



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

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Hearing:
Curbing Prescription Drug Abuse in Medicare

Senate Committee on Homeland Security
and Governmental Affairs

June 24, 2013
Dirksen 342
3:00 PM



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Good afternoon Chairman Carper, Ranking Member Coburn, and other distinguished Members of the Committee. The Office of Inspector General's (OIG) testimony today discusses prescription drug fraud schemes; vulnerabilities in the Medicare Part D Prescription Drug program (Part D); and recommendations to protect the program against fraud, waste, and abuse and to protect program beneficiaries from harmful and unsafe prescribing.

With \$66.9 billion in expenditures and 37.4 million beneficiaries enrolled,¹ it is essential that various players work together to protect the integrity of the Part D program and the health and welfare of the people it serves. Combating fraud, waste, and abuse involves a number of key partners, including the Centers for Medicare & Medicaid Services (CMS), CMS's contractor called the Medicare Drug Integrity Contractor (MEDIC), Part D plan sponsors, the Drug Enforcement Administration (DEA), State Medicaid agencies, and State and local law enforcement. CMS is responsible for overseeing the program and paying plan sponsors; the plan sponsors are responsible for preventing and detecting fraud, waste, and abuse and appropriately paying for drugs under Part D; and the MEDIC is responsible for identifying and investigating potential fraud and abuse, as well as referring cases to law enforcement. OIG often partners with DEA, the agency responsible for enforcing the controlled substances laws and regulations, on cases where we have dual jurisdiction.

Since the inception of Part D, OIG has extensively examined the monitoring and oversight of the program and the effectiveness of controls to ensure appropriate payment and patient safety. Our work has found limitations in program safeguards that leave Part D vulnerable to fraud, waste, and abuse and Medicare patients vulnerable to potentially harmful prescribing. Notably, OIG has uncovered extreme prescribing patterns by hundreds of general-care physicians and questionable billing by thousands of retail pharmacies. Moreover, in a report we are releasing today, we found that Medicare paid millions of dollars for prescriptions from unauthorized prescribers, such as massage therapists and athletic trainers.

These vulnerabilities are even more concerning in light of our increasing investigations into drug diversion. Since 2008, OIG's investigations relating to Medicare Part D have nearly quadrupled.

¹The Boards of Trustees, *Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, 2013 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medicare Insurance Trust Funds*, p. 10. ²The Centers for Disease Control and Prevention (CDC) characterized prescription drug abuse as an epidemic. In 2010, for example, overdoses of prescription painkillers were among the leading causes of accidental death in the United States.

The serious and growing problem of prescription drug abuse lends a greater urgency to address drug diversion and to improve monitoring and oversight of the Part D program.²

Drug Diversion Is a Complex Crime Involving Many Co-Conspirators

Prescription drug diversion is a complex crime that can involve many co-conspirators—drug distributors and traffickers, health care professionals, drug-seeking patients, and pharmacies may all play a role, and criminal enterprises are becoming an increasing presence in prescription drug diversion.

Drug distributors, traffickers, and criminal enterprises

Prescription drug diversion often involves drug distributors and traffickers.³ Criminal enterprises have also historically been engaged in the illegal drug trade. Of concern is that they are becoming an increasing presence in OIG’s prescription drug diversion cases and represent a greater risk to our law enforcement officers, witnesses, and others engaged in investigating this crime. They frequently associate with and use other criminals, such as identity thieves and money launderers, to facilitate the fraud scheme.

Health care providers

Medical doctors, physician assistants, nurse practitioners, and other health care professionals can also be involved in drug diversion. Some health care providers become so entangled in the financial gain from prescription drug diversion that their entire practices are focused on writing illicit prescriptions. Clinics or health care practices that focus primarily on prescription drug diversion are known as “pill mills.” While some providers bill for medical services that were never rendered and simply provide prescriptions to the patients, others may provide medically unnecessary and potentially harmful services to increase their financial profits. Some health care providers that engage in drug diversion schemes also struggle with prescription drug addiction.

Drug-seeking patients

Drug-seeking patients often visit multiple health care providers and pharmacies to obtain medically unnecessary prescriptions. Some use multiple false identities and may themselves be identity thieves. Drug-seeking patients often consume the drugs, sell them on the street for profit, or both.

² The Centers for Disease Control and Prevention (CDC) characterized prescription drug abuse as an epidemic. In 2010, for example, overdoses of prescription painkillers were among the leading causes of accidental death in the United States.

³ According to DEA, a prescription drug distributor is a person who is selling, furnishing, or delivering a controlled substance. The offense of drug trafficking refers primarily to the weight of the substances involved. Both distributors and traffickers may use multiple false identities in committing the crime.

http://www.getsmartaboutdrugs.com/identify/what_is_distribution_whats_drug_trafficking.html

Some criminals, often known as “recruiters,” target locations where drug-seeking patients are known to gather and offer them money for the use of their Medicare or Medicaid numbers. In some cases, recruiters offer several hundred dollars to drug-seeking patients to be transported to multiple medical appointments and then bill Medicare or Medicaid for those services.

Of particular concern are those cases when patient deaths occur as a result of the prescription drug diversion scheme. These are generally associated with “pill mills,” which are sometimes advertised as pain management clinics. One particular pain management clinic was associated with the deaths of over 60 patients in a 5-year period. The patients were billed for minimal services or services that were not rendered and were required to return monthly to receive their prescriptions, without regard for medical necessity. The doctor and his wife were sentenced to over 30 years of imprisonment and ordered to pay \$114,772, 524 in restitution to several government and private insurance plans and individuals.

Pharmacies

Pharmacies also play a role in drug diversion. Fraudulent pharmacies have been known to use patient Medicare numbers to bill for tens of thousands of dollars in unneeded prescriptions. In some fraud schemes, pharmacies stock or re-label expired and counterfeit medications and bill for them and sell them as legitimate prescriptions to unsuspecting patients. They may also bill for recurring refills that were never filled. Other pharmacies contribute to the fraud by filling prescriptions despite clear indicators they have been fraudulently obtained. Some pharmacies are even complicit in the scheme by paying patients with cash or narcotics to fill illegitimate and expensive prescriptions at their locations.

In one particular case, a licensed pharmacist who owned 26 pharmacies was the mastermind of a scheme that used an elaborate web of physicians, pharmacists, and patient recruiters to fraudulently bill Part D, Medicaid, and private health insurance carriers. This pharmacist paid kickbacks, bribes, and other inducements to physicians to write prescriptions for controlled drugs and expensive noncontrolled drugs. In addition, the physicians billed for services that were medically unnecessary or were never provided. The physicians directed their patients to fill their prescriptions at 1 of the 26 pharmacies, which then billed Medicare and Medicaid for expensive noncontrolled drugs but did not dispense them. The pharmacist then took his existing physical inventory of expensive noncontrolled drugs, repackaged them, and sold them to pharmaceutical suppliers. The pharmacist responsible for this egregious scheme was convicted along with 5 other connected individuals at trial, and an additional 14 conspirators have entered into plea agreements and await sentencing.

A unique set of fraud schemes involves what are termed as “phantom pharmacy” and “bust-out” schemes. Phantom pharmacies exist virtually or perhaps in an abandoned warehouse or office storefront. There is no legitimate pharmacy that provides services, but the pharmacy itself has an address or a P.O. box, a Medicare billing number, a bank account, and an electronic funds transfer number for transferring funds into the bank account. The identities of doctors, pharmacists, and patients are often stolen to perpetuate the fraud.

Another variation of this theme involves “bust-out” pharmacies, i.e., usually a small pharmacy that is about to go out of business. The pharmacy owner may advertise online or in the newspaper that the pharmacy is for sale with an active Medicare number. If the pharmacy is purchased by a criminal involved in the prescription drug diversion trade, it bills Medicare a large amount in a short period of time, collects the proceeds, and disappears.

It is important to note that prescription drug diversion cases investigated by OIG are not limited to controlled substances. OIG also has investigated matters that involve noncontrolled but high-cost prescriptions, such as respiratory, anti-psychotic, and HIV/AIDS medications. In one particular case, a pharmacy billed for very expensive medications that included anti-psychotics and respiratory and cardiac drugs but never dispensed the drugs. The perpetrators of this scheme were sentenced to 57 months of imprisonment and ordered to pay \$4.9 million in restitution.

With the rise in prescription drug abuse, concerns about Medicare fraud, particularly pharmacy and prescriber fraud, have increased. These concerns are reinforced by OIG’s recent evaluations, which focus on unauthorized prescribers, questionable prescribing patterns, and questionable billing by pharmacies for Part D drugs.

Medicare Paid for Drugs Ordered by Individuals Without the Authority To Prescribe

In the report that we are releasing today, OIG found that one of the most basic safeguards – that an item or a service was performed, provided, or prescribed by an appropriate medical professional – is not always operating effectively.

To be covered under 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. We found that, nationwide, Part D inappropriately paid \$5.4 million in 2009 for 72,552 prescriptions ordered by individuals who clearly did not have the authority to prescribe. These individuals included massage therapists, athletic trainers, dental hygienists, and contractors responsible for home repairs. We even found that interpreters, lodging companies, and veterinarians ordered prescriptions. Medicare should never pay for drugs ordered by these individuals.

Additionally, in 10 States that we reviewed in depth, Part D inappropriately paid for drugs 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. In total, we identified almost 350,000 prescriptions ordered by these prescriber types in the 10 States. Part D paid \$26.2 million for these drugs. It is important to note that our review focused on selected types of providers; they do not represent all provider types without the authority to prescribe.

Further, tens of thousands of drugs ordered by individuals without prescribing authority were controlled substances. These drugs are of particular concern because they have potential for abuse.

We found many examples in which Medicare paid for drug claims in which the prescribers were individuals without the authority to prescribe:

- One Florida massage therapist was listed as the prescriber on 3,756 prescriptions, amounting to \$183,132.
- An Ohio social worker was listed as the prescriber on 1,639 prescriptions, which were all filled at 1 retail pharmacy.
- A registered nurse from California was listed as the prescriber on 1,111 prescriptions, which were filled at a single retail pharmacy in New York.

From the claims data, we could not determine whether the drugs were actually ordered by the unauthorized individuals listed on the claims or whether the providers' identification numbers were being misused. Either scenario is problematic and resulted in inappropriate payments and may have put patients' health and safety at risk.

These findings build on earlier OIG work that found that Part D paid for prescription drugs for which the claims had invalid prescriber identifiers. Specifically, in 2007, Part D sponsors and beneficiaries paid pharmacies \$1.2 billion for claims that contained prescriber identifiers that had never been assigned or had been retired. For almost one-fifth of these claims, the prescriber identifiers did not meet the format specifications, yet sponsors' systems did not include edits to reject or flag claims with obviously inaccurate prescriber identifiers. For example, for some claims, the prescriber identification field contained the wrong number of characters.

CMS has reported taking several steps to address the problems we identified with invalid prescriber identifiers. CMS now requires that sponsors ensure that prescriber identifiers on Part D claims are active and valid. Today's report demonstrates the need for further action to ensure that each claim for a prescription contains not only a valid prescriber identifier but also one that corresponds to an authorized prescriber.

Hundreds of Physicians Had Extreme Prescribing Patterns

Vulnerabilities in the Part D program are not limited to unauthorized prescribers. In a report issued last week, OIG raised concerns about questionable prescribing patterns for 736 general-care physicians. These physicians were extreme outliers and prescribed very differently than their peers—they ordered an extremely high number of drugs per beneficiary; they had prescriptions filled at an extremely high number of pharmacies; they ordered extremely high percentages of brand-name drugs; or they ordered extremely high percentages of Schedule II or Schedule III drugs, which have the potential for abuse.⁴ These drugs include oxycodone and morphine.

⁴ Drugs and other substances that are considered controlled substances under the Controlled Substances Act are divided into five schedules. Drugs are placed on a certain schedule on the basis of having a medically accepted use in treatment in the United States, their potential for abuse, and the likelihood that dependence will result from that abuse.

Our analysis identified many examples of questionable prescribing patterns. A couple of them include:

- Medicare paid a total of \$9.7 million—151 times more than the average—for 1 California physician’s prescriptions. Most of this physician’s prescriptions were filled by just two independent pharmacies, both of which OIG identified in a prior review as having questionable billing.
- Seventy-eight percent of the prescriptions ordered by one Florida physician were for Schedule II drugs. Schedule II drugs have the highest potential for abuse of any prescription drugs legally available in the United States. This physician prescribed massive amounts of Schedule II drugs for a single beneficiary, including a 20-month supply of morphine sulfate and a 17-month supply of oxycodone HCl.

In total, Medicare paid \$352 million for Part D drugs ordered by the physicians with questionable prescribing patterns in 2009. Notably, 110 of these physicians were associated with 1 or more of the retail pharmacies we identified as having questionable billing as discussed below.⁵ It is important to note that questionable billing does not necessarily mean fraudulent billing. However, these patterns raise flags that warrant further attention.

Thousands of Retail Pharmacies Billed Far Outside the Norm

Our prior analysis of Part D data also uncovered disturbing billing patterns by some pharmacies. When we examined the records for Part D drugs, we found that 2,637 retail pharmacies nationwide had billing patterns far outside the norm. These pharmacies billed extremely high numbers of drugs per beneficiary or per prescriber or billed extremely high percentages of Schedule II or Schedule III drugs, brand-name drugs, or refills relative to other pharmacies. While some pharmacies with questionable billing may be billing these amounts for legitimate reasons, this type of billing warrants further scrutiny. Medicare paid these pharmacies a total of \$5.6 billion in 2009.

We uncovered many examples of pharmacies billing far outside the norm:

- One pharmacy had 85 percent of its total prescriptions for the year ordered by a single prescriber. Billing patterns like this may indicate that the pharmacy and prescriber were working together to defraud the Part D program.
- One pharmacy billed an average of \$132,845 per prescriber, which is 73 times the national average. Virtually all of these prescriptions were for brand-named drugs. These included Dovonex (a drug that treats psoriasis), Zyprexa (an antipsychotic), and Flovent HFA (a drug that treats asthma).

⁵ We considered a physician to be associated with a retail pharmacy if the retail pharmacy billed for at least 25 percent of the total cost of the Part D drugs that physician prescribed in 2009.

Medicare Paid for Schedule II Drugs Billed as Refills, Which Are Prohibited by Federal Law

In another review, we found that Medicare Part D inappropriately paid \$25 million for Schedule II drugs billed as refills in 2009. Sponsors should not have paid for any of these drugs because Federal law prohibits the refilling of Schedule II controlled substances. A new prescription authorizing the pharmacy to provide the drug is required each time a Schedule II is dispensed. Paying for refills of highly addictive drugs raises public health concerns and may contribute to the diversion and resale of controlled substances. Some of these refills may have been inaccurately billed. However, three-quarters of Part D sponsors paid for these refills, indicating that many sponsors do not have adequate controls in place to prevent refills of Schedule II drugs.

Oversight and Monitoring by CMS, Plan Sponsors, and CMS's Contractor Are Limited

OIG's findings of claims for questionable, inappropriate, and potentially dangerous Part D drugs indicate that safeguards should be strengthened to better protect the program and beneficiaries. In addition to analyzing these claims, we have examined Part D oversight and the systems in place to protect program integrity. These reviews have focused on CMS's oversight functions; plan sponsors' identification of fraud and abuse; and the MEDIC's abilities to detect, investigate, and refer fraud in the Part D program.

All these reviews have identified vulnerabilities in efforts to combat Part D fraud and abuse. For example, we found that some plan sponsors did not identify any potential fraud and abuse incidents and that most potential fraud and abuse incidents were associated with only a small number of plan sponsors.

Further, the MEDIC has not fully utilized data analytics to identify potential fraud and abuse. CMS's plans had called for data analysis to serve as a cornerstone of its Part D integrity strategy. However, OIG's work revealed that only a small percentage of the MEDIC's investigations and case referrals originated through proactive methods, such as data analysis.

The MEDIC also faces challenges in effectively resolving instances of potential fraud, waste, or abuse. For example, there is no administrative mechanism to recover payments associated with inappropriate Part D claims. The MEDIC is also prohibited from sharing specific information with program integrity contractors that oversee Medicare Parts A and B and Medicaid. Further, the MEDIC lacks the authority to obtain information directly from pharmacies, physicians, and pharmacy benefit managers; it must obtain information through the plan sponsors. Finally, CMS does not require plan sponsors to refer instances of suspected fraud and abuse to the MEDIC, so it may be missing opportunities to develop and pursue fraud cases.

OIG Recommends Improvements in Part D Oversight and Monitoring

Taken together, OIG's findings consistently demonstrate the need for CMS to strengthen Part D monitoring and oversight. OIG has recommended numerous improvements to more effectively safeguard the Part D program from fraud, waste, and abuse. We have recommended that CMS:

- Require sponsors to verify that prescribers have the authority to prescribe drugs.
- Strengthen the MEDIC's monitoring of prescribers and pharmacies so that it systematically monitors them using measures such as the ones used by OIG and identifies the prescribers and pharmacies with questionable patterns.
- Strengthen sponsors' monitoring of prescribers and pharmacies by providing additional guidance on effective monitoring methods, emphasizing the importance of data analysis, and recommending that sponsors routinely generate and review reports on billing.
- Ensure that Part D does not pay for refills of Schedule II drugs, as such refills are prohibited by Federal law. CMS should exclude these drugs when calculating its final payments to sponsors at the end of each year.
- Require sponsors to refer potential fraud and abuse incidents that may warrant further investigation to CMS and other appropriate entities, instead of relying on sponsors to voluntarily report.
- Develop and implement an administrative mechanism to recover payments from plan sponsors for inappropriate Part D claims. CMS currently does not have such a mechanism to help safeguard Medicare funds.
- Clarify its policy and instruct the MEDIC regarding the circumstances under which it may share specific information with other entities, including State agencies. This would improve the MEDIC's ability to effectively identify and investigate potential fraud and abuse.
- Facilitate access to information necessary to ensure accurate coverage and reimbursement determinations. Requiring diagnosis codes on Part D claims could help plan sponsors and CMS determine whether a drug is covered under Medicare.
- Amend regulations to authorize the MEDIC to obtain information directly from entities such as pharmacies, physicians, and pharmacy benefit managers.
- Provide education and training for prescribers, including issuing reports similar to Comparable Billing Reports issued for other services, such as those provided under Part B. These reports would provide prescribers with important educational information and insight about their prescribing patterns.

CMS has agreed with many of our recommendations and it has taken some steps to strengthen Part D monitoring. While we appreciate CMS's agreement to implement certain recommendations, many of the vulnerabilities that OIG has identified stem from a lack of basic checks that should be occurring. It is important that CMS effectively follow through and implement these basic checks. OIG's next steps in oversight will be to review the effectiveness

of sponsors' drug utilization programs to ensure that Medicare payments meet program guidelines.

Conclusion: More Needs To Be Done To Safeguard the Program and Protect Patient Safety

The Part D program provides outpatient prescription drug coverage for 37 million Medicare beneficiaries at a cost of almost \$67 billion. Numerous health care fraud investigations involving Part D and drug diversion have revealed complex crimes, some involving criminal enterprises. Ineffective or nonexistent program controls can cost beneficiaries and taxpayers millions of dollars. In addition, serious health consequences can result from inappropriate prescription drug use. Effective monitoring and oversight are essential to ensuring patient safety and preventing fraud, waste, and abuse.

To that end, all of the players discussed in OIG's testimony need to do more. CMS needs to improve its oversight and take the specific steps outlined above. The MEDIC needs to improve its monitoring of claims data and effectively develop and refer potential fraud cases to OIG. Sponsors need to strengthen their payments controls and reporting of fraud and abuse. The program needs effective controls that prevent problems from occurring and effective and aggressive responses in instances when problems occur.

For our part, OIG is committed to continuing our vigilant oversight of Part D integrity and investigating cases of suspected fraud to hold perpetrators accountable and protect beneficiaries. This mission is challenged by the declining resources that OIG has to bring to bear at a time when Part D fraud, waste, and abuse and prescription drug diversion cases are on the rise. While our Part D investigative caseload has almost quadrupled over the past 5 years, we are in the process of reducing our staff by about 20 percent as a result of expiring funding sources, compounded by the effects of sequestration. We are leveraging our analytic, investigative, and oversight tools as well as our Federal, State, and local partnerships to maximize the impact of our efforts.

Thank you for your interest in this important issue and for the opportunity to present the results of our most recent work related to Part D. OIG remains committed to carrying out our oversight and enforcement responsibilities in this area as comprehensively and effectively as possible with the tools and resources we have available.