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MEDICARE PART D

CMS Oversight of Part D Sponsors' Fraud and Abuse Programs Has Been Limited, but CMS Plans Oversight Expansion

Statement of Kathleen M. King
Director, Health Care





Highlights

Highlights of GAO-10-481T, a testimony before the Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security, Homeland Security and Governmental Affairs Committee, U.S. Senate

Why GAO Did This Study

Medicare Part D, the voluntary, outpatient prescription drug benefit for eligible individuals 65 years and older and certain individuals with disabilities, is at risk for fraud, waste, and abuse. Part D is administered by the Centers for Medicare & Medicaid Services (CMS). All Part D sponsors—private companies that operate Part D benefit plans—are required to have programs to safeguard the Part D program from fraud, waste, and abuse. GAO refers to these programs as fraud and abuse programs.

This statement discusses CMS's oversight of Part D sponsors' fraud and abuse programs, including its past efforts and planned oversight activities. It is primarily based on the GAO report, *Medicare Part D: Some Plan Sponsors Have Not Completely Implemented Fraud and Abuse Programs, and CMS Oversight Has Been Limited* (GAO-08-760). The five Part D sponsors GAO reviewed for that report had not completely implemented all of CMS's elements for Part D fraud and abuse programs at that time. CMS agreed with GAO's recommendation in the report that it conduct timely audits of Part D sponsors' fraud and abuse programs.

For the 2008 report, GAO reviewed laws, regulation, and CMS documents, including fraud and abuse program guidance. GAO also interviewed CMS officials. For this statement, GAO updated selected information on CMS's oversight by interviewing CMS officials and reviewing agency documents.

View GAO-10-481T or key components. For more information, contact Kathleen M. King at (202) 512-7114 or kingk@gao.gov.

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What GAO Found

In July 2008, GAO reported that CMS's review of fraud and abuse program plans was limited to the review and approval of Part D sponsors' fraud and abuse program plans submitted as part of the initial contract-application process. For example, CMS indicated that the agency did not require Part D sponsors to submit new or updated fraud and abuse program plans during the contract renewal process for program years 2007 or 2008. Further, in the July 2008 report, GAO noted that CMS had not conducted audits as it had detailed in its 2005 Part D Oversight Strategy to ensure that sponsors had implemented fraud and abuse program plans. In February 2010, CMS officials told us the agency had completed desk audits (reviews of requested documents) in 2008 and 2009 and was beginning to implement an expanded oversight strategy. CMS officials reported that between October 2008 and April 2009 the agency's contractors had completed 16 desk audits of selected Part D sponsors' fraud and abuse programs. These officials reported that the agency has revised its audit protocol and piloted on-site audits (which include interviews and other face-to-face evaluations) to assess the effectiveness of these programs more thoroughly. In addition, CMS issued a proposed rule in 2009 to increase its oversight efforts and ensure that sponsors have effective compliance programs in place. CMS noted in issuing the proposed rule that GAO requested that CMS take actions to evaluate and oversee fraud and abuse programs. CMS expects the rule to be finalized in March 2010.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss CMS's oversight of programs that address the risks for fraud, waste, and abuse in Medicare Part D. The Medicare Part D program, administered by the Centers for Medicare & Medicaid Services (CMS), provides a voluntary, outpatient prescription drug benefit for eligible individuals 65 years and older and eligible individuals with disabilities. CMS contracts with private companies—such as health insurance companies and companies that manage pharmacy benefits—to provide Part D prescription drug benefit plans for Medicare beneficiaries. These companies are referred to as Part D sponsors. About 27 million individuals were enrolled as of December 2009, and estimated Medicare Part D spending was \$51 billion in fiscal year 2009. Because of its vulnerability to fraud, waste, and abuse, GAO has designated Medicare as a high-risk program since 1990.¹ We and others have previously reported that the size, nature, and complexity of the Part D program make it a particular risk for fraud, waste, and abuse.²

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA),³ which established the Part D program, requires all Part D sponsors to have programs to safeguard Part D from fraud, waste, and abuse.⁴ CMS regulations require Part D sponsors to have compliance plans detailing their fraud and abuse programs.⁵ In April 2006, CMS issued

¹GAO's audits and evaluations identify federal programs and operations that we determine are high risk due to their greater vulnerabilities to fraud, waste, abuse, and mismanagement. See GAO, *High-Risk Series: An Update*, GAO-05-207 (Washington, D.C.: January 2005).

²GAO, *Prescription Drugs: Oversight of Drug Pricing in Federal Programs*, GAO-07-481T (Washington, D.C.: Feb. 9, 2007). U.S. House of Representatives Ways and Means Subcommittees on Health and Oversight, 110th Cong., March 8, 2007 (testimony of Daniel R. Levinson, HHS Inspector General) and U.S. House of Representatives Oversight and Government Reform Committee, 110th Cong., February 9, 2007 (testimony of Lewis Morris, Chief Counsel to the HHS Inspector General).

³Pub. L. No. 108-173 § 101, 117 Stat. 2066, 2086 (adding Social Security Act § 1860D-4(c)(1)(D)) (codified at 42 U.S.C. § 1395w-104(c)(1)(D)).

⁴Hereafter, we refer to programs to control fraud, waste, and abuse as fraud and abuse programs.

⁵42 C.F.R. § 423.504(b)(4)(vi).

guidance in chapter 9 of its Medicare Prescription Drug Benefit Manual on the seven required elements of these plans.⁶ (See table 1.)

Table 1: Description of Required Medicare Part D Compliance Plan Elements for Fraud and Abuse Programs

Compliance plan elements	Description
Written Policies, Procedures, and Standards of Conduct	Include written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable federal and state standards.
Compliance Officer and Compliance Committee	Designate a compliance officer and a compliance committee that are accountable to senior management.
Effective Training and Education	Include effective training and education pertaining to fraud, waste, and abuse for the organization's employees, contractors and directors.
Effective Lines of Communication	Include effective lines of communication between the compliance officer and the organization's employees, contractors, directors, and the members of the compliance committee.
Enforcement of Standards through Disciplinary Guidelines	Have well-publicized disciplinary guidelines through which sponsors must enforce standards.
Internal Monitoring and Auditing	Include effective internal monitoring and auditing procedures.
Prompt Responses to Detected Offenses	Include procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives, including responses to potential offenses.

Source: GAO summary of regulations.

In this testimony, we focus on the extent of CMS's oversight of Part D sponsors' fraud and abuse programs, including its past efforts and planned oversight activities. My statement is based primarily on our July 2008 report, which focused on Part D sponsors' implementation of fraud and abuse programs and CMS's oversight of those Part D sponsors' programs.⁷

⁶The Medicare Prescription Drug Benefit Manual consists of multiple chapters related to various Part D program areas and outlines Part D program requirements and CMS guidance. The chapter in the manual entitled "chapter 9—Part D Program to Control Fraud, Waste, and Abuse" addresses fraud, waste, and abuse in Part D.

⁷GAO, *Medicare Part D: Some Plan Sponsors Have Not Completely Implemented Fraud and Abuse Programs, and CMS Oversight Has Been Limited*, GAO-08-760 (Washington, D.C.: July 21, 2008).

Our July 2008 report is part of a larger GAO body of ongoing work on Part D oversight and fraud, waste, and abuse prevention (see "Related GAO Products," attached). This statement also includes selected updated information on CMS's oversight obtained from CMS since our July 2008 report.

In our July 2008 report, we found that the five Part D sponsors we reviewed, which covered more than one-third of total Part D enrollees, had not completely implemented all seven of CMS's required compliance plan elements for a Part D fraud and abuse program. All Part D sponsors had completely implemented the requirements for three of the seven required compliance plan elements. However, Part D sponsors varied in their implementation of the remaining required elements.⁸ For example, only two of the five sponsors met the requirements for effective training and education related to fraud and abuse prevention.

To conduct our evaluation of CMS's oversight for the July 2008 report, we reviewed relevant laws, regulations, and CMS guidance to determine the elements of a comprehensive compliance plan including fraud and abuse programs. We also interviewed officials from CMS and the Department of Health and Human Services' (HHS) Office of the Inspector General (OIG). In addition, we reviewed documentation from CMS, including CMS's Part D oversight strategy, program audit strategies, contracts related to Part D program integrity efforts, and technical assistance provided by CMS specific to the fraud and abuse program. A detailed explanation of our methodology is included in our July 2008 report. For this statement, we also interviewed officials from CMS and reviewed agency documents to obtain selected updated information on CMS oversight. We discussed the information in this statement with a CMS official responsible for Part D oversight.

We conducted the performance audit for the July 2008 report from October 2006 through June 2008 and we updated information regarding CMS's oversight of Part D sponsors' fraud and abuse programs in February 2010, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe

⁸We conducted on-site reviews at five of the largest Part D sponsors to examine the extent to which these Part D sponsors implemented fraud and abuse programs.

that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

While CMS's Oversight of Part D Sponsors' Fraud and Abuse Programs Has Been Limited, the Agency Plans to Expand Its Oversight

While CMS oversight of Part D fraud and abuse programs has been limited, the agency plans to expand this oversight, including adding on-site audits (which include interviews and other face-to-face evaluations) in place of the desk audits (reviews of requested documents only) it has completed. In July 2008, we reported that CMS's review of fraud and abuse program plans was limited to the review and approval of Part D sponsors' compliance plans detailing their fraud and abuse program plans submitted as part of the initial contract-application process. For example, CMS officials reported that Part D sponsors with approved fraud and abuse program plans prior to the issuance of chapter 9 of CMS's Medicare Prescription Drug Benefit Manual in April 2006 were not required to resubmit program plans. In addition, CMS told us the agency did not require Part D sponsors to submit new or updated fraud and abuse program plans during the contract-renewal process for program years 2007 or 2008, which limited CMS's ability to ensure that existing Part D sponsors continued to maintain compliance with this requirement.

In 2008, we also reported that CMS had not conducted audits of sponsors' fraud and abuse program plans as it had detailed in its 2005 Part D Oversight Strategy. In its 2005 comprehensive Oversight Strategy for the program, CMS noted that it would mainly rely on self-reported, unaudited data provided by Part D sponsors, but acknowledged that program audits would be necessary to ensure compliance and to document that CMS had fulfilled its program oversight responsibilities. CMS further stated that it would reserve enforcement activities to large, repeated, or extreme Part D program violations.⁹

Offices within CMS with oversight authority cited resource problems in 2006, Part D's first year of operation, that either prevented audits from occurring or changed the audit strategy to use desk audits rather than on-site audits. In 2007, CMS assessed Part D sponsors' compliance with selected program areas, but did not assess sponsors' implementation of fraud and abuse programs. Moreover, the agency said it did not plan to audit sponsors' implementation of fraud and abuse programs in 2008. In addition, CMS originally estimated that 10 of these audits would be

⁹CMS, Part D Oversight Strategy for Contractors/Industry (Oct. 24, 2005).

completed by the Medicare Drug Integrity Contractors (MEDICs) during the 2005-2006 contract year of the program and that 35 of these audits would be conducted during the 2006-2007 contract year. However, these audits did not occur.¹⁰

In February 2010, CMS officials told us the agency had completed desk audits in 2008 and 2009 and is beginning to implement an expanded oversight strategy. CMS officials reported that between October 2008 and April 2009 its MEDICs completed 16 desk audits of selected Part D sponsors' fraud and abuse programs. Since then, these officials reported that CMS has revised its audit protocol and piloted on-site audits, rather than desk audits, to assess the effectiveness of these programs more thoroughly. The agency has conducted two on-site audits in the pilot so far and plans to conduct additional on-site audits of selected Part D sponsors' fraud and abuse programs by April 2010. Similar to our July 2008 findings, in conducting their desk and pilot on-site audits, CMS officials told us they found that sponsors had deficiencies in implementation of two of the required compliance elements—internal auditing and monitoring and training and education. However, the effectiveness of CMS's planned audits cannot be assessed until they are completed.

In addition, CMS issued a proposed rule in 2009 to increase its oversight efforts and ensure that sponsors have effective compliance programs in place.¹¹ In issuing the proposed rule, CMS noted that we requested the agency take actions to evaluate and oversee fraud and abuse programs to ensure sponsors have effective programs in place.¹² The proposed rule would clarify existing policies regarding the elements of sponsors' compliance plans and CMS expects it to be finalized in March 2010. CMS officials told us that once the proposed rule is finalized, the agency will incorporate it into its expanded on-site audit protocol and update its

¹⁰CMS contracted with the MEDICs to support its audit, oversight, and antifraud and abuse efforts in Part D. In addition to audits, the MEDICs have been engaged to detect fraud, waste, and abuse in Part D and investigate reports from beneficiaries, sponsors, and other sources; conduct enrollment, eligibility, and marketing surveillance; and identify high-risk sponsors requiring further investigations. These tasks were outside the scope of the July 2008 report and are outside the scope of our current testimony.

¹¹*Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs*, 74 Fed. Reg. 54,634 (proposed Oct. 22, 2009).

¹²In the July 2008 report, we recommended that CMS conduct timely audits of Part D sponsors' fraud and abuse programs. CMS agreed with our recommendation.

guidance in chapter 9 of the Medicare Prescription Drug Benefit Manual to reflect the changes.

Mr. Chairman, this concludes my prepared statement. I would be happy to answer any questions you or other members of the subcommittee may have.

GAO Contact and Staff Acknowledgments

For further information about this statement, please contact Kathleen M. King at (202) 512-7114 or kingk@gao.gov.

Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Catina Bradley and Martin T. Gahart, Assistant Directors; Jennie F. Apter, Jennel Harvey, Amy Shefrin, and Jennifer Whitworth were key contributors to this statement.

Related GAO Products

Improper Payments: Improper Payments: Responses to Posthearing Questions Related to Eliminating Waste and Fraud in Medicare and Medicaid. GAO-09-838R. Washington, D.C.: July 20, 2009.

Medicare Part D: Opportunities Exist for Improving Information Sent to Enrollees and Scheduling the Annual Election Period. GAO-09-4. Washington, D.C.: December 12, 2008.

Medicare Part D Prescription Drug Coverage: Federal Oversight of Reported Price Concessions Data. GAO-08-1074R. Washington, D.C.: September 30, 2008.

Medicare Part D Low-Income Subsidy: Assets and Income Are Both Important in Subsidy Denials, and Access to State and Manufacturer Drug Programs Is Uneven. GAO-08-824. Washington, D.C.: September 5, 2008.

Medicare Part D: Some Plan Sponsors Have Not Completely Implemented Fraud and Abuse Programs, and CMS Oversight Has Been Limited. GAO-08-760. Washington, D.C.: July 21, 2008.

Medicare Part D: Complaint Rates Are Declining, but Operational and Oversight Challenges Remain. GAO-08-719. Washington, D.C.: June 27, 2008.

Medicare Part D: Plan Sponsors' Processing and CMS Monitoring of Drug Coverage Requests Could Be Improved. GAO-08-47. Washington, D.C.: January 22, 2008.

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