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Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

"Medicare Part D: Measures Needed To Strengthen Program Integrity"

Testimony of:

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Good morning, Chairman Murphy, Ranking Member DeGette, and other Members of the Subcommittee. 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 fraud, waste, and abuse trends in the Medicare Part D Program and the status of our recommendations to address the underlying vulnerabilities of the program. During my testimony, I will be drawing heavily from two OIG products, our portfolio report, *Ensuring the Integrity of Medicare Part D* (OEI-03-15-00180) and our data brief, *Questionable Billing and Geographic Hotspots Point to Potential Fraud and Abuse in Medicare Part D* (OEI-02-15-00190), both of which were issued in June 2015. With your permission, Mr. Chairman, I would like to submit both of those reports for the record.

OIG has made stopping Part D fraud a top priority. With over 39 million Americans depending on the program for their prescription drugs costing over $120 billion a year, OIG finds it imperative to take a comprehensive approach to combat Part D fraud.

I will first describe our investigative efforts and analysis of potential fraud indicators to describe the scale of the fraud challenge in Part D. While we understand that enforcement is an important tool in addressing fraud in Part D, it cannot address the systemic changes that the Centers for Medicare & Medicaid Services (CMS) needs to make to protect the integrity of the program. In this vein, I will then provide an overview of the unimplemented recommendations OIG has made to CMS that if implemented, would significantly increase CMS's ability to improve the Part D program's effectiveness and protect its beneficiaries. I will close by suggesting action that would improve program integrity.

THE MEDICARE PART D PROGRAM IS VULNERABLE TO FRAUD

In June 2015, OIG deployed more than 300 special agents and forensic specialists, alongside hundreds of other law enforcement personnel, to execute arrest and search warrants across the country. It was the largest national health care fraud takedown to date and resulted in more than 240 subjects being charged with defrauding the Medicare and Medicaid programs involving over $700 million in false billings. Much of the fraud involved prescription drugs and those charged included doctors, pharmacy owners, and others. Twenty-eight individuals

from South Florida alone were charged with Part D fraud totaling more than $38 million in Medicare overpayments.

This takedown put into sharp focus the threat that fraud schemes pose to the Part D program. These schemes increasingly involve criminal networks, which have become a pervasive problem in health care fraud. Schemes include billing for drugs that are not dispensed, illegal dispensing of expired or adulterated drugs, doctor shopping, and drug diversion when a prescription drug is redirected for an illegal purpose, such as recreational use or resale. For example, two individuals arrested in the June takedown in South Florida allegedly sold diverted prescription drugs worth a total of approximately $200,000 to undercover agents on three separate occasions. The diversion of controlled substances, such as opioids, is of particular concern due to its severe health risk and potential for abuse. However, we are also concerned with the diversion of noncontrolled substances, such as HIV and antipsychotic medications, as these drugs are becoming more common in fraud schemes. Fraud related to these drugs can harm beneficiaries and present a significant financial loss to Medicare.

OIG pursues such fraud cases through coordinated Federal and State enforcement efforts, including the Medicare Fraud Strike Force teams. During the last three years (FY 2012−2014), OIG's Part D investigations resulted in 339 criminal actions, 31 civil actions, and over $720 million in investigative receivables. Yet, as successful as these enforcement efforts have been, they alone do not solve the problem of prescription drug fraud. Vulnerabilities still exist in the Part D program, where spending has risen sharply, pharmacies practice questionable billing, and hotspots for noncontrolled substances have developed.

Medicare spending for Part D drugs has more than doubled since 2006, and spending for commonly abused opioids has grown even faster.

Spending for Part D drugs represents 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. Over the same time, spending for commonly abused opioids grew from $1.5 billion to $3.9 billion, an increase of 156 percent. These drugs are narcotics intended to manage pain from surgery, injury, and illness. They can create a euphoric effect, which in turn makes them very vulnerable to abuse.

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 more rapidly for commonly abused opioids than for all drugs.

More than 1,400 pharmacies had questionable billing for Part D drugs in 2014, raising concerns about fraud and abuse.

When OIG examined pharmacy billing patterns to look for questionable billing that might be an indicator of fraud, we identified 1,432 retail pharmacies that had questionable billing. Together these pharmacies billed $2.3 billion to Part D in 2014. These pharmacies each billed excessively high amounts for at least one of the five questionable billing measures we reviewed. Although some of this billing may be legitimate, all pharmacies that bill extremely high amounts warrant further scrutiny. Examples of measures and associated questionable billing in 2014 are described below.

- A total of 468 pharmacies billed for commonly abused opioids in an extremely high percentage of their prescriptions. This may indicate that a pharmacy is billing for medically unnecessary drugs that may be used inappropriately or diverted and resold for a profit. Each of the pharmacies we identified billed for commonly abused opioids in at least 17 percent of its Part D prescriptions—nearly three times the national average.

- A total of 216 pharmacies billed for beneficiaries who had an unusually high number of prescribers for commonly abused opioids. This may indicate that the beneficiaries have been "doctor shopping" for the purpose of inappropriately obtaining prescriptions. These pharmacies billed for beneficiaries who, on average, had at least four prescribers for commonly abused opioids. In comparison, the national average was two prescribers per beneficiary for these drugs.

- A total of 314 pharmacies billed for a high number of different types of drugs, per beneficiary, which may indicate that a pharmacy is billing for drugs that were not provided or that were provided, but were medically unnecessary. Each of these pharmacies billed, on average, for more than 12 different types of drugs for each beneficiary in 2014. This was double the national average.

Geographic hotspots for certain drugs point to possible fraud and abuse.

OIG also identified a number of metropolitan areas where average Medicare payments per beneficiary for certain drugs was significantly higher than the average payments nationwide. We focused this analysis on noncontrolled substances because fraud related to these drugs is becoming more common and can present a substantial financial loss to Medicare and pose the danger of patients taking improperly prescribed medications. Although medical need and prescriber practices may vary across different areas of the country, the patterns in these hotspots warrant further scrutiny, as they may indicate fraud and abuse. Selected hotpots include:

- In the San Juan area in Puerto Rico, the billing for diclofenac potassium, a generic anti-inflammatory used for conditions such as rheumatoid arthritis and osteoarthritis, was 31

times higher than the national average. Almost one-third of all Medicare spending for diclofenac potassium was in this one hotspot.

- In the New York area, billing for Solaraze, a brand-name topical ointment used to treat a skin condition in which lesions form as a result of sun damage, were almost nine times the national average. Half of all Part D spending for this drug, for which there is a less expensive generic equivalent, was in this one hotspot.

- In the McAllen area in Texas, 17 percent (more than four times the national average) of beneficiaries received the prescription version of Nexium, used to treat conditions such as gastroesophageal reflux disease. Medicare paid $20 million for Nexium in this hotspot, even though there is an over-the-counter version available.

These billing patterns raise questions about whether the drugs were medically necessary or were even provided to beneficiaries in the first place. Also, because some of the drugs are available as generics or over the counter, there are questions about whether pharmacies are billing for the higher priced brand-name drug while providing a less expensive drug.

CHANGES CMS CAN MAKE TO PROTECT THE INTEGRITY OF THE MEDICARE PART D PROGRAM

Since Part D went into effect, OIG has raised concerns about oversight and made a number of recommendations to CMS to better safeguard the program and protect beneficiaries. CMS has made some progress. However, CMS, its National Benefit Integrity Medicare Drug Integrity Contractor (MEDIC), and Part D plan sponsors all need to do more to protect the Medicare Part D Program. OIG recommendations center around two themes: (1) leveraging Part D data to identify vulnerabilities and (2) employing additional tools to enhance the oversight of the Part D Program. Our Part D Portfolio, which we have submitted for the record, goes into each of the unimplemented recommendations in detail.

CMS Needs To Do More To Leverage Part D Data To Identify Vulnerabilities

The availability and proactive use of data are essential to identify and address program vulnerabilities, identify providers with questionable billing, and meaningfully target program integrity resources to the areas of greatest vulnerability. A program as expansive as Part D requires the sophisticated use of data to maintain the visibility and vigilance necessary to uncover, address, and prevent fraud. CMS has taken steps to improve data coordination among the key players tasked with safeguarding Part D. Specifically, CMS has begun sharing plan sponsors' voluntarily reported fraud data with the MEDIC. In addition, CMS and the MEDIC developed a Pharmacy Risk Assessment tool and distributed it to plan sponsors to use in conducting additional analysis. However, much remains to be done. For example:

Increased use of data should include collecting and analyzing data necessary to hold plan sponsors accountable. Plan sponsors are the private insurance companies responsible for administering the program and the program's first line of defense against fraud and abuse. However, CMS does not require plan sponsors to report the number of instances of potential fraud, waste, and abuse they identify, nor the actions they took to address them. In lieu of a requirement, CMS established a mechanism for plan sponsors to voluntarily report data to CMS. But less than half of Part D plan sponsors did so between 2010 and 2012. Without this information from plan sponsors, it is impossible for CMS to review the effectiveness of plan sponsors' fraud detection programs.

Increased use of data should also involve making better use of the data already collected. 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 review to cover certain noncontrolled substances, such as HIV and antipsychotic medications.

Additionally, while the MEDIC is CMS's key program integrity contractor for Part D and is required to investigate potential fraud and abuse, OIG found that the MEDIC used proactive data analysis to initiate only a small percentage of investigations and case referrals, and instead relied on external sources to identify most incidents of potential fraud and abuse. Although the percentage of the MEDIC's investigations initiated from proactive analysis has increased over the years, it still remains around 10 percent—a rather small percentage.

CMS Needs To Employ Additional Measures to Enhance Its Monitoring of Fraud, Waste, and Abuse In Part D

Each entity involved in Part D has a role in detecting and preventing fraud, waste, and abuse. Plan sponsors have the primary responsibility for reviewing and paying claims. As such, they must have adequate controls in place to prevent improper payments. CMS, in turn, must exercise proper oversight of both the plan sponsors and the MEDIC to ensure that those entities are working to reduce the program's vulnerability to fraud, waste, and abuse.

Recently, CMS has implemented measures to bolster its monitoring and oversight of providers in Part D. For example, CMS provided the MEDIC with the authority to request and collect information that it needs to investigate potential fraud directly from pharmacies and other entities. CMS now requires plan sponsors to verify that prescribers have the authority to prescribe drugs and that claims contain valid prescriber identifiers. CMS recouped some payments made after beneficiaries' deaths. It also provided data to plan sponsors to help them identify claims associated with excluded providers. In addition, CMS expanded its guidance regarding the proper billing of Schedule II drugs, and plan sponsors

have reported strengthening their controls for these drugs. But, again, more remains to be done.

CMS, the MEDIC, and plan sponsors need to strengthen program oversight by employing additional tools. Our work has shown that the current approach to oversight is not sufficient to protect Part D. There are four key areas where we recommend further action.

Strengthen controls to prevent payments for drugs not covered by Part D such as payments to providers who are excluded from Federal health care programs. OIG has found that plan sponsors do not have adequate controls to prevent improper payments. OIG has found that plan sponsors' processes have sometimes compromised their ability to detect, correct, and prevent fraud, waste, and abuse. CMS has not exercised sufficient oversight of plan sponsors to prevent improper payments, such as payment for drugs that are not covered by Part D. For instance, OIG has found that appropriate controls were not in place to prevent Part D payments for drugs prescribed by providers excluded from Federal health care programs. It is important that claims for drugs prescribed by excluded providers be denied to protect beneficiaries from inappropriate or even harmful services.

Conduct a more robust oversight of plan sponsors' compliance programs. Plan sponsor compliance programs provide the roadmap for sponsors' efforts to prevent and detect fraud, waste, and abuse. They outline the protections the plan sponsor will put in place. However, OIG has identified weaknesses in CMS's oversight of plan sponsors' implementation of compliance programs. Rectifying these weaknesses would lead to stronger and more consistent prevention measures to avoid fraud, waste, and abuse at the very beginning of the Part D payment process. For these reasons, CMS should provide additional oversight of plan sponsors to ensure effective implementation of compliance programs, one of the primary tools for Part D program integrity.

CMS needs a mechanism that would allow it to recover inappropriate payments in cases that have been declined by law enforcement agencies. The MEDIC currently does not have administrative authority to recommend recoupment of payments associated with inappropriate services. When law enforcement agencies do not accept MEDIC cases for further action, the MEDIC simply closes these cases because there are no established procedures to recommend recoupment of inappropriate payments.

The law should be changed to more effectively deal with beneficiaries who may be abusing the program or inflicting harm on themselves by overutilizing drugs. OIG investigations have found that Part D beneficiaries can be both victims and perpetrators of fraud. Beneficiaries can be harmed by overprescribing. On the other hand, some of the fraud trends prevalent in Part D involve beneficiaries who act as complicit patients. For example, in one investigation, the complicit beneficiary received unnecessary prescriptions, filled them at various pharmacies, and sold the pills to drug-trafficking organizations. This could be addressed by *restricting* beneficiaries to a limited number of pharmacists or prescribers when

warranted. This is commonly referred to as "lock-in" and has been successfully implemented by State Medicaid programs. However, CMS has stated that it would require legislative authority to implement these restrictions.

CONCLUSION

As the agency charged with administering and overseeing Part D, CMS is responsible for improving the program's effectiveness and protecting its beneficiaries. To protect the integrity of Part D, CMS should take action on OIG's unimplemented recommendations. OIG believes that CMS should employ all the tools at its disposal. CMS needs to more effectively collect and analyze program data to proactively identify and resolve program vulnerabilities and prevent fraud, waste, and abuse before it occurs. CMS also needs to implement a robust oversight plan designed to ensure proper payments, prevent fraud, and protect beneficiaries.

As the Part D program continues to evolve and new fraud schemes emerge, OIG will continue to investigate fraud and offer recommendations to improve oversight and establish new methods for early detection and prevention of fraud, waste, and abuse.

Thank you again for inviting me to speak with the committee today to share the results of OIG's audits, evaluations, and investigations on Part D. I would be happy to answer any questions the committee may have.