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ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

MEMORANDUM

July 12, 2015

To: Subcommittee on Oversight and Investigations Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on "Medicare Part D: Measures Needed to Strengthen Program Integrity"

On Tuesday, July 14, 2015, at 10:00 a.m. in room 2322 of the Rayburn House Office Building, the Subcommittee on Oversight and Investigation will hold a hearing titled "Medicare Part D: Measures Needed to Strengthen Program Integrity." The hearing will examine efforts and actions taken by the Centers for Medicare and Medicaid Services to address program integrity in the Medicare Part D program, as well as two recent reports on the matter authored by the Department of Health and Human Services Office of Inspector General (OIG).

I. BACKGROUND

Medicare Part D, which was signed into law as part of the Medicare Modernization Act in 2003, was launched in 2006. Part D is an optional benefit designed to subsidize prescription drug costs and prescription drug insurance premiums for Medicare beneficiaries.[1] To receive Part D benefits, beneficiaries must enroll in a stand-alone prescription drug plan (PDP) or a Medicare Advantage prescription drug (MA-PD) plan.[2] Approximately 60 percent of beneficiaries are enrolled in PDPs; the rest are enrolled in MA-PD plans.[3] In 2015, approximately 42 million beneficiaries were Part D enrollees.[4]

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[1] Kaiser Family Foundation, *A Primer on Medicare: Key Facts About the Medicare Program and the People it Covers* (Mar. 20, 2015).

[2] Centers for Medicare and Medicaid Services, *Medicare & You 2015* (Dec. 2014).

[3] Kaiser Family Foundation, *Medicare Part D: A First Look at Plan Offerings in 2015* (Oct. 10, 2014).

[4] Congressional Budget Office, *March 2015 Medicare Baseline* (Mar. 9, 2015).

The current standard Part D benefit carries a $320 deductible and 25 percent coinsurance up to the initial coverage limit of $2,690 in total drug costs. Above that point, there is a coverage gap (the "donut hole") where enrollees are responsible for a larger share of their total drug costs.

In 2015, beneficiaries pay 45 percent of brand-name drug costs and 65 percent of the costs for generic drugs within the coverage gap.[5] As part of the Affordable Care Act (ACA), Medicare is phasing in additional subsidies to lower the rate enrollees must pay in the coverage gap to 25 percent by 2020.[6] As a result, since enactment of the ACA, 9.4 million seniors and people with disabilities have saved over $15 billion on prescription drugs, an average of $1,598 per beneficiary. In 2014 alone, nearly 5.1 million beneficiaries saved $4.8 billion or an average of $941 per beneficiary.[7]

Catastrophic coverage begins once a beneficiary has paid up to $3,720 in out-of-pocket spending, at which point 95 percent of drug costs are covered.[8]

The Centers for Medicare and Medicaid Services (CMS) contracts with private companies, known as plan sponsors, to offer prescription drug plans to beneficiaries. The plans are "the first line of defense against waste, fraud, and abuse in Part D."[9] Plan sponsors are responsible for paying claims, monitoring billing patterns, and establishing compliance plans that specify procedures for preventing and detecting waste, fraud, and abuse.[10] Plan sponsors are also responsible for monitoring their downstream entities, such as pharmacy benefit managers (PBMs) and pharmacies.[11]

CMS also contracts with a Medicare Drug Integrity Contractor (MEDIC) to detect and prevent fraud, waste, and abuse. The MEDIC is required to identify potential fraud and abuse by means of proactive methods (such as analyzing claims data) as well as through external sources,

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[5] Centers for Medicaid and Medicare Services, *Medicare & You 2015* (Dec. 2014).

[6] *A Primer on Medicare: Key Facts About the Medicare Program and the People it Covers*, Kaiser Family Foundation (Mar. 20, 2015).

[7] Department of Health and Human Services, *Since 2010, 9.4 Million People with Medicare Have Saved Over $15 Billion on Prescription Drugs* (Feb. 24, 2015) (online at www.hhs.gov/news/press/2015pres/02/20150224a.html).

[8] National Council on Aging, *What Are Part D Costs?* (online at www.mymedicarematters.org/costs/part-d/?SID=55a0275aa5b8f) (accessed July 7, 2015).

[9] U.S. Department of Health and Human Services, Office of Inspector General, *Ensuring the Integrity of Medicare Part D* (June 2015).

[10] *Id.*

[11] Government Accountability Office, *Medicare Program Integrity: CMS Pursues Many Practices to Address Prescription Drug Fraud, Waste, and Abuse* (Oct. 2014) (GAO-15-66).

such as leads from beneficiaries, law enforcement agencies, and Part D plan sponsors.[12] CMS oversees the plan sponsors and the MEDIC.[13]

CMS conducts various types of audits of plan sponsors, including audits of their compliance plans. Among plan sponsors audited in 2013, there were fraud, waste, and abuse findings in nearly all of (94 percent) the conducted audits. Specifically, CMS found an absence of evidence to show that:

- plan sponsors' downstream entities had been trained in compliance or in how to identify and report potential fraud, waste, or abuse;
- plan sponsors were conducting reasonable inquiries of potential fraud, waste, or abuse in a timely manner; and
- plan sponsors were implementing procedures to ensure appropriate corrective actions had been taken in response to potential fraud, waste, or abuse.[14]

The Office of Management and Budget (OMB) has deemed Medicare Part D a "high-error" program, meaning it has an improper payment rate above a certain threshold.[15] The most recently recorded improper payment rate for 2014 was 3.3 percent, which amounts to $1.9 billion in improper payments out of the $58.5 billion in total payments.[16] HHS projects that the improper payment rate will rise to 3.5 percent in 2015.

II. EFFORTS TO STRENGTHEN MEDICARE PROGRAM INTEGRITY

The ACA included a number of provisions to strengthen Medicare program integrity. Some of the most important provisions shift the traditional "pay and chase" model to a preventive approach that seeks to keep fraudulent suppliers out of the program before fraud, waste, and abuse can occur. CMS issued a final rule in May of 2014, establishing an enrollment requirement for Part D prescribers.[17] The new regulation implements Section 6405 of the ACA, which gives the Secretary authority to deny reimbursement requests and pharmacy claims unless the prescriber is enrolled in Medicare.

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[12] *Id.*

[13] *Id.*

[14] *Id.*

[15] PaymentAccuracy.gov, *High Error Programs* (accessed July 8, 2015).

[16] PaymentAccuracy.Gov, *Medicare Prescription Drug Benefit (Part D)* (accessed July 8, 2015).

[17] Centers for Medicare & Medicaid Services, *Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs* (Final Rule), 79 Federal Register 29843 (May 23, 2014).

The regulation will help ensure that Part D drugs are only prescribed by individuals who are qualified under state law and under the requirements of the Medicare program. OIG has raised this as a point of concern in the past.[18]

The rule also gives CMS authority to revoke a provider's Medicare Part D enrollment status if CMS determines that (1) the provider has a pattern or practice of prescribing Part D drugs that is abusive and represents a threat to the health and safety of Medicare beneficiaries or otherwise fails to meet Medicare requirements; (2) the provider's Drug Enforcement Agency (DEA) certificate of registration is suspended or revoked; (3) or the applicable licensing or administrative body for any state in which a physician or eligible professional practices has suspended or revoked the provider's ability to prescribe drugs.[19]

The rule also gives CMS and its designees the authority to audit, evaluate, collect, and inspect any records from downstream entities such as PBMs and pharmacies. This provision responds directly to work by the OIG highlighting barriers faced by the MEDIC in obtaining information in a timely manner.[20]

Through rulemaking finalized in 2012, CMS also requires Part D sponsors to submit Part D claims data with active and valid individual prescriber National Provider Identifiers (NPI) beginning on January 1, 2013. CMS began to apply edits to any claims without an active and valid individual NPI on May 6, 2013.[21]

Finally, to reduce prescription drug diversion and monitoring, CMS has implemented a number of measures to prevent overutilization of prescribed medications. As of January 1, 2013, CMS requires plan sponsors to have a drug utilization management programs in place, with the following components: (1) point of sale controls, including safety edits and quantity limits; (2) retrospective drug utilization review to identify at-risk beneficiaries; (3) case management with the beneficiaries' prescribers; and (4) data-sharing between Part D sponsors when a beneficiary moves from one Part D plan to another.[22]

CMS has also established an Overutilization Monitoring System (OMS) to oversee plans' drug utilization management programs for acetaminophen and opioids. OMS provides quarterly reports to sponsors on beneficiaries with potential opioid or acetaminophen overutilization issues

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[18] Department of Health and Human Services, *Medicare Inappropriately Paid for Drugs Ordered by Individuals Without Prescribing Authority* (June 2013) (OEI-02-00608).

[19] Centers for Medicare & Medicaid Services, *Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs* (Final Rule), 79 Federal Register 29843 (May 23, 2014).

[20] *Id.*

[21] Centers for Medicare and Medicaid Services, *CMS Strategy to Combat Medicare Part D Prescription Drug Fraud and Abuse* (Jan. 6, 2014).

[22] Centers for Medicare & Medicaid Services, *Medicare Part D Overutilization Monitoring System* (July 5, 2013).

identified through analyses of Part D claims data, and requires plan sponsors to respond to CMS within 30 days on the status each beneficiary case.[23] An initial comparison with 2011 data shows there has already been a substantial reduction in the number of acetaminophen and opioid overutilizers in Part D.[24]

III. RECENT OIG REPORTS ON PART D PROGRAM INTEGRITY

The HHS OIG recently issued two reports related to Medicare Part D program integrity and potential fraud, waste, and abuse.

A. Portfolio Report – "Ensuring the Integrity of Medicare Part D"

This Part D program integrity report documents CMS's progress in addressing Part D program vulnerabilities and highlights OIG's unimplemented recommendations.[25] The program integrity vulnerabilities concentrate on actions taken by Part D plan sponsors, the MEDIC, and CMS. The report focuses on use of program data and enhancing oversight tools.[26]

The report summarizes OIG investigations into complaints and cases for Part D fraud. These investigations have uncovered cases that resulted in financial harm to Part D and serious medical and financial harm to individuals. The report notes that recent growth in this casework—a 134 percent increase in the last five years—demonstrates the continued vulnerability of Part D to widespread fraud.[27] The OIG also notes an increase in organized criminal networks committing healthcare fraud involving pharmacies and prescription drugs.

The OIG found that CMS is missing opportunities to leverage data to identify fraud, waste, and abuse. For example, CMS does not require plan sponsors to report information on fraud, and most have chosen not to voluntarily report this information. In 2012, only 35 percent of plan sponsors voluntarily reported data on potential fraud and abuse. Such low response rates complicate the development of effective assessments of sponsors' fraud and abuse detection programs.[28]

In addition, the report found that the MEDIC could do more proactive data analysis to detect fraud, waste, and abuse. The OIG found that only a small percentage of investigations and referrals are the result of proactive data analysis.

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[23] *Id.*

[24] Centers for Medicare and Medicaid Services, *CMS Strategy to Combat Medicare Part D Prescription Drug Fraud and Abuse* (Jan. 6, 2014).

[25] U.S. Department of Health and Human Services Office of Inspector General, *Ensuring the Integrity of Medicare Part D* (June 2015).

[26] *Id.*

[27] *Id.*

[28] *Id.*

The OIG report highlighted unimplemented recommendations to CMS to more effectively collect and proactively analyze program data including: (1) requiring plan sponsors to report all potential fraud and abuse to CMS and/or the MEDIC; (2) requiring plan sponsors to report data on the inquiries and corrective actions they take in response to fraud and abuse; and (3) expanding drug utilization review programs to include additional drugs susceptible to fraud, waste, and abuse.[29]

The OIG found that plan sponsors do not have adequate controls to prevent improper payments. Inadequate controls by plan sponsors have allowed improper payments for claims with invalid prescriber identifiers, prescriptions from excluded providers, inappropriately billed refills for drugs with high potential for abuse and diversion (Schedule II drugs), and claims for deceased beneficiaries. CMS has taken action to address each of these failures, but the OIG recommends additional actions.

The OIG highlights several additional recommendations to CMS to more fully implement robust oversight including: (1) adjusting claims processing to reject prescriptions written by excluded providers; (2) excluding Schedule II drug refills when calculating final payments to plan sponsors at the end of each year; (3) seeking authority to restrict certain beneficiaries to a limited number of pharmacies or prescribers; (4) developing and implementing a mechanism to recover payments from plan sponsors when law enforcement agencies do not accept case referrals; (5) determining the effectiveness of plan sponsors' fraud and abuse detection programs; and (6) ensuring that plan sponsors' compliance plans address all regulatory requirements and CMS guidance.

B. Data Brief – "Questionable Billing and Geographic Hotspots Point to Potential Fraud and Abuse in Medicare Part D"

The OIG also released a data analysis of trends in spending for Part D drugs from 2006 to 2014 and examined 2014 retail pharmacy billing data and geographic hotspots for non-controlled drugs. The data brief found that Medicare spending for Part D drugs has more than doubled since 2006, with spending for commonly abused opioids growing faster than spending for all drugs.[30] The OIG found over 1,400 pharmacies with questionable billing, raising concerns about pharmacy-related fraud schemes.[31] Some examples of questionable billing patterns include extremely high numbers of prescriptions per beneficiary, or extremely high numbers of prescriptions for commonly abused opioids as a percentage of overall pharmacy billings.[32]

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[29] *Id.*

[30] U.S. Department of Health and Human Services Office of Inspector General, *Questionable Billing and Geographic Hotspots Point to Potential Fraud and Abuse in Medicare Part D* (June 2015).

[31] *Id.*

[32] *Id.*

In addition, the OIG identified geographic hotspots— metropolitan areas where average Medicare payments per beneficiary for certain drugs are significantly higher than the average payments nationwide—that point to possible fraud and abuse of non-controlled drugs. The OIG concludes that these findings and patterns demonstrate that more needs to be done to address fraud and abuse in Part D.[33]

IV. WITNESSES

The following witnesses have been invited to testify:

Ann Maxwell
Assistant Inspector General, Evaluation and Inspections
Department of Health and Human Services
Office of Inspector General

Shantanu Agrawal
Deputy Administrator and Director
Center for Program Integrity
Centers for Medicare & Medicaid Services

[33] *Id.*