Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

OKLAHOMA COMPLIED WITH THE FEDERAL MEDICAID REQUIREMENTS FOR BILLING MANUFACTURERS FOR REBATES FOR PHYSICIAN-ADMINISTERED DRUGS

Inquiries about this report may be addressed to the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

Patricia Wheeler
Regional Inspector General

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Office of Inspector General

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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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

OFFICE OF AUDIT SERVICES, REGION VI
1100 COMMERCE STREET, ROOM 632
DALLAS, TX 75242

September 19, 2013

Report Number: A-06-12-00059

Mr. Kelly Shropshire
Director – Program Integrity & Accountability
Oklahoma Health Care Authority
2401 NW 23rd, Suite 1A
Oklahoma City, OK 73107

Dear Mr. Shropshire:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled *Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs.* We will forward a copy of this report to the HHS action official noted below.

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 https://oig.hhs.gov.

If you have any questions or comments about this report, please direct them to the HHS action official. Please refer to report number A-06-12-00059 in all correspondence.

Sincerely,

/Patricia Wheeler/
Regional Inspector General
for Audit Services

Enclosure

HHS Action Official:

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INTRODUCTION

Oklahoma complied with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs.

WHY WE DID THIS REVIEW

For a covered outpatient drug to be eligible for Federal reimbursement under the Medicaid program's drug rebate requirements, manufacturers must pay rebates to the States. States bill the manufacturers for the rebates to reduce the cost of the drugs to the program. However, a recent Office of Inspector General review found that States did not always bill and collect all rebates due for drugs administered by physicians in an office or hospital outpatient facility. (Appendix A lists previous reviews.)

OBJECTIVE

Our objective was to determine whether the Oklahoma Health Care Authority (State agency) complied with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs.

BACKGROUND

Medicaid Drug Rebate Program

The Medicaid drug rebate program became effective in 1991 (the Social Security Act (the Act), § 1927). For a covered outpatient drug to be eligible for Federal reimbursement under the program, the drug's 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 have specific functions under the program.

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.[1] On the basis of this information, CMS calculates a unit rebate amount for each drug and provides the information to the States each quarter.

Section 1903(i)(10) of the Act prohibits Federal reimbursement for States that do not capture the information necessary for billing manufacturers for rebates as described in section 1927 of the Act.[2] To bill for rebates, States must capture drug utilization data that identifies, by National Drug Code (NDC), the number of units of each drug for which the States reimbursed Medicaid providers, and must report the information to the manufacturers (the Act, § 1927(b)(2)(A)).

[1] Section 1927(b) of the Social Security Act and section II of the Medicaid rebate agreement.

[2] All single-source and the top 20 multiple-source physician-administered drugs are required to be invoiced for rebates for the State to receive Federal reimbursement.

The number of units is multiplied by the unit rebate amount to determine the actual rebate amount due from each manufacturer.

States report drug rebate accounts receivable data on the Medicaid Drug Rebate Schedule. This is part of the Form CMS-64, Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program (Form CMS-64), which contains a summary of actual Medicaid expenditures for each quarter and is used by CMS to reimburse States for the Federal share of Medicaid expenditures.

Physician-Administered Drugs

Drugs administered by a physician in an office setting are typically billed to the Medicaid program on a claim form using Healthcare Common Procedure Coding System (HCPCS) codes. Drugs administered by a physician in an outpatient hospital setting are typically billed on a claim form using a revenue code to identify the type of service.

Before the Deficit Reduction Act of 2005, many States did not collect rebates on physician-administered drugs if the drug claims did not contain NDCs. The Deficit Reduction Act amended section 1927 of the Act to require States to capture the necessary information, including NDCs, to bill manufacturers for rebates on such drugs. However, section 1927(a)(7) of the Act allowed CMS to delay some collection and submission requirements for States that demonstrated a need for additional time for implementation.

The State Agency's Medicaid Drug Rebate Program

The State agency is responsible for billing and collecting Medicaid drug rebates for physician-administered drugs. Providers may submit claim forms electronically or in paper form. The State agency contracts with HP Enterprise Services, LLC, to process claims and prepare drug rebate invoices. The State agency works with the contractor to verify utilization details prior to invoice preparation. Invoices are sent to contracted pharmaceutical manufacturers quarterly for rebates due on single-source drugs and all multiple-source physician-administered drugs.[3] The manufacturers pay the rebates directly to the State agency. The State agency maintains the accounts receivable information and works with manufacturers to resolve any unpaid rebates.[4]

[3] States are required to bill for rebates only on the top-20 multiple-source drugs. However, Oklahoma billed for all multiple-source drugs.

[4] The invoices and accounts receivable identify drugs by NDC and do not distinguish between pharmacy and physician-administered drugs.

HOW WE CONDUCTED THIS REVIEW

Our audit covered physician-administered drug claims paid during calendar years 2009 through 2011. We tested the $7,945,132 in claims that the State agency made for physician-administered drugs and that were paid between July 1 and September 30, 2011.[5]

We reviewed the CMS-64.9R for the 12 quarters of our audit period.[6] After selecting the fourth quarter of 2011 to test,[7] we judgmentally selected from the summary drug utilization information 13 NDCs associated with 6 manufacturers. We traced these items through the rebate invoicing and collection process. We also obtained all physician-administered drug claims paid during the quarter, removed claims exempt from being rebated, and compared the remaining paid claims to claims that were invoiced for Medicaid rebates for the quarter. Because we did not find any material errors, we did not test transactions from the other quarters in our audit period.

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.

Appendix B contains the details of our audit scope and methodology.

RESULTS OF AUDIT

The State agency complied with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs. The State agency properly billed rebates for the $7,945,132 in claims for the sampled quarter. Therefore, no recommendations are provided.

[5] We limited our scope to Medicaid fee-for-service drug claims. We did not include the drug utilization of managed care organizations in this review.

[6] The CMS-64.9R, *Medicaid Drug Rebate Schedule,* is a summary of drug rebate transactions for the quarter; it is part of the Form CMS-64 that the State submits each quarter to CMS.

[7] The information presented in the fourth-quarter CMS-64 Report is based on transactions from the third quarter (July1 through September 30, 2011).

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
Medicaid Rebates for Physician-Administered Drugs	OEI-03-02-00660	04/04
States' Collection of Medicaid Rebates for Physician-Administered Drugs	OEI-03-09-00410	06/11
Nationwide Rollup Report for Medicaid Drug Rebate Collections	A-06-10-00011	08/11

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered physician-administered drug claims paid during calendar years 2009 through 2011. We tested the $7,945,132 in claims that the State agency made for physician-administered drugs and that were paid between July 1 and September 30, 2011.

Our audit objective did not require an understanding or assessment of the complete internal structure of the State agency. We limited our internal control review to obtaining an understanding of the State agency's processes and controls over billing for Medicaid rebates for physician-administered drugs.

We performed our fieldwork at the State agency in Oklahoma City, Oklahoma, in November 2012.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance pertaining to the Medicaid drug rebate program and physician-administered drugs;
- reviewed State agency regulations and guidance to providers, including billing instructions for physician-administered drugs;
- reviewed State agency policies and procedures for Medicaid drug rebates;
- interviewed State agency personnel to gain an understanding of the administration of and controls over the Medicaid drug rebate process for physician-administered drugs;
- obtained and reviewed the CMS-64.9R for the 12 quarters of our review;
- selected the fourth quarter of 2011 to test; and
- tested the billing and collection of rebates by:
    - obtaining from the State agency the claims for physician-administered drugs listed on the fourth quarter CMS-64 for calendar year 2011 totaling $7,945,132;
    - judgmentally selecting, from the quarter, drug utilization claim details for 13 NDCs associated with 6 manufacturers;

- reviewing (1) copies of rebate invoices submitted to the 6 manufacturers and the resultant remittances to verify the billing of rebates by NDC and (2) receipt of rebates for the sampled NDCs;

- obtaining information regarding physician-administered claims that were exempt from Medicaid rebates (e.g., 340B claims and vaccine claims) and requesting exclusion reason codes;

- requesting rebated claims detail for claims from the fourth-quarter Form CMS-64; and

- removing claims not eligible for rebate and comparing the remaining paid claims to rebate invoicing data.

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.