Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

OVERSIGHT OF PRESCRIPTION
DRUG PLAN SPONSORS’
COMPLIANCE PLANS

Daniel R. Levinson
Inspector General

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EXECUTIVE SUMMARY

OBJECTIVE

To determine what oversight the Centers for Medicare & Medicaid Services (CMS) has conducted of prescription drug plan (PDP) sponsors’ compliance plans.

BACKGROUND

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established Medicare Part D to provide prescription drug benefits under the Medicare program beginning January 1, 2006. Part D prescription drug coverage is provided by private entities known as plan sponsors.

An effective compliance plan helps PDP sponsors protect the integrity of Medicare funds by preventing and detecting fraud, waste, and abuse. Federal regulations in effect since March 22, 2005, require that PDP sponsors have compliance plans in place and that these compliance plans address eight elements. Chapter 9 of CMS’s “Prescription Drug Benefit Manual” includes the eight elements as well as additional requirements and recommendations for addressing each of these elements.

The Office of Inspector General (OIG) released a report on PDP sponsors’ compliance plans in December 2006 that found that most sponsors’ compliance plans did not address all of the CMS requirements or recommendations. In comments on the report, CMS stated that account managers would follow up with PDP sponsors regarding deficiencies in their compliance plans. CMS also stated that it would conduct routine audits of PDP sponsors’ compliance plans beginning in January 2007. Routine audits are scheduled audits conducted to ensure compliance with program requirements. CMS can also conduct focused audits outside the routine audit process to confirm the correction of previously identified deficiencies.

We collected documentation and interviewed CMS staff regarding their oversight activities related to PDP sponsors’ compliance plans. Data collection was conducted in April and May 2008.
EXECUTIVE SUMMARY

FINDINGS

**CMS conducted one audit of a PDP sponsor’s compliance plan in 2007.** CMS conducted 17 routine audits and 2 focused audits of PDP sponsors in 2007. However, CMS did not include a compliance plan review in any of the 17 routine audits conducted. One of the two focused audits included a review of one PDP sponsor’s compliance plan. The audit found that the sponsor did not have a comprehensive plan to detect, correct, and prevent fraud, waste, and abuse.

In April 2008, CMS reported that it plans to begin specific audits of compliance plans in the summer of 2008. However, as of early August 2008, CMS had not yet conducted any specific audits of PDP sponsors’ compliance plans.

**PDP sponsors completed a compliance plan self-assessment but CMS did not verify sponsors’ responses.** In response to OIG’s December 2006 report, CMS instructed all 91 PDP sponsors to complete a compliance plan self-assessment in June 2007. The self-assessment was based on Chapter 9 of the “Prescription Drug Benefit Manual”; however, CMS did not include all requirements from Chapter 9 in the self-assessment. In addition, CMS did not request documentation to support sponsors’ responses to the self-assessment.

Twenty-three of the ninety-one PDP sponsors attested in June 2007 that they had not implemented 1 or more of 11 compliance plan requirements included in the self-assessment. In April 2008, CMS had account managers follow up with these 23 PDP sponsors. Based on this followup, only one sponsor reported that it was not meeting all of the requirements included in the self-assessment. However, CMS did not instruct account managers to request supporting documentation to confirm that PDP sponsors made corrections to their compliance plans.

RECOMMENDATION

Effective compliance plans are a fundamental tool in preventing and detecting fraud, waste, and abuse in the Part D program. Although CMS originally planned to begin routine compliance plan audits in January 2007, as of early August 2008, CMS had not conducted any routine audits of PDP sponsors’ compliance plans. In addition, while CMS instructed all PDP sponsors to complete a compliance plan
EXECUTIVE SUMMARY

self-assessment, the self-assessment did not include all requirements from Chapter 9 of the “Prescription Drug Benefit Manual.” Also, CMS did not ensure that PDP sponsors’ attestations were accurate by independently verifying their responses. Therefore, CMS has only self-reported information to determine whether PDP sponsors’ compliance plans are meeting Federal requirements.

Therefore, we recommend that CMS:

**Conduct audits to verify that PDP sponsors’ compliance plans meet requirements.** CMS should conduct routine audits of PDP sponsors’ compliance plans to ensure that these compliance plans meet all Federal requirements. Specifically, these audits should cover all compliance plan requirements contained in regulations as well as requirements included in Chapter 9 of the “Prescription Drug Benefit Manual.” CMS may also want to assess the degree to which PDP sponsors have implemented the recommendations described in Chapter 9.

AGENCY COMMENTS

CMS concurred with our recommendation that it should conduct audits of PDP sponsors’ compliance plans. CMS noted that due to critical funding shortfalls, it was not able to conduct compliance plan audits prior to the issuance of this report. However, CMS stated that it will begin audits of sponsors’ compliance plans in the near future. These audits will consist of a limited number of desk audits; however, as more resources become available, CMS stated that it will include more audits, onsite reviews, and other more comprehensive fraud prevention activities.
# Table of Contents

**Executive Summary** ............................................. i

**Introduction** .................................................. 1

**Findings** ...................................................... 7

CMS conducted one audit of a PDP sponsor’s compliance plan. . . . 7

CMS did not verify PDP sponsors’ self-assessment responses . . . 7

**Recommendation** ................................................ 10

Agency Comments. ............................................... 10

**Appendix** ...................................................... 12

Agency Comments. ............................................... 12

**Acknowledgments** ............................................ 14
INTRODUCTION

OBJECTIVE

To determine what oversight the Centers for Medicare & Medicaid Services (CMS) has conducted of prescription drug plan (PDP) sponsors’ compliance plans.

BACKGROUND

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established Medicare Part D to provide prescription drug benefits under the Medicare program beginning January 1, 2006.¹ Part D prescription drug coverage is provided by private entities known as plan sponsors. Plans offered by sponsors include PDPs and Medicare Advantage prescription drug plans (MA-PD) that offer integrated coverage for both prescription drugs and other health care. As of August 2008, 26 million beneficiaries were enrolled in a Part D plan. Two-thirds of these beneficiaries were enrolled in a PDP.² Medicare expenditures for Part D benefits were approximately $49.5 billion in 2007.³

Compliance Plan Requirements

An effective compliance plan helps PDP sponsors protect the integrity of Medicare funds by preventing and detecting fraud, waste, and abuse. Federal regulations in effect since March 22, 2005, require that PDP sponsors have compliance plans in place and that these compliance plans address eight elements.⁴ The eight elements PDP sponsors’ compliance plans must contain are:

1. written policies, procedures, and standards of conduct articulating the organization’s commitment to comply with all applicable Federal and State standards;

2. the designation of a compliance officer and compliance committee accountable to senior management;

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⁴ 42 CFR § 423.504(b)(4)(vi).
(3) effective training and education between the compliance officer and organization employees, contractors, agents, and directors;

(4) effective lines of communication between the compliance officer and the organization’s employees, contractors, agents, directors, and members of the compliance committee;

(5) enforcement of standards through well-publicized disciplinary guidelines;

(6) procedures for effective internal monitoring and auditing;

(7) procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives relating to the organization’s contract as a Part D plan sponsor; and

(8) a comprehensive fraud and abuse plan to detect, correct, and prevent fraud, waste, and abuse. This fraud and abuse plan should include procedures to voluntarily self-report potential fraud or misconduct related to the Part D program to the appropriate Government authority.

In December 2007, CMS issued a final rule that revises Federal regulations and clarifies that the elements relating to training and education and effective lines of communication must include PDP sponsors’ first tier, downstream, and related entities (e.g., contractors). In addition, this final rule removes the eighth compliance plan element regarding a fraud and abuse plan effective January 1, 2009. Although this element is being removed, CMS has added language to the regulation which specifies that PDP sponsors’ compliance plans must include measures to detect, correct, and prevent fraud, waste, and abuse. Also, CMS is working on additional regulatory changes to make self-reporting of potential fraud or misconduct mandatory rather than voluntary.

Chapter 9 of CMS’s “Prescription Drug Benefit Manual” includes additional requirements and recommendations for addressing each of the required compliance plan elements. CMS is currently updating
Chapter 9 in response to the recent regulatory changes and will publish the revised chapter when all of the additional changes are finalized.

**Oversight Strategy**

**Audit procedures.** CMS uses audits as part of its oversight strategy to ensure compliance with program requirements. In November 2006, CMS issued a memorandum outlining its plans for auditing Part D sponsors.\(^8\) CMS stated in this memorandum that it would conduct regularly scheduled (i.e., routine) program audits of PDP sponsors using selected chapters of the “Prescription Drug Plan Sponsor Part D Audit Guide” (hereafter referred to as the “Audit Guide”). For these audits, CMS requires PDP sponsors to provide supporting documentation to demonstrate their compliance with Federal requirements.

The Audit Guide contains 14 chapters corresponding to various program areas, such as enrollment and disenrollment, claims processing, and compliance plans. Each chapter has individual components that can be reviewed. Chapter 10 of the Audit Guide covers compliance plans and includes components that correspond with the eight required compliance plan elements.\(^9\) For example, one component states that PDP sponsors’ compliance plans must include a comprehensive plan to detect, correct, and prevent fraud, waste, and abuse.

CMS can also conduct focused audits to confirm the correction of previously identified deficiencies or in response to indications of noncompliance. Focused audits are conducted outside of the routine audit process.

**Request for PDP self-assessment.** As part of its activities to monitor the implementation of the Part D program, CMS instructed PDP sponsors to complete a self-assessment regarding their compliance plans in June 2007.\(^10\) CMS indicated that it would use this self-assessment to determine the extent to which PDP sponsors had implemented the

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requirements and recommendations outlined in Chapter 9 of the “Prescription Drug Benefit Manual.”

**Account managers.** Account managers within CMS perform the day-to-day oversight of PDP sponsors. Account managers serve as the primary point of contact for PDP sponsors and ensure PDP sponsors’ compliance with program rules and guidance. Account managers also coordinate all audits of PDP sponsors.

**Medicare Drug Integrity Contractors.** Medicare Drug Integrity Contractors (MEDIC) are responsible for many Part D oversight activities. According to the MEDICs’ umbrella statement of work, their responsibilities may include analyzing claims and other data, investigating complaints, and reviewing the fraud and abuse components of PDP sponsors’ compliance plans. CMS issues individual task orders to define the specific responsibilities of MEDICs. CMS has contracted with three companies to serve as MEDICs. MEDICs’ early efforts focused on processing complaints regarding Part D fraud, waste, and abuse.

**Previous Office of Inspector General Work**

In December 2006, the Office of Inspector General (OIG) issued a report entitled “Prescription Drug Plan Sponsors’ Compliance Plans” (OEI-03-06-00100). The report found that most PDP sponsors’ compliance plans did not address all of the CMS requirements or recommendations. For example, 71 of 79 PDP sponsors’ compliance plans reviewed did not address all requirements related to internal monitoring and auditing. OIG recommended that CMS take steps to ensure that PDP sponsors’ compliance plans address all requirements. In its comments on the report, CMS stated that account managers would follow up with the PDP sponsors identified in the report regarding deficiencies in their compliance plans. In addition, CMS stated that in January 2007, it would begin routine audits that would include PDP sponsors’ compliance plans.

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METHODOLOGY

Data Collection and Analysis
We collected documentation and interviewed CMS staff regarding the following oversight activities:

- all audits of PDP sponsors conducted between January 1, 2007, and March 31, 2008;
- any planned audits of PDP sponsors’ compliance plans scheduled for 2008;
- PDP sponsors’ self-assessment of their compliance plans and any steps taken to address deficiencies;
- CMS’s followup with PDP sponsors regarding the findings of OIG’s December 2006 report; and
- any other oversight conducted to ensure that PDP sponsors’ compliance plans meet Federal requirements.

We collected this information from CMS officials with responsibility for oversight of PDP sponsors’ compliance plans. CMS respondents included representatives from the Center for Beneficiary Choices’ Medicare Drug Benefit Group and Plan Oversight and Accountability Group as well as the Office of Financial Management’s Program Integrity Group. Data collection was conducted in April and May 2008.

We reviewed CMS staff responses to our interview questions to determine what oversight has been conducted or planned regarding PDP sponsors’ compliance plans. In addition, CMS provided data on audits of PDP sponsors conducted in 2007. We analyzed the data to determine the number and types of audits conducted and whether any audits included a review of compliance plans. CMS did not provide data on audits conducted between January and March 2008 because no PDP sponsors were audited during this time.

CMS also provided data on the results of the June 2007 self-assessment and the followup to the self-assessment conducted by account managers in April 2008. We reviewed these results to determine which compliance plan requirements PDP sponsors reported that they had not implemented and what steps were taken to address compliance plan deficiencies. In addition, we reviewed Chapter 9 of the “Prescription Drug Benefit Manual” and the self-assessment to determine which requirements were included in both documents.
INTRODUCTION

Standards
This study was conducted in accordance with the “Quality Standards for Inspections” issued by the President’s Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.
CMS conducted one audit of a PDP sponsor’s compliance plan in 2007. CMS reported that it would begin routine audits of PDP sponsors in January 2007 that would assess the effectiveness of sponsors’ compliance plans. CMS conducted 19 audits of PDP sponsors in 2007: 17 routine audits and 2 focused audits. CMS did not include a compliance plan review in any of the 17 routine audits. One of the two focused audits included a review of one PDP sponsor’s compliance plan. This focused audit was of a PDP sponsor that had deficiencies in several other program areas. The audit reviewed the PDP sponsor’s compliance plan for one required component and found that the sponsor did not have a comprehensive plan to detect, correct, and prevent fraud, waste, and abuse.

In April 2008, CMS staff reported that they plan to have the MEDICs conduct specific audits of compliance plans. CMS originally intended to have the MEDICs start the compliance plan audits in the fall of 2007; however, CMS did not begin the audits at that time because of budget constraints. CMS reported that the MEDICs would begin conducting these compliance plan audits in the summer of 2008. However, as of early August 2008, the MEDICs had not yet audited any PDP sponsors’ compliance plans.

PDP sponsors completed a compliance plan self-assessment but CMS did not verify sponsors’ responses. In response to OIG’s December 2006 report, CMS stated that it would have account managers follow up with sponsors identified in the report to ensure that sponsors corrected their compliance plan deficiencies. CMS staff reported in April 2008 that, rather than follow up specifically with PDP sponsors identified in OIG’s report, they had requested all PDP sponsors to complete a compliance plan self-assessment. The self-assessment was the only followup conducted by CMS in response to OIG’s report.

CMS developed the self-assessment and sent it to all 91 PDP sponsors in June 2007. All 91 PDP sponsors completed the self-assessment. The self-assessment included 50 questions, 11 regarding required compliance plan items and 39 regarding recommended items. CMS did not request that PDP sponsors submit documentation to verify their responses.

Results of self-assessment. Twenty-five percent of PDP sponsors (23 of 91) attested that they did not implement 1 or more of the
11 requirements included in the self-assessment. For example, 14 percent of PDP sponsors (13 of 91) attested that they did not have documented procedures for internal monitoring and auditing of their Part D compliance programs. Nine percent (8 of 91) attested that they did not provide training and education between the compliance officer and employees, contractors, subcontractors, agents, and directors. Five percent of PDP sponsors (5 of 91) attested that they did not have a documented comprehensive plan to detect, correct, and prevent Part D fraud, waste, and abuse.

The other 39 questions in the self-assessment pertained to recommendations, according to CMS. While not required by regulation, CMS drafted these recommendations to assist PDP sponsors in implementing an effective compliance plan. For example, CMS recommends that PDP sponsors have a process in place to identify claims for drugs prescribed by excluded or deceased providers and a process to report and properly repay any overpayments. However, 45 percent of PDP sponsors (41 of 91) attested that their plans for preventing fraud, waste, and abuse did not include such processes. CMS also recommends that PDP sponsors distribute their code of conduct to first tier, downstream, and related entities. However, 52 percent (47 of 91) attested that they did not do so.

**Self-assessment did not include all compliance plan requirements.** CMS stated that the self-assessment was based on Chapter 9 of the “Prescription Drug Benefit Manual.” Chapter 9 includes the eight regulatory compliance plan elements as well as additional requirements and recommendations for addressing these elements. Chapter 9 states that statutory or regulatory program requirements are reflected by use of the terms “must” or “shall.” CMS’s self-assessment included 11 requirements. However, our review of Chapter 9 identified an additional 12 items that were referred to using the words “must,” “shall,” or, in one case, “will” that were not included in the self-assessment as requirements. Six of these twelve items were included in the self-assessment as recommendations, but the remaining six were not included as part of the self-assessment. For example, the Chapter 9 requirement that a PDP sponsor “must ensure the Part D Compliance Officer does not hold other responsibilities that could lead
to self-policing of his/her activities”\textsuperscript{13} was not included in the self-assessment.

**CMS followed up with 23 PDP sponsors but did not request documentation to ensure that sponsors corrected deficiencies identified through the self-assessment**

In April 2008, CMS asked account managers to follow up with 23 PDP sponsors regarding the June 2007 self-assessment. These 23 PDP sponsors attested in June 2007 that they had not implemented 1 or more of 11 compliance plan requirements included in the self-assessment.

As followup, CMS asked the 23 PDP sponsors whether they had come into compliance since responding to the self-assessment, or whether they misunderstood a question and had actually been in compliance from the beginning. All 23 PDP sponsors responded to CMS’s request for follow-up information.

We reviewed a summary of the 23 PDP sponsors’ follow-up responses to CMS’s request regarding the implementation of the compliance plan requirements. Based on CMS’s followup, only one sponsor reported that it was not meeting all of the requirements included in the self-assessment. However, CMS did not instruct account managers to request supporting documentation to confirm that PDP sponsors made corrections to their compliance plans.

In addition, CMS did not follow up with PDP sponsors that attested that they had not implemented one or more of the recommended items included in the self-assessment. This included six items that were requirements in Chapter 9 of the “Prescription Drug Benefit Manual” but were considered recommended items in the self-assessment.

Effective compliance plans are a fundamental tool in preventing and detecting fraud, waste, and abuse in the Part D program. OIG’s December 2006 report on PDP sponsors’ compliance plans found that many PDP sponsors’ compliance plans did not meet all of the requirements. In response to that report, CMS indicated that it would conduct routine audits of PDP sponsors’ compliance plans and have account managers follow up with PDP sponsors identified in the report as having compliance plan deficiencies.

Although CMS originally planned to begin routine compliance plan audits in January 2007, as of early August 2008, CMS had not conducted any routine audits of PDP sponsors’ compliance plans. In addition, while CMS instructed all PDP sponsors to complete a compliance plan self-assessment, the self-assessment did not include all requirements from Chapter 9 of the “Prescription Drug Benefit Manual.” Also, CMS did not ensure that PDP sponsors’ attestations were accurate by independently verifying their responses. Therefore, CMS has only self-reported information to determine whether PDP sponsors’ compliance plans are meeting Federal requirements.

Therefore, we recommend that CMS:

**Conduct Audits To Verify That PDP Sponsors’ Compliance Plans Meet Requirements**

CMS should conduct routine audits of PDP sponsors’ compliance plans to ensure that these compliance plans meet all Federal requirements. Specifically, these audits should cover all compliance plan requirements contained in regulations as well as requirements included in Chapter 9 of the “Prescription Drug Benefit Manual.” CMS may also want to assess the degree to which PDP sponsors have implemented the recommendations described in Chapter 9.

**AGENCY COMMENTS**

CMS concurred with our recommendation that it should conduct audits of PDP sponsors’ compliance plans. CMS noted that due to critical funding shortfalls, it was not able to conduct compliance plan audits prior to the issuance of this report. However, CMS stated that it will begin audits of sponsors’ compliance plans in the near future. These
RECOMMENDATION

audits will consist of a limited number of desk audits; however, as more resources become available, CMS stated that it will include more audits, onsite reviews, and other more comprehensive fraud prevention activities. The full text of CMS’s comments are included in the Appendix.
Agency Comments

DATE: SEP 26 2008

TO: Daniel R. Levinson
Inspector General

FROM: Kerry Weepes
Acting Administrator


Thank you for the opportunity to review and respond to this OIG draft report. The Centers for Medicare & Medicaid Services (CMS) appreciates the OIG’s efforts in reviewing our oversight of the Medicare Part D program. CMS agrees that it is important to conduct reviews of compliance plans. However, it is important to note that CMS had to reprioritize its program integrity oversight activities due to critical funding shortfalls. As a result, we were not able to conduct compliance plan audits prior to the issuance of this report. CMS will begin the Part D compliance plan audits in September 2008.

We made several requests for funding, through an adjustment to discretionary spending totals, in fiscal year (FY) 2007 ($118 million) and FY 2008 ($183 million). In each year, Congress failed to enact our budget request. These requests would have allowed us to fully fund the Medicare Drug Integrity Contractors (MEDIC) and other program integrity oversight activities.

Due to funding shortfalls, we chose to focus the MEDICs' efforts in the following four areas:

- Handling, assessing, and investigating incoming complaints alleging fraud, waste, and abuse in the Part D program. Between December 2006 and May 2008, the 3 MEDICs addressed approximately 3,595 complaints, conducted 1,343 investigations, referred 59 cases to law enforcement, and sent 54 immediate advisements to law enforcement;
- Establishing the MEDIC data infrastructure and operations. These activities included training the MEDICs on how to access and use Part D data for program integrity activities;
- Performing both proactive and reactive data analysis on Part D data, as well as incoming complaint data. The MEDICs utilize their data resources for trending and vulnerability forecasting; and
- Processing law enforcement requests for information and providing guidance and technical assistance on Part D data and how to use these data to further an investigation.
One of the initial successes of the MEDIC program was the identification of fraud schemes in which scam artists trick beneficiaries into releasing personal and bank account information by promising to enroll them in Medicare Part D. These cases identified by the MEDICs involved a one-time payment of $299. The MEDICs provided their investigative results and complaint information to law enforcement authorities who took action against one of the processors identified by the MEDIC. The MEDICs’ information helped the Department of Homeland Security-Immigration and Customs Enforcement (ICE) freeze the subject’s assets. The accounts of the scam processing centers were put into receivership and utilized to reimburse victims, some of whom were Medicare beneficiaries, for the fraudulent debits from their bank accounts. The MEDICs continue to identify these types of fraud schemes and have worked closely with law enforcement to establish administrative processes to expedite the referral and resolution of these cases.

The CMS concurs with OIG’s recommendation that the MEDICs should be performing Part D compliance plan audits, and we are expanding the priorities of our MEDIC program to include these activities with our available resources. Beginning in September 2008, the MEDICs will conduct a limited amount of desk audits of Part D compliance plans. In addition, as more resources become available for the MEDICs, CMS will continue to enhance our Part D program integrity efforts to include more audits, onsite reviews, and other more comprehensive fraud prevention activities.

**OIG Recommendation**
Recommend that CMS conduct audits to verify that PDP sponsors’ compliance plans meet requirements.

**CMS Response**
We concur with this recommendation. CMS will begin the audits of Part D sponsors’ compliance plans in September 2008.

The CMS thanks OIG for its efforts on this report. We look forward to continuing to work with you in the future to strengthen our oversight efforts and identify and prevent fraud, waste, and abuse in the Medicare Part D program.
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.

Tara J. Bernabe served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the Philadelphia regional office who contributed to the report include Nancy J. Molyneaux; central office staff who contributed include Rita Wurm.