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The Honorable Thomas R. Carper
Chairman
Subcommittee on Federal Financial Management,
Government Information, Federal Services, and
International Security
Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable John McCain
United States Senate

Subject: *Medicare Part D: CMS Conducted Fraud and Abuse Compliance Plan Audits, but All Audit Findings Are Not Yet Available*

The Medicare Part D program, administered by the Department of Health and Human Services' (HHS) 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 plans for Medicare beneficiaries. These companies are referred to as Part D sponsors.[1] About 27 million individuals were enrolled in Medicare Part D as of December 2009, and estimated Medicare Part D spending was $51 billion in fiscal year 2009. Because of Medicare's vulnerability to fraud, waste, and abuse, GAO has designated Medicare as a high-risk program.[2] We and HHS's Inspector General have previously reported that the size, nature, and complexity of the Part D program make it a particular risk for fraud, waste, and abuse.[3]

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which established the Part D program, requires all Part D sponsors to have programs to safeguard

[1]Part D sponsors offer drug coverage either through stand-alone prescription drug plans (PDP) or through Medicare Advantage prescription drug (MA-PD) plans for beneficiaries enrolled in Medicare Advantage, Medicare's managed care program.

[2]GAO'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-11-278 (Washington, D.C.: February 2011).

[3]GAO, *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).

Part D from fraud, waste, and abuse.[4] CMS is responsible for managing and overseeing the Part D program. CMS regulations require Part D sponsors to have compliance plans that must include measures that detect, correct, and prevent fraud, waste, and abuse.[5] In April 2006, CMS issued guidance in chapter 9 of its Medicare Part D Prescription Drug Benefit Manual on the seven required elements of these plans.[6] (See table 1.) These compliance plans, which must be approved by CMS, articulate policies, processes, and procedures for Part D sponsors to detect, correct, and prevent fraud, waste, and abuse. Implementation of a compliance plan includes conducting the activities described in the plan and developing comprehensive written procedures for activities referenced in the plan.

Table 1: Description of Required Medicare Part D Sponsors' 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 and contractors.
Effective Lines of Communication	Include effective lines of communication among the compliance officer and the organization's employees, contractors, directors, and the members of the compliance committee.
Enforcement of Disciplinary Standards	Have well-publicized disciplinary guidelines through which sponsors enforce standards and encourage participation in the compliance program.
Internal Monitoring and Auditing	Establishing and implementing effective routine systems for monitoring and identifying compliance risks.
System to Promptly Respond and Investigate Potential Compliance Issues.	Include procedures for ensuring prompt responses to detected offenses, developing corrective action initiatives, and making timely inquiries into potential offenses.

Source: GAO summary of regulations.

CMS oversees Part D sponsors' fraud and abuse programs and may conduct audits to ensure that sponsors are in compliance with program requirements.[7] Specifically, the Center for Medicare, Program Compliance and Oversight Group (CM/PCOG)—the lead office for CMS's Part D audits (including compliance plan audits) and enforcement of program requirements—coordinates with the Center for Program Integrity (CPI)—the focal point for program integrity, fraud, and abuse issues—to oversee fraud and abuse program compliance.

[4]Pub. 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)). Hereafter, we refer to programs to control fraud, waste, and abuse as fraud and abuse programs.

[5]42 C.F.R. § 423.504(b)(4)(vi) (2010).

[6]The 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. In November 2010, CMS officials told us that they were in the process of updating chapter 9 to reflect the final rule issued in 2010 that clarifies and codifies the existing policies regarding the required compliance plan elements. For example, CMS added language specifying the groups and individuals among a sponsor's employees that are required to have compliance training and education and that training should occur at least once a year and be made part of orientation for new employees and specified entities. 75 Fed. Reg. 19,678 (April 15, 2010)(amending 42 C.F.R. § 423. 504 (b)(4)).

[7]CMS is required to conduct financial audits for at least one-third of Part D sponsors each year. 42 U.S.C. § 1395w-112(b)(3)(C). These audits are outside the scope of this report.

CMS has contracted with Medicare Drug Integrity Contractors (MEDICs) to support its Part D audit efforts.[8]

In a March 2010 hearing, we and CMS described the extent of CMS's oversight of Part D sponsors' programs to control fraud, waste, and abuse, including its past efforts and planned oversight activities.[9] CMS's testimony detailed several of the agency's program integrity activities, including its plans to conduct on-site compliance plan audits using newly developed audit protocols focused on evaluating and validating the effectiveness of sponsors' compliance plans, including measures to detect, correct, and prevent fraud, waste, and abuse.[10] At that time, CMS reported that the agency had completed 16 desk audits (reviews of requested documents only) between October 2008 and April 2009 and two pilot on-site audits (interviews and face-to-face evaluations in addition to document reviews) of selected Part D sponsors' compliance plans and planned to conduct additional on-site compliance plan audits by April 2010. Until these were completed, however, we could not assess the effectiveness of those audits in ensuring that Part D sponsors had compliance programs in place. You asked us to examine the extent of CMS's implementation of planned oversight of Part D sponsors' compliance plans to ensure that sponsors have effective programs in place to protect Part D from fraud, waste, and abuse. Specifically, this report provides an update on the status of CMS's implementation of on-site audits of sponsors' compliance plans that the agency described in its March 2010 testimony.

To conduct our update of CMS's implementation of on-site audits of Part D sponsors' compliance plans that CMS described in its March 2010 testimony, we examined recent CMS progress and relied on our 2008 report and our 2010 testimony.[11] To update the status of CMS's implementation of on-site audits, we interviewed officials from CMS's CM/PCOG and CPI and reviewed agency documents that included CMS's audit strategy and compliance plan audit protocols. We did not evaluate the results or effectiveness of CMS's oversight activities and audits. To describe the number of enrollees in audited plans, we report CMS's published enrollment statistics as of April 2010. We conducted this performance audit from November 2010 through February 2011 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

[8]There are two MEDICs—SafeGuard Services, LLC, and Health Integrity, LLC.

[9]GAO, *Medicare Part D: CMS Oversight of Part D Sponsors' Fraud and Abuse Programs Has Been Limited, but CMS Plans Oversight Expansion*, GAO-10-481T (Washington, D.C.: Mar. 3, 2010). Our statement was based on a July 2008 report in which we found that CMS's oversight of Part D sponsors fraud and abuse programs was limited; specifically the agency had not conducted audits of sponsors' fraud and abuse programs as detailed in its 2005 Part D Oversight Strategy. Audits of fraud and abuse programs had not been conducted in 2006, 2007, or 2008. In addition, we found that certain sponsors had not completely implemented required elements for fraud and abuse programs.

[10]Hearing on Oversight Challenges In The Medicare Prescription Drug Program, Before U.S. Senate Committee on Homeland Security and Government Affairs, Subcommittee on Federal Financial Management, Government Information, Federal Services and International Security, 111th Cong. (Mar. 3, 2010) (Statement of Jonathan Blum, Director, Center for Medicare Management).

[11]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 HHS's 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 fraud and abuse programs. A detailed explanation of our methodology is included in our July 2008 report. To prepare our March 2010 testimony statement, we interviewed officials from CMS and reviewed agency documents to obtain selected updated information on CMS oversight.

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

CMS Conducted Planned 2010 On-Site Audits of Sponsors' Compliance Plans; All Audit Findings Are Not Yet Available

CMS conducted its planned on-site compliance plan audits of 33 sponsors in 2010. Findings for all of these 2010 audits are not yet available; however, CMS anticipated finalizing them in early 2011.

CMS Conducted Planned On-Site Compliance Plan Audits of 33 Sponsors in 2010

Consistent with the audit plans CMS officials reported to us in February 2010, the agency scheduled on-site compliance plan audits to assess more thoroughly the effectiveness of sponsors' fraud and abuse programs. CMS officials reported that the agency scheduled and conducted on-site compliance plan audits of 33 of the 290 Medicare Part D sponsors in 2010, the majority of which were conducted as part of wider risk-based on-site performance audits. Performance audits are also conducted by CM/PCOG and assess compliance with certain CMS program requirements, such as Part D formulary administration and compliance plans, that CMS considers to be at risk for deficiencies or compliance issues.[12] In auditing sponsors' compliance plans, CM/PCOG audits sponsors' implementation of the compliance plan requirements, including a fraud and abuse program for Part D. CMS officials stated that although the performance audits conducted in 2010 assessed Part D sponsors' compliance plans, the audits did so as part of overall assessments of sponsors' compliance with all Medicare requirements. While performance audits are more expansive than the compliance-plan-only audits, CMS's completion of these on-site audits was consistent with their plans to complete compliance plan audits that they reported to us in February 2010. The audits were conducted by CMS central and regional staff as well as CMS contractors between January and September 2010.[13] The 33 sponsors represented 11 percent of Part D sponsors, 56 percent of plans, and covered 62 percent of enrolled beneficiaries in 2010 according to agency officials.[14]

CMS used a 2010 risk assessment—which was informed by a focused fraud, waste, and abuse evaluation—to choose sponsors for an on-site audit: either a compliance-plan-only audit or a wider performance audit that included an audit of the sponsor's compliance plan in addition to other program compliance areas. Specifically, the selection of sponsors subject to a compliance-plan-only audit was based on certain sponsors' inclusion in previously conducted

[12]Other areas include Part D grievances, coverage determinations, redeterminations and appeals, enrollment and disenrollment, premium billing, etc. CMS told us that they use a risk assessment to determine which program area(s) represents risk for noncompliance, and then CMS conducts a performance audit on these areas.

[13]MEDICs assisted CMS with completing its compliance plan audits under separate contracts with CM/PCOG and CPI according to CMS officials. CM/PCOG also contracted with an additional private contractor to assist CMS with conducting performance audits for requirements other than CMS's compliance plan requirements.

[14]CMS selects the top, or parent, level of sponsor organizations for performance audits, making all contracts and plans therein subject to the audit. Therefore, for the purposes of this report, "sponsor" refers to the parent organization. Sponsors may have multiple contracts with CMS with each contract offering one or more distinct Part D plans.

desk audits[15] and other factors such as whether the sponsor was identified in a fraud, waste, and abuse evaluation conducted by one of the MEDICs.[16] The selection criteria for sponsors subject to a performance audit (including a compliance plan audit) was based on CMS's 2010 risk assessment that included an evaluation of sponsors' past performance and enrollment including compliance/enforcement referrals as well as the MEDIC's focused fraud, waste, and abuse evaluation. Moreover, CMS officials told us that they used the risk assessment to schedule audits of sponsors that the agency concluded posed the most risk—those that had past performance problems, large enrollment,[17] and/or were identified as high risk by the MEDIC's evaluation—to be audited first. In total, 22 sponsors received a full on-site performance audit (that included a compliance plan audit) and 11 sponsors received an on-site compliance-plan-only audit. (See table 2.)

Table 2: On-Site Compliance Plan Audits Conducted in 2010

	Sponsors[a]		Plans		Enrollees	
Audit conducted	**Number**	**Percentage of sponsors[b]**	**Number**	**Percentage of plans[b]**	**Number**	**Percentage of enrollees[b]**
Performance (including compliance plan)[c]	22[d]	8	2,227	37	10,863,791	37
Compliance-plan-only performance	11[e]	4	1,122	19	7,203,639	25
Total[f]	**33**	**11**	**3,349**	**56**	**18,067,430**	**62**

Source: GAO summary of CMS data.

[a]CMS selects the top, or parent, level of sponsor organizations for performance audits, making all contracts and plans therein subject to the audit.

[b]Calculated as percentage of total sponsors (N= 290), total plans (N= 6020), and enrolled beneficiaries (N= 29,147,145) in April 2010 according to CMS.

[c]All sponsors that were chosen for an on-site performance audit based on CMS's risk assessment also received an on-site compliance plan audit.

[d]Nine of these sponsors received a compliance plan desk audit in 2009.

[e]Seven of these sponsors received a compliance plan desk audit in 2009.

[f]Due to rounding, percentages do not add up to 100 percent.

CMS officials reported that they piloted and developed new on-site compliance plan audit protocols that included interviews and reviews of documentation. Officials told us that they first conducted three on-site performance audits between January and April 2010 as a result of enforcement/compliance referrals for those sponsors and used these audits as a testing ground for the on-site performance audit process, including review of the seven fraud and abuse elements of compliance plans. The agency then re-designed and tested the on-site performance audit process and protocols, including on-site compliance plan audit protocols, in a pilot audit before completing the remaining planned audits. Officials reported that they revised the on-site audit process and protocols throughout the audit process to incorporate lessons learned, making changes as necessary. The on-site compliance plan audit protocols included interviews with sponsor officials and on-site review of compliance plan

[15]CMS officials told us they selected all sponsors that received a compliance plan desk audit in 2009 for on-site compliance plan audit in 2010. Of the 16 sponsors that received a 2009 compliance plan desk audit, 9 were also selected for and received a wider performance audit based on CMS's 2010 risk assessment or compliance/enforcement referrals, and 7 received a compliance-plan-only audit.

[16]The evaluation identified plans at risk for having poorly designed compliance plans through measures such as high complaint or grievance rates, poor outcomes from previous audits, or problems reporting required information to CMS.

[17]Six of the audited sponsors had enrollment of over one million beneficiaries.

implementation documentation for each of the seven fraud and abuse compliance plan elements.[18] For example, to test sponsors' implementation of the requirement to have a Compliance Officer and Compliance Committee, auditors were to interview the Compliance Officer and Committee members as well as obtain relevant documentation.

Complete 2010 Audit Findings Are Not Yet Available but Anticipated in Early 2011

As of February 2011, CMS had not made all audit findings available but had taken formal enforcement actions against several sponsors resulting from the on-site audits according to agency officials. CMS officials reported that they anticipated finalizing all audit findings in early 2011.[19] Potential oversight or enforcement actions resulting from the audits could include issuing audit report notices, giving sponsors an opportunity to correct deficiencies, or where appropriate for serious violations, imposing civil monetary penalties, imposing intermediate sanctions, or terminating a contract. As of December 2010, officials reported that the agency had issued five marketing and enrollment sanctions and one contract termination action based, in part, on the results of these audit findings noting failure to comply with CMS compliance plan requirements. CMS officials also reported that they were deliberating about what, if any, additional enforcement actions should be taken as a result of audit findings.[20] In addition, CMS officials told us they were reviewing the findings and the on-site audit processes programmatically to identify opportunities for improvements in its oversight mechanisms, in addition to addressing specific sponsor problems.[21]

Agency officials reported that although still in development, they anticipate completing their 2011 audit and oversight plans early in the year. Officials told us that they needed to finalize their audit findings, re-assess risks in the program, and assess agency resources before completing their audit strategy for 2011—which includes determining the number of compliance plan audits CMS will complete. The officials reported that, assuming CMS resources are available, any future compliance plan audits would be on-site rather than desk audits, as on-site audits provide a more thorough evaluation of sponsors and had a positive effect on educating sponsors about the importance of maintaining fraud and abuse programs. Officials we spoke with said they planned to improve future on-site audits based on their experience in 2010 as one monitoring tool they use to oversee sponsors' performance on a day-to-day basis.

[18]CMS officials told us that although they were in the process of updating guidance in chapter 9 of the Part D Prescription Drug Benefit Manual related to the rule issued in April 2010, the 2010 compliance plan audit protocols incorporated the changes made to CMS regulations because many of these requirements were already reflected in existing sub-regulatory guidance.

[19]As of February 2011, CMS officials reported that the agency had issued compliance plan audit findings to the sponsors that were subject to 2010 enforcement actions in CMS's notice of those actions. Also, CMS had issued reports to sponsors for 11 of the compliance plan audits conducted.

[20]In an additional effort to strengthen Part D oversight, CMS hired a contractor to assess the MEDIC program. That study was completed in April 2010. Officials told us that the agency made changes to its MEDIC oversight strategy for Parts C and D as a result of the study. Review of the MEDIC tasks are outside the scope of this report.

[21]For our March 2010 testimony, CMS officials told us that in conducting the 16 desk and 2 pilot on-site audits they found that sponsors had deficiencies in implementation of two of the required compliance elements—internal auditing and monitoring and training and education. These findings were similar to our July 2008 findings.

Agency Comments and Our Evaluation

We received technical comments on a draft of this correspondence from HHS, which we incorporated as appropriate.

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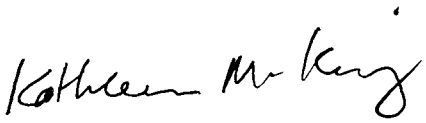
As arranged with your offices, unless you publicly announce the contents of this correspondence earlier, we plan no further distribution until 30 days from the date of this report. At that time, we will send copies of this correspondence to the Secretary of Health and Human Services and other interested parties. In addition, the report will be available at no charge on the GAO Web site at https://www.gao.gov. If you or your staff have any questions about this correspondence please contact me 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 report. GAO staff who made major contributions to this report are listed in enclosure I.



Kathleen M. King
Director, Health Care

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Enclosure I

GAO Contact and Staff Acknowledgments

GAO Contact

Kathleen M. King at (202) 512-7114 or kingk@gao.gov

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Enclosure II

Related GAO Products

Medicare Fraud, Waste, and Abuse: Challenges and Strategies for Preventing Improper Payments. GAO-10-844T. Washington, D.C.: June 15, 2010.

Medicare Part D: CMS Oversight of Part D Sponsors' Fraud and Abuse Programs Has Been Limited, but CMS Plans Oversight Expansion. GAO-10-481T. Washington, D.C.: March 3, 2010.

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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