



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

Testimony Before the United States Senate Special Committee on Aging

**“Opioid Use Among Seniors –
Issues and Emerging Trends”**

Testimony of:

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Good morning, Chairman Collins, Ranking Member McCaskill, and other Members of the Committee. I am Ann Maxwell, Assistant Inspector General for Evaluation and Inspections of the Office of Inspector General (OIG), U.S. Department of Health and Human Services (HHS). Thank you for the opportunity to testify about our work on opioid use and the Medicare Part D program, the prescription drug benefit for Medicare beneficiaries. My testimony will draw heavily from OIG's data brief, *Questionable Billing and Geographic Hotspots Point to Potential Fraud and Abuse in Medicare Part D* (OEI-02-15-00190) and our Portfolio report, *Ensuring the Integrity of Medicare Part D* (OEI-03-15-00180), both issued in June 2015. With your permission, Chairman Collins, I would like to submit both of those reports for the record.

Prescription drug abuse is a growing problem in this country from which seniors are not immune. The Centers for Disease Control and Prevention (CDC) has declared prescription drug abuse an epidemic.¹ More people in the United States died from drug overdoses in 2014 than during any previous year on record. Opioids are the main drugs associated with overdose deaths.² Drug diversion—the redirection of prescription drugs for an illegal purpose—is also a serious problem. Examples of drug diversion include the illegal resale of opioids.

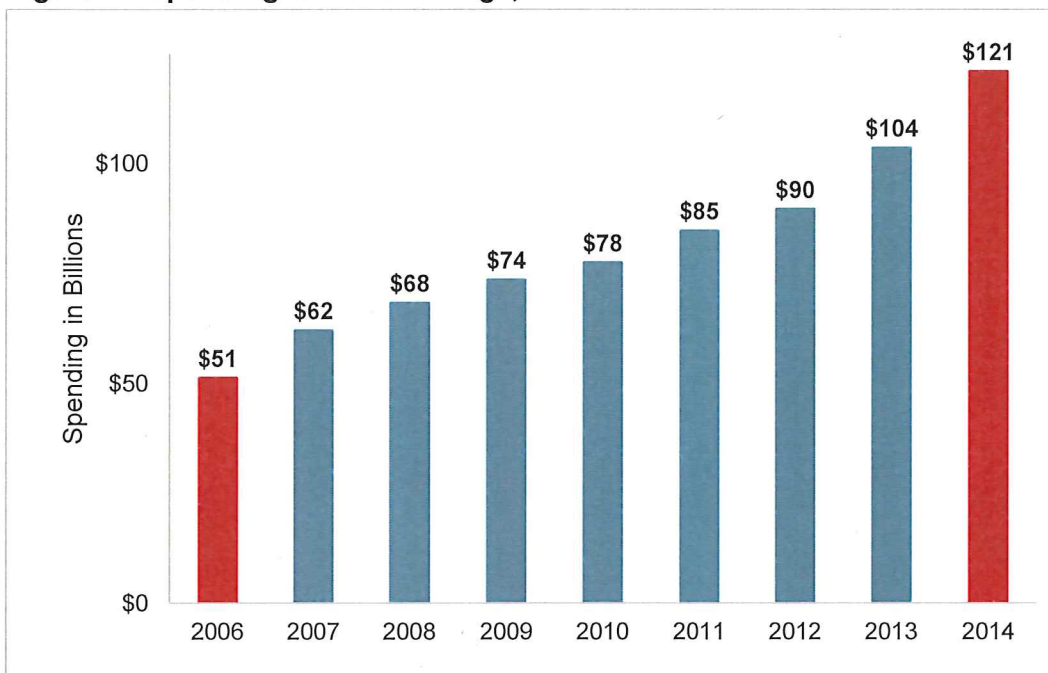
My testimony will describe the substantial growth in spending for Part D drugs, particularly commonly abused opioids. I will also describe questionable billing patterns and related investigations associated with these drugs and highlight key improvements needed to address opioid overutilization and drug diversion. OIG has pursued a multifaceted approach to address these problems. In addition to conducting investigations, OIG has used sophisticated claims analysis to reveal trends in the use of opioids and identify questionable billing associated with pharmacies, prescribers, and beneficiaries for these drugs.³

OPIOID OVERUTILIZATION IS A CONCERN FOR THE MEDICARE PART D PROGRAM

Spending for Part D drugs more than doubled from 2006 to 2014.

Spending for Part D drugs is the amount that the Government, beneficiaries, and plan sponsors paid to pharmacies for drugs. From 2006 to 2014, spending for Part D drugs increased by 136 percent, from \$51.3 billion to \$121.1 billion.⁴ (See Figure 1.)

Figure 1: Spending for Part D Drugs, 2006–2014



Source: OIG analysis of Medicare Part D data, 2015.

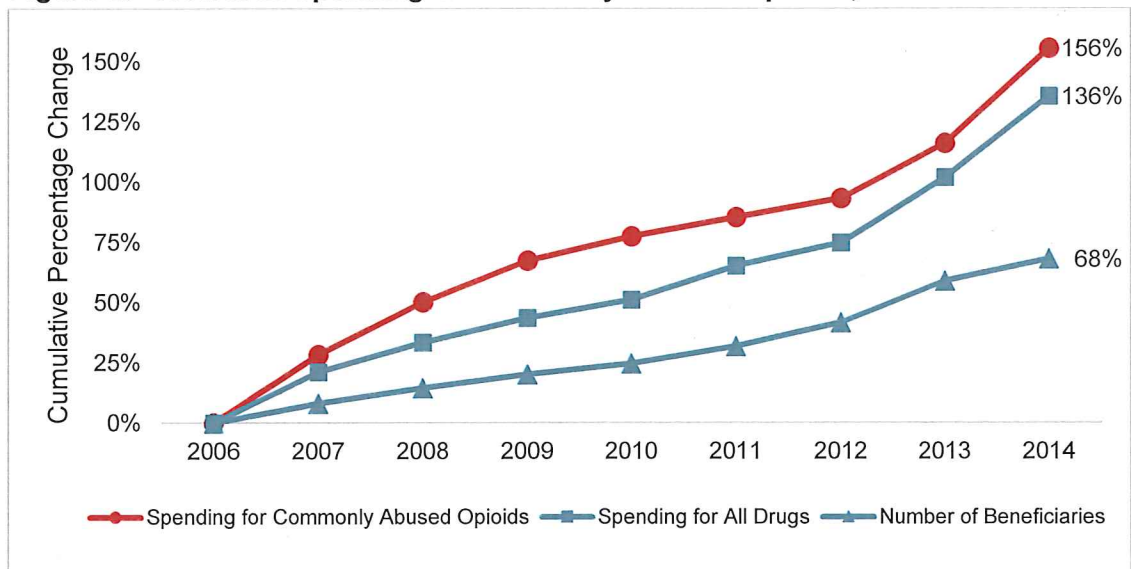
In 2014, \$7.8 billion—or 6 percent of all Part D spending—was for controlled substances. Controlled substances of particular concern are Schedule II and III opioids, hereafter referred to as “commonly abused opioids.”⁵ They are narcotics intended to manage pain from surgery, injury, and illness. They can create a euphoric effect, which makes them very vulnerable to abuse. In 2014, Part D spending for these opioids was highest for OxyContin (the brand-name version of oxycodone), hydrocodone-acetaminophen, fentanyl, and morphine sulfate.

Spending for commonly abused opioids grew at a faster rate than spending for all drugs.

Between 2006 and 2014, spending for commonly abused opioids grew from \$1.5 billion to

\$3.9 billion, an increase of 156 percent. (See Figure 2.) Growth in spending for these opioids outpaced both the growth in spending for all Part D drugs (which grew 136 percent) and the growth in the number of beneficiaries receiving Part D drugs (which grew 68 percent).

Figure 2: Growth in Spending of Commonly Abused Opioids, 2006–2014



Source: OIG analysis of Medicare Part D data, 2015.

The increase in spending for commonly abused opioids appears to have been driven by an increase both in the number of beneficiaries receiving these opioids and in the average number of prescriptions per beneficiary. Both of these numbers have increased faster for commonly abused opioids than for all drugs. The total number of beneficiaries receiving these opioids grew by 92 percent, compared to 68 percent for all drugs, while the average number of prescriptions for commonly abused opioids per beneficiary grew by 20 percent, compared to 3 percent for all drugs.

Part D spending averaged \$105 per beneficiary for commonly abused opioids in 2014. Additionally, 32 percent of beneficiaries received at least one prescription for a commonly abused opioid in 2014.

Many pharmacies had questionable billing for commonly abused opioids.

As spending for commonly abused opioids increases, so do concerns about program integrity, fraud, and abuse. One way to identify pharmacies that may be involved in schemes is to evaluate their billing patterns using measures that may indicate potentially fraudulent activity. One such measure is the percentage of a pharmacy’s prescriptions that are for commonly abused opioids. Billing for commonly abused opioids in a high percentage of prescriptions may indicate that a pharmacy is billing for medically unnecessary drugs that

may be used inappropriately or diverted and resold for a profit.

A total of 468 pharmacies billed for commonly abused opioids in an extremely high percentage of their prescriptions in 2014. Nationwide, commonly abused opioids accounted for 6 percent of each pharmacy's prescriptions, on average. However, each of these 468 pharmacies billed for commonly abused opioids in at least 17 percent of its Part D prescriptions—nearly three times the national average. Thirty of these pharmacies billed for commonly abused opioids in over half of their prescriptions. For example, one Detroit-area pharmacy billed for commonly abused opioids for 93 percent of its beneficiaries, which amounted to 58 percent of all its Part D prescriptions.

Another pharmacy measure that could indicate potentially fraudulent activity involves beneficiaries who had an unusually high number of prescribers for commonly abused opioids. In 2014, a total of 216 pharmacies billed for beneficiaries who, on average, had at least 4 prescribers for commonly abused opioids. In comparison, the national average was two prescribers per beneficiary for these drugs.

When beneficiaries have a high number of prescribers for commonly abused opioids it may indicate that they are “doctor shopping,” which is when a beneficiary consults a number of doctors for the purpose of inappropriately obtaining prescriptions.

Many general-care physicians had questionable prescribing patterns for controlled substances.

In addition to identifying questionable billing by pharmacies, OIG has developed measures and assessed questionable prescribing patterns by physicians. In 2009, a total of 483 general-care physicians ordered an extremely high percentage of Schedule II or III drugs, which have a high risk for abuse and include commonly abused opioids.⁶ Specifically, 343 general-care physicians ordered a high percentage of Schedule II drugs; at least 14 percent of the prescriptions ordered by each of these physicians were for Schedule II drugs. This was seven times the national average for general-care physicians. The most common Schedule II drugs ordered by these physicians were oxycodone HCl, morphine sulfate, and methadone HCl.

Although some of this prescribing may be appropriate, prescribing a high percentage of these drugs may indicate that a physician is ordering medically unnecessary drugs, which may be used inappropriately or diverted and resold. Misuse of these drugs has serious human and financial costs.

In one example, about 80 percent of the prescriptions ordered by one Ohio physician were for Schedule II drugs. Also troubling is that this physician had 106 Part D beneficiaries, 98 of whom received oxycodone HCl. In another example, a California physician ordered 115

Schedule II drugs for 1 beneficiary in 2009. Medicare paid \$425,711 for these drugs, which were dispensed by 11 pharmacies.

OIG has increased Part D investigations of fraud, including diversion of opioids

The growing use of opioids among Part D beneficiaries and prevalence of questionable billing and questionable prescribing for these drugs raise concern. These trends may indicate that beneficiaries are receiving unnecessary opioids. They may also indicate that the Part D program is paying for prescription drugs that are diverted and resold for illegal purposes. As a result, OIG has stepped up the number of investigations in this crucial area.

OIG has seen a 134-percent increase in cases and complaints involving Part D in the last 5 years. OIG has identified several Part D fraud trends, including billing for non-rendered services and prescription drug diversion. For example, a pharmacy would bill for but not dispense a prescription drug. Prescription drug diversion is the redirection of prescription drugs for illegitimate purposes. It often involves overprescribing of controlled drugs, such as opioids, but can also include billing for unnecessary non-controlled prescriptions that can be combined with controlled substances to enhance the euphoric effect and chance of overdose. Fraud associated with non-controlled substances typically involves brand-name, high-cost medications, including respiratory, HIV, and antipsychotic medications.

OIG's investigations have also identified an increase in organized criminal networks committing health care fraud. The influx of criminal networks has become a pervasive problem in fraud schemes involving pharmacies and prescription drugs. These schemes typically involve kickbacks, nominee owners, recruiters, and money laundering. Cases often involve multiple co-conspirators ranging from informal networks of street traffickers to complex criminal enterprises comprised of health care professionals, pharmacies, and even patients.

As a result of one OIG investigation, a physician was convicted of prescribing oxycodone-based products to complicit patients. The complicit patients received unnecessary prescriptions, filled them at various pharmacies, and sold the pills to six different drug-trafficking organizations, which resold the drugs on the street. This scheme resulted in the illegal distribution of more than 700,000 opioid pills and 1 patient death. A total of 64 defendants connected to this scheme have been sentenced to a combined 254 years in prison. The physician was sentenced to 25 years in prison and was ordered to forfeit \$10 million.

During fiscal years 2012–2015, OIG's Part D investigations resulted in 482 criminal actions, 47 civil actions, and over \$784 million in investigative receivables.

CHANGES TO HELP ADDRESS OPIOID OVERUTILIZATION

OIG has focused its efforts on identifying and preventing Part D fraud, including the illegal or unnecessary prescribing of opioids. We have made a series of recommendations to the Centers for Medicare & Medicaid Services (CMS) to strengthen program integrity in Part D. CMS has made a number of important changes based on these recommendations. For example, CMS now identifies physicians that prescribe high levels of Schedule II drugs compared to their peers and identifies high risk pharmacies. CMS provides this information to Part D plan sponsors for follow-up. In addition, CMS leadership has prioritized working toward implementing several recommendations that remain outstanding. These recommendations focus on leveraging Part D data to identify vulnerabilities and employing additional measures to enhance its monitoring of fraud, waste, and abuse.

The following two recommendations particularly relevant to opioid use have yet to be implemented.

Restrict certain beneficiaries to a limited number of pharmacies or prescribers.

CMS should be granted the authority to restrict certain beneficiaries to a limited number of pharmacies or prescribers when warranted by excessive or questionable billing patterns. This practice is commonly referred to as “lock-in” and has been successfully used by State Medicaid programs.

Restricting certain beneficiaries to a limited number of pharmacies or prescribers could both reduce inappropriate use of opioids among Medicare beneficiaries and reduce Part D fraud: it would target beneficiaries being harmed by overprescribing and beneficiaries who are “doctor shopping” or intentionally seeking unnecessary prescriptions.

Expand drug utilization review programs to include additional drugs susceptible to fraud, waste, and abuse.

Drug utilization reviews are intended to protect beneficiaries and reduce fraud, waste, and abuse. However, CMS’s requirements for these reviews apply only to certain types of drugs. We recommend that CMS and plan sponsors monitor beneficiary utilization for a wider range of drugs susceptible to abuse than they currently do. In particular, we recommend expanding sponsors’ and CMS’s drug utilization reviews to cover certain non-controlled substances, such as HIV and antipsychotic medications. It is important to expand these reviews because fraud related to non-controlled substances can contribute to opioid-related fraud. For example, some of these drugs can enhance the effects of the opioids, when taken with them.

CONCLUSION

Recent trends in opioid use among Medicare Part D beneficiaries are concerning. Spending for commonly abused opioids grew at a faster rate than spending for all drugs and reached \$3.9 billion in 2014. The number of beneficiaries receiving these opioids and the average number of prescriptions per beneficiary also increased. This growth—in addition to the CDC’s declaring prescription drug abuse an epidemic— demonstrates that this issue warrants continued action.

To date, OIG has focused its efforts on identifying and preventing Part D fraud, including the illegal or unnecessary prescribing of opioids. We have identified both pharmacies and prescribers with questionable billing patterns. We have also had numerous cases that have found that the Part D program is paying for opioids that are illegally diverted for resale and recreational use.

CMS has made a number of important changes based on the recommendations from our work. However, more needs to be done. Notably, creating a “lock-in” program in Part D would provide CMS with an additional tool to protect beneficiaries from over-utilizing opioids. OIG continues to work with CMS and remains committed to combating the issue of opioid overutilization and to protecting beneficiaries and the integrity of the Part D program.

Thank you again for inviting me to speak with the committee today to share the results of OIG’s work related to opioid use in Part D. We join you in your concern and applaud your leadership in continuing to focus attention on this issue. I would be happy to answer any questions the committee may have.

ENDNOTES

¹ CDC, Prescription Painkiller Overdoses at Epidemic Levels, November 1, 2011. Accessed at http://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html on May 5, 2015.

² CDC, Increases in Drug and Opioid Deaths – United States, 2000-2014, January 1, 2016. Accessed at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm?s_cid=mm6450a3_w on February 19, 2016.

³ OIG, *Retail Pharmacies With Questionable Part D Billing*, OEI-02-09-00600, May 2012; OIG, *Prescribers With Questionable Part D Billing*, OEI-02-09-00603, May 2012; and OIG, *Part D Beneficiaries With Questionable Utilization Patterns for HIV Drugs*, OEI-11-00170, August 2014.

⁴ This represents the negotiated price paid to the pharmacy. It is not adjusted for any rebates, coverage gap discounts, or other Direct and Indirect Remuneration paid to the sponsors.

⁵ We refer to Schedule II and III opioids as “commonly abused opioids.” According to the National Institute on Drug Abuse—part of the National Institutes of Health—prescription opioids are among the most commonly abused drugs. See National Institute on Drug Abuse, *Commonly Abused Drugs Charts*, January 2016. Accessed at <https://www.drugabuse.gov/drugs-abuse/commonly-abused-drugs-charts> on February 19, 2016.

⁶ OIG, *Prescribers With Questionable Part D Billing*, OEI-02-09-00603, May 2012.