Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

AUDITS OF MEDICARE PRESCRIPTION DRUG PLAN SPONSORS

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EXECUTIVE SUMMARY

OBJECTIVES

To determine:

(1) the extent to which stand-alone Medicare prescription drug plan (PDP) sponsor contracts were audited between 2006 and 2009,

(2) the extent to which these audits identified problems, and

(3) whether the Centers for Medicare & Medicaid Services (CMS) had evidence to show that corrective actions were taken to resolve these problems.

BACKGROUND

CMS contracts with private companies, known as plan sponsors, to offer Part D coverage to beneficiaries. One of CMS's oversight activities is to audit plan sponsors to ensure that they comply with Part D laws and regulations. CMS staff identified seven types of audits, other than financial audits, that CMS used for auditing stand-alone PDP contracts in the first 4 years of the Part D program (2006 through 2009): autoenrollment readiness audits, benefit integrity audits, bid audits, compliance plan audits, long-term-care pharmacy contract audits, pharmacy access audits, and program audits. CMS selects auditees based on risk analysis and other factors. It is not required by law to conduct any of these audits.

In this report, we provide a broad overview of CMS's use of the seven types of audits from 2006 through 2009. The Office of Inspector General (OIG) is conducting a separate review of CMS's use of financial audits.

A stand-alone PDP is a Part D insurance plan that covers only prescription drugs. We focused on stand-alone PDPs because the majority of the 27 million beneficiaries who enrolled in Part D in 2009 were in stand-alone PDPs. In this report, PDPs refer to stand-alone PDPs.

We requested that CMS provide us with a list of all PDP audits it completed for the seven audit types during the first 4 years of the Part D program. We also collected information from CMS on the audits that found problems. We then selected a sample from the audits that identified problems for a more detailed review.

FINDINGS

Some PDP sponsor contracts were never audited between 2006 and 2009. CMS had 125 active, unique PDP sponsor contracts during the first 4 years of the Part D program. Fifty of these contracts, which covered 1.1 million beneficiaries, were never audited in any way. PDP contracts were active between 1 and 4 years. Of the 68 contracts that were active for all 4 years, 13 (19 percent) were never audited. CMS had no parameters regarding the number of audits it should conduct and did not complete any compliance plan audits during the 4-year period.

Seventy-nine percent of the 245 PDP audits completed between 2006 and 2009 identified problems. Two-thirds of the 673 problems reviewed involved beneficiaries' coverage status or payment issues. For example, 41 percent of problems identified through program audits involved plan sponsors' enrollment and disenrollment processes. Forty-two percent of the problems identified through bid audits involved issues such as adjustments to cost-sharing amounts and the categorization of direct and indirect costs that might affect beneficiaries' Part D premiums.

CMS did not have evidence to show that all corrective actions were implemented for two audit types. CMS did not document that corrective action was taken for 88 of 506 problems (17 percent) identified by program audits and autoenrollment readiness audits. Most of these problems were identified through program audits.

RECOMMENDATIONS

CMS is responsible for overseeing the Part D program. Auditing is one way CMS ensures that plan sponsors comply with laws and regulations related to the Part D program. Although CMS is not required to conduct the seven types of audits in our report, it developed them to identify problems and correct deficiencies within the Part D program. However, CMS did not have parameters regarding the number of audits it should conduct. In addition, CMS did not always have evidence to show that all problems were addressed for certain audit types.

Prior OIG reports have shown that CMS delayed beginning some types of audits. This report shows that some PDP contracts were never audited, and that CMS completed no compliance plan audits between 2006 and 2009. This report also shows that when audits were

conducted, they frequently identified problems that may directly affect beneficiaries' coverage status or payments. Audits can potentially identify problems that might not be detected through other forms of oversight.

We recommend that CMS:

Establish a comprehensive Part D auditing strategy that ensures that each plan sponsor will be audited in some way within a certain timeframe.

Ensure that evidence is available to show that corrective actions have been implemented.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS partially concurred with the first recommendation, stating that it believes all sponsors should undergo a bid audit and that it plans to complete a bid audit by 2013 of every PDP parent organization in the program since 2006. CMS is not in favor of establishing a comprehensive Part D auditing strategy. It believes a comprehensive oversight strategy, developed in coordination with offices responsible for the management of Part D, is more effective than an auditing strategy. CMS also believes that its heavy reliance on monitoring, defined as systematic evaluation of the complete universe of sponsors, allows it to assess key performance indicators across 100 percent of PDP sponsors. CMS stated that monitoring is the only efficient approach for assessing critical performance areas across all PDP contracts.

OIG stands by its first recommendation, to establish a comprehensive Part D auditing strategy. This recommendation is not meant to be a substitute for a comprehensive oversight strategy or a substitute for monitoring.

CMS concurred with the second recommendation. CMS stated that in 2010, it began a more comprehensive process for validating corrections made by sponsors as a result of deficiencies found during audits. CMS stated that it now maintains, and will continue to maintain, documentation of corrective actions implemented for all audits.

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BACKGROUND

This report adds to the Office of Inspector General's (OIG) body of work regarding CMS's oversight of the Medicare Part D program, also known as the Voluntary Prescription Drug Benefit Program, which went into effect on January 1, 2006.[1] One of CMS's oversight activities is to audit plan sponsors to ensure that they comply with laws and regulations related to the Part D program. Plan sponsors are private companies under contract with CMS to provide Part D coverage to beneficiaries. OIG's previous work has found that CMS delayed beginning various types of Part D audits. Audits can identify problems that might not be detected through other forms of oversight. This report examines the extent to which CMS has completed audits and identified problems in the first 4 years of the Part D program.

This report provides a broad overview of seven types of audits—excluding financial audits—that CMS planned to use to audit plan sponsors of stand-alone PDPs between 2006 and 2009. We did not include financial audits in this report because OIG reviewed these audits separately.

Two types of plans provide Part D coverage. Medicare Advantage prescription drug plans cover a variety of medical services, including prescription drugs, while stand-alone PDPs cover only prescription drugs. We focused on stand-alone PDPs because the majority of beneficiaries in the Part D program were enrolled in stand-alone PDPs. In 2009, 17 million of the 27 million beneficiaries enrolled in Part D

[1] Social Security Act § 1860D-1, 42 U.S.C. § 1395w-101.

were in stand-alone PDPs.[2] In this report, PDPs refer to stand-alone PDPs.

PDP Contracts

A plan sponsor's PDP contract with CMS may include more than one plan. As of February 2011, plan sponsors had 84 PDP contracts that included a total of 1,304 plans.[3] Plans within a contract may differ in coverage and copayments.

Part D Expenditures

In 2009, total expenditures for Part D were $60.8 billion.[4] CMS makes monthly prospective payments to plan sponsors to provide drug coverage to Medicare beneficiaries. These payments are based on bid amounts approved by CMS. Bid amounts are cost estimates that plan sponsors provide to CMS prior to the beginning of each plan year. After the close of the plan year, CMS reconciles these payments with the plan sponsors' actual costs to determine whether plan sponsors owe money to Medicare or Medicare owes money to them.

CMS Offices That Conduct Part D Audits

Several CMS offices audit plan sponsors with PDP contracts. Some offices have overlapping responsibilities for the same type of audit.

The following CMS offices were responsible for the audits in this report during the period we reviewed:

- the Office of the Actuary (OACT),
- the Program Compliance and Oversight Group (PCOG),
- the Program Integrity Group, and
- the Medicare Drug Benefit and C & D Data Group (MDBG).

Offices may conduct offsite or onsite Part D audits. The teams that conduct the audits may include CMS central office staff, CMS regional office staff, or CMS contractors, including the Medicare Drug Integrity

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[2] CMS, *Monthly Contract and Enrollment Summary Report,* June 2009. Accessed at http://www.cms.gov/MCRAdvPartDEnrolData/ on July 14, 2009.

[3] CMS, *Monthly Enrollment by Contract, Monthly Enrollment by Plan,* February 2011. Accessed at http://www.cms.gov/MCRAdvPartDEnrolData/ on July 12, 2011.

[4] The Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, *2010 Annual Report*, August 5, 2010, p. 135. Accessed at http://www.cms.gov/ReportsTrustFunds/downloads/tr2010.pdf on February 22, 2011.

Contractors (MEDIC). MEDICs perform specific program integrity activities in the Part D program.[5]

Seven Types of Audits

In addition to financial audits, CMS began conducting seven types of audits between 2006 and 2009. Although CMS is required by law to conduct financial audits, there are no legal requirements for it to conduct any of these seven types of audits.[6] CMS conducts these audits at the plan sponsor's parent organization, contract, or plan level, depending on the audit type. Each CMS office that conducts Part D audits selects plan sponsors to audit based on certain criteria, including enrollment levels, recommendations from other CMS offices, risk analysis, and resource limitations.

Autoenrollment readiness audits. MDBG and PCOG were the CMS offices responsible for this type of audit. Autoenrollment readiness audits assess a plan sponsor's automated systems and processes to ensure that the plan is ready to receive autoenrollments of beneficiaries who qualify for low-income subsidies. When beneficiaries qualify for such subsidies but fail to enroll in Part D plans, CMS automatically enrolls them in a PDP. Each year, CMS identifies PDPs qualified to accept autoenrollees and selects plan sponsors from this group to audit. The audit measures the plan sponsors' readiness to autoenroll beneficiaries in the coming contract year and to provide timely notices and evidence of enrollment to beneficiaries so they can immediately use the plan services.

Benefit integrity audits. These audits are conducted on an ad hoc basis to identify and investigate Part D fraud cases. At the time of our review, the CMS office with oversight responsibility for these audits was the Program Integrity Group, then operating within the Office of Financial Management.

Benefit integrity audits may be performed on any entity in the Part D program. CMS, a MEDIC, or a plan sponsor can recommend and conduct a benefit integrity audit. With CMS's approval, MEDICs may participate in plan sponsors' audits of pharmacies.

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[5] CMS, *Prescription Drug Benefit Manual*, Rev. 2, April 25, 2006, ch. 9, § 10.1. Accessed at http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp on September 22, 2011.

[6] Social Security Act § 1860D-12, 42 U.S.C. § 1395w-112.

Bid audits. OACT is the CMS office responsible for reviewing, approving, and auditing bid amounts. Before it approves a sponsor's bid, CMS conducts a review to ensure that the bid meets CMS's requirements.

Once a bid is approved, CMS may conduct a bid audit, i.e., an audit of the plan sponsor's bid development for selected plans offered by the sponsor. The bid development includes the bid amount, which is the plan sponsor's per-member, per-month estimated cost of providing drug coverage. Bid audits are reviews of the reasonableness of the data and the support for actuarial assumptions used to develop the plan sponsor's bid. Bid audits review base period data, which are a previous year's actual utilization, drug cost, and administrative fee data that help determine the bid amount.

CMS categorizes deficiencies found through bid audits as findings or observations. Findings are deficiencies that, if corrected, could lead to reduced payments from CMS, additional benefits to enrollees, or reduced enrollee premiums. Observations are inconsistencies, errors, omissions, and unreasonable assumptions and practices that do not significantly affect the bid.[7]

CMS reviews plan sponsors' subsequent bids to determine whether issues identified by previous bid audits were addressed. Findings and observations identified through bid audits are forwarded to MDBG to be used in performance analysis of those plan sponsors.

Compliance plan audits. Late in 2009, the responsibility for compliance plan audits was transitioned to PCOG. Prior to that time, the Program Integrity Group was responsible for these audits. All sponsors are required to have a compliance plan. Compliance plans detail sponsors' policies and procedures regarding fraud, waste, and abuse. The compliance plan must include certain elements such as "procedures for effective internal monitoring and auditing" and "procedures for ensuring prompt responses to detected offenses."[8] Compliance plan audits determine whether sponsors have these elements in their plans and the extent to which their compliance plans are effective.

Long-term-care pharmacy contract audits. MDBG was responsible for this type of audit at the time of our review. Long-term-care pharmacies

[7] CMS, *Audit Procedures for Calendar Year 2008 Bids*, p. 3.

[8] 42 CFR § 423.504(b)(4)(vi).

dispense prescription drugs to beneficiaries in institutional settings such as nursing homes. Long-term-care pharmacy contract audits were performed on plan sponsors with the largest number of beneficiaries in long-term institutional settings. These audits reviewed agreements between the plan sponsors and long-term-care pharmacies to ensure that they met CMS requirements, such as convenient access to long-term-care pharmacies for institutionalized enrollees. CMS conducted these audits in response to complaints about long-term-care pharmacy negotiations.

Pharmacy access audits. Pharmacy access audits were another type of audit for which MDBG was responsible. These were audits of contracts between plan sponsors and pharmacies and pharmacy benefit managers that administer sponsors' prescription drug benefits. The audits determined whether the contracts met CMS requirements. These requirements include, but are not limited to, meeting retail pharmacy access standards, abiding by privacy regulations, and charging the correct cost-sharing amount. CMS did not conduct pharmacy access audits after 2007 because it began requiring PDPs to submit analyses of Part D pharmacy access to CMS each year.

Program audits. Also known as program compliance audits, program audits examine a broad array of policies, procedures, and operations related to sponsors' Part D plans.[9] These audits are conducted by PCOG and examine areas such as enrollment and disenrollment; marketing; coordination of benefits; formularies; and enrollee coverage determinations, grievances, and appeals.

Corrective Action Plans

CMS requires plan sponsors to develop and implement corrective action plans to address problems identified through most types of audits. Within certain types of audits and for certain types of problems, CMS takes corrective actions, such as warning or monitoring the sponsor.

For bid audits, CMS does not use a corrective action plan process. Instead, CMS determines whether the problems identified through bid audits are resolved when it reviews plan sponsors' bids for the following contract year.

[9] We use the term program audit instead of program compliance audit throughout this report to distinguish program audits from compliance plan audits.

Problems identified through benefit integrity audits conducted by plan sponsors are addressed through a corrective action process that is controlled by the sponsor.

During our review, CMS described the corrective action plan process as an iterative one that begins when the plan sponsor submits an initial corrective action plan. After it reviews the corrective action plan, CMS can require the plan sponsor to modify it and resubmit it until CMS is satisfied that the corrective action plan addresses the audit findings and approves it.

Monitoring

According to CMS, audits are just one part of its strategy to ensure that PDP sponsors are in compliance with Part D laws, regulations, and guidance. CMS reported that although its initial approach was to use auditing to ensure compliance, it was faced with a number of urgent issues surrounding Part D that drove the creation of a more intensive monitoring program. CMS stated that as day-to-day monitoring has become more sophisticated, particularly in the past few years, it has not had to rely as heavily on audits as a source of information about PDP sponsor performance. The new monitoring program includes the collection of measurements from all plans on key issues, e.g., beneficiary complaints, call center response times, disenrollment rates, and Part D pricing accuracy. CMS reported that monitoring provides more timely information than audits and also results in compliance actions.

Related OIG Work

OIG has issued several reports concerning CMS's oversight of the Part D program that have included information about audits.

Three reports found delays in starting financial audits.[10] Two of these reports, issued in 2007, found that financial audits had not yet begun. The third report found that only 4 percent of the required number of financial audits for contract year 2006 had begun as of April 2008.

[10] 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, *Tracking Beneficiaries' True Out-of-Pocket Costs for the Part D Prescription Drug Benefit*, OEI-03-06-00360, December 2007; and OIG, *Centers for Medicare & Medicaid Services Audits of Medicare Part D Bids*, OEI-05-07-00560, November 2008.

Two reports, issued in 2008 and 2010, found weaknesses in the bid audit process.[11] In 2008, OIG found that one-quarter of all bid audits for 2006 and 2007 identified at least one finding. However, bid audits were not designed to lead to sanctions, such as civil monetary penalties or suspension of enrollment. OIG recommended that CMS modify the bid audit process so that plan sponsors can be held more accountable and subject to corrective actions when bid audits identify findings. CMS responded that it would carefully consider modifying the bid audit process to hold plans more accountable for findings. In 2010, OIG found that the bid review and audit process needed improvements, including consideration of bid audit findings in the year-end reconciliation process.

Three other OIG reports contained information regarding plan sponsors' compliance plans.[12] These reports found delays in starting compliance plan audits and that CMS did not have information on Part D fraud and abuse that would help it determine the effectiveness of sponsors' compliance plans. OIG also found that although MEDICs were prepared to conduct compliance plan audits, CMS did not give MEDICs approval to do so in fiscal year 2008.

In its comments on several of these reports, CMS cited budget shortfalls and lack of necessary data as reasons that audits had not begun.

METHODOLOGY

Data Collection and Analysis

For this review, we included all PDP audit types identified by various CMS offices, with the exception of financial audits. We collected all audit information from CMS's central office, whether the audits were conducted by the central office, CMS regional offices, or contractors. We collected information in two phases. Data collection for this study began in December 2009. However, after receiving responses for both phases of data collection from CMS, we had to request clarifying information. For

[11] OIG, *Centers for Medicare & Medicaid Services Audits of Medicare Part D Bids*, OEI-05-07-00560, November 2008; OIG, *Medicare Part D – Prescription Drug Event Reconciliation Process*, A-18-08-30102, June 2010.

[12] OIG, *Oversight of Prescription Drug Plan Sponsors' Compliance Plans*, OEI-03-08-00230, October 2008; OIG, *Medicare Drug Plan Sponsors' Identification of Potential Fraud and Abuse*, OEI-03-07-00380, October 2008; OIG, *Medicare Drug Integrity Contractors' Identification of Potential Part D Fraud and Abuse,* OEI-03-08-00420, October 2009.

some audit types, we made repeated requests for clarification. We completed data collection in August 2010.

First phase. In the first phase of data collection and analysis, we collected the following information on plan sponsors for each of 4 years, 2006 through 2009:

- CMS's audit protocols;
- CMS's criteria for selecting PDPs to be audited;
- a list of PDP contracts; and
- a list of the PDPs for which audits were completed for each of the seven audit types in this study, the date each audit was completed (i.e., final report issued), and whether these audits identified problems. We defined "problem" as any audit finding that CMS determined needed to be addressed by plan sponsors.

We reviewed the audit protocols and the criteria CMS used for selecting PDPs to audit for each of the audit types.

From the lists of PDP contracts and completed audits, we summarized the number of contracts CMS had with plan sponsors each year, and calculated the percentage of contracts for which CMS completed each of the seven types of audits. If a parent organization was audited, we deemed that all contracts under that parent organization were audited. We also summarized the number of audit types completed each year and across all 4 years. Finally, we calculated the number and percentage of audits that identified problems.

Data stratification and sample selection. From the population of 194 audits that identified problems, we selected a stratified random sample of 129 to review in more detail. Each stratum of the sample represents an audit type. For each audit type, if there were 35 or fewer audits that identified problems in 4 years, we reviewed all of the audits. As a result, we reviewed the entire population of autoenrollment readiness audits, benefit integrity audits, long-term-care pharmacy contract audits, and pharmacy access audits that identified problems. Bid audits and program audits were the only two audit types for which we did not review the entire population.

Table 1 shows the population of audits that identified problems, the number of sample audits from this population, and the number of problems in sample audits.

Table 1: Sample Audits and Problems in Sample Audits, 2006–2009

Stratum	Type of Audit	Population of Audits That Identified Problems	Sample Audits	Number of Problems in Sample Audits
1	Autoenrollment readiness audits	19	19	51
2	Benefit integrity audits	27	27	38
3	Bid audits	72	37	107
4	Compliance plan audits	NA[1]	NA[1]	NA[1]
5	Long-term-care pharmacy contract audits	9	9	9
6	Pharmacy access audits	2	2	2
7	Program audits	65	35	466
Total		**194**	**129**	**673**

Source: OIG analysis of CMS responses to 2010 OIG data request.
[1] Compliance plan audits were not completed during our review period.

Second phase. In the second phase of data collection and analysis, we collected the following information for all problems identified though our sample audits:

- a description of each problem and each corrective action used to address it,
- the date that CMS accepted the corrective action plan to address each problem and the date the problem was resolved, and
- a description of the evidence CMS used to determine that the problem was resolved.

We also collected CMS's policies and procedures for implementing corrective actions.

We calculated the number of problems identified by each type of audit and across audit types. We categorized the types of problems and corrective actions and determined the frequency of each category by audit type.

For each type of audit, we determined whether CMS had evidence that corrective actions were taken to address the problems. If CMS's description of evidence lacked specifics or did not correspond specifically to the corrective action, we determined that there was no evidence that the corrective action was taken.

We did not project findings from our sample because we could not make reliable projections for bid and program audit problem types. Therefore, to

present all the findings in a consistent manner, we provide information based only on our review of the sample data.

Limitations

We did not independently verify data provided by CMS. We also did not evaluate whether the audit types described by CMS met general accounting or auditing standards.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

Some PDP sponsor contracts were never audited between 2006 and 2009

CMS had 125 active, unique PDP sponsor contracts over the first 4 years of the Part D program. As shown in Table 2, 50 of the 125 contracts were never audited in any way. These 50 contracts covered 1.1 million beneficiaries.[13] PDP contracts were active between 1 and 4 years. Of the 68 contracts that were active for 4 years, 13 (19 percent) were never audited. Table 2 shows the number and percentage of contracts never audited.

Table 2: Number of Contracts That Were Never Audited, 2006–2009

Number of Years Contracts Were Active	Number of Contracts	Number of Contracts Never Audited	Percentage of Contracts Never Audited
4	68	13	19%
3	28	13	46%
2	5	1	20%
1	24	23	96%
Total	**125**	**50**	**40%**

Source: OIG analysis of CMS responses to 2010 data request.

CMS did not set parameters regarding the number of audits to conduct

Whether a plan sponsor is audited depends on selection criteria developed by the different CMS offices responsible for conducting the audits. None of these offices had requirements regarding the number of audits to conduct.

As shown in Table 3, in some years, CMS did not complete any audits for certain audit types. Audits can identify problems that might not be detected through other forms of oversight.

Autoenrollment readiness audits. CMS completed autoenrollment readiness audits in all 4 years. Thirty-four autoenrollment readiness audits were completed between 2006 and 2009.

[13] The enrollment estimate for these 50 contracts is based on the number of enrollees in December of the most recent year each contract was active between 2006 and 2009. As of February 2011, 19 million beneficiaries were enrolled in PDPs.

Table 3: Types of Audits Completed Each Year, 2006–2009

Type of Audit	2006	2007	2008	2009	Total for All 4 Years
Autoenrollment readiness audits	7	11	8	8	**34**
Benefit integrity audits[1]	0	1	17	18	**36**
Bid audits	41	24	14	NA[2]	**79**
Compliance plan audits[3]	0	0	0	0	**0**
Long-term-care pharmacy contract audits	NA[4]	NA[4]	NA[4]	10	**10**
Pharmacy access audits	0	9	NA[5]	NA[5]	**9**
Program audits	0	21	31	25	**77**
Total	**48**	**66**	**70**	**61**	**245**

Source: OIG analysis of CMS responses to 2010 data request.

[1] Benefit integrity audits were conducted by sponsors. They were audits of pharmacies in sponsors' networks.
[2] Fourteen bid audits begun in 2009 were not completed in 2009.
[3] Although CMS did not complete any compliance plan audits between 2006 and 2009, it did begin a number of these audits in 2010.
[4] CMS did not begin conducting long-term-care pharmacy contract audits until 2009.
[5] CMS discontinued pharmacy access audits after 2007.

Benefit integrity audits. Plan sponsors completed benefit integrity audits of pharmacies in 3 of the 4 years we reviewed. The number of audits completed varied from as few as 1 in 2007 to as many as 18 in 2009.

Bid audits. The number of bid audits CMS completed each year ranged from 41 for contract year 2006 to 14 for contract year 2008. Because bid audits are always begun in October of the contract year and completed in April of the following year, the bid audits that were begun in 2009 were not completed in 2009.

Compliance plan audits. CMS did not complete any compliance plan audits in the first 4 years of the Part D program. CMS began 10 compliance plan audits in 2008 and another 7 in 2009. Sponsors were selected for compliance plan audits based on performance data, risk factors, and enrollment levels. Although the selected sponsors presented the greatest risk, the compliance plan audits begun in 2008 and 2009 were never completed. CMS began conducting compliance plan audits in 2010 and completed a number of these audits.

Long-term-care pharmacy contract audits. CMS did not conduct this type of audit in the first 3 years of the Part D program. It began conducting long-term-care pharmacy contract audits only after receiving complaints from plan sponsors about negotiations with long-term-care pharmacies. CMS selected plan sponsors with the largest number of enrollees living in long-term-care settings for these audits. Ten audits of this type were completed in 2009. CMS reported that after 2009, it did not conduct these audits because it did not receive similar complaints in subsequent years.

Pharmacy access audits. In the first year of the Part D program, no pharmacy access audits were conducted because all plan sponsors' pharmacy access networks were reviewed as part of the Part D application process. CMS completed nine audits of this type in 2007. For these audits, CMS selected 10 percent of plan sponsors that made changes between 2006 and 2007 regarding the first-tier entity (e.g., a pharmacy benefit manager) performing key functions on their behalf. After 2007, no pharmacy access audits were conducted because CMS began requiring plan sponsors to submit an analysis of Part D access under new annual reporting requirements.

Program audits. CMS did not conduct program audits in the first year of the Part D program. It completed 21, 31, and 25 program audits in 2007, 2008, and 2009, respectively.

Seventy-nine percent of the 245 PDP audits completed between 2006 and 2009 identified problems

For six of the seven audit types in our review, 245 audits were completed between 2006 and 2009. Of those, 194 (79 percent) identified problems. For four audit types, at least three-quarters of the audits identified problems.

Table 4 shows, by audit type, the total number of audits completed and the number and percentage of audits that identified problems.

Table 4: Percentage of Audits That Identified Problems, 2006–2009

Audit Type	Number of Audits Completed	Number of Audits That Identified Problems	Percentage of Audits That Identified Problems
Bid audits	79	72	91%
Long-term-care pharmacy contract audits	10	9	90%
Program audits	77	65	84%
Benefit integrity audits	36	27	75%
Autoenrollment readiness audits	34	19	56%
Pharmacy access audits	9	2	22%
Compliance plan audits	0	NA	NA
Total	**245**	**194**	**79%**

Source: OIG analysis of CMS responses to 2010 OIG data request.

Two-thirds of the problems identified involved beneficiaries' coverage status or payments

Between 2006 and 2009, the 129 audits reviewed identified 673 problems. As shown in Table 5, two-thirds of these problems (447 of 673) may directly affect beneficiaries' coverage status or payments.

Table 5: Total Number of Problems by Audit Type, 2006–2009

Audit Type	Number of Problems	Number of Problems That May Directly Affect Beneficiaries
Program audits	466	358
Bid audits	107	45
Autoenrollment readiness audits	51	23
Benefit integrity audits	38	21
Long-term-care pharmacy contract audits	9	0
Pharmacy access audits	2	0
Compliance plan audits	No audits completed	No audits completed
Total	**673**	**447**

Source: OIG analysis of CMS responses to 2010 data request.

Appendix A lists all categories of problems identified through the audits and the number of problems in each category.

Program audits. Forty-one percent of the problems identified through program audits were deficiencies in the plan sponsors' enrollment and disenrollment processes. Examples of these deficiencies include failure to provide beneficiaries with membership materials prior to the effective date of enrollment, failure to notify beneficiaries of denial of enrollment requests, and failure to disenroll beneficiaries who move out of the sponsor's service area. Problems in these processes may affect beneficiaries' understanding of their coverage and, therefore, affect their decisions about obtaining needed prescriptions.

Another 36 percent of the problems identified through program audits were deficiencies in plan sponsors' coverage determination, grievance, and/or appeals processes. Examples of deficiencies of this type include failure to notify a beneficiary of a coverage determination or decision regarding a grievance within required timeframes. Problems in these processes could affect beneficiaries' ability to obtain the prescription drugs they need.

Bid audits. Forty-two percent of problems identified through bid audits involved adjustment, calculation, or categorization errors. These errors included inappropriate adjustments to cost sharing amounts, inappropriate calculation of indirect costs, and inappropriate categorization of direct and indirect costs. Problems in plan sponsors' bids can affect the premiums beneficiaries pay for Part D coverage and the amount CMS pays plan sponsors to administer the Part D benefit. As stated previously, CMS categorizes problems identified by bid audits as either findings or observations, and findings are more serious than observations. Of the 107 problems identified through bid audits, 13 were findings. Of the 13 findings, 5 involved adjustment, calculation, or categorization errors.

Autoenrollment readiness audits. Two categories of problems represented 45 percent of problems identified through autoenrollment readiness audits. The two problem categories were deficiencies in testing the systems for processing enrollment transactions and deficiencies in processes for handling four types of identifying information, called 4Rx data, needed to route prescription drug claims. If a plan sponsor is unable to autoenroll low-income subsidy beneficiaries or route their claims correctly, these beneficiaries could be left without Part D coverage.

Benefit integrity audits. Fifty-five percent of problems identified through benefit integrity audits involved inappropriate billing by pharmacies, such as pharmacies billing for services not rendered. When pharmacies bill inappropriately, the Part D program and beneficiaries may be harmed.

CMS did not have evidence to show that all corrective actions were implemented for two audit types

CMS did not document that corrective action was taken for 88 of 506 problems (17 percent) identified by program and autoenrollment readiness audits.[14] Eighty-six of these eighty-eight problems (98 percent) were identified by program audits. The categories of program audit problems for which there was no evidence of correction varied and included deficiencies in enrollment and disenrollment processes and deficiencies in coverage determination, grievances, and appeals processes.

For two problems identified by autoenrollment readiness audits, CMS did not have evidence to show that corrective actions were taken. The corrective actions for these two problems were to submit policies and procedures and take corrective action under a different audit type.[15]

Appendix B lists all the categories of corrective action used to address problems identified through each type of audit.

[14] For this calculation, we excluded 11 sample problems from the 517 problems identified through these 2 audit types either because the problems were unresolved or the PDP contracts were not renewed.

[15] There was no evidence to show that corrective action was implemented under the other audit, which was a program audit.

RECOMMENDATIONS

CMS is responsible for overseeing the Part D program. Auditing is one way CMS ensures that plan sponsors comply with laws and regulations related to the Part D program. Although CMS is not required to conduct the seven types of audits in our report, it developed them to identify problems and correct deficiencies within the Part D program. However, CMS did not have requirements regarding the number of audits it should conduct. Nor did CMS always have evidence to show that all problems were addressed for certain audit types.

Prior OIG reports have shown that CMS delayed beginning some types of audits. This report shows that some PDP contracts were never audited, and that no compliance plan audits were completed between 2006 and 2009. This report also shows that when audits were conducted, they frequently identified problems that may directly affect beneficiaries' coverage status or payments. Audits can identify problems that might not be detected through other forms of oversight. The sooner audits are performed and problems identified, the sooner problems can be addressed.

We recommend that CMS:

Establish a comprehensive Part D auditing strategy that ensures that each plan sponsor will be audited in some way within a certain timeframe

The strategy should include parameters for conducting each audit type. The strategy should also ensure coordination among the CMS offices responsible for auditing activities so that no contract goes 4 successive years without an audit of some type.

Ensure that evidence is available to show that corrective actions have been implemented

CMS should maintain documentation that corrective actions were implemented.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS partially concurred with the first recommendation, stating that it believes that all sponsors should undergo a bid audit and that it plans to complete a bid audit by 2013 of every PDP parent organization in the program since 2006. CMS is not in favor of establishing a comprehensive Part D auditing strategy. It believes a comprehensive oversight strategy, developed in coordination with offices responsible for the management of Part D, is more effective than an auditing strategy. CMS also believes

that its heavy reliance on monitoring, defined as systematic evaluation of the complete universe of sponsors, allows it to assess key performance indicators across 100 percent of PDP sponsors. CMS stated that monitoring is the only efficient approach for assessing critical performance areas across all PDP contracts. CMS added that in 2011, it systematically monitored PDP sponsors' performance across more than a dozen topic areas, e.g., call center wait times and complaint rates.

CMS also stated the 2010 program audits and compliance plan audits were conducted on sponsors that posed the most risk to the program, and that these sponsors were identified through risk assessments using information gathered through monitoring efforts.

OIG stands by its first recommendation, to establish a comprehensive Part D auditing strategy. This recommendation is not meant to be a substitute for a comprehensive oversight strategy or for monitoring. It is meant to be a tool CMS can use to ensure that parameters are established and followed regarding the auditing of Part D plan sponsors, regardless of the types of audits CMS chooses to conduct from year to year.

CMS concurred with the second recommendation. CMS stated that in 2010, it began a more comprehensive process for validating corrections made by sponsors as a result of deficiencies found during audits. CMS stated that it now maintains, and will continue to maintain, documentation of corrective actions implemented for all audits. For the full text of CMS's comments, see Appendix C.

APPENDIX ~ A

Table A-1: Categories of Problems Identified Through Sampled Audits, 2006–2009

Audit Type	Problem Category	Number of Problems
Autoenrollment readiness audits	Deficient systems testing	12
	Deficient system for handling the identifying information needed to route claims	11
	Deficient beneficiary call center	5
	Deficient formulary transition process	5
	Technical concerns including inappropriate use of Transaction Reply Report weekly files[1]	4
	Deficient system for correcting low-income subsidy data with best available evidence of Medicaid eligibility	4
	Deficient autoenrollment process	3
	Deficient low-income subsidy process	2
	Deficient point-of-sale process	2
	Deficient process for providing beneficiary confirmation notices and/or ID cards	2
	Inadequate or insufficient documentation	1
Subtotal		**51**
Benefit integrity audits[2]	Inappropriate billing	21
	Inappropriate transfer, storage, disposal, or processing of drugs	8
	Inappropriate dispensing of drugs	6
	Inappropriate technician-to-pharmacist ratio	2
	Owner indicted for Medicaid fraud and sponsor not notified	1
Subtotal		**38**
Bid audits	Adjustment, calculation, or categorization error	45
	Inadequate or insufficient documentation	24
	Inconsistent, missing, or questionable information	22
	Bid not developed according to instructions from Centers for Medicare & Medicaid Services (CMS)	15
	Inconsistent development of rebates among plans	1
Subtotal		**107**

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Table A-1: Categories of Problems Identified Through Sampled Audits, 2006–2009 (Continued)

Audit Type	Problem Category	Number of Problems
Long-term-care pharmacy contract audits	Deficient contracts	9
Subtotal		**9**
Pharmacy access audits	Deficient contracts	2
Subtotal		**2**
Program audits	Deficient enrollment and/or disenrollment process	189
	Deficient coverage determination, grievance, and/or appeals process	169
	Deficient marketing process	21
	Deficient formulary transition process	17
	Deficient notices and/or materials for beneficiaries	13
	Deficient process for true out-of-pocket costs and/or coordination of benefits	12
	Deficient provider communications	11
	Deficient policies and procedures	10
	Deficient contracts with first-tier or downstream entities	6
	Deficient compliance plan	4
	Deficient claim processing and/or payment system	4
	Deficient pharmacy access for beneficiaries	3
	Deficient documentation of reviews by Pharmacy and Therapeutics Committee	2
	Deficient drug utilization review process	2
	Deficient in providing CMS information on its quality assurance program to reduce medication errors	1
	Deficient process for employer group plans' low-income premium subsidy	1
	Deficient process for revising its Medication Therapy Management Program	1
Subtotal		**466**
Total		**673**

Source: Office of Inspector General (OIG) analysis of CMS's responses to 2010 OIG data request.
[1] Weekly Transaction Reply Reports contain information on changes in beneficiary enrollment information.
[2] Benefit integrity audits, conducted by sponsors, were audits of pharmacies in sponsors' networks.

APPENDIX ~ B

Table B-1: Categories of Corrective Action Taken To Address Problems Identified Through Sampled Audits, 2006–2009

Audit Type	Corrective Action Category	Number of Problems Addressed[1]
Autoenrollment readiness audits	Centers for Medicare & Medicaid Services (CMS) requested additional information	16
	CMS monitoring	10
	Sponsor submitted policies and procedures	9
	CMS denied autoenrollees or reassignments	7
	CMS conducted followup audit	6
	Sponsor submitted audit, compliance, performance, or other reports to CMS	3
	CMS warning letter	2
	Sponsor established or revised policies and procedures	2
	Sponsor implemented policies and procedures	2
	Sponsor conducted training	1
	Sponsor submitted documentation of training to CMS	1
	Sponsor took corrective action under a different audit	1
Benefit integrity audits[2]	Pharmacy terminated from network	22
	Pharmacy referred to Office of Inspector General (OIG)	19
	Pharmacy put on corrective action plan	4
	Pharmacy under investigation by Medicare Drug Integrity Contractor	2
	Sponsor pursued internal corrective action	2
	Pharmacy notified of overpayment	1
Bid audits	Rather than using a corrective action process for problems identified by bid audits, CMS determined that problems found in bid audits were resolved when it reviewed the sponsor's bid for the next contract year	94[3]
Long-term-care pharmacy contract audits	Sponsor submitted revised contracts to CMS	7
	Sponsor established or revised policies and procedures	3
Pharmacy access audits	CMS requested a corrective action plan	2

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Table B-1: Categories of Corrective Action Taken To Address Problems Identified Through Sampled Audits, 2006–2009 (Continued)

Audit Type[1]	Corrective Action Category	Number of Problems Addressed[1]
Program audits	Sponsor established or revised policies and procedures	356
	Sponsor conducted training	334
	Sponsor submitted documentation of training to CMS	332
	Sponsor implemented policies and procedures	162
	Sponsor submitted policies and procedures to CMS	102
	Sponsor established monitoring and oversight procedures	75
	Sponsor submitted audit, compliance, performance, or other reports to CMS	69
	Sponsor implemented monitoring and oversight procedures	52
	Sponsor conducted internal audits	49
	Sponsor submitted template of beneficiary notices to CMS	44
	Sponsor implemented internal controls	43
	Sponsor submitted analysis of deficiency to CMS	42
	Sponsor submitted name of staff responsible for implementing corrective action to CMS	24
	Sponsor revised contracts, contract addenda, or agreements	13
	CMS conducted followup audit	12
	Sponsor submitted accurate data to CMS	11
	Sponsor developed internal controls	6
	Sponsor submitted target compliance dates to CMS	5
	Sponsor developed, updated, or implemented a tracking system	3
	Sponsor developed provider education materials	2
	Sponsor revised its Web site	2
	Sponsor improved accountability for accuracy and completeness of information	1

Source: OIG analysis of CMS's responses to 2010 OIG data request.

[1] One problem may have been addressed through more than one corrective action. Therefore, the total number of problems addressed by a corrective action may be greater than the number of problems in an audit type.

[2] Benefit integrity audits, conducted by sponsors, were audits of pharmacies in sponsors' networks.

[3] The bid audits reviewed identified 107 problems. Of these, only 94 were associated with contracts that were renewed the next contract year. All of these 94 problems were resolved.

APPENDIX ~ C

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: OCT 2 7 2011

TO: Daniel R. Levinson
Inspector General

FROM: Donald M. Berwick, M.D. /S/
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Audits of Medicare Prescription Drug Plan Sponsors," OEI-03-09-00330

Thank you for the opportunity to review and comment on the Office of Inspector General's (OIG's) draft report, "Audits of Medicare Prescription Drug Plan Sponsors." The Centers for Medicare & Medicaid Services (CMS) appreciates the time and resources the OIG has invested in examining CMS' use of audits in overseeing Prescription Drug Plan (PDP) sponsors.

As part of this study, the OIG identified seven types of audits that CMS used for auditing stand-along PDP's during the first 4 years of the program, 2006 – 2009, and provided an overview of CMS' use of these types of audits to oversee PDP sponsors. These seven audit types were: autoenrollment readiness audits, benefit integrity audits, bid audits, compliance plan audits, long-term-care pharmacy audits, pharmacy access audits, and program audits. As the report notes, CMS is not required by law to conduct any of these types of audits, but developed them to identify problems and correct deficiencies within the Part D program.

The OIG identified three findings as a result of their study. First, the OIG found that some PDP sponsor contracts were never audited between 2006 and 2009; second, that seventy-nine percent of the 245 PDP audits completed between 2006 and 2009 identified problems; and third, that CMS did not have evidence to show that all corrective actions were implemented for two audit types.

The OIG made the following recommendations:

OIG Recommendation 1:
Establish a comprehensive Part D auditing strategy that ensures that each plan sponsor will be audited in some way within a certain timeframe. The strategy should include parameters for conducting each audit type. The strategy should also ensure coordination among the CMS offices responsible for auditing activities so that no contract goes 4 successive years without an audit of some type.

CMS Response:
We partially concur. We believe that all plan sponsors should undergo a bid audit, and plan to complete a bid audit of every Medicare PDP parent organization that has remained in the program since 2006 by the end of 2013, regardless of size or risk.

However, CMS believes a comprehensive oversight strategy, developed in coordination with the offices responsible for the management of the Part D program, is more effective than an auditing strategy. Rather, auditing is just one facet of CMS' overall oversight strategy. While audits provide meaningful and useful information, CMS does not wholly rely on auditing as the only mechanism for program oversight. On page 6 of the report, the OIG discusses CMS' use of *monitoring* as part of our strategy to assess PDP sponsor compliance, and we wish to reiterate the importance of this approach. CMS defines monitoring as the systematic evaluation of the complete universe of program sponsors relative to a particular requirement or set of requirements. Monitoring relies heavily on data in CMS systems (including the results from the bid and financial audits) and studies performed by CMS contractors (including the MEDIC's focused fraud, waste, and abuse evaluation), which therefore allows us to assess key performance indicators across 100% of PDP and other types of program sponsors. Given that CMS oversees more than 750 contracts (including Medicare Advantage and stand-alone PDP) offered by nearly 500 legal entities owned by more than 290 parent organizations, monitoring is the only efficient approach for assessing critical performance areas across *all* contracts.

In 2011, CMS systematically monitored PDP sponsors' performance across more than a dozen topic areas, including: call center wait times and dropped calls; information accuracy provided by plan representatives; interpreter availability at call centers; timely provision of "4Rx" data (i.e., data that CMS collects and makes available to pharmacies to allow pharmacists to process claims when the beneficiary does not have his or her insurance card); enrollment timeliness; reporting requirements data submission; adherence to Best Available Evidence requirements; submission and accuracy of pricing data for display on the Medicare Plan Finder; meeting requirements of the Online Enrollment Center; transferring True Out-of-Pocket costs mid-year from one sponsor to another; timely submission of Prescription Drug Event data and other key payment information to CMS; correct maintenance of Low Income Subsidy data; and complaint rates, among others. Sponsors whose performance has been shown to be lacking based on results of monitoring and other CMS oversight approaches, such as day-to-day Account Management, receive a more intensive performance audit.

In 2010, using the results of the monitoring efforts, CMS conducted a risk assessment to identify sponsors that posed the most risk and conducted 22 performance and 11 compliance-only audits. Performance audits, also referred to as program audits, assess compliance with certain CMS program requirements such as Part D formulary administration, Part D coverage determinations, appeals and grievances, enrollment and disenrollment, premium billing, as well as an evaluation of the sponsor's compliance program. A compliance-only audit is a focused assessment of the sponsor's compliance program, and does not assess other performance areas. In total, sponsoring organizations selected for audit represented almost 62% of all Medicare Advantage and Prescription Drug Plan enrollees or approximately 18 million beneficiaries. Based on the most serious 2010 audit results, CMS imposed five marketing and enrollment sanctions and

terminated one contract. For the remaining audit results, CMS obtained corrective actions from the sponsors, validated the corrections, and closed all audits except eight which are currently under a secondary review. CMS expects to close these audits by November 2011.

In 2011, CMS conducted a similar risk assessment and conducted 11 program audits. These audits assessed the same program areas described above, with two exceptions. First, CMS added a review of agent/broker oversight based on monitoring results that indicated low performance in this area; and second, we removed reviews of enrollment, disenrollment and premium billing processes due to changes in CMS' enrollment process. In total, sponsoring organizations selected for audit represented 42% of all Medicare Advantage and Prescription Drug Plan enrollees or approximately 13 million beneficiaries. CMS anticipates finalizing the audit findings before December 2011 and will decide if any additional corrective actions will be necessary.

OIG Recommendation 2: Ensure that evidence is available to show that corrective actions have been implemented. CMS should maintain documentation that corrective actions were implemented.

CMS Response: We concur with this recommendation. Beginning in 2010, subsequent to the period covered by this particular study, CMS began a more comprehensive process for validating corrections made by sponsoring organizations as a result of deficiencies found during audit. Thus, CMS now maintains and will continue to maintain documentation of corrective actions implemented for all audits.

CMS looks forward to continuing to work with the OIG on issues related to program oversight and audits.

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.

Isabelle Buonocore 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; other central office staff who contributed include Kevin Farber, Robert L. Gibbons, and Rita M. Wurm.

Office of Inspector General

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