



U.S. Department of Health and Human Services Office of Inspector General

ENSURING THE INTEGRITY OF MEDICARE PART D



June 2015

An OIG Portfolio

OEI-03-15-00180

This portfolio presents an overview of Office of Inspector General (OIG) investigations, audits, evaluations, and legal guidance related to Part D. It synthesizes numerous OIG reports that have identified weaknesses in Part D program integrity, and provides updates on Departmental efforts to address these weaknesses. In particular, OIG has identified weaknesses in the use of data to identify vulnerabilities, as well as in the oversight by all parties responsible for protecting Part D: Part D plan sponsors, the Medicare Drug Integrity Contractor, and the Centers for Medicare & Medicaid Services (CMS). OIG has made recommendations to strengthen Part D program integrity, and progress has been made. However, Part D remains vulnerable to fraud, as evidenced by ongoing investigations. To fully protect Part D from fraud, waste, and abuse, CMS should take further action and implement OIG's unimplemented recommendations.

Office of Inspector General

<http://oig.hhs.gov>

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

Table of Contents

Background	1
Summary Findings	5
CMS is missing opportunities to leverage data to identify fraud, waste, and abuse	5
CMS and plan sponsor oversight is not sufficient to protect Part D	8
Part D remains vulnerable to fraud	13
Unimplemented OIG Recommendations for Part D Program Integrity	16
Appendixes	19
Appendix A: Highlighted OIG Reports on Part D Program Integrity	19
Appendix B: Highlighted OIG Products on Part D Program Integrity	21
Endnotes	23
Acknowledgments	26

BACKGROUND

What is Medicare Part D?

It is an optional prescription drug benefit available to Medicare beneficiaries.

How many are enrolled in Part D?

Approximately 39 million beneficiaries receive Part D benefits through more than 2,000 plans sponsored by private companies.

What does Part D cost?

Payments for Part D drugs are approximately \$121 billion per year.

Who oversees Part D?

Part D plan sponsors are responsible for monitoring and paying Part D drug claims. CMS is responsible for overseeing the program, and has contracted with the MEDIC to perform program integrity functions.

The Medicare Part D Program

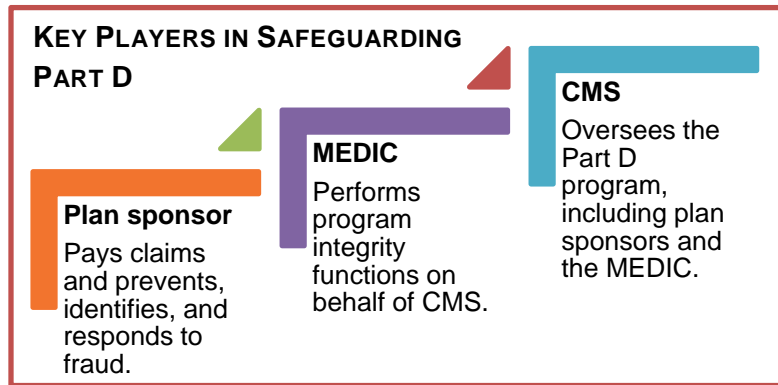
The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established Medicare Part D to provide an optional prescription drug benefit for Medicare beneficiaries beginning January 1, 2006. Individuals enrolled in Part D can choose to receive benefits through stand-alone prescription drug plans, or through Medicare Advantage prescription drug plans that provide integrated medical coverage, including drugs. The Centers for Medicare & Medicaid Services (CMS) contracts with private companies, known as plan sponsors, that offer prescription drug plans to their beneficiaries, with varying drug coverage and cost-sharing requirements. Most beneficiaries enrolled in Part D are responsible for certain costs, which may include a monthly premium, an annual deductible, and coinsurance or copayments.

Key Players in Protecting Part D

CMS relies on plan sponsors to be the first line of defense against fraud, waste, and abuse in Part D. Plan sponsors are responsible for paying claims, monitoring billing patterns, and establishing compliance plans that specify their procedures for preventing and detecting fraud, waste, and abuse. Plan sponsors must also ensure that entities with which they subcontract (e.g., pharmacies) meet regulatory and compliance requirements.

CMS also contracts with a private company to serve as the Medicare Drug Integrity Contractor (MEDIC) to detect and prevent fraud, waste, and abuse in Part D. The MEDIC's responsibilities include identifying and investigating potential fraud and abuse, referring cases to law enforcement, and fulfilling requests for information from law enforcement. The MEDIC is required to investigate potential fraud and abuse referred to it through external sources, such as complaints, as well as identify potential fraud and abuse through proactive methods, such as data analysis.

Ultimately, CMS is responsible for ensuring Part D program integrity. CMS oversees the plan sponsors and the MEDIC, defines their requirements for carrying out program integrity functions, and monitors their performance.



Office of Inspector General (OIG) Work in Part D

In the 9 years since Part D began, OIG has produced a wide range of investigations, legal guidance, audits, and evaluations related to Part D program integrity. This work has resulted in the prosecution of individuals accused of defrauding Part D, as well as the identification of systemic program vulnerabilities that raise concerns related to quality of care and improper payments. To assist in identifying potential fraud and other emerging issues, OIG has established a Hotline at 1-800-HHS-TIPS as a resource for individuals to submit tips and complaints regarding potential fraud, waste, and abuse.

OIG has seen an increase in Part D fraud complaints. OIG has investigated cases involving multiple co-conspirators, including health care professionals, patient recruiters, pharmacies, and beneficiaries. In one example, a pharmacy benefits manager settled a case for over \$2 million involving allegations of fraudulent Part D claims. Part D fraud can result in financial losses to the program and patient harm when prescription drugs are not used as intended. As such, OIG has made Part D fraud a top priority. This effort includes cases of non-controlled drugs being billed but not dispensed, in which beneficiaries obtain prescriptions for high-cost medications in exchange for monetary kickbacks.

EXAMPLES OF PART D FRAUD

DRUG DIVERSION – individual obtains prescription drugs and gives or sells them to someone else.

DOCTOR SHOPPING – beneficiary consults a number of doctors to inappropriately obtain multiple prescriptions.

INDUCEMENTS, KICKBACKS, OR BRIBES
prescriber receives unlawful payments as inducement or reward for writing prescriptions.

INAPPROPRIATE DISPENSING – pharmacy dispenses expired or adulterated prescription drugs, or dispenses drugs without a prescription.

OIG also has issued legal guidance as part of its efforts to curtail fraudulent and illegal activities. For example, shortly before the implementation of Part D, OIG issued a Special Advisory Bulletin regarding pharmaceutical manufacturers' patient assistance programs for Medicare Part D beneficiaries. In 2014, OIG also issued a Supplemental Special Advisory

Bulletin that expanded upon this issue, as well as a Special Advisory Bulletin regarding the anti-kickback statute implications when pharmaceutical manufacturers offer copayment coupons to Part D beneficiaries.

In addition to these enforcement and guidance efforts, OIG has conducted audits and evaluations that identify systemic weaknesses that make Part D fraud and abuse possible. The program integrity vulnerabilities that OIG has identified relate to the three key players charged with safeguarding the program: plan sponsors, the MEDIC, and CMS. OIG audits have examined the adequacy of oversight mechanisms, such as plan sponsors' internal claims processing edits to prevent improper payments. OIG evaluations have reviewed plan sponsor, MEDIC, and CMS oversight of Part D, such as the adequacy of the data that CMS requires plan sponsors to submit, and how effectively data are being used to target program integrity efforts.

The findings and recommendations developed through this body of work have led OIG to conclude that Part D's underlying vulnerabilities cluster around two issues involving all three levels of program oversight (plan sponsors, the MEDIC, and CMS): (1) the need to more effectively collect and analyze program data to proactively identify and resolve program vulnerabilities and prevent fraud, waste, and abuse before it occurs; and (2) the need to more fully implement robust oversight designed to ensure proper payments, prevent fraud, and protect beneficiaries.

Over the last 9 years, plan sponsors, the MEDIC, and CMS have taken steps to address OIG recommendations in these areas, and progress has been made. However, Part D remains vulnerable to fraud, as evidenced by ongoing investigations and an analysis of claims data that OIG is releasing in tandem with this portfolio. The OIG data brief, *Questionable Billing and Geographic Hotspots Point to Potential Fraud and Abuse in Medicare Part D* (OEI-02-15-00190), finds substantial growth in spending for Part D drugs, especially for commonly abused opioids. It also identifies questionable billing by pharmacies that may indicate fraudulent activity. This data brief further identifies geographic hotspots for certain drugs, where average Medicare payments per beneficiary are higher than average payments nationwide.

To continue improving Part D program integrity, CMS should take action to fully implement OIG's recommendations. OIG has prepared this portfolio to document key progress in addressing Part D program vulnerabilities and to highlight our unimplemented recommendations in this area. OIG will continue to monitor these vulnerabilities and other emerging Part D program integrity issues.

Standards

The work referenced throughout this portfolio was conducted in accordance the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency, generally accepted government auditing standards, and investigative and legal professional standards, as applicable.

SUMMARY FINDINGS

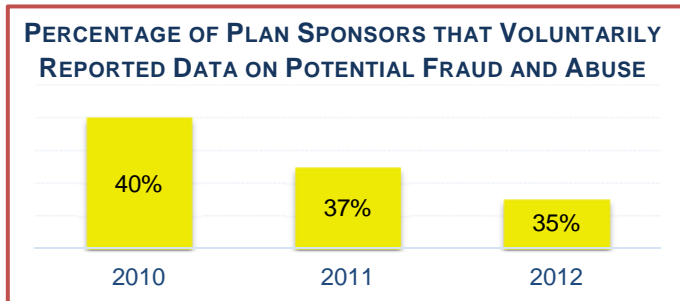
CMS IS MISSING OPPORTUNITIES TO LEVERAGE DATA TO IDENTIFY FRAUD, WASTE, AND ABUSE

Ensuring the integrity of a program as expansive as Part D requires constant and proactive efforts to detect and prevent fraud, waste, and abuse. 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. However, OIG's reports have found that the use of data by plan sponsors, the MEDIC, and CMS for Part D program integrity purposes has been limited. This makes Part D vulnerable to improper payments, drug diversion, overprescribing, and other quality-of-care issues.

CMS does not require plan sponsors to report information on fraud, and most have chosen not to voluntarily report this information

By requiring plan sponsors to report potential fraud, CMS could enhance its ability to review the effectiveness of plan sponsors' processes for fraud detection. However, plan sponsors are not required to report to the MEDIC or CMS the number

of specific instances of potential fraud, waste, and abuse they identify, nor the actions they took to address these issues. In lieu of a mandatory requirement to report specific instances, CMS established a mechanism for plan sponsors to voluntarily report aggregate data to CMS. Less than half of Part D plan sponsors chose to do so between 2010 and 2012.¹





Without specific requirements to report potential fraud, CMS has received inconsistent data from plan sponsors, which it cannot effectively use to assess plan sponsors' program integrity efforts. The wide variation in voluntarily reported fraud incidents could reflect differences in actual fraud among plan sponsors, or disparities in the actions plan sponsors take to identify and address incidents of fraud, waste, and abuse. CMS also does not require plan sponsors to report information on the steps they took after identifying instances of potential fraud and abuse, such as initiating inquiries and taking corrective actions. Without this

information, CMS cannot hold plan sponsors accountable for protecting Part D from fraud, waste, and abuse.²

When OIG requested plan sponsor information on potential fraud, waste, and abuse for the first 6 months of 2007, we found that the number of identified incidents varied significantly. In fact, 28 percent of stand-alone plan sponsors did not identify any potential fraud and abuse. Most potential incidents of fraud and abuse were associated with only a small number of plan sponsors. The low level of fraud identified by some plan sponsors raises questions about the sufficiency of their fraud and abuse detection programs. Furthermore, OIG's review found that among those plan sponsors that identified potential fraud and abuse, not all of them used this information to conduct inquiries, initiate corrective actions, or make referrals for further investigation.³

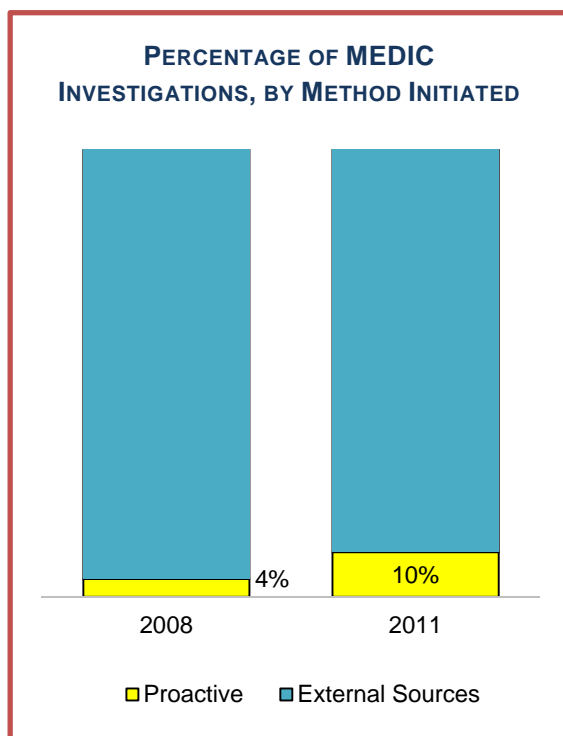
OIG found similar results for Medicare Advantage plans that include Part D coverage: 34 percent of these organizations did not identify any potential Part D fraud and abuse in 2009, and those that did identified between 1 and 100,909 incidents (with a median of 15 incidents).⁴

Progress Update: Plan Sponsor Reporting of Data

-  *CMS stated that it has begun sharing plan sponsors' voluntarily reported data on potential fraud, waste, and abuse with the MEDIC.*
-  *However, CMS does not require plan sponsors to report information on instances of potential fraud, waste, and abuse, or the actions plan sponsors take in response to such instances. Without this information, CMS and the MEDIC are hindered in their ability to ensure that plan sponsors are adequately fulfilling their program integrity functions.*

The MEDIC does not capitalize on proactive data analysis to detect fraud, waste, and abuse

OIG has found that the MEDIC has not taken full advantage of the data it has at its disposal. OIG reviews found that the MEDIC used proactive data analysis to initiate only a small percentage of investigations and case referrals, and instead



Note: This graph compares MEDIC activities during fiscal year 2008 to activities from April 2010 through March 2011.

relied on external sources (e.g., beneficiary complaints through the MEDIC’s toll-free number) to identify most incidents of potential fraud and abuse.⁵


QUESTIONABLE BILLING WENT


UNDETECTED. When OIG conducted its own proactive analyses of Part D claims, we identified potentially problematic billing patterns. The results of these analyses raise concerns about the extent to which all Part D entities are using data for oversight purposes, and whether further improper billing is going undetected. One OIG report found that a number of retail pharmacies had questionable billing patterns, such as extremely high dollar amounts or numbers of prescriptions per

beneficiary or per prescriber, which could indicate that the drugs were not medically necessary or were never provided.⁶

OIG has identified questionable billing by physicians (over 700 physicians, most of whom ordered extremely high percentages of drugs with the potential for abuse) and also on behalf of beneficiaries (over 1,500 beneficiaries with questionable utilization patterns for HIV drugs). These beneficiaries did not have an HIV diagnosis or indication of HIV treatment in their claims histories, received an excessive dose or supply of HIV drugs, and/or received HIV drugs from a high number of pharmacies or prescribers. CMS and plan sponsors have drug utilization review and monitoring programs that are designed to address inappropriate utilization and place restrictions (such as quantity limits) on beneficiaries receiving certain drugs. However, OIG’s analysis showed that there are additional drugs susceptible to fraud, waste, and abuse that are not affected by these restrictions.⁷

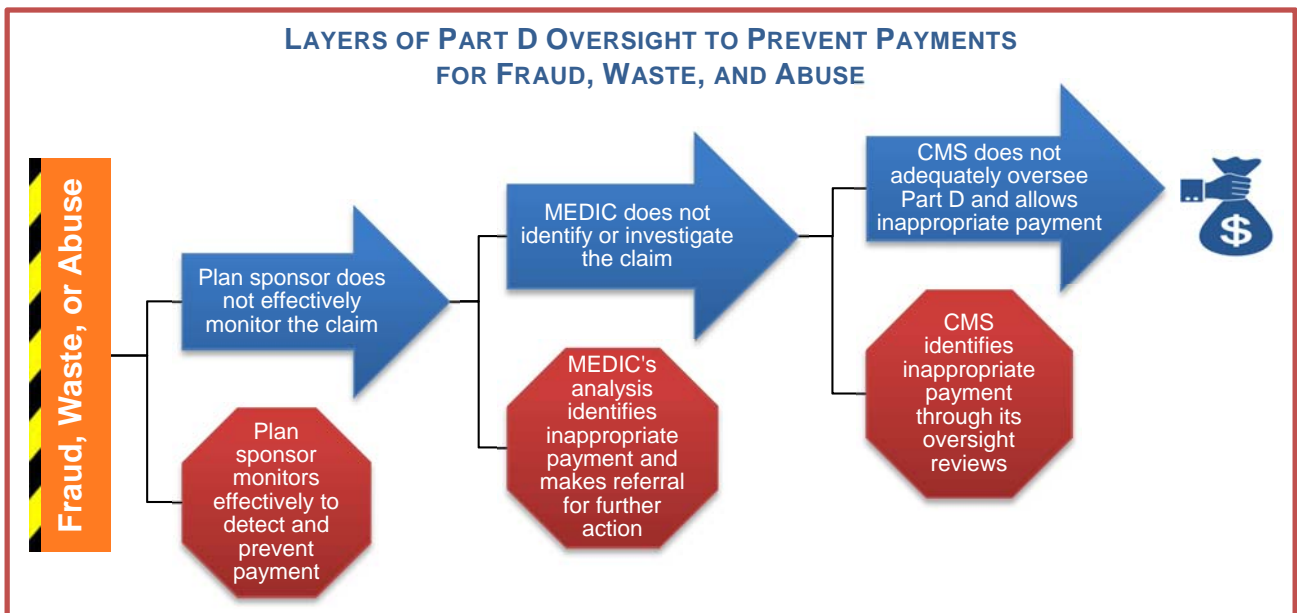
Progress Update: Proactive Data Analysis

-  *In response to OIG's report that highlighted the need for more proactive analysis, CMS and the MEDIC developed a Pharmacy Risk Assessment tool and shared this information with plan sponsors for their use in conducting additional analysis. The MEDIC also reviewed pharmacies with questionable billing as identified by OIG to determine what actions needed to be taken. The MEDIC has been given access to claims data from Medicare Parts A and B, which will enhance its ability to identify and investigate potential fraud and abuse. Although the MEDIC still does not initiate a majority of its investigations through proactive methods, OIG reviews found that it has increased the percentage it initiates proactively.*

 -  *When beneficiaries are associated with a high number of pharmacies or prescribers, it may be an indication of fraud, abuse, or inappropriate utilization of prescription drugs. CMS could expand drug utilization review programs to include additional drugs susceptible to fraud, waste, and abuse. CMS also could analyze claims data to identify beneficiaries whose utilization appeared aberrant and seek statutory authority to restrict certain beneficiaries to a limited number of pharmacies or prescribers. This practice is commonly referred to as "lock-in" and has been successfully implemented by some State Medicaid programs.*
-

CMS AND PLAN SPONSOR OVERSIGHT IS NOT SUFFICIENT TO PROTECT 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.



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. In addition, CMS is ultimately responsible for ensuring the integrity of Part D, but it has not exercised sufficient oversight of plan sponsors to prevent improper payments.⁸

OVER \$1 BILLION IN PART D PAYMENTS WERE MADE FOR DRUG CLAIMS WITH INVALID PRESCRIBER IDENTIFIERS. Prescriber identifiers are the only data on Part D drug claims that indicate whether a drug was prescribed by a legitimate practitioner, and are therefore an important tool for payment reviews and fraud investigations. However, OIG found that plan sponsors and CMS did not institute adequate procedures or oversight to identify claims with invalid prescriber identifiers. In fact, Part D paid \$1.2 billion for claims with invalid prescriber identifiers in 2007. Approximately \$20.6 million was paid in 2007 for Schedule II drug claims with invalid prescribers; these drugs have a high potential for abuse and diversion.⁹

OIG also has found that Part D inappropriately paid for drugs ordered by individuals who clearly do not have the authority to prescribe, such as massage therapists and athletic trainers. This vulnerability also has drug diversion implications, as tens of thousands of drugs ordered by individuals without prescribing authority were controlled substances.¹⁰



EXCLUDED PROVIDERS HAVE CONTINUED TO PRESCRIBE PART D DRUGS. A health care provider may be excluded from participation in Federal health care programs when convicted of a criminal offense related to patient abuse or neglect, or related to the misuse of controlled substances, among other reasons. It is therefore important that claims for drugs prescribed by excluded providers be denied to protect beneficiaries from inappropriate or even harmful services. However, OIG found that controls failed to prevent Part D payments for drugs prescribed by excluded providers. Specifically, there is no claims processing edit that will reject prescription drug event (PDE) records for prescriptions written by excluded providers. CMS accepted PDE data from plan sponsors with gross drug costs totaling \$15 million over a 3-year period for prescriptions written by excluded providers, contrary to Federal law.¹¹


PART D INAPPROPRIATELY PAID FOR SCHEDULE II DRUGS BILLED AS REFILLS, PRESENTING A RISK FOR DRUG DIVERSION AND ABUSE. Schedule II drugs are particularly susceptible to abuse and diversion, and present a risk to Part D and its beneficiaries. OIG has found that plan sponsors frequently lack adequate controls to prevent Schedule II drug refills, which are prohibited by Federal law to control access to these drugs. CMS's oversight also has not been sufficient to prevent these potentially inappropriate payments. Allowing Schedule II refills may result in the diversion of controlled substances or drug misuse, both of which have public health implications. In 2009, Part D inappropriately paid \$25 million for Schedule II drugs billed as refills.¹²

SCHEDULE II drugs have a high potential for abuse and diversion, and are considered dangerous. Using Schedule II drugs can potentially lead to severe psychological or physical dependence. Examples of Schedule II drugs include oxycodone, fentanyl, meperidine, and amphetamine.

PAYMENTS AFTER BENEFICIARIES' DEATHS MAKE PART D VULNERABLE TO FRAUD.

CMS had insufficient safeguards to prevent payments after beneficiaries' deaths. Between 2006 and 2007, CMS paid approximately \$3.6 million on behalf of deceased beneficiaries. After CMS reported implementing an automated process to prevent these payments, it still allowed Part D payments on behalf of 5,101 deceased beneficiaries in 2011. These claims present a risk to Part D, as health care fraud schemes have involved providers or suppliers submitting claims for deceased beneficiaries.¹³


Progress Update: Controls to Prevent Improper Payments

 **INVALID PRESCRIBERS:** *CMS now requires plan sponsors to identify invalid prescriber identifiers on Part D drug claims, and submit to CMS only claims with valid prescriber identifiers. CMS also now requires plan sponsors to verify that prescribers have the authority to prescribe. In addition, CMS has increased monitoring of prescribers through the MEDIC and has begun identifying claims related to providers without prescribing authority.*

EXCLUDED PROVIDERS: *CMS provided data to plan sponsors that will help identify claims for prescriptions from excluded providers. CMS's contractors have conducted audits of excluded providers in the Part D program.*

SCHEDULE II DRUGS: *Plan sponsors have reported strengthening their controls, and CMS has expanded its guidance to plan sponsors and providers regarding proper billing of these drugs. Through its contractors, CMS has conducted an audit of refills of controlled substances in the Part D program.*

DECEASED BENEFICIARIES: *CMS recouped some Part D payments that OIG determined were made after beneficiaries' deaths.*

 **INVALID PRESCRIBERS:** *The effectiveness of improved controls to prevent invalid prescribers has not yet been evaluated. The Medicare Access and CHIP Reauthorization Act of 2015 (the MACRA) requires OIG to undertake this evaluation.*

EXCLUDED PROVIDERS: *CMS has not implemented a claims processing edit to reject PDE data for prescriptions written by excluded providers.*

SCHEDULE II DRUGS: *CMS has not taken action to exclude Schedule II refills when calculating payments to plan sponsors at the end of each year.*

DECEASED BENEFICIARIES: *Congress has recognized that more needs to be done to prevent Part D improper payments. The MACRA requires CMS to establish procedures to ensure that Part D payments are not made for claims on behalf of deceased beneficiaries, and that OIG evaluate those efforts.*



CMS has not leveraged all oversight tools to protect Part D

CMS has not done all it could to oversee plan sponsors. For instance, CMS conducts summary analyses of plan sponsor-reported data but does not use these data to monitor or oversee plan sponsors. When sponsors voluntarily reported data on incidents of potential fraud and abuse, CMS did not follow up with plan sponsors about their fraud and abuse detection activities. CMS also did not use these data to determine the reasons for variation in plan sponsors' reporting of fraud and abuse.¹⁴

Furthermore, CMS is unable to fully evaluate the MEDIC's proactive workload because it does not capture the percentage of investigations or case referrals that are based on proactive methods. In addition, when law enforcement agencies do not accept the MEDIC's case referrals, there are no established procedures to recommend recoupment of inappropriate payments. CMS has no mechanism to recover the inappropriate payments in these cases.¹⁵

Finally, OIG reports have identified weaknesses in CMS's oversight of plan sponsors' compliance plans. These compliance plans provide the roadmap for sponsors' efforts to prevent and detect fraud, waste, and abuse. However, during the initial implementation of Part D, CMS conducted limited audits of compliance plans, and OIG determined through its own review that the compliance plans did not always address all CMS requirements. CMS has since requested that plan sponsors complete self-assessments of their compliance plans. However, without rigorous CMS oversight, these self-assessments will not ensure compliance with all requirements. This points to the need for additional CMS oversight of plan sponsors to ensure effective implementation of compliance plans, one of the primary tools for Part D program integrity.¹⁶

Progress Update: Oversight Tools

-  *The MEDIC has been given new regulatory authority (42 CFR § 423.505(i)(2)(ii)) to request and collect directly from entities (such as pharmacies) information that it needs to identify and investigate potential fraud and abuse. Previously, the MEDIC was unable to always request this information directly from those entities, which hindered its oversight efforts.*
-  *CMS has not enhanced the MEDIC's data reporting requirements in a way that would strengthen CMS's oversight. Furthermore, when the MEDIC refers cases involving inappropriate services to law enforcement, CMS still has no*

mechanism to recover those payments if law enforcement agencies decline to accept the case.

CMS also could use plan sponsor-reported information to determine the effectiveness of plan sponsors' fraud and abuse detection programs, and determine why certain sponsors report especially high or low volumes of potential fraud and abuse incidents. Finally, CMS could perform more extensive auditing to ensure that plan sponsors' compliance plans address all requirements.

PART D REMAINS VULNERABLE TO FRAUD

OIG investigates prescription drug diversion and other types of fraud that disproportionately affect the Part D program. As of May 2015, OIG had 540 pending complaints and cases involving Part D, a 134-percent increase in the last 5 years. The growth in this casework demonstrates the continued vulnerability of the Part D program to widespread fraud. This fraud could be mitigated or avoided through better oversight.

These investigations have uncovered serious medical harm to individual patients and financial harm to the overall Part D program. During the last three years (FY 2012 – FY 2014), OIG's Part D investigations resulted in 339 criminal actions, 31 civil actions, and over \$720 million in investigative receivables. OIG pursues these cases through coordinated Federal and State enforcement efforts, including the Medicare Fraud Strike Force teams operating in geographic fraud hotspots across the country.¹⁷

OIG Investigates Criminal Network

One OIG investigation led to the conviction of a pharmacist who created an expansive criminal network involving 26 pharmacies and an elaborate web of physicians, pharmacists, and patient recruiters to fraudulently bill nearly \$58 million. This pharmacist paid kickbacks, bribes, and other inducements to physicians to write unnecessary prescriptions. The physicians directed patients to fill prescriptions at the 26 pharmacies that the pharmacist controlled. The pharmacies then billed Medicare Part D and Medicaid for unnecessary controlled drugs it dispensed to the beneficiaries, and for expensive non-controlled drugs that it did not dispense. The pharmacist was sentenced to 17 years in prison and ordered to pay \$18.8 million in restitution.

Criminal networks are a pervasive problem in Part D fraud schemes

OIG casework has identified several Part D fraud trends, including billing for non-rendered services and prescription drug diversion. Fraud associated with the billing of non-rendered

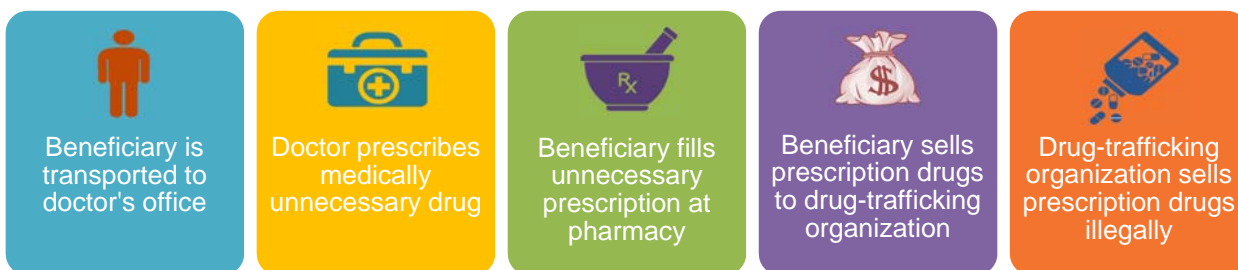
services typically involves a pharmacy billing for but not dispensing the prescription drug. Prescription drug diversion is the redirection of prescription drugs for illegitimate purposes. Prescription drug diversion often involves overprescribing of controlled drugs, but can also include billing for unnecessary non-controlled prescriptions. Fraud associated with non-controlled substances typically focuses on brand-name, high-cost medications, including respiratory, HIV, and anti-psychotic medications.

Additionally, OIG's investigations have identified an increase in organized criminal networks committing health care fraud, as well as medical identify theft. 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.

Part D beneficiaries can be both victims and perpetrators of fraud

Part D beneficiaries can be both victims and perpetrators of fraud. Beneficiaries can be harmed by the overprescribing of controlled substances, in some cases, leading to death. On the other hand, a fraud trend prevalent in Part D schemes involves beneficiaries who act as complicit patients.

PART D FRAUD INVOLVING COMPLICIT PATIENTS



As a result of an 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.

Although beneficiaries can be complicit in prescription drug fraud, they also can be victims of medical identity theft, a common element in many schemes investigated by OIG. Medical identity theft in relation to Part D occurs when the personally identifiable information (PII) of a beneficiary or prescriber is stolen and used to fraudulently bill for prescription drugs. This crime takes many forms but can be accomplished by insiders with access to large volumes of beneficiary PII, which is then sold to prescribers, recruiters, or pharmacies.

The fact that fraud remains significant in Part D reinforces the need for additional program integrity actions that will address systemic vulnerabilities and enhance enforcement efforts.

OIG Investigates Identity Theft

One OIG investigation involved the owner of a pharmacy chain who, with the assistance of two employees, billed for prescription refills that customers had not requested and did not receive. As soon as the prescriptions were eligible for refill, the pharmacy owner and technicians used the names and insurance identification numbers of hundreds of customers to bill Part D and other insurance programs, and created false logs that made it appear as though customers had received these drugs. Expensive HIV and cancer medications were targeted most often. The pharmacy owner was convicted of health care fraud and aggravated identity theft for his role in the \$2.5 million scheme.

UNIMPLEMENTED OIG RECOMMENDATIONS FOR PART D PROGRAM INTEGRITY

As the Part D program continues to evolve, the key to effective oversight is to monitor the program and establish methods to detect and prevent fraud, waste, and abuse. Those methods include more proactive use of data, as well as more rigorous oversight mechanisms. OIG has made recommendations to address vulnerabilities, and in many instances action has been taken to implement our recommendations and strengthen Part D program integrity. However, more work needs to be done to protect the program from fraud, waste, and abuse.

As the agency charged with administering and overseeing Part D, CMS is responsible for improving the program's effectiveness and protecting its beneficiaries. To that end, we are highlighting the following recommendations made to CMS in previous OIG reports that remain unimplemented.

RECOMMENDATIONS TO CMS REGARDING USE OF DATA

- **Require plan sponsors to report all potential fraud and abuse to CMS and/or the MEDIC.** The reporting of this information is voluntary, and OIG found that most plan sponsors chose not to report it. If plan sponsors were required to consistently report this information, CMS and the MEDIC could more actively monitor plan sponsors' efforts to protect Part D from fraud, waste, and abuse.

OIG reports:

- *Less than Half of Part D Sponsors Voluntarily Reported Data on Potential Fraud and Abuse* (OEI-03-13-00030), March 2014.
- *Retail Pharmacies with Questionable Part D Billing* (OEI-02-09-00600), May 2012.
- *Medicare Advantage Organizations' Identification of Potential Fraud and Abuse* (OEI-03-10-00310), February 2012.
- *Medicare Drug Integrity Contractors' Identification of Potential Part D Fraud and Abuse* (OEI-03-08-00420), October 2009.
- *Medicare Drug Plan Sponsors' Identification of Potential Fraud and Abuse* (OEI-03-07-00380), October 2008.

- **Require plan sponsors to report data on the inquiries and corrective actions they take in response to incidents of fraud and abuse.** When plan sponsors identify potential fraud and abuse, they are required to initiate inquiries and take corrective actions, as necessary. However, CMS does not

require plan sponsors to report data concerning those actions. When OIG requested those data, we found that not all plan sponsors took such actions.

OIG reports:

- *Medicare Advantage Organizations' Identification of Potential Fraud and Abuse* (OEI-03-10-00310), February 2012.
- *Medicare Drug Plan Sponsors' Identification of Potential Fraud and Abuse* (OEI-03-07-00380), October 2008.

- **Expand drug utilization review programs to include additional drugs susceptible to fraud, waste, and abuse.** Drug utilization reviews are designed to protect beneficiaries and reduce fraud, waste, and abuse. However, CMS's requirements for these reviews apply only to a limited selection of drugs.

OIG report:

- *Part D Beneficiaries With Questionable Utilization Patterns for HIV Drugs* (OEI-02-11-00170), August 2014.

RECOMMENDATIONS TO CMS REGARDING OVERSIGHT

- **Implement an edit to reject prescriptions written by excluded providers.** It is important to deny payments for drugs prescribed by providers who have been excluded from participation in Federal health programs, but controls failed to prevent these payments in Part D.

OIG report:

- *Review of Excluded Providers in the Medicare Part D Program* (A-07-10-06004), December 2011.

- **Exclude Schedule II refills when calculating final payments to plan sponsors at the end of each year.** Schedule II drugs have a high potential for abuse and diversion. Although Federal law prohibits the refilling of Schedule II drugs, OIG found that Part D inappropriately paid for these drugs billed as refills, raising concerns for public health and the potential for diversion. Furthermore, CMS does not exclude these inappropriate claims when calculating its final payments to plan sponsors at the end of each year.

OIG report:

- *Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills* (OEI-02-09-00605), September 2012.

- **Restrict certain beneficiaries to a limited number of pharmacies or prescribers.** As a means to more appropriately manage prescription drug utilization by beneficiaries, CMS should seek statutory 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 implemented by some State Medicaid programs.

OIG report:

- *Part D Beneficiaries With Questionable Utilization Patterns for HIV Drugs* (OEI-02-11-00170), August 2014.

➤ **Develop and implement a mechanism to recover payments from plan sponsors when law enforcement agencies do not accept cases.**

Because of resource limitations, law enforcement agencies cannot accept every case referral. However, CMS has not established a mechanism in Part D to recover inappropriate payments when case referrals are not accepted by law enforcement.

OIG report:

- *MEDIC Benefit Integrity Activities in Medicare Parts C and D* (OEI-03-11-00310), January 2013.

➤ **Determine the effectiveness of plan sponsors’ fraud and abuse detection programs.** If CMS were to require plan sponsors to consistently report information related to their fraud and abuse detection programs, CMS could use that information to help evaluate the effectiveness of those programs. CMS also could use this information to determine whether variation in plan sponsor reporting is a natural variation or whether it is indicative of problems such as weaknesses in plan sponsors’ fraud and abuse detection programs, or a lack of common understanding of fraud and abuse terms used in reporting.

OIG reports:

- *Less than Half of Part D Sponsors Voluntarily Reported Data on Potential Fraud and Abuse* (OEI-03-13-00030), March 2014.
- *Medicare Advantage Organizations’ Identification of Potential Fraud and Abuse* (OEI-03-10-00310), February 2012.
- *Medicare Drug Plan Sponsors’ Identification of Potential Fraud and Abuse* (OEI-03-07-00380), October 2008.

➤ **Ensure that plan sponsors’ compliance plans address all regulatory requirements and CMS guidance.** A successfully implemented compliance plan can help plan sponsors protect program integrity. However, these plans have not always addressed all requirements, or included specific descriptions of how plan sponsors will actually implement the requirements.

OIG report:

- *PDP Sponsors’ Compliance Plans* (OEI-03-06-00100), December 2006.

APPENDIX A

Highlighted OIG Reports on Part D Program Integrity

All of these reports are available on OIG's website at oig.hhs.gov.

Report Number	Report Title	Date Issued
OEI-02-11-00172	Medicare Paid for HIV Drugs for Deceased Beneficiaries	October 2014
OEI-02-11-00170	Part D Beneficiaries With Questionable Utilization Patterns for HIV Drugs	August 2014
OEI-03-13-00030	Less than Half of Part D Sponsors Voluntarily Reported Data on Potential Fraud and Abuse	March 2014
OEI-04-12-00130	Medicare Payments Made on Behalf of Deceased Beneficiaries in 2011	October 2013
OEI-02-09-00603	Prescribers with Questionable Patterns in Medicare Part D	June 2013
OEI-02-09-00608	Medicare Inappropriately Paid for Drugs Ordered by Individuals Without Prescribing Authority	June 2013
OEI-03-11-00310	MEDIC Benefit Integrity Activities in Medicare Parts C and D	January 2013
A-09-12-02031	Review of Medicare Part D Prescription Drug Event Data for Schedule II Drugs at Humana Insurance Company	October 2012
OEI-02-09-00605	Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills	September 2012
A-09-11-02023	Review of Medicare Part D Prescription Drug Event Data for Schedule II Drugs at United HealthCare Medicare & Retirement	July 2012
A-06-10-00059	Medicare Could Be Paying Twice for Prescription Drugs for Beneficiaries in Hospice	June 2012
OEI-02-09-00600	Retail Pharmacies with Questionable Part D Billing	May 2012
A-09-11-02074	Review of Medicare Part D Prescription Drug Event Data for Schedule II Drugs at CVS Caremark Corporation	February 2012
OEI-03-10-00310	Medicare Advantage Organizations' Identification of Potential Fraud and Abuse	February 2012
A-07-10-06004	Review of Excluded Providers in the Medicare Part D Program	December 2011
A-09-11-02028	Review of Medicare Part D Prescription Drug Event Data for Schedule II Drugs at Hawaii Medical Service Association	December 2011
OEI-03-09-00330	Audits of Medicare Prescription Drug Plan Sponsors	December 2011

Report Number	Report Title	Date Issued
OEI-03-10-00500	Addressing Vulnerabilities Reported by Medicare Benefit Integrity Contractors	December 2011
A-09-10-02046	Review of Medicare Part D Prescription Drug Event Data for Schedule II Drugs at Health Net, Inc.	September 2011
A-05-09-00027	Review of Medicare Payments to Prescription Drug Plans on Behalf of Deceased Enrollees	May 2011
A-14-09-00302	Oversight of the Prescriber Identifier Field in Prescription Drug Event Data for Schedule II Drugs	February 2011
A-07-09-03136	Review of Sterling Life Insurance Company's Internal Controls to Guard Against Fraud, Waste and Abuse for The Medicare Part D Program	August 2010
OEI-03-09-00140	Invalid Prescriber Identifiers on Medicare Part D Drug Claims	June 2010
A-07-09-03124	Review of SilverScript Insurance Company's Internal Controls to Guard Against Fraud, Waste and Abuse for The Medicare Part D Program	January 2010
OEI-03-08-00420	Medicare Drug Integrity Contractors' Identification of Potential Part D Fraud and Abuse	October 2009
OEI-03-07-00380	Medicare Drug Plan Sponsors' Identification of Potential Fraud and Abuse	October 2008
OEI-03-08-00230	Oversight of Prescription Drug Plan Sponsors' Compliance Plans	October 2008
OEI-06-06-00280	CMS's Implementation of Safeguards During Fiscal Year 2006 to Prevent and Detect Fraud and Abuse in Medicare Prescription Drug Plans	October 2007
OEI-03-06-00100	PDP Sponsors' Compliance Plans	December 2006

Highlighted OIG Products on Part D Program Integrity

All of these items are available on OIG's website at oig.hhs.gov.

OIG, testimony before the House Committee on Ways and Means, Subcommittee on Oversight. "Fraud in Medicare," testimony of Gary Cantrell, Deputy Inspector General for Investigations. March 24, 2015.

OIG, 2014 Top Management & Performance Challenges, "Challenge 2: Ensuring Appropriate Use of Prescription Drugs in Medicare and Medicaid," 2014.

OIG, "Podcast on Fraud and Abuse with HIV Drugs," 2014.

OIG, "Special Advisory Bulletin: Pharmaceutical Manufacturer Copayment Coupons," September 2014.

OIG, testimony before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations. "Medicare Program Integrity: Screening Out Errors, Fraud, and Abuse," testimony of Gary Cantrell, Deputy Inspector General for Investigations. June 25, 2014.

OIG, "Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs," May 30, 2014.

OIG, testimony before the House Committee on Oversight and Government Reform, Subcommittee on Energy Policy, Health Care and Entitlements. "Medicare Mismanagement: Oversight of the Federal Government Efforts to Recapture Misspent Funds," testimony of Brian P. Ritchie, Acting Deputy Inspector General for Evaluation and Inspections. May 20, 2014.

OIG, testimony before the House Committee on Ways and Means, Subcommittee on Health. "Ideas to Improve Medicare Oversight To Reduce Waste, Fraud, and Abuse," testimony of Gloria L. Jarmon, Deputy Inspector General for Audit Services. April 30, 2014.

OIG, testimony before the House Committee on Energy and Commerce, Subcommittee on Health. "Keeping the Promise: How Better Managing Medicare Can Protect Seniors," testimony of Robert A. Vito, Regional Inspector General for Evaluation and Inspections. March 4, 2014.

OIG, "Spotlight on Drug Diversion," 2013.

OIG, "Podcast on Drug Diversion Overview," 2013.

OIG, testimony before the Senate Committee on Homeland Security and Governmental Affairs. "Curbing Prescription Drug Abuse in Medicare," testimony of Gary Cantrell, Deputy Inspector General for Investigations, and Stuart Wright, Deputy Inspector General for Evaluation and Inspections. June 24, 2013.

OIG, testimony before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations. "Medicare Contractors' Efforts to Fight Fraud – Moving Beyond 'Pay and Chase,'" testimony of Robert A. Vito, Regional Inspector General for Evaluation and Inspections. June 8, 2012.

OIG, testimony before the Senate Special Committee on Aging. "Overprescribed: The Human and Taxpayers' Costs of Antipsychotics in Nursing Homes," testimony of Daniel R. Levinson, Inspector General. November 30, 2011.

OIG, testimony before the Senate Committee on Homeland Security and Governmental Affairs, Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security. Testimony of Robert A. Vito, Acting Assistant Inspector General for CMS Audits. July 15, 2010.

OIG, testimony before the Senate Committee on Homeland Security and Governmental Affairs, Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security. "Oversight Challenges in the Medicare Prescription Drug Program," testimony of Robert A. Vito, Regional Inspector General for Evaluation and Inspections. March 3, 2010.

OIG, "Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees," November 22, 2005.

ENDNOTES

- ¹ OIG, *Less than Half of Part D Sponsors Voluntarily Reported Data on Potential Fraud and Abuse* (OEI-03-13-00030), March 2014.
- ² OIG, *Less than Half of Part D Sponsors Voluntarily Reported Data on Potential Fraud and Abuse* (OEI-03-13-00030), March 2014; OIG, *Medicare Drug Plan Sponsors' Identification of Potential Fraud and Abuse* (OEI-03-07-00380), October 2008.
- ³ OIG, *Medicare Drug Plan Sponsors' Identification of Potential Fraud and Abuse* (OEI-03-07-00380), October 2008.
- ⁴ OIG, *Medicare Advantage Organizations' Identification of Potential Fraud and Abuse* (OEI-03-10-00310), February 2012.
- ⁵ OIG, *MEDIC Benefit Integrity Activities in Medicare Parts C and D* (OEI-03-11-00310), January 2013; OIG, *Addressing Vulnerabilities Reported by Medicare Benefit Integrity Contractors* (OEI-03-10-00500), December 2011; OIG, *Medicare Drug Integrity Contractors' Identification of Potential Part D Fraud and Abuse* (OEI-03-08-00420), October 2009.
- ⁶ OIG, *Retail Pharmacies with Questionable Part D Billing* (OEI-02-09-00600), May 2012.
- ⁷ OIG, *Part D Beneficiaries With Questionable Utilization Patterns for HIV Drugs* (OEI-02-11-00170), August 2014; OIG, *Prescribers with Questionable Patterns in Medicare Part D* (OEI-02-09-00603), June 2013.
- ⁸ OIG, *Medicare Could Be Paying Twice for Prescription Drugs for Beneficiaries in Hospice* (A-06-10-00059), June 2012; OIG, *Audits of Medicare Prescription Drug Plan Sponsors* (OEI-03-09-00330), December 2011; OIG, *Review of Sterling Life Insurance Company's Internal Controls to Guard Against Fraud, Waste and Abuse for the Medicare Part D Program* (A-07-09-03136), August 2010; OIG, *Review of SilverScript Insurance Company's Internal Controls to Guard Against Fraud, Waste and Abuse for the Medicare Part D Program* (A-07-09-03124), January 2010.
- ⁹ OIG, *Oversight of the Prescriber Identifier Field in Prescription Drug Event Data for Schedule II Drugs* (A-14-09-00302), February 2011; OIG, *Invalid Prescriber Identifiers on Medicare Part D Drug Claims* (OEI-03-09-00140), June 2010.

- ¹⁰ OIG, *Medicare Inappropriately Paid for Drugs Ordered by Individuals Without Prescribing Authority* (OEI-02-09-00608), June 2013.
- ¹¹ OIG, *Review of Excluded Providers in the Medicare Part D Program* (A-07-10-06004), December 2011; OIG, *Review of SilverScript Insurance Company's Internal Controls to Guard Against Fraud, Waste, and Abuse for the Medicare Part D Program* (A-07-09-03124), January 2010.
- ¹² OIG, *Review of Medicare Part D Prescription Drug Event Data for Schedule II Drugs at Humana Insurance Company* (A-09-12-02031), October 2012; OIG, *Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills* (OEI-02-09-00605), September 2012; OIG, *Review of Medicare Part D Prescription Drug Event Data for Schedule II Drugs at United HealthCare Medicare & Retirement* (A-09-11-02023), July 2012; OIG, *Review of Medicare Part D Prescription Drug Event Data for Schedule II Drugs at CVS Caremark Corporation* (A-09-11-02074), February 2012; OIG, *Review of Medicare Part D Prescription Drug Event Data for Schedule II Drugs at Hawaii Medical Service Association* (A-09-11-02028), December 2011; OIG, *Review of Medicare Part D Prescription Drug Event Data for Schedule II Drugs at Health Net, Inc.* (A-09-10-02046), September 2011.
- ¹³ OIG, *Medicare Paid for HIV Drugs for Deceased Beneficiaries* (OEI-02-11-00172), October 2014; OIG, *Medicare Payments Made on Behalf of Deceased Beneficiaries in 2011* (OEI-04-12-00130), October 2013; OIG, *Review of Medicare Payments to Prescription Drug Plans on Behalf of Deceased Enrollees* (A-05-09-00027), May 2011.
- ¹⁴ OIG, *Less than Half of Part D Sponsors Voluntarily Reported Data on Potential Fraud and Abuse* (OEI-03-13-00030), March 2014; OIG, *Oversight of Prescription Drug Plan Sponsors' Compliance Plans* (OEI-03-08-00230), October 2008; OIG, *CMS's Implementation of Safeguards During Fiscal Year 2006 to Prevent and Detect Fraud and Abuse in Medicare Prescription Drug Plans* (OEI-06-06-00280), October 2007.
- ¹⁵ OIG, *MEDIC Benefit Integrity Activities in Medicare Parts C and D* (OEI-03-11-00310), January 2013.
- ¹⁶ OIG, *Oversight of Prescription Drug Plan Sponsors' Compliance Plans* (OEI-03-08-00230), October 2008; OIG, *CMS's Implementation of Safeguards During Fiscal Year 2006 to Prevent and Detect Fraud and Abuse in Medicare Prescription Drug Plans* (OEI-06-06-00280), October 2007; OIG, *Prescription Drug Plan Sponsors' Compliance Plans* (OEI-03-06-00100), December 2006.

¹⁷ The Health Care Fraud Prevention & Enforcement Action Team (HEAT) was established in 2009 and is a joint effort of the Department of Health and Human Services, OIG, and the Department of Justice. The Medicare Fraud Strike Force teams are a key component of HEAT.

ACKNOWLEDGMENTS

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and Linda M. Ragone, Deputy Regional Inspector General.

Kevin McAloon served as team leader for this study, and Stefanie Vance served as lead analyst. Other Office of Evaluation and Inspections staff from the Philadelphia regional office who conducted the study include Edward K. Burley, Courtney Fanslau, and Amy Sernyak.

Central office staff who provided support include Jeffrey Cohen, Michael Cohen, Darlene Hampton, Meghan Kearns, Brian Ritchie, Jennifer Trussell, and Christy Wells.