November 28, 2011

**TO:** Donald M. Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services

**FROM:** /Gloria L. Jarmon/
Deputy Inspector General for Audit Services

**SUBJECT:** Review of the Centers for Medicare & Medicaid Services' Audits of Part D Sponsors' Financial Records (A-03-10-00007)

The attached final report provides the results of our review of the Centers for Medicare & Medicaid Services' Audits of Part D sponsors' financial records.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that the Office of Inspector General (OIG) post its publicly available reports on the OIG Web site. Accordingly, this report will be posted at http://oig.hhs.gov.

If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Stephen Virbitsky, Regional Inspector General, at (215) 861-4470 or through email at Stephen.Virbitsky@oig.hhs.gov. We look forward to receiving your final management decision within 6 months. Please refer to report number A-03-10-00007 in all correspondence.

Attachment

Department of Health and Human Services

**OFFICE OF INSPECTOR GENERAL**

# REVIEW OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES' AUDITS OF PART D SPONSORS' FINANCIAL RECORDS


Daniel R. Levinson
Inspector General

November 2011
A-03-10-00007

# *Office of Inspector General*

http://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

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Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site.

## OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

# EXECUTIVE SUMMARY

## BACKGROUND

### Medicare Part D

Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 amended Title XVIII of the Social Security Act (the Act) by establishing the Medicare Part D prescription drug program. Under Part D, which began January 1, 2006, individuals entitled to benefits under Part A or enrolled in Part B may obtain drug coverage.

To provide prescription drug benefits under Part D, the Centers for Medicare & Medicaid Services (CMS) contracts with private organizations called "sponsors" that act as payers and insurers. Sponsors may offer these benefits through a standalone prescription drug plan or as part of a Part C managed care plan, known as a Medicare Advantage Prescription Drug Plan (collectively, plans).

Section 1860D-12(b)(3)(C) of the Act and 42 CFR § 423.504(d)(1) require CMS to audit the financial records of at least one-third of Part D sponsors that offer Part D drug plans annually (one-third audits).

## OBJECTIVE

Our objective was to determine whether CMS complied with certain Federal requirements in conducting and resolving one-third audits of sponsors' financial records.

## SUMMARY OF FINDINGS

CMS did not fully comply with Federal requirements in conducting one-third audits of sponsors' financial records. Specifically, CMS did not perform audits for a full one-third of the sponsors in any of the audited contract years. CMS excluded certain contracts subject to audit because it interpreted the statutory requirement as allowing it to do so.

Further, at the time of our fieldwork, CMS had not updated its standard operating procedure (SOP) for audit resolution to reflect actual practices and to help ensure that sponsors reported corrective actions to CMS in a timely manner. This diminished CMS's ability to ensure that corrective action was taken as rapidly as possible.

## RECOMMENDATIONS

We recommend that CMS:

- audit one-third of all part D sponsors and

- update its SOP to ensure that policies and procedures are consistent with actual practices and help ensure that sponsors' corrective actions are reported to CMS in a timely manner.

## CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CMS generally concurred with our recommendations and described the actions it had taken or planned to take.

CMS also provided technical comments, which we addressed as appropriate. This information did not cause us to amend our findings or recommendations. CMS's comments, excluding technical comments, are included as the Appendix.

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# INTRODUCTION

## BACKGROUND

### Medicare Part D

Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 amended Title XVIII of the Social Security Act (the Act) by establishing the Medicare Part D prescription drug program. Under Part D, which began January 1, 2006, individuals entitled to benefits under Part A or enrolled in Part B may obtain drug coverage.

To provide prescription drug benefits under Part D, the Centers for Medicare & Medicaid Services (CMS) contracts with organizations called "sponsors" that act as payers and insurers. Sponsors provide a minimum set of prescription benefits, referred to as the "basic" benefit. Sponsors may offer these benefits through a standalone prescription drug plan (PDP) or as part of a Part C managed care plan, known as a Medicare Advantage Prescription Drug Plan (MA-PD), (collectively, plans). Sponsors may offer multiple plans under each contract. For example, in 2006, there were approximately 200 organizations, 560 active contracts, and 3,939 plans.

### Centers for Medicare & Medicaid Services One-Third Audits

Section 1860D-12(b)(3)(C) of the Act and 42 CFR § 423.504(d)(1) require CMS to annually audit the financial records of at least one-third of Part D sponsors offering Part D plans (one-third audits). A Part D sponsor as defined by 42 CFR § 423.4 is "a PDP sponsor, MA organization offering a MA-PD plan, a PACE [Program of All-Inclusive Care for the Elderly] organization offering a PACE plan including qualified prescription drug coverage, and a cost plan offering qualified prescription drug coverage."[1]

CMS's Office of Financial Management (OFM) is responsible for the one-third audits. OFM interprets the one-third audit requirement as applying at the contract level for active contracts. However, OFM generally selects just one plan (the plan with the largest enrollment offering Part D benefits) to audit from each selected contract. OFM contracts with certified public accounting (CPA) firms to perform the one-third audits, selects the contracts to audit, reviews and approves the CPA firms' audit reports, and forwards the approved reports to CMS's Center for Medicare. The Center for Medicare (1) reviews the approved reports to determine whether the findings warrant compliance actions and (2) follows up with sponsors.

OFM's one-third audit goals and objectives include reviewing audited plan solvency; related party transactions; administrative costs; direct medical costs; and Part D costs and payments, including direct and indirect remuneration and true out-of-pocket costs. CMS provides the CPA firms with an audit guide covering these areas. OFM does not require the CPA firms to report whether a finding might be a systemic issue found in all the plans under a contract. For the audit

[1] The Balanced Budget Act of 1997, P.L. No. 105-33, authorized the PACE program to provide comprehensive services through a managed care arrangement to the elderly who are eligible for Medicare and Medicaid and require nursing-home level services.

period, OFM requested that CPA firms audit some plans simultaneously for 2006 and 2007 to satisfy the requirement for both years.

## OBJECTIVE, SCOPE, AND METHODOLOGY

### Objective

Our objective was to determine whether CMS complied with certain Federal requirements in conducting and resolving one-third audits of sponsors' financial records.

### Scope

We reviewed the audit process for the one-third audits for 2006 and 2007. We reviewed the selection process and 369 final one-third audit reports: 169 reports for 2006 and 200 reports for 2007. We reviewed one-third audit letters issued to sponsors with findings reported on their audits. We also reviewed the audit selection process for the planned one-third audits for 2008.

Our audit objective did not require an understanding or assessment of the complete internal control structure of CMS. We limited our internal control review to obtaining an understanding of CMS's policies and procedures for completing sponsor one-third audits.

We performed fieldwork at CMS's Central Office in Baltimore, Maryland, and at CPA firms located in Alexandria, Virginia, and Baltimore and Timonium, Maryland.

### Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- reviewed CMS's policies and procedures relating to one-third audits;
- reviewed CMS's methodology for selecting sponsors;
- interviewed CMS and CPA firm officials to obtain an understanding of the procedures used to conduct the one-third audits;
- reviewed all one-third audit reports and one-third audit letters for 2006 and 2007 finalized on or before our field work;
- determined which sponsors had a one-third audit performed on any active plans for 2006 through 2008; and
- summarized the audit findings and compliance actions for the one-third audits.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

## FINDINGS AND RECOMMENDATIONS

CMS did not fully comply with Federal requirements in conducting one-third audits of sponsors' financial records. Specifically, CMS did not perform audits for a full one-third of the sponsors in any of the audited contract years. CMS excluded certain contracts subject to audit because it interpreted the statutory requirement as allowing it to do so.

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Further, at the time of our fieldwork, CMS had not updated its standard operating procedure (SOP) for audit resolution to reflect actual practices and to ensure that sponsors reported corrective actions to CMS in a timely manner. This diminished CMS's ability to ensure that corrective action was taken as rapidly as possible.

### ONE-THIRD AUDIT REQUIREMENTS

#### Federal Requirements

Section 1860D-12(b)(3)(C) of the Act and 42 CFR § 423.504(d)(1) require that CMS audit at least one-third of sponsors annually. Federal regulations (42 CFR § 423.4) refer to a sponsor as "… a PDP sponsor, MA organization offering a MA-PD plan, a PACE organization offering a PACE plan including qualified prescription drug coverage, and a cost plan offering qualified prescription drug coverage."

Section 1860D-21(c)(2) of the Act allows the Secretary of Health and Human Services to waive the provisions of Part D "to the extent the Secretary determines that such provisions duplicate, or are in conflict with, provisions otherwise applicable to the organization or plan under Part C or as may be necessary in order to improve coordination of this part with the benefits under this part."

#### One-Third Audit Requirement Not Met

CMS did not perform audits for one-third of the sponsors in any of the audited contract years. We calculated the number of audits needed to fulfill the one-third audit requirement by counting the total active contracts subject to audit, including PACE program and demonstration contracts that CMS excluded from 2006 through 2008. As shown in the table on the next page, CMS did not meet the one-third audit requirement by 17 audits for 2006 and 15 audits for 2007. In addition, CMS will not meet the one-third audit requirement by 25 audits for 2008.

**Contracts To Meet One-Third Audit Requirement**

| Contract Year | Total Active Contracts Subject to Audit per OIG[2] | Total Active Contracts Subject to Audit per CMS | OIG-Calculated One-Third Requirement | Contracts Audited | Discrepancy |
|---|---|---|---|---|---|
| 2006 | 560 | 495 | 186 | 169 | 17 |
| 2007 | 647 | 562 | 215 | 200[3] | 15 |
| 2008 | 780 | 694 | 260 | 235 | 25 |

**Exclusion of Certain Contracts**

*Program of All-Inclusive Care for the Elderly Plans*

CMS waived the one-third audit requirement for PACE organizations because it concluded that the one-third audit provisions duplicated the audit requirements for PACE. However, the PACE audit guide did not include the financial audit provisions required in the one-third audit guide. Specifically, the audits conducted using the PACE audit guide were not designed to determine the accuracy of the costs submitted for payment. For example, the one-third audit guide requires that the contractors test for unreported direct and indirect remuneration, such as drug rebates received from pharmaceutical manufacturers, whereas PACE audits do not include a review of direct and indirect remuneration. One-third audits include tests of Prescription Drug Event (PDE) data to verify the reported costs, whereas PACE audits match plan data to the summary claims data received from the PDE contractor for consistency but do not verify that the reported costs are accurate. Therefore, Part D audits of sponsors' financial records do not duplicate or conflict with CMS's audits of PACE organizations.

*Demonstration Contracts*

CMS did not provide documentation that it had waived the one-third audit requirement for its demonstration MA-PDs. CMS officials said that CMS excluded the contracts for demonstration MA-PDs because these contracts, which are generally short term (1–3 years), are closely monitored by other CMS components. However, of the 13 demonstration contracts active in 2008, 7 had been in effect for the entire 3-year audit period, and CMS did not provide any documentation to indicate how one-third audits would duplicate or conflict with CMS's monitoring of these contracts. CMS also said that its one-third audit program would not apply to many aspects of the demonstration program but did not provide support that the one-third audit requirement did not apply to the demonstration projects. Rather, CMS officials stated that CMS is planning to audit demonstration MA-PDs in its 2009 one-third audits.

[2] Office of Inspector General.

[3] Eighty-seven of the two hundred contracts were audited simultaneously for plan year 2006.

## AUDIT POLICIES AND PROCEDURES

### Federal Guidance

Federal agencies should establish policies and procedures to ensure that audit findings are promptly resolved. The Government Accountability Office has published guidance on *Standards for Internal Control in the Federal Government*. This guidance states that Federal agencies document policies and procedures and that the documentation should be complete and updated to reflect any changes to the policies and procedures. The guidance also states:

> Monitoring of internal controls should include policies and procedures for ensuring that the findings of audits and other reviews are promptly resolved. Managers are to… complete, within established time frames, all actions that correct or otherwise resolve the matters brought to management's attention. The resolution process begins when audit or other review results are reported to management, and is completed only after action has been taken that (1) corrects identified deficiencies, (2) produces improvements, or (3) demonstrates the findings and recommendations do not warrant management action.[4]

### Actual Practices Not Reflected in Policies and Procedures

CMS's audit policies and procedures have not been updated to reflect changes in actual practices and to help ensure that sponsors' corrective actions are reported to CMS in a timely manner. In March 2010, CMS issued an SOP document entitled *One-Third Financial Audits Contract Management Compliance Process*. The purpose of the SOP is to provide CMS with uniform guidelines for implementing any contract compliance actions, such as the requirement for sponsors to take any necessary corrective actions resulting from one-third audit findings. The SOP includes a template for the letter that CMS was going to issue to sponsors. Although the SOP states that sponsors must respond to and resolve findings requiring corrective action before CMS can close the matter, the template letter does not include language instructing sponsors to report corrective action to CMS. In May 2010, CMS began issuing letters to sponsors regarding 2006 and 2007 one-third audit findings with language that differed from the template letter. This version of the letter instructed providers to report corrective action taken to CMS within 60 days of date of the letter. However, the template letter included in the SOP was not updated to reflect this change.

## RECOMMENDATIONS

We recommend that CMS:

- audit one-third of all part D sponsors and

- update its SOP to ensure that policies and procedures are consistent with actual practices and help ensure that sponsors' corrective actions are reported to CMS in a timely manner.

[4] GAO/IAMDAIMD-00-21-.3.1, *Standards for Internal Control in the Federal Government*, p. 20, November 1999.

## CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CMS generally concurred with our recommendations and described the actions it had taken or planned to take.

CMS also provided technical comments, which we addressed as appropriate. This information did not cause us to amend our findings or recommendations. CMS's comments, excluding technical comments, are included as the Appendix.

# OTHER MATTERS

## ALL CONTRACTS NOT AUDITED AT LEAST ONCE EVERY 3 YEARS

Although the Act does not require CMS to audit every contract at least once every 3 years, CMS's current selection methodology does not ensure that contracts with increasing enrollment are subject to a one-third audit on a timely basis. The number of active contracts varied from year to year, but 443 contracts consistently remained active through the 3-year period 2006 through 2008. Of these 443 contracts, CMS did not select 84 contracts (19 percent) for a one-third audit in any of the 3 years. Many of the 84 contracts had increasing enrollment. For example, one contract had four plans under its Part D contract in 2006. The number of plans under this same contract increased to 17 by 2008. Total enrollment under this contract grew from approximately 2,385 beneficiaries in 2006 to approximately 23,270 beneficiaries in 2008.

## SPONSOR SYSTEMIC ISSUES NOT ADDRESSED BY ONE-THIRD AUDITS

The Act and regulations allow CMS latitude in determining what satisfies the one-third audit requirement. However, the effectiveness of the one-third audit requirement is limited because the CPA firms are not required to report when deficiencies found under a single audited plan may be systemic. Identifying systemic deficiencies would increase the impact of one-third audits.

CPA firms audited one plan under each contract even though sponsors might have offered multiple plans under each contract. For example, in 2006, there were approximately 560 active contracts subject to audit offering approximately 3,939 plans. The CPA firms audited only one plan in each of 169 contracts (approximately 4 percent of plans) and were not required to determine whether a finding in an audited plan could be a systemic issue in all plans under the contract.

At the time of our audit, CPA firm officials disagreed as to whether or not deficiencies found in the plan audited could also be assumed to exist in the other plans under the same contract. One CPA firm official did acknowledge, however, that he was able to determine the overall effect of some findings for all plans under a contract. The CPA firm listed the overall effect in its report, but the finding was based only on the plan it audited.

# APPENDIX

## APPENDIX: CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

*Administrator*
Washington, DC 20201

**DATE:** SEP 2 9 2011

**TO:** Daniel R. Levinson
Inspector General

**FROM:** Donald M. Berwick, M.D.
Administrator

**SUBJECT:** Office of Inspector General (OIG) Draft Report: Review of the Centers for Medicare & Medicaid Services' Audits of Part D Sponsors' Financial Records (A-03-10-00007)

Thank you for the opportunity to review and comment on the above OIG Draft Report. The OIG's audit focused on the annual audits of the Part D Sponsors and provided the Centers for Medicare & Medicare Services (CMS) with recommendations to improve the auditing process. CMS appreciates the time and resources the OIG has invested in the audit and is committed to improving its oversight of the Part D program.

Since the implementation of the Part D program, CMS has strived to continuously improve the audit process. In the past few years, CMS has completed 609 audits for contract years 2006-2008 and is in the process of performing 253 audits for contract year 2009. Additionally, CMS is preparing to audit 252 organizations for contract year 2010.

The CMS welcomes constructive suggestions for improving the audit process, and we are in the process of implementing some of the recommendations included in your report. For example, CMS included the demonstration contracts in the calculation of the one-third financial audit requirement and is currently working to either incorporate some of the applicable one-third financial audit procedures into the Program of All-Inclusive Care for the Elderly (PACE) program audits or include PACE organizations as part of the current one-third audit process. Additionally, CMS enhanced our standard operating procedures (SOP) for ensuring audit findings are promptly resolved in the SOP revisions published in August 2011.

The CMS addressed each of the report's recommendations. Also, we included technical comments for your consideration.

**OIG Recommendation**
Audit one-third of all part D sponsors.

**CMS Response**

We concur with this recommendation though we note that current policy is compliant with one-third audit requirements. The OIG notes that CMS omitted both demonstrations and PACE program organizations from the determination of the one-third audit requirement. In reference to demonstrations, CMS included these contracts in the calculation of the one-third audit requirement effective contract year 2008 and will continue to include them for future year audits. Additionally, although PACE organizations have been exempt from the one-third financial audits, CMS will evaluate ways for incorporating applicable one-third audit procedures into the current PACE program audits or include PACE organizations as part of the current one-third audit process. Specifically, CMS will incorporate procedures for verification of direct and indirect remuneration (DIR) and Part D costs submitted to CMS.

**OIG Recommendation**

Update its SOP to ensure that policies and procedures are consistent with actual practices and help ensure that sponsors' corrective actions are reported to CMS in a timely manner.

**CMS Response**

We concur with this recommendation. Since the OIG audit, CMS enhanced its process for ensuring audit findings are promptly resolved and updated the SOP to reflect the actual practices of this process. From July 2010 to August 2011 CMS enhanced the actual process for submission and reporting of the one-third audit corrective action plans (CAPs). The standard operating procedure updates are ongoing, with the latest version published in August 2011. As a result, sponsors are reporting corrective actions timely. In addition, CMS will continue to update the SOP to reflect any changes to our process.

We thank the OIG for presenting its findings and appreciate their perspective on these issues.