

September 2011

MEDICARE PART D

Instances of Questionable Access to Prescription Drugs

U.S. Government Accountability Office

GAO 90

YEARS

1921-2011

ACCOUNTABILITY ★ INTEGRITY ★ RELIABILITY

Why GAO Did This Study

In 2009, GAO reported on doctor shopping in Medicaid, where individuals see several doctors and pharmacies, receiving more of a drug than was intended by any single physician. Questions have been raised about whether similar activity exists in Medicare Part D.

GAO was asked to (1) determine the extent to which Medicare beneficiaries obtained frequently abused drugs from multiple prescribers, (2) identify examples of doctor shopping activity, and (3) determine the actions taken by the Centers for Medicare & Medicaid Services (CMS) to limit access to drugs for known abusers. To meet the objectives, GAO analyzed Medicare Part D claims for calendar year 2008 to identify potential doctor shoppers. To identify examples, GAO chose a nonrepresentative selection of 10 beneficiaries based on a number of factors, including the number of prescribers. GAO also interviewed policy officials from CMS and from prescription drug plans that administer the drug benefit program.

What GAO Recommends

GAO recommends that CMS review its findings and consider steps such as a restricted recipient program for identified doctor shoppers and seek congressional authority, as appropriate. CMS agreed with the overall recommendation to improve its efforts to curb overutilization in Part D, but disagreed that a restricted recipient program is necessarily the appropriate control for the Part D program.

View [GAO-11-699](#). For more information, contact Gregory Kutz at (202) 512-6722 or kutzg@gao.gov.

MEDICARE PART D

Instances of Questionable Access to Prescription Drugs

What GAO Found

GAO found indications of doctor shopping in the Medicare Part D program for 14 categories of frequently abused prescription drugs. About 170,000 beneficiaries (about 1.8 percent of beneficiaries receiving these 14 categories of drugs) acquired the same class of frequently abused drugs, primarily hydrocodone and oxycodone, from five or more medical practitioners during calendar year 2008 at a cost of about \$148 million (about 5 percent of the total cost for these drugs). About 120,000 of these beneficiaries were eligible for Medicare Part D because of a disability. There may be justifiable reasons for receiving prescriptions from multiple medical practitioners, such as visiting specialists or several prescribers in the same medical group. However, one individual received prescriptions from 87 different medical practitioners in 2008. In such situations, there is heightened concern that Medicare beneficiaries are seeing several medical practitioners to support and disguise an addiction.

GAO judgmentally selected 10 beneficiaries and found that they were doctor shopping for prescription drugs. These cases are among the more egregious and cannot be generalized beyond the examples presented.

Examples of Doctor Shopping Activity

State	Type of drug	Details
GA	Oxycodone	<ul style="list-style-type: none"> Beneficiary received prescriptions in 2008 for 3,655 oxycodone pills (a 1,679-day supply) written by 58 different prescribers. Two pharmacies later refused to fill prescriptions for the beneficiary because of suspicions of forgery.
CA	Fentanyl	<ul style="list-style-type: none"> Beneficiary received prescriptions in 2008 for 1,758 days worth of fentanyl written by 21 different prescribers. Beneficiary's physician received a letter from the state of California stating that within a 4-month period the beneficiary had received 33 prescriptions for controlled substances from 10 different prescribers.
TX	Hydrocodone	<ul style="list-style-type: none"> Beneficiary received prescriptions in 2008 for 4,574 hydrocodone pills (a 994 days supply) written by 25 different prescribers. One of the beneficiary's physicians stated it is dangerous to be consuming the amount of narcotics being prescribed.

Source: GAO.

CMS has systems in place to identify individuals with doctor shopping behavior; however, according to CMS policy officials, federal law may not authorize them to restrict these individuals' access to drugs, including highly abused drugs, such as hydrocodone and oxycodone. One option to control doctor shopping used by Medicaid and some private sector plans is the restricted recipient program. It limits individuals identified as doctor shoppers to one prescriber, one pharmacy, or both for receiving prescriptions. There are issues to consider with a restricted recipient program, such as potentially denying legitimate drug needs and unknown administrative costs. These issues should be balanced against the potential protections such a program can provide. Doctor shopping for frequently abused drugs can increase the cost of the Part D program and jeopardize patient care. Controls proven to reduce doctor shopping could be considered by CMS.

Contents

Letter		1
	Background	5
	Some Medicare Beneficiaries Received Prescriptions from Five or More Medical Practitioners to Obtain the Same Class of Frequently Abused Drugs	9
	Examples of Doctor Shopping in Medicare Part D	13
	Systems Are in Place to Identify Inappropriate Drug Use, but Measures to Stop the Activity Are Limited	18
	Conclusion	19
	Recommendation for Executive Action	20
	Agency Comments and Our Evaluation	20
Appendix I	Comments from the Centers for Medicare & Medicaid Services	23
Appendix II	GAO Contact and Staff Acknowledgments	27
Tables		
	Table 1: Fourteen Frequently Abused Prescription Drug Classes	11
	Table 2: Number of Beneficiaries Who Received 1 of 14 Prescription Drug Classes from Five or More Prescribers in 2008	12
	Table 3: Examples of Doctor Shopping of Prescription Drugs in Medicare Part D	13
Figure		
	Figure 1: States with Operational Prescription Drug Monitoring Programs as of February 2011	8

Abbreviations

CMS	Centers for Medicare & Medicaid Services
CSA	Controlled Substances Act of 1970
DEA	Drug Enforcement Administration
DOJ	Department of Justice
DUR	drug utilization review
HHS	Department of Health and Human Services
LICS	Low-Income Cost-Sharing Subsidy
MEDIC	Medicare Drug Integrity Contactor
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
NPI	National Provider Identifier
PDMP	prescription drug monitoring program

This is a work of the U.S. government and is not subject to copyright protection in the United States. The published product may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.



G A O

Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

September 6, 2011

The Honorable Thomas R. Carper
Chairman
The Honorable Scott P. Brown
Ranking Member
Subcommittee on Federal Financial Management, Government
Information, Federal Services, and International Security
Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable John McCain
United States Senate

Prescription drug abuse is a serious and growing public health problem. According to the Centers for Disease Control and Prevention, drug overdoses, including those from prescription drugs, are the second leading cause of deaths from unintentional injuries in the United States, exceeded only by motor vehicle fatalities. Unlike addiction to heroin and other drugs that have no accepted medical use, addiction to some controlled substances can be unknowingly financed by insurance companies and public programs, such as Medicare. There are reports and allegations that criminals and drug abusers are able to illegitimately acquire controlled substances by filing fraudulent claims, seeking treatment from medical practitioners for feigned injuries and illnesses, and perpetrating other fraudulent activities. The financial cost associated with controlled substance fraud and abuse is more than the cost of drug purchases since there are related medical services, such as doctor and emergency room visits, that precede the dispensing of these medications.

GAO reported, in September 2009, on an investigation of Medicaid fraud and abuse related to controlled substances in selected states.¹ The investigation found about 65,000 Medicaid beneficiaries and providers involved in potential fraudulent or abusive purchases of controlled substances in five selected states. These Medicaid beneficiaries in the five selected states acquired the same class of controlled substance from

¹ GAO, *Medicaid: Fraud and Abuse Related to Controlled Substances Identified in Selected States*, [GAO-09-957](#) (Washington, D.C.: Sept. 9, 2009).

six or more different medical practitioners during fiscal years 2006 and 2007. Such activities, known as doctor shopping, resulted in about \$63 million in Medicaid payments. According to the Drug Enforcement Administration (DEA), doctor shopping generally refers to visits by an individual to several doctors, each of whom writes a prescription for a controlled substance. The individual will visit several pharmacies, receiving more of the drug than intended by any single physician, typically for the purpose of abuse.² Based on the findings from the Medicaid investigation, you expressed concern about whether similar doctor shopping was taking place in the Medicare Part D program.

Medicare Part D provides voluntary, outpatient prescription drug coverage for eligible individuals 65 years and older and eligible individuals with disabilities. The Medicare Part D program, which began in January 2006, is administered by the Department of Health and Human Services' (HHS) Centers for Medicare & Medicaid Services (CMS). CMS contracts with private companies—such as health insurance companies and pharmacy benefit managers—to serve as Medicare Part D prescription drug plans. Over 27 million individuals were enrolled in Medicare Part D in 2010 and benefit expenditures were about \$53 billion.³ Because of Medicare's vulnerability to fraud, waste, and abuse, GAO has designated Medicare as a high-risk program.⁴ We and HHS's Inspector General have previously reported that the size, nature, and complexity of the Medicare

² U.S. House of Representatives, *Subcommittee on Criminal Justice, Drug Policy, and Human Resources, Government Reform Committee, July 26, 2006* (testimony of Mr. Joseph T. Rannazzisi, Deputy Assistant Administrator Office of Diversion Control, Drug Enforcement Administration).

³ Our analysis covered Medicare Part D claims for calendar year 2008. As of March 2008, Medicare Part D had 25 million enrollees. Net operating costs for fiscal year 2008 were \$43 billion.

⁴ GAO's audits and evaluations identify federal programs and operations that we determine are high risk because of their greater vulnerabilities to fraud, waste, abuse, and mismanagement. See GAO, *High-Risk Series: An Update*, [GAO-11-278](#) (Washington, D.C.: February 2011).

Part D program make it particularly at risk for fraud, waste, and abuse.⁵ You asked us to (1) determine the extent to which Medicare beneficiaries obtained frequently abused drugs from multiple medical prescribers, (2) identify examples of doctor shopping activity, and (3) determine the actions taken by CMS to limit access to prescription drugs for known abusers.

To determine the extent to which Medicare beneficiaries obtained frequently abused drugs through the prescriptions of multiple medical prescribers, we extracted the claims for the 14 selected classes of drugs from the approximately 1 billion Medicare Part D paid claims for calendar year 2008. From this subset of claims we determined the number of beneficiaries who saw at least five different medical practitioners for the same class of drugs. We selected the 14 classes of drugs, 12 of which are controlled substances, and the five or more prescribers threshold based on our review of drug diversion literature and prior GAO work and discussions with a criminal investigator whose recognized expertise is in drug diversion and with an official representing state prescription drug monitoring programs. To determine the total number of different prescribers from which a beneficiary received a prescription, we identified and totaled the number of different prescribers shown in each beneficiary's claims data by each class of drug.⁶ Some duplication may have occurred in our estimate of doctor shoppers because the Medicare Part D prescription claims identify prescribers using either their own

⁵ U.S. Senate, *Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security, Committee on Homeland Security and Governmental Affairs, July 15, 2010* (testimony of Mr. Robert Vito, Acting Assistant Inspector General for CMS Audits, Office of the Inspector General, U.S. Department of Health and Human Services), and GAO, *Medicare Part D: CMS Oversight of Part D Sponsors' Fraud and Abuse Programs Has Been Limited, but CMS Plans Oversight Expansion*, [GAO-10-481T](#) (Washington, D.C.: Mar. 3, 2010). Also see U.S. House of Representatives, Ways and Means Subcommittees on Health and Oversight, 110th Cong., March 8, 2007 (testimony of Daniel R. Levinson, HHS Inspector General), and U.S. House of Representatives, Oversight and Government Reform Committee, February 9, 2007 (testimony of Lewis Morris, Chief Counsel to the HHS Inspector General).

⁶ From the calendar year 2008 claims, we used those with either a National Provider Identifier (NPI) or a DEA number identifying the prescriber. For those claims with a DEA number, we assigned the corresponding NPI number. Based on this NPI number assignment, we determined the total number of different prescribers from which each beneficiary received prescriptions. We did not evaluate the number of Medicare beneficiaries who had fewer than five prescribers for 1 class of drugs but in total may have had five or more prescribers for any of the 14 highly abused classes of drugs.

identifier or a group practice identifier. However, our analysis showed that the extent of claims with group level identifiers was insignificant.⁷

To identify examples of doctor shopping activity, we selected beneficiaries from those identified as seeing at least five different medical practitioners for the same class of drugs from a nonrepresentative selection of five states: California, Georgia, Maryland, Massachusetts, and Texas. These states were selected based on geographical location and to provide a mixture of states that did and did not have programs for monitoring prescriptions for controlled substances.⁸ We further narrowed the number of individuals for our investigation primarily based on data showing a high number of prescriptions filled within the 14 classes of drugs, a high number of different prescribers involved, and the overlap of prescriptions. To further develop these examples, we identified overlapping prescriptions for the same class of drug from different prescribers, and interviewed selected employees from pharmacies and medical practitioners to confirm that these individuals were doctor shopping. Although our 10 case studies allowed us to identify issues related to the doctor shopping of Medicare Part D drugs, circumstances of each case are unique and cannot be generalized.

To determine the actions taken by CMS to limit access to prescription drugs for known abusers, we obtained and reviewed agency documents, including CMS regulations and program integrity requirements related to Medicare Part D. We also interviewed policy officials from CMS, CMS's fraud contractor, and three Medicare Part D contractors. We selected the Medicare Part D contractors based primarily on the number of beneficiaries enrolled in their plans whom we identified as potential doctor shoppers for these 14 classes of highly abusive drugs. These interviews included a review of the various controls either in place or available for use by prescription drug plans, along with their benefits and implementation issues.

To determine the reliability of the Medicare claims data, we reviewed related documentation and performed electronic testing to determine the

⁷ For the 14 classes of drugs, the extent of claims with NPI group level only identifiers was 1.2 percent.

⁸ Neither Georgia nor Maryland had a prescription drug monitoring program in place in 2008.

validity of specific data elements in the databases that we used to perform our work.⁹ Based on the results of this work, we concluded that the data elements used for this report were sufficiently reliable for our purposes.

We conducted this forensic audit from May 2010 to May 2011 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives. We conducted our related investigative work in accordance with standards prescribed by the Council of the Inspectors General on Integrity and Efficiency.

Background

Medicare Part D Provides Prescription Drug Benefits

The Medicare Part D program, administered by CMS, provides a voluntary, outpatient prescription drug benefit for eligible individuals 65 years and older and eligible individuals with disabilities. Beneficiaries may pay for part of the drug benefit through monthly premiums, deductibles, and co-pays. Low-income beneficiaries can receive substantial premium and cost sharing assistance. CMS data indicate that about 19 percent of the individuals who received Medicare Part D benefits in 2008 were eligible because of their disabilities. CMS contracts with private companies—such as health insurance companies and companies that manage pharmacy benefits—to provide Part D prescription drug benefit plans for Medicare beneficiaries. These companies are referred to as Part D plan sponsors.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which established the Part D program, requires all Part D plan sponsors to have programs to safeguard Part D from fraud, waste, and abuse. CMS regulations establish the requirements for comprehensive compliance plans for Part D plan sponsors. To guide

⁹ Data validation edits include (1) tests to see if numeric fields contain non-numeric data and (2) tests on a value to see if it falls within the range established for the data element.

Medicare Part D plan sponsors in designing a fraud and abuse program that addressed Medicare Part D risks, in April 2006 CMS issued recommendations for Medicare Part D plan sponsors' fraud and abuse programs based on input from various sources, including law enforcement and industry representatives. The guidance, issued as chapter 9 in the Prescription Drug Benefit Manual, contains further interpretation and guidelines on the steps sponsors should take to detect, correct, and prevent fraud, waste, and abuse in Part D. In the chapter 9 guidance, CMS identifies examples of potential fraud, waste, and abuse by Medicare beneficiaries, such as beneficiaries engaging in doctor shopping, where a patient seeks prescriptions from multiple physicians with the intent to abuse or sell drugs, and directs the Part D plan sponsors to report potential cases to the Medicare Drug Integrity Contactor (MEDIC). The MEDIC contracts with CMS to support audit, oversight, and antifraud and abuse efforts in Part D.

Controlled Substances Act Classifies Drugs Based on Their Potential for Abuse and Dependence

The Controlled Substances Act of 1970 (CSA)¹⁰ established a classification structure for certain drugs and chemicals used in drug manufacturing. Controlled substances are classified into five schedules on the basis of their currently accepted medical use and potential for abuse and dependence. Schedule I drugs—including heroin, marijuana, and hallucinogens such as LSD—have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Schedule II drugs—including methylphenidate (Ritalin) and opiates such as hydrocodone, morphine, and oxycodone—have a high potential for abuse and may lead to severe physical or psychological dependence but have a currently accepted medical use. Drugs on Schedules III through V have medical uses and successively lower potentials for abuse and dependence. Schedule III drugs include anabolic steroids, some preparations of codeine, hydrocodone in combination with aspirin or acetaminophen, and some barbiturates. Schedule IV contains such drugs as the antianxiety medications diazepam (Valium) and alprazolam (Xanax). Schedule V includes preparations such as cough syrups with codeine. All drugs but those in Schedule I are legally available to the public with a prescription.

¹⁰ Pub. L. No. 91-513, Title II, 84 Stat. 1236, 1242 (1970).

CSA mandates that DEA establish a closed system of control for manufacturing, distribution, and dispensing of controlled substances. Specifically, any person who manufactures, dispenses, imports, exports, or conducts research with controlled substances must register with DEA (unless exempt), keep track of all stocks of controlled substances, and maintain records to account for all controlled substances received, distributed, or otherwise disposed of. Although all registrants, including pharmacies, are required to maintain records of controlled substance transactions, only manufacturers, distributors, and pharmacies authorized to dispense controlled substances by means of the Internet are required to report certain controlled substance transactions,¹¹ including sales to the retail level, to DEA. The data provided to DEA are available for use in investigations of illegal diversions at the manufacturer and distributor levels. The act does not require pharmacies to report information on dispensing to the patient level to DEA.¹²

Prescription Drug Monitoring Programs Have Been Implemented by Most States

Most states have implemented prescription drug monitoring programs (PDMP). These programs can help prevent and detect the diversion and abuse of pharmaceutical controlled substances, particularly at the retail level. States that have implemented PDMPs have the capability to collect and analyze data on filled and paid prescriptions, including those from the Medicare Part D program, more efficiently than those without such programs, where the collection of prescription information can require a time-consuming manual review of pharmacy files. If used properly, PDMPs can detect diversion of the drugs by health care prescribers, pharmacies, and patients. We have reported that states with PDMPs have realized benefits in their efforts to reduce drug diversion.¹³

Figure 1 shows that a total of 34 states had operational PDMPs as of February 2011. These states vary in the extent to which schedules of controlled substances are monitored. Some states also monitor certain

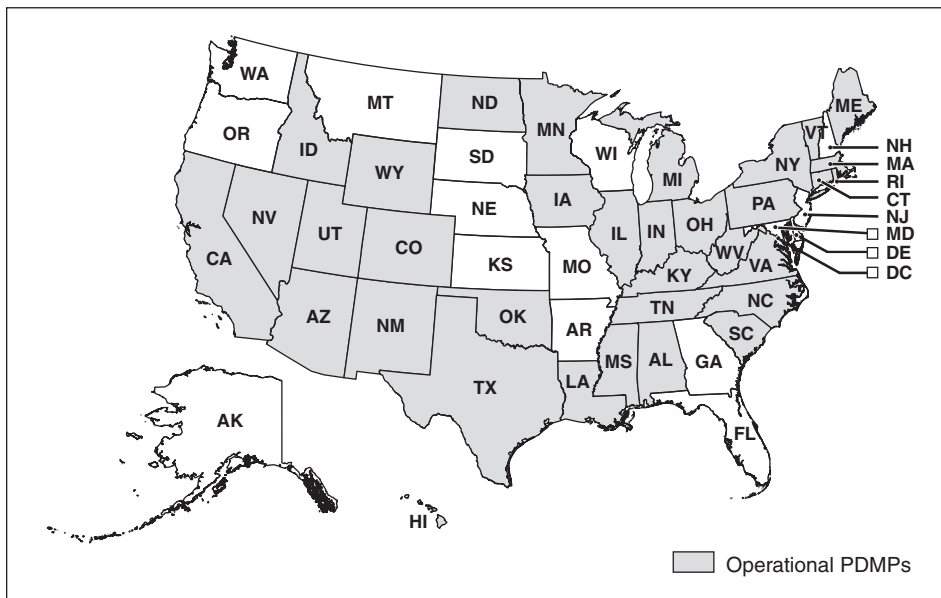
¹¹ 21 C.F.R. § 1304.33 lists the specific controlled substances to be included in these reports from manufacturers and distributors, while 21 C.F.R. § 1304.55 covers the information in reports by online pharmacies.

¹² An Internet pharmacy is required to report the total quantity of each controlled substance that the pharmacy dispenses each month, but not each patient transaction.

¹³ GAO, *Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion*, [GAO-02-634](#) (Washington, D.C.: May 17, 2002).

noncontrolled substances. According to the Department of Justice (DOJ), in states that have implemented PDMPs, doctor shopping has decreased. However, since determined doctor shoppers can travel to nearby states to bypass a PDMP, DOJ has also reported an increased need for information sharing between neighboring states to facilitate the interstate exchange of PDMP data.¹⁴

Figure 1: States with Operational Prescription Drug Monitoring Programs as of February 2011



Sources: GAO; Alliance of States with Prescription Monitoring Programs (data).

¹⁴ DOJ, *National Prescription Drug Threat Assessment 2009 (NPDTA 09)* (Johnstown, Pa.: April 2009).

Some Medicare Beneficiaries Received Prescriptions from Five or More Medical Practitioners to Obtain the Same Class of Frequently Abused Drugs

Our analysis of Medicare Part D claims found that 170,000 Medicare beneficiaries received prescriptions from five or more medical practitioners for the 12 classes of frequently abused controlled substances and 2 classes of frequently abused noncontrolled substances in calendar year 2008. This represented about 1.8 percent of the Medicare Part D beneficiaries who received prescriptions for these 14 classes of drugs during the same calendar year. These individuals incurred approximately \$148 million in prescription drug costs¹⁵ for these drugs,¹⁶ much of which is paid by the Medicare program. Our analysis also found the following:

- Most of these 170,000 Medicare beneficiaries who were prescribed prescriptions from five or more practitioners were eligible for Medicare Part D benefits based on a disability. Specifically, approximately 120,000 Medicare beneficiaries (about 71 percent) were eligible for Medicare Part D benefits based on a disability.
- Of these 170,000 beneficiaries, approximately 122,000 beneficiaries (72 percent) received a Medicare Low-Income Cost-Sharing (LICS) subsidy.¹⁷
- Of the 14 classes of frequently abused drugs analyzed, hydrocodone and oxycodone were the most prevalent. These drugs represented over 80 percent of the instances of potential doctor shopping we identified.

¹⁵ Medicare Part D is financed from general revenues, beneficiary premiums, and state contributions for Medicare beneficiaries who are also eligible for Medicaid. A beneficiary premium is set to cover approximately 25 percent of the cost of standard drug coverage.

¹⁶ The \$148 million in prescription costs represents about 5 percent of total Medicare Part D prescription costs for these 14 classes of highly abused drugs. The prescription drug costs included in this study do not include related costs associated with obtaining prescriptions, such as the corresponding visits to the doctor's office and emergency room. These costs are billed separately from the prescription drug claims.

¹⁷ When Medicare Part D was established, it replaced Medicaid as the primary source of drug coverage for beneficiaries with coverage under both programs—referred to as dual-eligible beneficiaries. Part D provides substantial premium and cost-sharing assistance through the LICS for dual-eligible beneficiaries and other low-income beneficiaries. The amount of the subsidy for premiums, deductibles, co-payments, and catastrophic coverage varies depending on income and resources.

In some cases, beneficiaries may have a justifiable reason for receiving prescriptions from multiple medical practitioners, such as visiting specialists or several prescribers in the same medical group. However, our analysis of Medicare Part D claims found that about 600 Medicare beneficiaries received prescriptions from 21 to 87 medical practitioners in the same year. In these situations, there is heightened concern that these Medicare beneficiaries may be seeking several medical practitioners to support and disguise an addiction.¹⁸ According to DEA, drug abusers use diversion techniques such as doctor shopping to acquire controlled prescription drugs. Further, DEA has also stated that diverted controlled prescription drugs have been added to the supplies of some illicit drug distributors.¹⁹ For example, according to DOJ, in 2008 hydrocodone tablets and oxycodone tablets were illicitly sold in California, one of the five states we selected for more detailed case investigations, for \$5 and \$80 per tablet, respectively.²⁰

Our analysis of Medicare Part D claims did not focus on all prescription drugs, but instead targeted 12 classes of frequently abused controlled substances and 2 classes of frequently abused noncontrolled substances, as shown in table 1. Our analysis does have certain limitations based on the data. Specifically, the data submitted to CMS did not identify the prescriber for many Part D claims because of blank or invalid prescriber identification values. At least 5.8 percent of the prescription claims for these 14 categories of drugs contained blank or invalid prescriber identification values. These claims were not included in our analysis. Therefore, we potentially understated the total number of unique prescribers for each beneficiary who received a prescription for all the claims paid.

¹⁸ Our threshold of visiting five or more practitioners excludes those who successfully doctor shop by visiting fewer than five practitioners on a regular basis. For example, a Medicare beneficiary can regularly receive overlapping prescriptions of abused drugs by visiting as few as two practitioners.

¹⁹ DOJ, *National Prescription Drug Threat Assessment 2009 (NPDTA 09)*.

²⁰ DOJ, *National Prescription Drug Threat Assessment 2009 (NPDTA 09)*.

Table 1: Fourteen Frequently Abused Prescription Drug Classes

Prescription drug classes	Other names	DEA schedule ^a	Description
Amphetamine derivatives	Adderall	II	Non-narcotic stimulant
Benzodiazepines ^b (e.g., Diazepam, Alprazolam, Lorazepam, Clonazepam, Temazepam, and Triazolam)	Valium, Xanax, Klonopin, Ativan, Restoril, and Halcion	IV	Non-narcotic depressant
Carisoprodol	Soma	Not scheduled	Muscle relaxant
Codeine with Acetaminophen	Tylenol with Codeine	III	Narcotic painkiller
Fentanyl	Duragesic and Actiq	II	Narcotic painkiller
Hydrocodone combinations	Lorcet, Lortab, Norco, and Vicodin	III	Narcotic painkiller
Hydromorphone	Dilaudid	II	Narcotic painkiller
Meperidine	Demerol	II	Narcotic painkiller
Methadone ^c	Methadose and Dolophine	II	Narcotic painkiller
Methylphenidate	Ritalin, Concerta, and Methylin	II	Non-narcotic stimulant
Morphine	MS Contin, Roxanol, Avinza, and Kadian	II	Narcotic painkiller
Non-Benzodiazepine sleep aids (e.g., Zolpidem, Zopiclone, and Zaleplon)	Ambien, Sonata, and Lunesta	IV	Non-narcotic sedative
Oxycodone	OxyContin, Roxicodone, Percocet, Endocet, and Roxicet	II	Narcotic painkiller
Tramadol	Ultram and Ultracet	Not scheduled	Non-narcotic painkiller

Sources: National Institutes of Health and DEA.

^aDEA classifies controlled substances in schedules I through V. Schedule I drugs—including heroin, marijuana, and hallucinogens such as LSD—have a high potential for abuse and no federally accepted medical use. Schedule II drugs have a high potential for abuse and may lead to severe physical or psychological dependence but have a currently accepted medical use. Schedules III through V have medical uses and successively lower potentials for abuse and dependence.

^bPart D plans are not required to cover benzodiazepines. However, some plans choose to cover these drugs as an added benefit.

^cMethadone is also used for the treatment of narcotic withdrawal and dependence.

Table 2 shows the breakout by drug class for the approximately 170,000 Medicare Part D beneficiaries who were prescribed the same class of drug by five or more medical practitioners. Because Medicare Part D beneficiaries may be receiving multiple classes of prescription drugs from five or more medical practitioners, certain beneficiaries may be counted in more than one prescription drug class. As shown in table 2, hydrocodone and oxycodone were the two prescription drug classes that were most prescribed by multiple medical practitioners. Specifically, about 97,000 beneficiaries were prescribed hydrocodone by five or more medical practitioners. In addition, our analysis found that about 57,000 Medicare Part D beneficiaries received oxycodone drugs prescribed by five or more practitioners. According to DOJ, doctor shopping is the primary method to

obtain highly addictive prescription opioids (e.g., hydrocodone and oxycodone) for illegitimate use.²¹

Table 2: Number of Beneficiaries Who Received 1 of 14 Prescription Drug Classes from Five or More Prescribers in 2008

	DEA controlled	Number of prescribers						Total prescription cost
		5-10	11-15	16-20	21-50	51+	Total	
Amphetamine derivatives (e.g., Adderall)	Y	881	9	3	2		895	\$1,040,395
Benzodiazepine (e.g., Valium and Xanax)	Y	2,437	17	4	2		2,460	\$372,822
Carisoprodol (e.g., Soma)	N	3,026	51	4	2		3,083	\$592,751
Codeine with Acetaminophen (e.g., Tylenol with Codeine)	Y	1,500	21	4			1,525	\$244,930
Fentanyl (e.g., Duragesic)	Y	5,043	24	8	2		5,077	\$19,124,853
Hydrocodone (e.g., Vicodin and Lortab)	Y	92,801	3,553	700	335	5	97,394	\$18,949,677
Hydromorphone (e.g., Dilaudid)	Y	2,453	77	13	8		2,551	\$1,236,678
Meperidine (e.g., Demerol)	Y	149	8				157	\$90,236
Methadone (e.g., Dolophine and Methadose)	Y	3,414	9				3,423	\$859,208
Methylphenidate (e.g., Ritalin and Concerta)	Y	740	2	1			743	\$488,759
Morphine (e.g., MS Contin and AVINZA)	Y	6,354	33	4			6,391	\$9,311,773
Non-Benzodiazepine sleep aids (e.g., Ambien and Lunesta)	Y	4,496	15				4,511	\$2,917,465
Oxycodone (e.g., Oxycontin and Percodan)	Y	54,183	1,974	440	235	5	56,837	\$91,681,281
Tramadol (e.g., Ultram and Ultracet)	N	4,346	134	33	14		4,527	\$1,037,423
Total		181,823	5,927	1,214	600	10	189,574	\$147,948,251

Sources: GAO and DEA.

Notes: The totals do not necessarily represent unique beneficiaries. A single beneficiary could have been prescribed more than one class of drug by more than one prescriber. The number of unique beneficiaries represented in this table is 170,029. The maximum number of prescribers from which a beneficiary received 1 of the 14 classes of prescription drugs was 87. The total beneficiary counts for oxycodone and hydrocodone represent 2.8 percent and 1.8 percent of all beneficiaries receiving that class of drug, respectively.

²¹ DOJ, *National Prescription Drug Threat Assessment 2010 (NPDTA 10)* (Johnstown, Pa.: February 2010).

Examples of Doctor Shopping in Medicare Part D

We obtained additional information on 10 of the Medicare Part D beneficiaries that showed indications of doctor shopping. In each of the 10 cases, we found evidence that the beneficiary was acquiring highly abused drugs through doctor shopping. We also found that in each example physicians were not aware that their patients were receiving drugs prescribed by other prescribers. DEA's definition of doctor shopping specifies an individual receiving more of a drug than intended by any single physician. In several examples physicians stated that they would not have prescribed the drugs if they were aware that the patient was receiving the same class of drugs from other sources. Table 3 summarizes the 10 examples of doctor shopping for prescription drugs, including controlled substances, in the Medicare Part D program. The total prescription cost of the drugs discussed in table 3 was about \$86,000 of which \$2,200 was paid directly by the beneficiaries in co-payments or deductibles. We are referring these beneficiaries to the Medicare Part D fraud contractor, as appropriate, for further investigation.²²

Table 3: Examples of Doctor Shopping of Prescription Drugs in Medicare Part D

No.	State	Class of prescription drug(s)	Case details
1	CA	Fentanyl	<ul style="list-style-type: none"> The beneficiary received prescriptions for a total of 1,397 fentanyl patches and pills (a 1,758-day supply) from 21 different prescribers in 2008. One physician who treated the beneficiary prescribed fentanyl for lower back pain. The beneficiary did not inform the physician that he was seeing other doctors. The physician stated that he would not have prescribed any controlled substances had he known they were being prescribed by other doctors. Another physician who treated the beneficiary from March 2008 through August 2008 stated that the beneficiary did not disclose that he was seeing other doctors and that she would not have prescribed any controlled substances had she known they were being prescribed by other doctors. In August, 2008, the physician received an alert letter^a from the state PDMP informing her that within a 4-month period the beneficiary had received 33 prescriptions for controlled substances from 10 different prescribers. After the PDMP alerted the physician of these multiple prescribers, the physician informed the beneficiary that she would no longer treat him as a patient.

²² CMS guidance directs Part D plans to refer cases of potential fraud directly to the Medicare Part D fraud contractor.

No.	State	Class of prescription drug(s)	Case details
2	GA	Oxycodone	<ul style="list-style-type: none"> The beneficiary received prescriptions for a total of 4,543 oxycodone pills (a 1,667-day supply) from seven different prescribers in 2008. One pharmacist said that because Georgia does not have a PDMP, the state is “flooded” with people from Florida, Ohio, and Kentucky trying to fill narcotic prescriptions. He stated that many of these people become very upset if they are refused their prescriptions. The pharmacist stated that the beneficiary recently called and asked if the pharmacy had Oxycontin 30mg in stock so that the beneficiary would not be wasting time if the drug was not in stock. The pharmacist stated that this was strange and told the beneficiary that the pharmacy did not have the medicine in stock. A physician who has the beneficiary as a current patient stated that they have an appointment monthly and that the beneficiary signed a pain management agreement in 2007 prohibiting her from receiving controlled substances from any other physicians. The physician stated that he had no idea the beneficiary was obtaining narcotics from other physicians, and that there is no reason for the beneficiary to be seeing more than one physician to obtain narcotics. Based on the history the physician had with this patient, he stated that the beneficiary is likely selling the extra narcotics as opposed to taking them.
3	GA	Carisoprodol Hydrocodone Oxycodone	<ul style="list-style-type: none"> The beneficiary received prescriptions for a total of 1,984 carisoprodol pills (an 894-day supply), a total of 1,850 hydrocodone pills (a 617-day supply), and a total of 1,800 oxycodone pills (a 680-day supply) from 12 different prescribers in 2008. One pharmacy has a note in its system to verify the beneficiary’s prescriptions because of suspected prior forgeries. A pharmacy employee, originally from Virginia, told us that it was very easy to forge prescriptions in Georgia because there is no requirement for prescriptions to be printed on security paper, which makes it easy for someone to produce a fraudulent prescription at home. One physician, who has been treating the beneficiary for about 7 years, learned about the patient’s prior doctor shopping when the patient tried to refill a prescription from another doctor. The physician stated that he confronted the beneficiary about the concern and had him sign a pain management agreement prohibiting him from receiving controlled substances from any other physician and requiring that he get pain prescriptions filled at only one pharmacy. Although the physician discovered that the agreement was violated, the physician did not stop treating the beneficiary because the beneficiary had legitimate pain and needed treatment. Instead, the physician counseled the beneficiary and continues to provide medical services. Another physician has seen the beneficiary approximately once each month for the past several years. Although the physician asked the beneficiary, during each office visit, whether he was seeing other doctors or obtaining narcotics from any other source, the beneficiary denied doing so. The physician stated that although the beneficiary has legitimate need for narcotic medication for pain, there is no need for the beneficiary to obtain narcotics from more than one physician. A third physician treated the beneficiary from 2007 to 2009 at a clinic outside of her regular practice where she periodically worked. At that clinic, the physician discovered that the beneficiary was receiving drugs from another physician. Both the physician and the clinic discharged the beneficiary from their practices because the beneficiary failed to disclose that he was seeing other physicians.

No.	State	Class of prescription drug(s)	Case details
4	GA	Carisoprodol, Oxycodone	<ul style="list-style-type: none"> The beneficiary received prescriptions for a total of 3,846 oxycodone pills (a 991-day supply) and a total of 2,220 carisoprodol pills (a 740-day supply) from 14 different prescribers in 2008. A physician prescribed the controlled substances to treat pain that the beneficiary suffered after a fall. The physician stated that pain is subjective and that a physician cannot always tell if a patient is exaggerating his or her pain level to obtain more narcotics. The physician treated the beneficiary from 2006 to 2009 and required that the beneficiary sign an annual pain management agreement. The beneficiary did not inform the physician about seeing other doctors or receiving narcotics from them. The doctor stated that he conducts random drug tests of his patients and that the beneficiary was never found to have illicit drugs in her system. However, on one occasion, a drug test revealed that the beneficiary had a drug that was not prescribed by him. The beneficiary told the physician of a recent dentist visit during which the dentist prescribed the drug. The physician did state that the beneficiary called him in 2009 and stated that the current drug regime was not controlling the pain. The beneficiary requested that the physician prescribe Percocet, which the physician refused. The physician stated that this may be the reason why the beneficiary quit going to him for medical visits.
5	GA	Oxycodone	<ul style="list-style-type: none"> The beneficiary received prescriptions for a total of 3,655 oxycodone pills (a 1,679-day supply) from 58 different prescribers in 2008. The beneficiary received a prescription for at least 1 of the 14 selected drugs from at least 66 different prescribers, and she filled her prescriptions at 45 different pharmacies in 2008. A pharmacy discovered that the beneficiary was forging a prescription from a physician. The pharmacy has noted in its system that its store and other pharmacies in the chain should refuse to fill controlled substances prescriptions for this beneficiary. Another pharmacy refused to fill a prescription for the beneficiary, after believing that the beneficiary tried to fill a forged prescription at the store. The beneficiary has not returned to the store since that refusal. A physician who treated the beneficiary frequently saw her and was repeatedly asked for early refills of Oxycontin prescriptions. After the physician would no longer prescribe Oxycontin, the beneficiary's medical visits to him ceased. The beneficiary did not inform the physician about seeing other physicians. The physician would not have prescribed any controlled substances had he known they were being prescribed by other physicians. Another physician stated that he was suspicious of the beneficiary's need for the drugs because (1) the beneficiary stated a desire for Oxycontin because of an allergy to other drugs and (2) the beneficiary refused to see a specialist despite his repeated directions. The beneficiary quit seeing the physician after the physician refused to prescribe any more narcotics. The physician was not aware of any attempted forgeries, but stated that he would not be surprised because it is easy to forge prescriptions in Georgia. The physician stated that Georgia has no requirements that prescriptions be written on any type of special security paper and that an individual can simply print or copy a prescription at home using a personal computer and regular computer paper.

No.	State	Class of prescription drug(s)	Case details
6	MA	Oxycodone	<ul style="list-style-type: none"> The beneficiary received prescriptions for a total of 1,252 oxycodone pills (a 455-day supply) from 24 different prescribers in 2008. A physician treated the beneficiary from February 2008 through August 2008. In May 2008, the physician stated that he received an alert letter from the Medicare Part D plan sponsor that showed the beneficiary was obtaining prescriptions for Oxycontin from 10 other physicians. The beneficiary did not disclose to the physician that she was receiving medications from other physicians. The physician informed the beneficiary that he will no longer prescribe narcotics. The physician stated that at about that time, the beneficiary's office visits ceased. Another doctor treated the beneficiary from August 2008 through March 2009. The doctor had required the beneficiary to sign a pain management contract that required her to only obtain narcotics from his practice. The doctor discharged the beneficiary from his practice after the beneficiary tested positive for cocaine and hydrocodone during a random drug screening. Subsequent to the discharge, the doctor received an alert letter from the PDMP listing the various doctors being visited and the medications being prescribed. The physician stated that the amount of narcotics being obtained was medically unnecessary.
7	MD	Fentanyl	<ul style="list-style-type: none"> The beneficiary received prescriptions for a total of 280 fentanyl patches and pills (a 761-day supply) in 2008 from 12 different prescribers. The beneficiary's current physician stated that the beneficiary has legitimate medical problems that warrant the use of pain medication. However, after reviewing pharmacy reports on the prescriptions filled for the patient, the physician did not think that there was a legitimate medical reason to obtain so much pain medication. The physician was unaware that the beneficiary was seeing other doctors and obtaining additional prescriptions for controlled substances. The beneficiary was also a patient at a short-term rehabilitation facility. The facility's director of nursing stated that when the beneficiary was admitted, the beneficiary "threw a fit" and threatened to walk out if the facility did not provide him intravenous Dilaudid. The director of nursing stated that numerous individuals intentionally get themselves admitted to nursing homes or rehabilitation centers because they feel it is easier to obtain narcotics. A physician at the rehabilitation facility stated that he prescribed the beneficiary fentanyl even though the medical chart indicated that beneficiary was addicted to opiates. According to the physician, the facility's protocols require physicians to provide patients with a 30-day supply of the medication they were receiving in the hospital to provide continuity of care.

No.	State	Class of prescription drug(s)	Case details
8	MD	Oxycodone	<ul style="list-style-type: none"> The beneficiary received prescriptions for a total of 5923 oxycodone pills (a 1,450-day supply) from 11 different prescribers in 2008. One physician treated the beneficiary for chronic pain beginning in January 2008, and had the beneficiary sign a pain management agreement that among other things required the beneficiary to receive narcotics only from him. The physician received an alert letter from the Part D plan sponsor in October 2009 listing all the medications that were dispensed to the beneficiary over a 9-month period. At that time, the physician discharged the beneficiary from the practice. Another physician also received an alert from the Part D plan sponsor. The second physician confronted the beneficiary with the data about other narcotic prescribers. The physician stated that the beneficiary said it was a case of mistaken identity. At that time, the physician stated that he could no longer continue to treat the beneficiary. However, the beneficiary returned a few months later and claimed that a pain management specialist would only accept cash and thus the beneficiary could no longer afford to go there. The physician stated that he treated the beneficiary for a few months until the beneficiary found another pain specialist. However, the physician stated that he no longer prescribes narcotics to the beneficiary and that there is no legitimate medical reason for the beneficiary to see multiple doctors or obtain additional narcotics.
9	TX	Hydrocodone	<ul style="list-style-type: none"> The beneficiary received prescriptions for a total of 1,289 hydrocodone pills (a 490-day supply) from 22 different prescribers in 2008. The beneficiary signed a pain management agreement with the current physician, but the physician did not know that the beneficiary was seeing other physicians. The physician stated there was no medical necessity for the drugs and that there was no way possible that the beneficiary was consuming the dosages of the prescribed drugs as indicated. The beneficiary was required to sign a patient responsibility agreement at another practice. This agreement states that a patient must disclose all medications he or she is currently taking and other prescriptions received. The beneficiary's medical file did not indicate that the beneficiary was seeing other physicians, and his physician did not know that he was receiving controlled substances from other physicians. Had the physician known, the beneficiary would have been "fired." The beneficiary did stop seeking medical treatment from the physician for unknown reasons.
10	TX	Hydrocodone	<ul style="list-style-type: none"> The beneficiary received prescriptions for a total of 4,574 hydrocodone pills (a 994-day supply) from 25 different prescribers in 2008. A previous physician stated that the beneficiary was obligated to inform him about receiving other prescriptions for controlled substances. The physician stated that he did not know that other physicians were prescribing narcotics to the beneficiary. The physician stated that it was medically unnecessary, and possibly dangerous, to consume the amount of narcotics obtained by the beneficiary. Had he been informed that the beneficiary was receiving narcotics from other doctors, the physician would have ceased prescribing the drugs.

Source: GAO.

^aPrescribers can receive alert letters from state PDMPs and from Part D plan sponsors.

Systems Are in Place to Identify Inappropriate Drug Use, but Measures to Stop the Activity Are Limited

CMS, through its Part D plan sponsors, does not limit access to hydrocodone, oxycodone, and other highly abused drugs for beneficiaries who are known doctor shoppers. Although systems are in place to identify individuals with doctor shopping behavior, according to CMS Part D program officials, federal law does not authorize Part D plans to restrict the access of these individuals. CMS requires Part D plans to perform retrospective drug utilization review (DUR) analysis to identify prior inappropriate or unnecessary medication use. By analyzing historical prescription claims data, the drug plans can identify individuals who are likely obtaining excessive amounts of highly abused drugs or potentially seeking such drugs from multiple medical practitioners. However, unless restrictions are placed on these individuals, the current system will not prevent these known abusers from continuing these practices.

If a beneficiary is found to be inappropriately obtaining abused drugs, CMS guidance states that Part D plan sponsors would provide practitioner and beneficiary education as appropriate. For instance, if a potential doctor shopper is identified, intervention letters would be sent to all prescribers who ordered the drug type for that individual. An intervention might consist of an informational letter to the medical practitioner; a response form for the medical practitioner to complete, along with a preaddressed return envelope; and a patient drug profile. However, the effectiveness of such a notification may be limited because the physicians can overlook the intervention letters, or if a request for a prescription is denied by one physician, the beneficiary can go to another physician for the desired prescription.

Although not currently used in the Medicare Part D program, officials from the Part D plan sponsors we interviewed stated that additional controls already in place in the Medicaid program and in some private sector plans could be used to better restrict the dispensing of abused drugs, such as hydrocodone and oxycodone, to individuals identified as doctor shoppers through detecting a pattern of abuse during retrospective analysis. Such programs employ a restricted recipient program, where prescription drug plans restrict beneficiaries who have been identified as drug abusers to one prescriber, one pharmacy, or both for receiving prescriptions. However, according to CMS policy officials, the restricted recipient program cannot be utilized in the Medicare Part D program because MMA did not authorize CMS to establish such restrictions on beneficiaries. As such, Part D plan sponsors are prevented from implementing these controls on specific individuals to prevent doctor shopping. There are issues to consider with a restricted recipient program, such as potentially denying legitimate drug needs and unknown costs for administration.

These costs include developing and implementing criteria and procedures for placing individuals in the program, allowing them to change providers as appropriate, and ultimately releasing them from the program.

Effective retrospective DURs require prescription drug plans to be able to share information about individuals identified as doctor shoppers with other Part D plans, as appropriate. Even if a restricted recipient program were implemented, according to CMS officials, Medicare Part D plan sponsors are not allowed to share beneficiary information with other plans.²³ As a result, a Medicare Part D plan sponsor cannot forewarn another Medicare Part D plan sponsor when an identified doctor shopper has left its plan and enrolled in another. Because Medicare Part D beneficiaries can change prescription drug plans on at least a yearly basis,²⁴ beneficiaries may be able to switch plans and continue their doctor shopping activity. Thus, to prevent known doctor shoppers from circumventing a restricted recipient program, a mechanism would also need to be established that allows CMS or its fraud contractor to inform the new plan of the doctor shopping activities of the beneficiary. Without such notification, beneficiaries will be able to bypass a restricted recipient program merely by switching prescription drug plans.

Conclusion

Prescription drug abuse is a national problem and appears to exist in the Medicare Part D program. In addition to the costs to society of addiction, overdose, death, and related criminal activities, taxpayers and Medicare beneficiaries bear the additional costs for excessive prescriptions obtained to supply an addiction or for diversion to illicit drug distributors. Protecting patient health and combating the illegal diversion or abusive usage of prescription drugs, while ensuring that the pharmaceuticals remain available for those with legitimate medical needs, involves the efforts of both the prescription drug plans and the federal government.

²³ However, pursuant to 45 C.F.R. § 164.506(c)(4)(ii), a Medicare Part D sponsor may disclose protected health information to another Medicare Part D sponsor if each sponsor either has or had a relationship with the individual who is the subject of the protected health information being requested, the protected health information pertains to such relationship, and the disclosure is for the purpose of health care fraud and abuse detection or compliance. CMS policy officials were not able to explain why this would not apply to doctor shopping.

²⁴ LICS recipients are allowed to switch plans monthly. In 2010, 33 percent of Part D beneficiaries were enrolled under the LICS.

Although systems are in place to identify inappropriate drug use, measures to stop the activity are limited. The restricted recipient program is one tool that could be used to prevent doctor shopping in the Medicare Part D program. If such a tool were implemented for Medicare Part D, CMS would also need a mechanism to share information about restricted recipients between plans. This would allow a new plan to be informed about the beneficiary's prescription use and to take appropriate action. In considering a restricted recipient program, CMS could utilize the experience of Medicaid and private sector programs to facilitate implementation issues and address the costs and benefits of such a program. CMS could also consider piloting a restricted recipient program focusing on hydrocodone and oxycodone, the two drug classes where we identified the largest potential doctor shopping activity. Increased controls over dispensing highly abusive drugs can help reduce the risk that individuals will use Medicare to facilitate their dangerous drug activities, which increases the cost of the program and jeopardizes patient care. As part of any evaluation, additional controls, such as the restricted recipient program, may require additional legal review and based on that review may require congressional authority to implement.

Recommendation for Executive Action

To improve efforts to address doctor shopping by beneficiaries of highly abused prescription drugs, we recommend that the Administrator of CMS review our findings, evaluate the existing DUR program, and consider additional steps such as a restricted recipient program for Medicare Part D that would limit these beneficiaries to one prescriber, one pharmacy, or both for receiving prescriptions. CMS should consider the experiences from Medicaid and private sector use of such restricted recipient programs, including weighing the potential costs and benefits of instituting the control. CMS could consider piloting such a program with a focus on hydrocodone and oxycodone, the two drug classes where we identified the largest potential doctor shopping activity. Along with a restricted recipient program, CMS should also consider facilitating the sharing of information on identified doctor shoppers among the Part D drug plan sponsors so that those beneficiaries cannot circumvent the program by switching prescription drug plans. In considering such controls, CMS should seek congressional authority as appropriate.

Agency Comments and Our Evaluation

We provided a draft of this report to CMS and DOJ for comment. DOJ stated that it did not have comments on the report. CMS's comments are reprinted in appendix I, and its technical comments were incorporated in the report as appropriate.

CMS agreed with our overall recommendation to improve efforts to curb overutilization in Part D, but disagreed that a restricted recipient program is necessarily the appropriate control for the Part D program. CMS stated that GAO provided no evidence that a restricted recipient program would be more effective than existing DUR requirements. CMS also requested the data from the report to consider whether these data indicate a failure of Part D plan sponsors to effectively implement concurrent or point-of-sale DURs or whether there are additional approaches to supplement DURs while not jeopardizing patient access to care. It also stated that CMS officials are undertaking additional evaluation of MEDIC data on potential overutilization to identify potential solutions and that they will issue program guidance to Part D sponsors on any best practices and develop an internal monitoring strategy.

We appreciate that CMS agrees with us that more efforts could be undertaken to curb overutilization in the Part D program, and we recognize its challenge in balancing the need to combat fraud, waste, and abuse with the program's goal of providing beneficiaries sufficient access to medically necessary prescription drugs. To reflect the issues raised by CMS, we revised our recommendation to include other actions that may be taken by CMS to address overutilization of prescription drugs. CMS guidance states that Part D plans must perform retrospective DUR analysis to identify inappropriate prescriptions and provide education, such as alert letters, to the prescribers involved. However, our case study examples showed that the receipt of such letters by prior prescribers did not prevent inappropriate prescriptions from being obtained from other prescribers. We support CMS looking into both enhanced point-of-sale and retrospective controls and related actions to address overutilization and questionable access to specific drugs.

CMS said that GAO provided no evidence that a restricted recipient program would be more effective than existing DUR requirements. However, our intent is not to prescribe a restricted recipient program as the only solution, but instead for CMS to consider utilizing it along with existing controls. The Part D plan sponsor officials we interviewed stated that a restricted recipient program, already in place in Medicaid and the private sector, could better restrict the dispensing of abused drugs. A restricted recipient program is an additional control that can be used for known abusers identified by retrospective DUR while not jeopardizing legitimate patient access to care. Thus, a restricted recipient program warrants further consideration by CMS.

We used CMS's own prescription drug paid claims data for our analysis. We are referring the examples in table 1 to the MEDIC as appropriate. We are also referring to the MEDIC the identities of other more egregious potential cases we identified through our analysis. According to CMS paid claims data, these individuals visited 40 or more prescribers in 2008 for a single class of drug and had overlapping prescriptions for the same drug class from different prescribers.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Secretary of Health and Human Services, the Attorney General, and other interested parties. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have questions about this report, please contact me at (202) 512-6722 or kutzg@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff members who made key contributions to this report are listed in appendix II.

A handwritten signature in black ink that reads "Gregory D. Kutz". The signature is written in a cursive style with a large, stylized initial "G".

Gregory D. Kutz
Director, Forensic Audits and Investigative Services

Appendix I: Comments from the Centers for Medicare & Medicaid Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

AUG 5 - 2011

Greg Kutz, Director
Forensic Audits and Special Investigations
U.S. Government Accountability Office
441 G Street N.W.
Washington, DC 20548

Dear Mr. Kutz:

Attached are comments on the U.S. Government Accountability Office's (GAO) draft report entitled: "MEDICARE PART D: Instances of Questionable Access to Prescription Drugs" (GAO-11-699).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

A handwritten signature in cursive script that reads "Jim R. Esquea".

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "MEDICARE PART D - INSTANCES OF QUESTIONABLE ACCESS TO PRESCRIPTION DRUGS" (GAO-11-699)

Thank you for the opportunity to review and comment on this draft report. We appreciate GAO's efforts in working with the Centers for Medicare and Medicaid Services (CMS) to help determine if Medicare beneficiaries are inappropriately accessing frequently abused prescription drugs. CMS shares the concerns of the Congressional requesters that prescription drug abuse is a serious and growing public health problem.

High utilization of pain medications is not necessarily an indication of abuse, but could be an indication of poorly coordinated care in the treatment of pain symptoms. GAO acknowledged that the presence of multiple prescribers during the course of the year does not necessarily indicate abuse or doctor shopping. For example, of the 170,000 beneficiaries identified, the GAO did not determine how many of these beneficiaries had overlapping prescriptions for the same class of drugs from different prescribers - different prescriptions that were filled concurrently rather than sequentially during the course of the year. GAO also did not identify how many of these beneficiaries using multiple prescribers for the same class of drugs filled prescriptions in excess of dosages recommended by the Food and Drug Administration (FDA).

GAO recognizes beneficiaries may have justifiable reasons for receiving prescriptions from multiple providers, such as receiving care from multiple medical practitioners in a medical group. Even with the limitations on GAO's data analysis, the report shows that some Part D sponsors failed to implement appropriate controls against the abuse or misuse of prescription drugs, including controlled substances.

CMS agrees with the GAO that more efforts could be undertaken to curb overutilization in the Medicare Prescription Drug Program. We support solutions that curb not only the Federal costs of excessive prescription drug use, but improve the overall health and safety of Medicare beneficiaries. As CMS provides in more detail below, CMS must balance the need to combat fraud, waste and abuse and at the same time ensure our beneficiaries have sufficient access to medically necessary prescription drugs.

GAO Recommendation

To improve efforts to address doctor shopping by beneficiaries of highly abused prescriptions drugs, GAO recommends that CMS review GAO's findings and consider a restricted recipient program for Medicare Part D that would limit these beneficiaries to one prescriber, one pharmacy or both for receiving prescriptions. Along with a restricted recipient program CMS should consider facilitating the sharing of identified doctor shoppers among the Part D drug plan sponsors so that those beneficiaries cannot circumvent the program by switching prescription drug plans. In considering this control, CMS should seek congressional authority as appropriate.

CMS Response

CMS concurs with GAO's overall recommendation to improve efforts to curb overutilization in Part D, but disagrees that a restricted recipient program is necessarily the appropriate control for the Part D program. GAO provides no evidence in the report that a restricted recipient program

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "MEDICARE PART D - INSTANCES OF QUESTIONABLE ACCESS TO PRESCRIPTION DRUGS" (GAO-11-699)

would be more effective in preventing prescription drug abuse than current drug utilization review (DUR) requirements. These DUR controls are designed to perform safety and utilization edits at point-of-sale and retrospective of the dispensing event and provide Part D sponsors the tools necessary to prevent beneficiaries from using the Part D benefit to abuse or misuse prescription drugs without restricting their access to certain physicians or pharmacies.

We would like to evaluate the data from this report on questionable overutilization and consider whether this data indicates a failure of Part D plan sponsors to effectively implement concurrent DUR that would prevent overutilization and abuse and whether there are additional approaches to supplement DUR that will not jeopardize patient access to care. Therefore, we request that GAO provide CMS with the data used for this study.

In addition, CMS will:

1. Undertake additional evaluation of available Medicare Drug Integrity Contractor (MEDIC) data and findings on overutilization and questionable access to specific drugs to identify potential solutions appropriate for the Part D program.
2. Issue program guidance to Part D sponsors on any best practices or requirements that are identified through our evaluation of the overutilization data and develop an internal monitoring strategy.

We support solutions that will retain beneficiary access to care, curb not only the Federal costs of excessive prescription drug use, but also decrease the overall medical costs of drug abuse-related behavior such as costs of treating communicable diseases and injuries from drug-related violence. We thank you for the opportunity to respond to this report and look forward to continue working with the GAO to improve the Medicare program.

**TECHNICAL COMMENTS OF THE DEPARTMENT OF HEALTH AND
HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY
OFFICE'S (GAO) DRAFT REPORT ENTITLED, "MEDICARE PART D –
INSTANCES OF QUESTIONABLE ACCESS TO PRESCRIPTION DRUGS"
(GAO-11-699)**

Page 8 - GAO asserts that about 30,000 beneficiaries on disability receiving prescriptions for drugs in the 14 classes had "diagnosis codes relating solely to mental impairments." It appears these diagnosis codes are from Social Security Administration's (SSA) disability files and as such do not include diagnoses for conditions unrelated to SSA's disability determination for which they may be receiving treatment under Medicare. Without a review of the diagnoses on the beneficiaries' Part A and Part B claims, it is inappropriate for GAO to intimate that these beneficiaries do not have diagnoses for conditions that might be appropriately be treated by the prescription drugs in the 14 classes under review.

Footnote 25 - CMS recommends rewording to state: "This statement is the opinion of CMS policy officials and is not a legal opinion rendered by the HHS Office of General Counsel."

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

Gregory D. Kutz, (202) 512-6722 or kutzg@gao.gov

Staff Acknowledgments

In addition to the contact named above, the following individuals made major contributions to this report: Erika Axelson, Assistant Director; Matthew Harris, Assistant Director; Matthew Valenta, Assistant Director; John Ahern; Gary Bianchi; Scott Clayton; Eric Eskew; Maria Kabling; James Murphy; Jonathon Oldmixon; Philip Reiff; Barry Shillito; and April Van Cleef.

GAO's Mission

The Government Accountability Office, the audit, evaluation, and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's Web site (www.gao.gov). Each weekday afternoon, GAO posts on its Web site newly released reports, testimony, and correspondence. To have GAO e-mail you a list of newly posted products, go to www.gao.gov and select "E-mail Updates."

Order by Phone

The price of each GAO publication reflects GAO's actual cost of production and distribution and depends on the number of pages in the publication and whether the publication is printed in color or black and white. Pricing and ordering information is posted on GAO's Web site, <http://www.gao.gov/ordering.htm>.

Place orders by calling (202) 512-6000, toll free (866) 801-7077, or TDD (202) 512-2537.

Orders may be paid for using American Express, Discover Card, MasterCard, Visa, check, or money order. Call for additional information.

To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Web site: www.gao.gov/fraudnet/fraudnet.htm

E-mail: fraudnet@gao.gov

Automated answering system: (800) 424-5454 or (202) 512-7470

Congressional Relations

Ralph Dawn, Managing Director, dawnr@gao.gov, (202) 512-4400
U.S. Government Accountability Office, 441 G Street NW, Room 7125
Washington, DC 20548

Public Affairs

Chuck Young, Managing Director, youngc1@gao.gov, (202) 512-4800
U.S. Government Accountability Office, 441 G Street NW, Room 7149
Washington, DC 20548

