

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**

**June 2013
OEI-02-09-00608**

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.

MEDICARE INAPPROPRIATELY PAID FOR DRUGS ORDERED BY INDIVIDUALS WITHOUT PRESCRIBING AUTHORITY

OEI-02-09-00608

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.

TABLE OF CONTENTS

Objective	1
Background	1
Methodology	6
Findings.....	10
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.	10
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.	12
Tens of thousands of drugs ordered by individuals without prescribing authority were controlled substances	14
Conclusion and Recommendations.....	16
Agency Comments and Office of Inspector General Response.....	18
Appendix.....	20
A: Agency Comments.....	20
Acknowledgments.....	23

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 <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2012.pdf> 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 <http://www.drugabuse.gov/publications/topics-in-brief/prescription-drug-abuse> 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 <http://www.fbi.gov/tampa/press-releases/2010/ta031810.htm> 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 http://www.justice.gov/usao/flm/press/2012/may/20120518_Wagner.html 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 <http://www.stopmedicarefraud.gov/heattaskforce/index.html> 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.deaiversion.usdoj.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 <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter9.pdf> 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

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 https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoNPIPrescriberID_050108v2.pdf 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.

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

