

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

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

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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.

INTRODUCTION

Louisiana 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 Medicaid's drug costs. However, recent Office of Inspector General reviews 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 of the Medicaid drug rebate program.)

OBJECTIVE

Our objective was to determine whether the Louisiana Department of Health and Hospitals (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. Covered outpatient drugs reported by participating drug manufacturers are listed in the CMS Medicaid Drug File, which identifies drugs with fields such as National Drug Code (NDC), unit type, units per package size, and product name.

The Act prohibits Federal reimbursement for States that do not capture the information necessary for billing manufacturers for rebates as described in section 1927(a)(7) of the Act (§ 1903(i)(10)).² To bill for rebates, States must capture drug utilization data that identifies, by NDC, the number of units of each drug for which the States reimbursed Medicaid providers and

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

² Section 1927(a)(7) of the Act essentially requires the collection of information necessary to bill for rebates for all single-source and the top 20 multiple-source physician-administered drugs.

must report the information to the manufacturers (the Act, § 1927(b)(2)(A)). 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 to CMS on the Medicaid Drug Rebate Schedule. This schedule is part of the Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program (CMS-64 report), which contains a summary of actual Medicaid expenditures for each quarter and which CMS uses to reimburse States for the Federal share of Medicaid expenditures.

Physician-Administered Drugs

Drugs administered by a physician are typically billed to the Medicaid program on a claim form using Healthcare Common Procedure Coding System (HCPCS) codes. For purposes of the Medicaid drug rebate program, single-source drugs are those covered outpatient drugs produced or distributed under an original new drug application approved by the Food and Drug Administration (FDA).³ Multiple-source drugs are defined, in part, as those covered outpatient drugs that have at least one other drug rated as therapeutically equivalent by FDA.⁴

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 essentially amended section 1927 of the Act to require States to capture the necessary information, including NDCs, to bill manufacturers for rebates on such drugs.

The State Agency's Medicaid Drug Rebate Program

Louisiana provides Medicaid drug benefits under both fee-for-service and managed care systems. Section 1932(a) of the Act allows States to implement managed care delivery systems. Managed care is a system for delivering health care that is intended to improve the quality of care and to control costs. To these ends, the State agency pays managed care organizations a fixed monthly capitation payment for each enrollee to provide covered services. This approach is different from a fee-for-service system, in which the State agency pays providers for each service they furnish. Medicaid drug rebates are collected for covered drugs from both systems.

The State agency is responsible for billing and collecting Medicaid drug rebates for physician-administered drugs. The State agency contracts with the University of New Orleans (UNO) to manage its drug rebate program and with Molina Medicaid Solutions (Molina) for claims payment. Molina processes the claims for physician-administered drugs and sends the claims to UNO.⁵ Using this data, UNO identifies the units eligible for rebate, calculates the rebates due

³ Section 1927(k)(7) of the Act. Single-source drugs are commonly referred to as “brand-name” drugs.

⁴ Section 1927(k)(7) of the Act. According to the definition of “therapeutic equivalence” in the FDA glossary of terms, a therapeutically equivalent drug product can be substituted with another product to achieve the same clinical effect as the prescribed drug. Available online at <http://www.fda.gov/drugs/informationondrugs/ucm079436.htm>. Accessed on December 22, 2014.

⁵ A claim line represented one physician-administered drug service. Claims may include more than one claim line.

based on CMS's unit rebate amount, and bills the manufacturers by NDC. The manufacturers pay the rebates directly to the State agency. The State agency forwards copies of the payment information to UNO, which reconciles the invoiced amount with the paid amount. UNO maintains accounts receivable information and works with manufacturers to resolve any unpaid rebates.

HOW WE CONDUCTED THIS REVIEW

Our audit covered 236,047 fee-for-service claim lines totaling \$9,654,214 and 108,489 managed care claim lines⁶ for physician-administered drugs paid between July 1 and September 30, 2013 (audit period).

We interviewed State personnel regarding policies and procedures. We also obtained all physician-administered drug claim lines paid during the audit period, verified exemption reasons for claim lines that the State agency identified as being exempt from being rebated (i.e., claims provided under the 340B Program, claims for drugs not covered under Medicaid, and fee-for-service claims with zero-dollar payments), and tested the remaining lines for proper inclusion on Medicaid rebate invoices. We did not expand our testing to other quarters because we did not find material errors in the quarter reviewed.

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 excluded 256,062 claim lines (189,081 fee-for-service and 66,981 managed care) and properly billed rebates for 46,966 fee-for-service claim lines totaling \$2,282,678 and 41,508 managed care claim lines. Therefore, no recommendations are provided.

⁶ Managed care claim lines are included in capitated managed care payments. Therefore, a payment amount is not directly associated with each drug claim line.

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Medicaid Rebates for Physician-Administered Drugs</i>	<u>OEI-03-02-00660</u>	April 2004
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	<u>OEI-03-09-00410</u>	June 2011
<i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i>	<u>A-06-10-00011</u>	August 2011
<i>Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<u>A-06-12-00059</u>	September 2013
<i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-03-12-00200</u>	November 2013
<i>Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	<u>A-09-12-02080</u>	April 2014
<i>Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs</i>	<u>A-09-12-02079</u>	April 2014
<i>Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-13-06040</u>	August 2014
<i>The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-03-12-00205</u>	August 2014

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered 236,047 fee-for-service claim lines totaling \$9,654,214 and 108,489 managed care claim lines for physician-administered drugs paid between July 1 and September 30, 2013 (audit period).

Our audit objective did not require an understanding or assessment of the complete internal control 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 conducted our fieldwork at the State agency in Baton Rouge, Louisiana, in October 2014.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance on 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 the CMS Medicare part B crosswalk and the CMS Medicaid Drug Product file;
- obtained from the State agency the claim lines for physician-administered drugs listed on the CMS-64 report for the fourth quarter of calendar year 2013⁷ (236,047 fee-for-service claim lines totaling \$9,654,214 and 108,489 managed care claim lines);
- reviewed all physician-administered drug claim lines to determine proper inclusion or exclusion from Medicaid drug rebate invoicing; and
- discussed the results of our review with the State agency.

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

⁷ There is typically a one-quarter difference between when claims are paid and when they are reported to CMS (i.e., July through September 2013 paid claims were reported on the October through December quarterly report).

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.