prescribe. The 14 types included massage therapists, athletic trainers, and dental hygienists. None have the training necessary to prescribe drugs. In total, Medicare paid \$5.4 million for prescriptions ordered by the 14 prescriber types we reviewed.⁴⁹ (See Table 1.)

⁴⁹ This total includes the amounts paid by Part D sponsors, by the Government, and by or on behalf of beneficiaries.

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Prescriber Type	Number of Prescriptions	Number of Individuals Who Prescribed	Total Medicare Payments
Dietitian and Nutritionist	20,044	713	\$1,684,988
Audiologist or Other Hearing/Speech-Related Services	16,229	706	\$1,085,699
Massage Therapist	12,082	240	\$798,991
Athletic Trainer	8,795	398	\$694,288
Optician	3,860	157	\$261,285
Dental Hygienist, Dental Assistant, Denturist	3,085	223	\$144,177
Contractor	2,827	117	\$178,443
Home Health Aide or Other Personal Care Provider	1,781	117	\$287,527
Interpreter	1,529	7	\$68,225
Transportation or Lodging Company	890	26	\$49,689
Speech-Language Assistant	549	23	\$32,503
Music or Art Therapist	493	21	\$61,678
Nursing Technician	267	12	\$21,058
Veterinarian	121	20	\$6,080
Total	72,552	2,780	\$5,374,632

Table 1: Selected Prescriber Types Without the Authority To Prescribe,Nationwide, 2009

*Total does not equal \$5,374,632 because of rounding. It includes the amounts paid by Part D sponsors, by the Government, and by or on behalf of beneficiaries.

Note: The prescriber types in the table are not a comprehensive list of all types that do not have the authority to prescribe.

Note: For the purposes of this report, we considered a prescription to be one PDE record. Source: OIG analysis of Part D data, 2012.

Notably, massage therapists ordered 12,082 prescriptions in 2009. Athletic trainers ordered another 8,795. Contractors ordered 2,827 prescriptions; these individuals complete home repairs or modifications to accommodate a health condition, such as wheelchair ramps. Others who ordered prescriptions paid by Part D included personal care providers (e.g., home health aides, chore providers, and companions), interpreters, transportation companies (e.g., taxis, private vehicles, and drivers), lodging companies, and veterinarians. Examples of Individuals Without Prescribing Authority Who Ordered Extremely High Amounts of Part D Drugs

- One Florida massage therapist ordered 3,756 prescriptions, amounting to \$183,132.
- A Florida dietician ordered 2,645 prescriptions for a total of 165 beneficiaries.
- An interpreter ordered 1,210 prescriptions filled at 55 pharmacies.

In 10 States, Part D also inappropriately paid for drugs ordered by other individuals without the authority to prescribe, such as counselors and social workers

An in-depth analysis of 10 States revealed that Part D inappropriately paid for 344,714 prescriptions ordered by other selected types that did not have the authority to prescribe. In total, Medicare paid \$26.2 million for drugs ordered by counselors, chiropractors, social workers, physical therapists, registered nurses, occupational therapists, and speech-language pathologists. ⁵⁰ Our review of State laws found that these prescriber types did not have the authority to prescribe drugs in any of the 10 States. Although the seven selected prescriber types were the focus of the indepth State analysis, they do not represent all types without authority to prescribe in these States.

As shown in Table 2, counselors ordered 87,400 prescriptions, the most of the prescriber types reviewed in the 10 States. Counselors include such professions as marriage and family therapists. Chiropractors were next, with 70,681 prescriptions, followed by social workers, with 69,075 prescriptions.

⁵⁰ This total includes the amounts paid by Part D sponsors, by the Government, and by or on behalf of beneficiaries.

Prescriber Type	Number of Prescriptions	Number of Individuals	Total Medicare Payments
Counselor	87,400	2,838	\$7,374,910
Chiropractor	70,681	2,809	\$4,929,992
Social Worker	69,075	2,542	\$5,391,641
Physical Therapist	52,892	2,101	\$3,690,425
Registered Nurse	27,552	1,076	\$2,104,351
Occupational Therapist	19,900	674	\$1,481,768
Speech-Language Pathologist	17,214	664	\$1,199,122
Total	344,714	12,704	\$26,172,208*

Table 2: Selected Prescriber Types Without the Authority To Prescribe in 10 States, 2009

*Total does not equal \$26,172,208 because of rounding. It includes the amounts paid by Part D sponsors, by the Government, and by or on behalf of beneficiaries.

Note: For the purposes of this report, we considered a prescription to be one PDE record.

Source: OIG analysis of Part D data, 2012.

Part D paid for drugs ordered by 12,704 individuals without prescribing authority in the 10 States. On average, each of these individuals ordered 27 prescriptions, but a few ordered extremely high numbers. In fact, 32 of these individuals without prescribing authority ordered more than 1,000 prescriptions each.

Examples of Individuals Without Prescribing Authority Who Ordered Extremely High Amounts of Part D Drugs

- One Florida counselor ordered 2,912 prescriptions for • 217 beneficiaries, which were filled at 103 pharmacies.
- An Ohio social worker ordered 1,639 prescriptions, which were • all filled at one retail pharmacy.
- A registered nurse from California ordered 1,111 prescriptions, which were filled at a single retail pharmacy in New York.
- An Illinois social worker ordered 1,345 prescriptions, which were filled at 149 pharmacies for 312 beneficiaries. Almost all of these pharmacies were part of the same national chain.

As shown in Table 3, among the 10 States, California and Florida had the highest number of prescriptions ordered by such individuals. California accounted for 25 percent of all of these prescriptions, while Florida accounted for 20 percent.

State	Number of Prescriptions	Percentage of Prescriptions	Total Medicare Payments
California	86,494	25%	\$7,001,918
Florida	68,027	20%	\$4,570,107
New York	49,245	14%	\$3,887,613
Illinois	34,199	10%	\$2,564,564
Texas	30,362	9%	\$2,246,366
Pennsylvania	17,825	5%	\$1,317,686
Ohio	17,672	5%	\$1,206,428
New Jersey	14,581	4%	\$1,208,509
North Carolina	14,034	4%	\$1,188,530
Michigan	12,275	4%	\$980,486
Total	344,714	100%	\$26,172,208*

Table 3: Number of Prescriptions Ordered by Individuals Without Authority in Each of 10 States, 2009

*Total does not equal \$26,172,208 because of rounding. It includes the amounts paid by Part D sponsors, by the Government, and by or on behalf of beneficiaries.

Note: These calculations are based on the seven selected prescriber types. They do not include all types that do not have the authority to prescribe.

Note. For the purposes of this report, we considered a prescription to be one PDE record. Source: OIG analysis of Part D data, 2012.

Tens of thousands of drugs ordered by individuals without prescribing authority were controlled substances

Most of the prescriptions ordered by individuals who did not have the authority to prescribe were for commonly used drugs; however, thousands were for controlled substances.⁵¹ These drugs are of particular concern because they have potential for abuse. In total, 29,212 prescriptions for controlled substances were ordered by 4,863 individuals without

⁵¹ Overall, the drugs that the prescribers without authority most frequently ordered were simvastatin, lisinopril, hydrocodone-acetaminophen, amlodipine besylate, and levothyroxine sodium. A recent OIG report found that these drugs were also the five most common drugs dispensed by retail pharmacies in 2009. See OIG, Retail Pharmacies With Questionable Part D Billing, OEI-02-09-00600, May 2012.

nationwide and those from the 10 States for which we conducted an indepth review. In total, Medicare paid \$1,533,961 for controlled substances ordered by these individuals.

Of these prescriptions, 7,679 were Schedule II drugs. Schedule II drugs have the highest potential for abuse of any prescription drugs legally available in the United States. They include commonly abused painkillers, like oxycodone, that can be diverted and resold for profit. In one example, a counselor ordered 174 Schedule II drugs for 13 beneficiaries. In a second example, a contractor ordered 79 Schedule II drugs, which were all commonly abused painkillers.

CONCLUSION AND RECOMMENDATIONS

Nationwide, Medicare inappropriately paid for prescriptions ordered by individuals who clearly did not have the authority to prescribe, such as massage therapists and athletic trainers. Additionally, in 10 States we reviewed in more depth, Medicare paid for prescriptions ordered by others who did not have the authority to prescribe. These included counselors, social workers, chiropractors, registered nurses, physical therapists, occupational therapists, and speech-language pathologists. Even more concerning, tens of thousands of these prescriptions were for controlled substances.

Our findings raise concerns about the appropriateness of Medicare payments and about patient safety. They also show the need for increased oversight of prescribers to ensure that Medicare does not pay for drugs ordered by individuals who do not have the authority to prescribe. Drugs prescribed by such individuals may not be appropriate and may endanger patients. Such practices may also contribute to the prescription drug abuse problem in our Nation.

We recommend that CMS:

Require Sponsors To Verify That Prescribers Have the Authority To Prescribe Drugs

CMS requires sponsors to verify that the prescriber identifiers on the PDE records are currently assigned to a health care provider. However, having an NPI does not mean that an individual has the authority to prescribe drugs. CMS should also require sponsors to use the information available in the NPPES database to check that the prescriber on the PDE record is a type of prescriber that has the authority to prescribe under State law.

Increase the MEDIC's Monitoring of Prescribers

CMS should instruct the MEDIC to conduct additional proactive data analysis to identify individuals who do not have authority to prescribe drugs and further investigate and refer these individuals, as appropriate.

Ensure That Medicare Does Not Pay for Prescriptions From Individuals Without Prescribing Authority

CMS should issue guidance that requires sponsors to review PDE records to verify that the prescriber is associated with a type of prescriber that has the authority to prescribe and to submit adjustments and deletions when appropriate. This will help to ensure that payments are accurate. CMS should also monitor sponsors' performance to make sure they are appropriately adjusting the PDE records prior to the reconciliation process in which CMS finalizes payments to sponsors.

Follow Up on Individuals Without Prescribing Authority Who Ordered Prescriptions

In a separate memorandum, we will refer to CMS for appropriate action the individuals without prescribing authority who ordered Part D prescriptions, particularly those who ordered high numbers of controlled substances.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its comments on the draft report, CMS concurred with all four of our recommendations. It concurred with our first recommendation, stating that it will issue guidance requesting "sponsors to include a retrospective review in their required programs to combat fraud, waste, and abuse where data anomalies, such as those identified by OIG in this report, suggest possible inappropriate prescribing and to report any potential fraud to the MEDIC for further investigation." Further, CMS stated that it will examine ways to improve the reliability of data in the National Plan and Provider Enumeration System (NPPES) database. CMS stated that it is aware that there are limitations to the NPPES database and believes that instances identified in this report are likely due to administrative data input and maintenance issues. For example, prescribers may have a record that indicates the prescriber is a student, when other data indicates the individual has become a full licensed practitioner. We agree with CMS that the reliability of the NPPES should be improved and we support its efforts to do so; however, we do not agree with CMS's assertion that the instances in this report are due to limitations of the NPPES. As explained in the report, we took multiple steps to ensure that none of the individuals included in this report provided any information indicating they have prescribing authority. For example, we looked for credentials, such as M.D., and a DEA number. If they had either, we assumed they had the authority to prescribe. We also excluded all students from our review because some medical students, such as those on rotation, have the authority to prescribe under certain circumstances.

CMS concurred with our second recommendation and stated that "the MEDIC will continue to monitor prescribers and identify other proactive analyses targeted at prescribers." It further noted that the MEDIC currently conducts proactive analysis to identify prescribers who do not have the authority to prescribe drugs, validates these finding through further investigations, and refers to law enforcement and State licensing boards, as appropriate. Additionally, CMS noted that it has increased its monitoring of prescribers through the Part D Recovery Audit Contractor, with which it has contracted to identify and recover Part D improper payments.

CMS concurred with our third recommendation, stating that current PDE guidance provides Part D sponsors with a process to delete PDEs that are fraudulent. PDEs from prescribers confirmed by the MEDIC as not having prescribing authority would be communicated back to sponsors who would then delete the PDEs and implement point-of-sale edits to

reject claims from these fraudulent prescribers in the future. Finally, CMS concurred with our fourth recommendation to follow up on individuals without prescribing authority who ordered prescriptions.

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 Administrator Washington, DC 20201 DATE: MAY - 9 2013 TO: Daniel R. Levinson **Inspector General** attrance FROM: Acting Administrator SUBJECT: Office of Inspector General (OIG) Draft Report: "Medicare Inappropriately Paid for Drugs Ordered by Individuals Without Prescribing Authority" (OEI-02-09-00608) The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the above-referenced OIG draft report. The purpose of this report is to determine whether Medicare Part D paid for drugs ordered by individuals who did not have the authority to prescribe. The CMS is committed to preventing prescriber fraud, particularly when fraud is related to the serious and growing problem of prescription drug abuse. To help protect the Medicare Part D program, CMS requires plan sponsors to have compliance programs in place to help detect, prevent, and correct fraud, waste, and abuse. CMS also contracts with a Medicare Drug Integrity Contractor (MEDIC) that is tasked with identifying and investigating potential fraud and abuse, referring such cases to law enforcement, and fulfilling requests for information from law enforcement. We appreciate OIG's efforts in working with CMS to ensure that Medicare, particularly Medicare Part D, does not inappropriately pay for drugs ordered by individuals who lack the authority to prescribe such drugs. Our response to each of the OIG recommendations follows. **OIG Recommendation** The OIG recommends that CMS should require sponsors to verify that prescribers have the authority to prescribe drugs. **CMS** Response The CMS concurs with this recommendation. CMS currently requires Part D sponsors to verify that prescribers of controlled substances paid for under Part D have an active and valid individual National Provider Number (NPI) number to crosswalk to an individual Drug

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Enforcement Administration (DEA) number and to confirm that the controlled substance is consistent with that DEA schedule registration. We will issue guidance requesting our sponsors to include a retrospective review in their required programs to combat fraud, waste, and abuse where data anomalies, such as those identified by OIG in this report, suggest possible inappropriate prescribing and to report any potential fraud to the MEDIC for further investigation.

We will examine ways to improve the reliability of data in the National Plan and Provider Enumeration System (NPPES) database. We are aware there are limitations to the NPPES database and believe that the instances identified by OIG in this report are likely due to administrative data input and maintenance issues affecting database accuracy and reliability. NPPES data is self-reported by health care providers; it is not a credentialing mechanism. For example, prescribers may have a record that indicates the prescriber is a student, when other data indicates the individual has become a full licensed practitioner. CMS will place a reminder on the CMS NPI website reminding providers to provide communication to NPPES within 30 days of the effective change.

Such a preliminary effort will ensure this recommendation does not cause unintended and potentially significant beneficiary access issues in the Part D program due to administrative issues with database accuracy.

OIG Recommendation

The OIG recommends that CMS should increase the MEDIC's monitoring of prescribers.

CMS Response

The CMS concurs with this recommendation. The MEDIC currently conducts proactive analysis to identify prescribers who do not have the authority to prescribe drugs; uses the Medicare Exclusion Database, the Provider Enrollment, Chain and Ownership System, the National Technical Information Service's Drug Enforcement Administration's active and retired registrant files and third party subscription databases to verify identities and qualifications; and validates these findings through further investigation and refers to law enforcement or state licensing boards, as appropriate. The MEDIC will continue to monitor prescribers and identify other proactive analyses targeted at prescribers.

Additionally, CMS has increased its monitoring of prescribers through the Part D Recovery Audit Contractor (RAC), with which CMS has contracted to identify and recover Part D improper payments. The Part D RAC recently completed an analysis of prescription drug event (PDE) data to determine if any prescription drug claims were prescribed by individuals or entities on OIG's list of excluded individuals and entities (LEIE) for contract year 2007, and is currently reviewing LEIE data for contract years 2008 – 2011. Page 3 - Daniel R. Levinson

OIG Recommendation

The OIG recommends that CMS should ensure that Medicare does not pay for prescriptions from individuals without prescribing authority.

CMS Response

The CMS concurs with this recommendation. Current PDE guidance provides Part D sponsors with a process to delete PDEs that are fraudulent. PDEs from prescribers confirmed by the MEDIC as not having prescribing authority would be communicated back to sponsors who would then delete the PDEs and implement point of sale edits to reject claims from these fraudulent prescribers moving forward. As stated in our response to the first recommendation, we will also examine ways to improve the reliability of data in the NPPES system.

OIG Recommendation

The OIG recommends that CMS should follow up on individuals without prescribing authority who ordered prescriptions.

CMS Response

The CMS concurs with this recommendation. CMS awaits the data from OIG to follow up on individuals without prescribing authority who ordered prescriptions.

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

ACKNOWLEDGEMENTS

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; Christine Moritz; and Debra Roush.