



Office of Audit Services, Region IV
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October 29, 2009

Report Number: A-04-08-07006

Ms. Patricia Casanova
Director of Medicaid
Indiana Family and Social Services Administration
402 W. Washington Street, W461
Indianapolis, Indiana 46204-2739

Dear Ms. Casanova:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled "Follow-up Review of the Medicaid Drug Rebate Program in Indiana." We will forward a copy of this report to the HHS action official noted on the following page for review and any action deemed necessary.

The HHS action official will make final determination as to actions taken on all matters reported. We request that you respond to this official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

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. 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 contact Denise Rivera Novak, Audit Manager, at (305) 536-5309, extension 10, or through email at Denise.Novak@oig.hhs.gov. Please refer to report number A-04-08-07006 in all correspondence.

Sincerely,

/Peter J. Barbera/
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

Jackie Garner, Consortium Administrator
Consortium for Medicaid and Children's Health Operations
Centers for Medicare & Medicaid Services
233 North Michigan Avenue, Suite 600
Chicago, Illinois 60601

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**FOLLOW-UP REVIEW OF THE
MEDICAID DRUG REBATE
PROGRAM IN INDIANA**



Daniel R. Levinson
Inspector General

October 2009
A-04-08-07006

Office of Inspector General

<http://oig.hhs.gov>

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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

The Medicaid drug rebate program, which began in 1991, is set forth in section 1927 of the Social Security Act. For a manufacturer's covered outpatient drugs to be eligible for Federal Medicaid funding under the program, the manufacturer must enter into a rebate agreement with the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each undertake certain functions in connection with the drug rebate program. In Indiana, the Indiana Family and Social Services Administration (the State agency) administers the Medicaid drug rebate program.

In 2005, we issued a report on the results of audits of the Medicaid drug rebate programs in 49 States and the District of Columbia (A-06-03-00048). Those audits found that only four States had no weaknesses in accountability for and internal controls over their drug rebate programs. As a result of the weaknesses, we concluded that States lacked adequate assurance that all of the drug rebates due to the States were properly recorded and collected. Additionally, CMS did not have reliable information from the States to properly monitor the drug rebate program.

In our previous audit of the Indiana drug rebate program (A-05-03-00043), we determined that the State agency generally had established policies and procedures over operations of the drug rebate program. However, the controls in place to comply with program reporting requirements were inadequate. Specifically, the State agency submitted a Medicaid Drug Rebate Schedule (Form CMS-64.9R) that contained mathematical errors and inaccuracies. In addition, the State agency did not verify or reconcile reported amounts to supporting records. Furthermore, the State agency did not have controls to ensure all necessary unit and rate conversions were performed to accurately calculate the Medicaid drug rebate accounts receivable. We recommended that the State agency:

- submit a revised Form CMS-64.9R that corrects inaccurate and misstated amounts,
- establish controls and implement oversight procedures for the Form CMS-64.9R report preparation process that includes verification of fiscal agent-prepared amounts and reconciliation of the State agency rebate accounts receivable to the fiscal agent's supporting records, and
- establish controls and implement oversight to ensure all necessary Medicaid drug rebate unit and rate conversions conform to Federal financial reporting standards.

The State agency agreed with our findings and recommendations.

This current review of Indiana is part of a nationwide series of reviews conducted to determine whether States have addressed the weaknesses in accountability for and internal controls over their drug rebate programs found in the previous reviews. Additionally, because the Deficit Reduction Act of 2005 required States, as of January 1, 2006, to begin collecting rebates on

single source drugs administered by physicians, this series of reviews will also determine whether States have complied with the new requirement.

OBJECTIVES

Our objectives were to determine whether the State agency had (1) implemented the recommendations made in our previous audit of the Indiana drug rebate program and (2) established controls over collecting rebates on single source drugs administered by physicians.

SUMMARY OF FINDINGS

The State agency implemented two of the three recommendations from our previous audit. However, the State agency had not fully established controls or implemented oversight procedures for the Form CMS-64.9R report preparation process that included verification of fiscal agent-prepared amounts and reconciliation of the State agency rebate accounts receivable to the fiscal agent's supporting records. Additionally, the fiscal agent, Affiliated Computer Services, did not maintain adequate supporting documentation for the accounts receivable balances it reported on the Form CMS-64.9R. As a result, the State agency had no assurance that the balances on the Form CMS-64.9R report as of June 30, 2006, were accurate.

The State agency had established controls over collecting rebates on single source drugs administered by physicians.

RECOMMENDATION

We recommend that the State agency establish and implement procedures to ensure that it maintains documentation that supports and reconciles to all accounts receivable amounts on the Form CMS-64.9R.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency listed preventive controls and procedures it was implementing to follow our recommendation. The complete text of the State agency's comments is included in its entirety as the Appendix.

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INTRODUCTION

BACKGROUND

Pursuant to Title XIX of the Social Security Act (the Act), the Medicaid program provides medical assistance to certain low-income individuals and individuals with disabilities. The Federal and State Governments jointly fund and administer the Medicaid program. At the Federal level, the Centers for Medicare & Medicaid Services (CMS) administers the program. Each State administers its Medicaid program in accordance with a CMS-approved State plan. Although the State has considerable flexibility in designing and operating its Medicaid program, it must comply with applicable Federal requirements.

Drug Rebate Program

The Medicaid drug rebate program, which began in 1991, is set forth in section 1927 of the Act. For a manufacturer's covered outpatient drugs to be eligible for Federal Medicaid funding under the program, the manufacturer must enter into a rebate agreement with CMS and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each undertake certain functions in connection with the drug rebate program. In Indiana, the Indiana Family and Social Services Administration (the State agency) is responsible for the drug rebate program.

Pursuant to section II of the rebate agreement and section 1927(b) of the Act, manufacturers are required to submit a list to CMS of all covered outpatient drugs and to report each drug's average manufacturer price and, where applicable, best price. Based on this information, CMS calculates a unit rebate amount for each covered outpatient drug and provides the amounts to States quarterly.

Section 1927(b)(2)(A) of the Act requires States to maintain drug utilization data that identifies, by National Drug Code (NDC), the number of units of each covered outpatient drug for which the States reimbursed providers. The number of units is applied to the unit rebate amount to determine the actual rebate amount due from each manufacturer. Section 1927(b)(2) of the Act requires States to provide the drug utilization data to CMS and the manufacturer. States also report drug rebate accounts receivable data on Form CMS-64.9R. This form is part of Form CMS-64, "Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program," which summarizes actual Medicaid expenditures for each quarter and is used by CMS to reimburse States for the Federal share of Medicaid expenditures.

Physician-Administered Drugs

Section 6002(a) of the Deficit Reduction Act of 2005 (DRA) amends section 1927(a) of the Act and requires States, as of January 1, 2006, to collect and submit utilization data for single source drugs administered by physicians so that States may obtain rebates for the drugs.¹ Single source drugs are commonly referred to as "brand name drugs" and do not have generic equivalents.

¹This provision of the DRA expands the requirement to certain multiple source drugs administered by physicians after January 1, 2008.

In Indiana, physician-administered drugs are billed to the State Medicaid program on a physician claim form using procedure codes that are part of the Healthcare Common Procedure Coding System. The NDC is not included on the physician claim form. The procedure code identifies a drug by its active ingredient(s) and identifies the number of drug units (billing units) allowed per reimbursement for that procedure code. Because rebates are calculated and paid based on NDCs, each procedure code must be converted to an NDC. Additionally, the billing units for a procedure code may differ from the units used for rebate purposes (e.g., grams versus liters). Therefore, to determine rebates, the procedure codes must be converted into NDCs for single source drugs and procedure code billing units must be converted into equivalent NDC billing units.

Previous Office of Inspector General Reports

In 2005, we issued a report on the results of audits of the Medicaid drug rebate programs in 49 States and the District of Columbia.² Those audits found that only four States had no weaknesses in accountability for and internal controls over their drug rebate programs. As a result of the weaknesses, we concluded that States lacked adequate assurance that all of the drug rebates due to the States were properly recorded and collected. Additionally, CMS did not have reliable information from the States to properly monitor the drug rebate program.

In our previous audit of the Indiana drug rebate program, we determined that the State agency generally had established policies and procedures over operations of the drug rebate program. However, the controls in place to comply with program reporting requirements were inadequate. Specifically, the State agency submitted a Medicaid Drug Rebate Schedule (Form CMS-64.9R) that contained mathematical errors and inaccuracies. In addition, the State agency did not verify or reconcile reported amounts to supporting records. Furthermore, the State agency did not have controls to ensure all necessary unit and rate conversions were performed to accurately calculate the Medicaid drug rebate accounts receivable. We recommended that the State agency:

- submit a revised Form CMS-64.9R that corrects inaccurate and misstated amounts,
- establish controls and implement oversight procedures for the Form CMS-64.9R report preparation process that includes verification of fiscal agent-prepared amounts and reconciliation of the State agency rebate accounts receivable to the fiscal agent's supporting records, and
- establish controls and implement oversight to ensure all necessary Medicaid drug rebate unit and rate conversions conform to Federal financial reporting standards.

The State agency agreed with our findings and recommendations.

²“Multistate Review of Medicaid Drug Rebate Programs” (A-06-03-00048), issued July 6, 2005; Arizona was not included because it did not operate a drug rebate program.

Indiana Drug Rebate Program

The State agency contracts with its fiscal agent, Affiliated Computer Services (ACS), to perform all drug rebate program functions. The fiscal agent's responsibilities include creating and sending invoices to manufacturers, collection, CMS reporting, and accounting for rebates on single source drugs administered by physicians. In addition, the fiscal agent converts the procedure code billing units into equivalent NDC billing units.

The State agency reported an outstanding drug rebate balance of \$35,304,825 on its June 30, 2006, Form CMS-64.9R. However, \$18,964,122 of this amount related to quarterly billings and was not past due as of June 30, 2006. Of the remaining \$16,340,703 that was past due, \$6,521,991 was more than 1 year old. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately \$283.5 million and collections of \$220.5 million.

This current review of the Indiana drug rebate program is part of a nationwide series of reviews conducted to determine whether States have addressed the weaknesses in accountability for and internal controls over their drug rebate programs found in the previous reviews. Additionally, because the DRA required States, as of January 1, 2006, to begin collecting rebates on single source drugs administered by physicians, this series of reviews will also determine whether States have complied with the new requirement.

OBJECTIVES, SCOPE, AND METHODOLOGY

Objectives

Our objectives were to determine whether the State agency had (1) implemented the recommendations made in our previous audit of the Indiana drug rebate program and (2) established controls over collecting rebates on single source drugs administered by physicians.

Scope

We reviewed the State agency's current policies, procedures, and controls over the drug rebate program and the accounts receivable data reported on Form CMS-64.9R as of June 30, 2006.

We conducted our fieldwork at the State agency's fiscal agent in Atlanta, Georgia.

Methodology

To accomplish our objectives, we:

- reviewed section 1927 of the Act, section 6002(a) of the DRA, CMS guidance issued to State Medicaid directors, and other information pertaining to the Medicaid drug rebate program;

- reviewed the policies and procedures related to the fiscal agent’s drug rebate accounts receivable system;
- interviewed a State agency official and fiscal agent staff to determine the policies, procedures, and controls that related to the Medicaid drug rebate program;
- reviewed copies of Form CMS-64.9R for the period July 1, 2005, through June 30, 2006;
- interviewed fiscal agent staff to determine the processes used in converting physician services claims data into drug rebate data related to single source drugs administered by physicians; and
- reviewed rebate billings and reimbursements for procedure codes related to single source drugs administered by physicians for the period January 1 through June 30, 2006.

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 objectives.

FINDINGS AND RECOMMENDATION

The State agency implemented two of the three recommendations from our previous audit. However, the State agency had not fully established controls or implemented oversight procedures for the Form CMS-64.9R report preparation process that included verification of fiscal agent-prepared amounts and reconciliation of the State agency rebate accounts receivable to the fiscal agent’s supporting records. Additionally, ACS did not maintain adequate supporting documentation for the accounts receivable balances it reported on the Form CMS-64.9R. As a result, the State agency had no assurance that the balances on the Form CMS-64.9R report as of June 30, 2006, were accurate.

The State agency had established controls over collecting rebates on single source drugs administered by physicians.

IMPLEMENTATION OF PREVIOUS RECOMMENDATIONS

In our previous audit of the Indiana drug rebate program, we determined that the State agency did not submit an accurate Form CMS-64.9R. In addition, the State agency did not verify the accuracy of amounts reported on Form CMS-64.9R or reconcile reported amounts to supporting records. Furthermore, the State agency did not have controls to ensure all necessary unit and rate conversions were performed to accurately calculate the Medicaid drug rebate accounts receivable.

Since our previous audit, the State agency submitted a revised Form CMS-64.9R, which corrected inaccurate and misstated amounts cited in our prior report, and had established controls

and implemented oversight to ensure all necessary Medicaid drug rebate unit and rate conversions conform to Federal financial reporting standards. However, the State agency still had not fully established controls or implemented oversight procedures for the Form CMS-64.9R report preparation process that included verification of fiscal agent-prepared amounts and reconciliation of the State agency rebate accounts receivable to the fiscal agent's supporting records.

Pursuant to 45 CFR § 92.20(b)(3), States are required to provide for effective control over and accountability of all funds, property, and other assets. The State agency contracted with ACS to perform all of the drug rebate functions, including reporting accounts receivable amounts on the Form CMS-64.9R. During the time of our review, ACS did not maintain subsidiary ledgers or other documentation to support the outstanding accounts receivable balances. ACS did maintain documentation to support data entered on the Form CMS-64.9R, such as rebates invoiced and payments received from manufacturers for the quarterly period ended June 30, 2006. However, ACS had no documentation to support the ending balances on the Form CMS-64.9R. Consequently, if a typographical data entry error occurs during the report preparation process, or if the beginning balances are incorrect, then the lack of a periodic reconciliation process would not detect an inaccurate accounts receivable balance.

Additionally, the State agency had no controls or procedures to verify the accuracy of the outstanding accounts receivable amounts reported on Form CMS-64.9R or to reconcile those reported amounts to supporting records. As a result, the State agency had no assurance that the balances on the Form CMS-64.9R report were accurate.

PHYSICIAN-ADMINISTERED SINGLE SOURCE DRUGS

The State agency established controls over collecting rebates for single source drugs administered by physicians as required by the DRA. The State agency paid \$25,764,366 in claims for physician-administered drugs during the January through June 2006 period and billed manufacturers for rebates totaling \$5,777,534.

RECOMMENDATION

We recommend that the State agency establish and implement procedures to ensure that it maintains documentation that supports and reconciles to all accounts receivable amounts on the Form CMS-64.9R.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency listed preventive controls and procedures it was implementing to follow our recommendation. The complete text of the State agency's comments is included in its entirety as the Appendix.

APPENDIX

APPENDIX: STATE AGENCY COMMENTS



"People
helping people
help
themselves"

Mitchell E. Daniels, Jr., Governor
State of Indiana

Office of Medicaid Policy and Planning
MS07, 402 W. WASHINGTON STREET, ROOM W382
INDIANAPOLIS, IN 46204-2739

July 23, 2009

Mr. Peter J. Barbera
Regional Inspector General for Audit Services
Office of Inspector General
Office of Audit Services
Department of Health and Human Services—Region IV
61 Forsyth Street, S.W., Suite 3T41
Atlanta, Georgia 30303

RE: Follow Up Review of the Medicaid Drug Rebate Program
(Report number A04-08-07006)

Dear Mr. Barbera:

This letter is in response to the Office of Inspector General (OIG) draft report titled, "*Follow-Up Review of the Medicaid Drug Rebate Program in Indiana*" dated May 2009. We have reviewed the report, and the following is the response of the Office of Medicaid Policy and Planning (OMPP) to the recommendation contained in the report.

Recommendation: Establish and implement procedures to ensure the State maintain documentation to support and reconcile all accounts receivable amounts on the Form CMS-64.9R.

The OMPP has reviewed the above referenced OIG report. As a result of the audit report, OMPP has implemented preventive controls to ensure proper reporting on the CMS64-9R. Management reconciles ACS reports to drug rebates invoiced and to accounts receivable balances reported on Form 64-9R. The State utilizes DRAMS, the ACS system for processing drug rebates, to validate and monitor the details of invoicing, adjustments and receivables summarized on the Form 64-9R.

The OMPP, ACS and the fiscal agent, EDS continue to work toward a complete reconciliation of amounts received by the PBM to those transferred to the fiscal agent to offset Medicaid expenditures.

We appreciate the opportunity to comment on the draft report, and hope that you find our responses to be helpful to you in finalizing the report. Should you or your staff have any questions regarding this response letter, please contact Marc Shirley, R.Ph., Pharmacy Operations Manager for OMPP. He may be reached at (317) 232-4343 or marc.shirley@fssa.in.gov.

Sincerely,

Patricia Casanova
Director of Medicaid

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