

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**IDAHO DID NOT BILL MANUFACTURERS
FOR REBATES FOR SOME MEDICAID
PHYSICIAN-ADMINISTERED DRUGS**

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Deputy Inspector General

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A-09-12-02079

Office of Inspector General

<https://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

During 2010, Idaho did not bill manufacturers for rebates associated with \$2.6 million in paid claims 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.

Our objective was to determine whether Idaho's Department of Health and Welfare (State agency) complied with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs.

BACKGROUND

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

The Deficit Reduction Act of 2005 amended section 1927 of the Social Security Act to specifically address the collection of rebates on physician-administered drugs. To collect these rebates, States submit to the manufacturers the drug utilization data containing National Drug Codes (NDCs) for all single-source and the top 20 multiple-source physician-administered drugs. Federal reimbursement for covered outpatient drugs administered by a physician is not available to States that do not comply with Federal requirements for capturing NDCs to bill and collect rebates.

In Idaho, the State agency is responsible for billing and collecting Medicaid drug rebates for physician-administered drugs. The State agency contracts with a rebate contractor to bill for rebates. The rebate contractor receives from the data warehouse contractor a file containing claim lines (claim extract) that the rebate contractor uses to bill manufacturers.

WHAT WE FOUND

During calendar year (CY) 2010, the State agency did not always comply with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs. Of the \$7,288,288 in paid claims reviewed, the State agency properly billed for rebates associated with \$4,651,484. However, the State agency did not bill for rebates associated with \$2,636,804 because the rebate contractor did not receive the related claim lines to bill manufacturers for rebates:

- The rebate contractor did not receive claim lines totaling \$2,140,760 (\$1,483,130 Federal share) because the data warehouse contractor incorrectly excluded these claim lines from the claim extract provided to the rebate contractor. The data warehouse contractor excluded the claim lines on the basis of inaccurate State agency instructions, which were implemented when the data warehouse became operational on July 15, 2010. As a result of our audit, the State agency removed the instructions beginning with the March 31, 2013, rebate file.
- The rebate contractor did not receive claim lines totaling \$496,044 (\$342,555 Federal share) because NDCs were not present or valid NDCs were not captured. The State agency did not ensure that its Medicaid Management Information System (MMIS) captured valid NDCs for all claim lines for physician-administered drugs.

Because the State agency did not bill manufacturers for rebates associated with \$2,636,804 (\$1,825,685 Federal share), we are setting aside this amount for CMS resolution.

WHAT WE RECOMMEND

We recommend that the State agency:

- work with CMS to determine the amount that should be billed to manufacturers for rebates associated with the \$2,636,804 (\$1,825,685 Federal share) in claim lines for physician-administered drugs,
- bill manufacturers for rebates associated with the claim lines for any physician-administered drugs that were incorrectly excluded from the rebate process after CY 2010,
- ensure that the MMIS captures valid NDCs for all claim lines for physician-administered drugs, and
- ensure that all physician-administered drugs eligible for rebates are processed for rebates.

STATE AGENCY COMMENTS

The State agency concurred with our findings and provided information on actions that it had taken or planned to take to implement our recommendations.

TABLE OF CONTENTS

INTRODUCTION	1
Why We Did This Review	1
Objective	1
Background	1
Medicaid Drug Rebate Program	1
Physician-Administered Drugs	2
The State Agency’s Medicaid Drug Rebate Program.....	2
How We Conducted This Review.....	3
FINDINGS	4
Federal and State Requirements.....	4
The State Agency Did Not Bill for Rebates on Physician-Administered Drugs Because Claim Lines Were Incorrectly Excluded From the Rebate Process	5
The State Agency Did Not Bill Manufacturers for Rebates on Other Physician-Administered Drugs Because National Drug Codes Were Not Present or Valid Codes Were Not Captured.....	5
RECOMMENDATIONS	6
STATE AGENCY COMMENTS	6
OTHER MATTERS.....	6
The State Agency Paid Claims That Had National Drug Codes That Were Not Listed in the CMS Medicaid Drug File	6
The State Agency Reported Negative Balances for Rebates	6
APPENDIXES	
A: Related Office of Inspector General Reports	8
B: Audit Scope and Methodology.....	9
C: Audit Methodology Flowchart.....	11

D: Federal and State Requirements Related to
Physician-Administered Drugs12

E: State Agency Comments14

INTRODUCTION

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.¹ (Appendix A lists previous reviews of the Medicaid drug rebate program.)

OBJECTIVE

Our objective was to determine whether Idaho's Department of Health and Welfare (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.² 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 such fields as National Drug Code (NDC), unit type, units per package size, and product name.

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. To bill for rebates, States must capture drug utilization data that identify, by 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)). The number of units is multiplied by the unit rebate amount to determine the actual rebate amount due from each manufacturer.

¹ *States' Collection of Medicaid Rebates for Physician-Administered Drugs* (OEI-03-09-00410), issued June 2011.

² Section 1927(b) of the Act and section II of the Medicaid rebate agreement.

States report drug rebate accounts receivable data to CMS on the Medicaid Drug Rebate Schedule (CMS 64.9R). This schedule is part of the Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program report, 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. The Federal share is determined by the Federal medical assistance percentage, which varies depending on the State's per capita income.

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. NDCs allow States to identify the drug and its manufacturer to collect drug rebates. To comply with the data collection requirements of the Deficit Reduction Act, many States now require that claims for physician-administered drugs include NDCs.

The State Agency's Medicaid Drug Rebate Program

The State agency is responsible for paying claims and collecting Medicaid drug rebates for physician-administered drugs. The State agency requires providers to submit NDCs on claims for all physician-administered drugs.

The State agency contracts with three contractors to administer the drug rebate process: a paid claims contractor, a data warehouse contractor, and a rebate contractor. The following describes the three contractors' roles in the rebate process:

- The **paid claims contractor**⁵ is responsible for adjudicating and paying claims for physician-administered drugs using the State agency's Medicaid Management Information System (MMIS). During the adjudication process, if a provider submits NDCs on its claims, MMIS edits generally ensure that the claims include valid NDCs, valid HCPCS codes, and valid HCPCS-NDC combinations. The paid claims contractor

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 therapeutic equivalent drug product can be substituted with another product to achieve the same clinical effect as the prescribed drug. <http://www.fda.gov/drugs/informationondrugs/ucm079436.htm>. Accessed on December 16, 2013.

⁵ The paid claims contractor was HP Enterprise Services from January through May 2010 and Molina Medicaid Solutions from June through December 2010.

validates the HCPCS-NDC combinations using a crosswalk maintained by the rebate contractor. (A crosswalk identifies the NDCs associated with an HCPCS code.) The paid claims contractor pays the claims and forwards them to the data warehouse contractor.

- The **data warehouse contractor**,⁶ according to State agency instructions, forwards to the rebate contractor a file containing claim lines⁷ (claim extract).
- The **rebate contractor**,⁸ using the claim extract, identifies the rebatable units, calculates the rebates due on the basis of CMS's unit rebate amount, and bills the manufacturers by NDC for rebates on all single-source and all multiple-source drugs.⁹ The manufacturers pay the rebates directly to the rebate contractor, which maintains accounts receivable information and works with manufacturers to resolve any unpaid rebates. The rebate contractor forwards the rebate payment information to the State agency.

HOW WE CONDUCTED THIS REVIEW

Our audit covered \$7,656,152 of State agency fee-for-service claims¹⁰ for physician-administered drugs paid in CY 2010.¹¹ We excluded from our review \$367,864 of certain fee-for-service claims, such as claims that are exempt from Medicaid drug rebates (i.e., provider claims under the 340B Drug Pricing Program).¹² Therefore, we reviewed \$7,288,288 of fee-for-service claims for physician-administered drugs.

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

⁶ During calendar year (CY) 2010, the data warehouse contractor was part of the health care unit of Thomson Reuters Corporation. On June 6, 2012, a private equity firm purchased the unit and rebranded it as Truven Health Analytics.

⁷ A claim line represents one physician-administered drug service. Claims may include more than one claim line.

⁸ The rebate contractor was HP Enterprise Services in January 2010 and Magellan Medicaid Administration from February through December 2010. The rebate contractor also administers the State agency's pharmacy drug rebate processes; however, this review does not cover those processes.

⁹ Although the Medicaid drug rebate law specifically addresses rebates for only the top 20 multiple-source drugs, State agency officials told us that the rebate contractor billed for rebates on all multiple-source drugs.

¹⁰ Our scope was limited to Medicaid fee-for-service drug claims. We did not include the drug utilization of managed-care organizations in this review.

¹¹ Molina Medicaid Solutions provided us with the paid claims file we reviewed, which included claims from both paid claims contractors.

¹² Drug manufacturers are not required to pay rebates under the Medicaid drug rebate program for covered outpatient drugs that are subject to discounted pricing under the 340B Drug Pricing Program (42 U.S.C. § 256b(a)(5)).

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, and Appendix C shows our audit methodology in flowchart form.

FINDINGS

During CY 2010, the State agency did not always comply with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs. Of the \$7,288,288 in paid claims reviewed, the State agency properly billed for rebates associated with \$4,651,484.¹³ However, the State agency did not bill for rebates associated with \$2,636,804 because the rebate contractor did not receive the related claim lines to bill manufacturers for rebates:

- The rebate contractor did not receive claim lines totaling \$2,140,760 (\$1,483,130 Federal share) because the data warehouse contractor incorrectly excluded these claim lines from the claim extract provided to the rebate contractor. The data warehouse contractor excluded the claim lines on the basis of inaccurate State agency instructions, which were implemented when the data warehouse became operational on July 15, 2010. As a result of our audit, the State agency removed the instructions beginning with the March 31, 2013, rebate file.
- The rebate contractor did not receive claim lines totaling \$496,044 (\$342,555 Federal share) because NDCs were not present or valid NDCs were not captured. The State agency did not ensure that its MMIS captured valid NDCs for all claim lines for physician-administered drugs.

Because the State agency did not bill manufacturers for rebates associated with \$2,636,804 (\$1,825,685 Federal share), we are setting aside this amount for CMS resolution.

FEDERAL AND STATE REQUIREMENTS

The Deficit Reduction Act amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs. States must capture NDCs for single-source and top-20 multiple-source drugs (the Act, § 1927(a)(7)(C)). Federal regulations prohibit Federal reimbursement for physician-administered drugs unless the States submit to manufacturers drug utilization data containing the NDCs (42 CFR § 447.520).

Idaho's Medicaid Information Release (IR) MA04-06 requires the collection of NDC information on claims for medications from professional providers and states that collection will result in significant cost savings to the State's Medicaid program. According to IR MA04-06, the collection of NDC information allows the State agency to bill and collect rebates; claims for physician-administered drugs with incomplete NDC information will be denied.

¹³ We traced the \$4,651,484 in claim lines to a rebate claim file that the rebate contractor used to bill manufacturers for rebates.

Appendix D contains Federal and State requirements related to physician-administered drugs.

THE STATE AGENCY DID NOT BILL FOR REBATES ON PHYSICIAN-ADMINISTERED DRUGS BECAUSE CLAIM LINES WERE INCORRECTLY EXCLUDED FROM THE REBATE PROCESS

The rebate contractor did not receive 58,598 claim lines totaling \$2,140,760 (\$1,483,130 Federal share) because the data warehouse contractor incorrectly excluded these claim lines from the claim extract provided to the rebate contractor. As a result, the rebate contractor did not bill manufacturers for rebates on the State agency's behalf.

The data warehouse contractor excluded the claim lines on the basis of inaccurate State agency instructions, which were implemented when the data warehouse became operational on July 15, 2010. As a result of our audit, the State agency removed the instructions beginning with the March 31, 2013, rebate file. Therefore, additional claim lines for physician-administered drugs could have been incorrectly excluded from the claim extract provided to the rebate contractor after CY 2010. The State agency and its rebate contractor plan to retroactively bill manufacturers for rebates for physician-administered drugs that were not previously rebated.

We verified that the 58,598 claim lines were not billed for rebates even though the claim lines had NDCs that appeared in the CMS Medicaid Drug File. Because the State agency did not bill manufacturers for rebates associated with \$2,140,760 (\$1,483,130 Federal share), we are setting aside this amount for CMS resolution.

THE STATE AGENCY DID NOT BILL MANUFACTURERS FOR REBATES ON OTHER PHYSICIAN-ADMINISTERED DRUGS BECAUSE NATIONAL DRUG CODES WERE NOT PRESENT OR VALID CODES WERE NOT CAPTURED

The rebate contractor did not receive 4,755 claim lines totaling \$496,044 (\$342,555 Federal share) because NDCs were not present or valid NDCs were not captured. As a result, the rebate contractor did not bill manufacturers for rebates on the State agency's behalf.

- For 3,491 claim lines totaling \$332,983 (\$229,782 Federal share), we determined that NDCs were not present in the NDC fields. However, the State agency was able to retrieve the NDCs for most of these claim lines from a different source.
- For 1,264 claim lines totaling \$163,061 (\$112,773 Federal share), valid NDCs were not captured because the crosswalk that the State agency used in CY 2010 did not list all valid HCPCS-NDC combinations. The crosswalk was not updated in a timely manner and therefore could not ensure valid HCPCS-NDC combinations.

The State agency did not ensure that its MMIS captured valid NDCs for all claim lines for physician-administered drugs.

We verified that the 4,755 claim lines were not billed for rebates. Because the State agency did not bill manufacturers for rebates associated with \$496,044 (\$342,555 Federal share), we are setting aside this amount for CMS resolution.

RECOMMENDATIONS

We recommend that the State agency:

- work with CMS to determine the amount that should be billed to manufacturers for rebates associated with the \$2,636,804 (\$1,825,685 Federal share) in claim lines for physician-administered drugs,
- bill manufacturers for rebates associated with the claim lines for any physician-administered drugs that were incorrectly excluded from the rebate process after CY 2010,
- ensure that the MMIS captures valid NDCs for all claim lines for physician-administered drugs, and
- ensure that all physician-administered drugs eligible for rebates are processed for rebates.

STATE AGENCY COMMENTS

The State agency concurred with our findings and provided information on actions that it had taken or planned to take to implement our recommendations. The State agency's comments are included in their entirety as Appendix E.

OTHER MATTERS

THE STATE AGENCY PAID CLAIMS THAT HAD NATIONAL DRUG CODES THAT WERE NOT LISTED IN THE CMS MEDICAID DRUG FILE

In CY 2010, the State agency claimed Federal reimbursement of \$110,279 for 2,981 claim lines that had NDCs that were not listed in the CMS Medicaid Drug File, which lists covered outpatient drugs that are eligible for Federal reimbursement. It was beyond the scope of our review to determine whether these claim lines should have been paid and whether they were eligible for Federal reimbursement.

THE STATE AGENCY REPORTED NEGATIVE BALANCES FOR REBATES

The State agency reported negative beginning and ending accounts receivable balances for rebates on its CMS 64.9R. For example, the December 31, 2010, accounts receivable balance for rebates (for both physician-administered drugs and drugs dispensed by pharmacies) was approximately negative \$253 million. The accounts receivable rebate balance indicates the amount of outstanding rebates due from drug manufacturers and generally should be a positive amount.

Because the accounts receivable balances included pharmacy rebate amounts, which were beyond the scope of our review, we did not reconcile the balances and determine the extent to which Federal reimbursement was affected.

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-03-12-00200</u>	November 2013
<i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i>	<u>A-06-10-00011</u>	August 2011
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	<u>OEI-03-09-00410</u>	June 2011
<i>Follow-Up Audit of the Medicaid Drug Rebate Program in Idaho</i>	<u>A-09-07-00064</u>	April 2008
<i>Medicaid Rebates for Physician-Administered Drugs</i>	<u>OEI-03-02-00660</u>	April 2004

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$7,656,152 of State agency fee-for-service claims for physician-administered drugs paid in CY 2010. We excluded from our review \$367,864 of certain fee-for-service claims, such as claims that are exempt from Medicaid drug rebates (i.e., provider claims under the 340B Drug Pricing Program). Therefore, we reviewed \$7,288,288 of fee-for-service claims for physician-administered drugs.

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 for and controls over billing for Medicaid rebates for physician-administered drugs.

We conducted our audit from August 2012 to August 2013 and performed fieldwork at the State agency office in Boise, Idaho.

METHODOLOGY

To accomplish our objective, we:

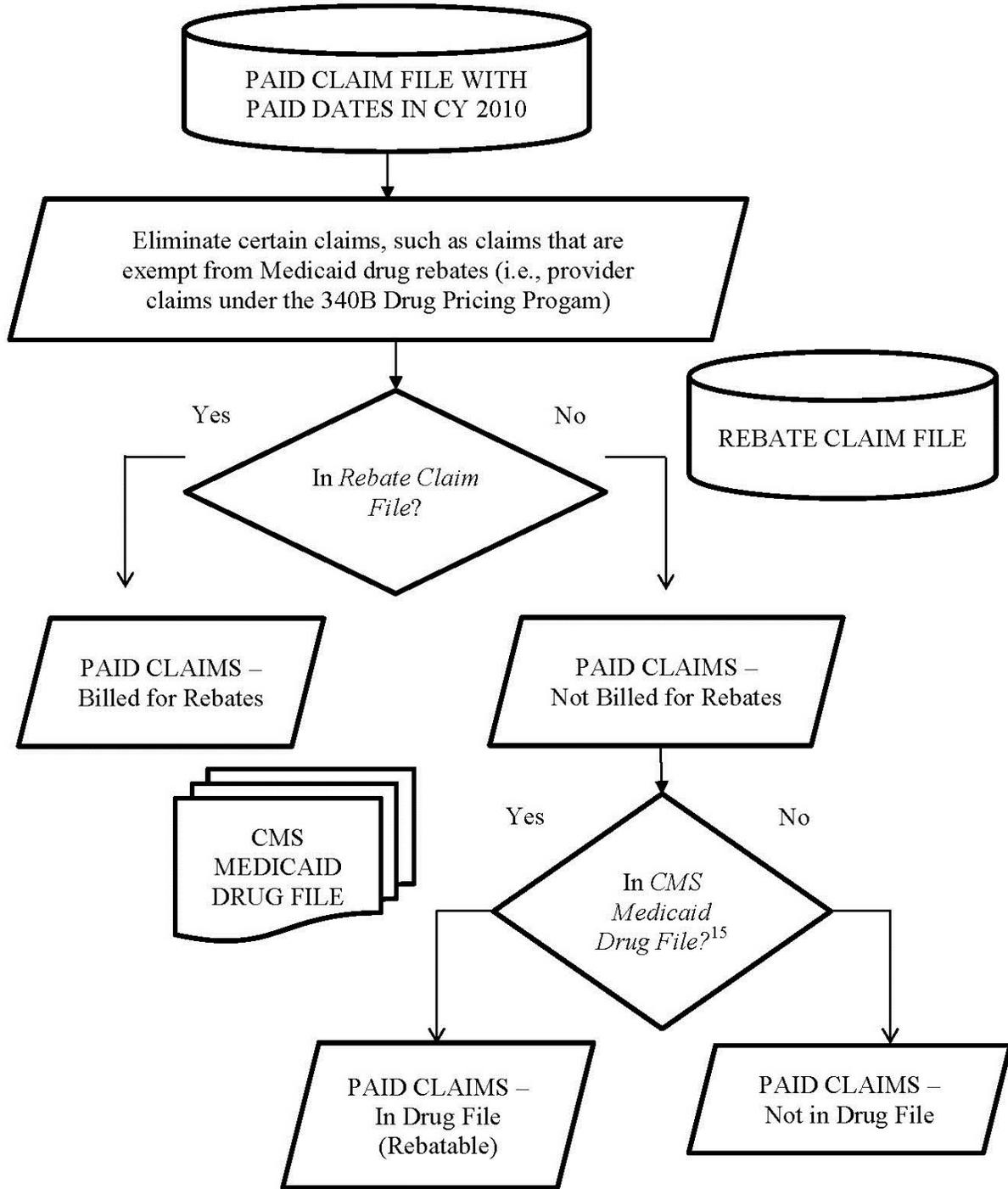
- reviewed Federal laws, regulations, and guidance pertaining to the Medicaid drug rebate program and physician-administered drugs;
- interviewed CMS officials about the Federal laws, regulations, and guidance governing physician-administered drugs under the Medicaid drug rebate program;
- reviewed State agency regulations and guidance to providers, including billing instructions for physician-administered drugs;
- reviewed State agency policies and procedures for processing rebates for physician-administered drugs;
- interviewed State agency and contractor personnel to gain an understanding of the administration of and controls over the Medicaid billing and rebate process for physician-administered drugs;
- obtained from the State agency the HCPCS-NDC crosswalk that its paid claims contractor used to validate the HCPCS-NDC combinations in CY 2010;
- obtained from the State agency the claims paid in CY 2010 for physician-administered drugs;

- obtained from the State agency the rebate claim file that the rebate contractor used to bill manufacturers for rebates associated with claims paid in CY 2010 for physician-administered drugs;¹⁴
- identified the paid claim details for 63,353 claim lines that the State agency had not billed for rebates by:
 - excluding certain fee-for-service claim lines not eligible for rebates,
 - identifying claim lines that were eligible for rebates by determining whether the NDCs in the drug utilization data were in the CMS Medicaid Drug File, and
 - verifying whether the claim lines eligible for rebates were billed for rebates; 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 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.

¹⁴ The rebate contractor did not bill manufacturers for these rebates until CY 2012. Adjustments and reversals after CY 2010 were taken into account by the rebate contractor when billing manufacturers.

APPENDIX C: AUDIT METHODOLOGY FLOWCHART



¹⁵ We verified whether the claim lines with no NDCs in the NDC field were in the rebate claim file. However, without NDCs, we were not able to analyze these claim lines against the CMS Medicaid Drug File.

APPENDIX D: FEDERAL AND STATE REQUIREMENTS RELATED TO PHYSICIAN-ADMINISTERED DRUGS

FEDERAL LAWS

Under the Medicaid program, States may provide coverage for outpatient drugs as an optional service (the Act, § 1905(a)(12)). Section 1903(a) of the Act provides for Federal financial participation (Federal share) in State expenditures for these drugs. The Medicaid drug rebate program, created by the Omnibus Budget Reconciliation Act of 1990 that added section 1927 to the Act, became effective on January 1, 1991. Manufacturers must enter into a rebate agreement with the Secretary of Health and Human Services and pay rebates for States to receive Federal funding for the manufacturer's covered outpatient drugs dispensed to Medicaid patients (the Act, § 1927(a)). Responsibility for the drug rebate program is shared among the drug manufacturers, CMS, and the States.

Section 6002 of the Deficit Reduction Act added section 1927(a)(7) to the Act to require that States capture information necessary to secure rebates from manufacturers for certain covered outpatient drugs administered by a physician. In addition, section 6002 of the Deficit Reduction Act amended section 1903(i)(10) of the Act to prohibit a Medicaid Federal share for covered outpatient drugs administered by a physician unless the States submit the utilization and coding data described in section 1927(a)(7) of the Act.

Section 1927(a)(7) of the Act requires that States collect utilization and coding data necessary to secure rebates for all single-source physician-administered drugs effective January 1, 2006, and for the top 20 multiple-source drugs effective January 1, 2008. Section 1927(a)(7)(C) of the Act stated that, effective January 1, 2007, the utilization data must be submitted using the NDC.

FEDERAL REGULATIONS

Federal regulations set conditions for States to obtain a Federal share for covered outpatient drugs administered by a physician and specifically state that no Federal share is available for physician-administered drugs for which a State has not required the submission of claims using codes that identify the drugs sufficiently for the State to bill a manufacturer for rebates (42 CFR § 447.520).

Federal regulations in effect during most of the audit period defined a brand-name drug as a single-source or innovator multiple-source drug and, in a relevant part, a multiple-source drug as a covered outpatient drug for which there is at least one other drug product that is rated as therapeutically equivalent (42 CFR § 447.502).¹⁶

¹⁶ On November 15, 2010, CMS amended 42 CFR § 447.502 to remove the definition of multiple-source drug (75 Fed. Reg. 69591, 69592).

STATE REGULATIONS AND GUIDANCE

Idaho's Medicaid IR MA04-06, issued December 30, 2003, states: "The collection of the NDC information will allow Medicaid to collect rebates due from drug manufacturers, resulting in significant cost saving to Idaho's Medicaid Program." It also states: "Professional claims for medications reported with HCPCS ... codes for dates of service on or after February 1, 2004 must include the NDC of the medication supplied Claims with incomplete NDC information will be denied"

APPENDIX E: STATE AGENCY COMMENTS



C.L. "BUTCH" OTTER – Governor
RICHARD M. ARMSTRONG – Director

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March 26, 2014

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Regional Inspector General
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Department of Health and Human Services
90 - 7th Street, Ste 3-650
San Francisco, CA 94103

RE: Report Number A-09-12-02079

Dear Ms. Ahlstrand:

In response to the draft findings detailed in Report Number A-09-12-02079, please find the Department's responses below.

- OIG Finding:** The State agency did not bill manufacturers for rebates associated with \$2,140,760 (\$1,483,130 Federal share), we are setting aside this amount for CMS resolution. The State agency did not bill manufacturers for rebates associated with \$496,044 (\$342,555 Federal share), we are setting aside this amount for CMS resolution.

OIG Recommendation: Work with CMS to determine the amount that should be billed to manufacturers for rebates associated with the \$2,636,804 (\$1,825,685 Federal share) in claim lines for physician-administered drugs.

State Response: We concur with the finding and have initiated an action plan to implement the OIG's specific recommendation as follows:

The OIG identified claims, detailed below, have been submitted or will be submitted to the rebate processor. The rebate processor determines which claims are eligible for rebate based on the CMS regulations for the rebate program. The processor then submits the number of units billed for those claims by NDC with the accurate rebate rate for the time period reflected for the adjudication date. The units for each NDC from the identified claims submitted have been added to the corresponding NDC summary for the same year and quarter as the identified claim. A prior period adjustment statement was sent to the manufacturer to reflect the increase in units, prescription count, and rebate amount due. The bulk of these claims were received by the rebate processor in June 2013 and included in the quarterly rebate invoice cycle. The State has directed the rebate processor to confirm receipt

of all claim numbers identified through this audit. Those not yet received will be resubmitted through the data warehouse and processed as described above during the next rebate invoicing cycle ending June 30, 2014. The identified claims are addressed as follows:

- Claims associated with the \$2,140,760 (\$1,483,130 Federal share) excluded by the data warehouse vendor.

These previously excluded claims were reprocessed and submitted to the rebate processor in June of 2013. Claims found eligible for rebate were invoiced and submitted with the 2013 second quarter rebate file to CMS in August 2013.

- Claims associated with the \$496,044 (\$342,555 Federal share) amounting to \$332,983, identified as no NDC code reported in the NDC field.

After reviewing the claims, the State found that the NDC code was being reported, but displayed in a different field. At the time of the audit the system collected the NDC in a system pharmacy claim table and copied it into the memo field, then cleared the claim table. This caused the NDC to display in a field not used for rebates. As of 2013, the claim table information previously deleted, has been restored and the table is no longer cleared after copying to the memo field. This allows the NDC to appear in a field used for rebate processing. These claims will be addressed and will be sent to the rebate processor as a part of the scheduled claim extract process from the data warehouse. Claims found eligible for rebate will be invoiced and submitted with the next quarterly CMS rebate file.

- Claims associated with the \$496,044 (\$342,555 Federal share) amounting to \$163,061, identified as having invalid HCPCS-NDC combinations.

Processes have been redesigned (see Finding No. 4 below) to prevent these errors from occurring in the future. The State is reviewing these claims and will work with providers and CMS to recoup and/or refund inappropriately paid claims.

2. **OIG Finding:** The State agency did not bill for rebates on physician-administered drugs because claim lines were incorrectly excluded from the rebate process.

OIG Recommendation: Bill manufacturers for rebates associated with the claim lines for physician-administered drugs that were incorrectly excluded from the rebate process after CY 2010.

State Response: We concur with the finding and have initiated an action plan to implement the OIG's specific recommendation as follows:

The exclusion criteria used by the data warehouse vendor was removed and redefined to department specifications in April 2013. Previously excluded claims were reprocessed and

sent to the rebate processor in June 2013. Rebate eligible claims were invoiced and submitted with the 2013 second quarter rebate file to CMS in August 2013.

- 3. OIG Finding:** The State agency did not ensure that its MMIS captured valid NDCs for all claim lines for physician-administered drugs.

OIG Recommendation: Ensure that the MMIS captures valid NDCs for all claim lines for physician-administered drugs.

State Response: We concur with the finding and have initiated an action plan to implement the OIG's specific recommendation as follows:

The State changed vendors for both claims adjudication and rebate processing during the OIG audited period. The issues noted reflect transitional difficulties and replaced processes. Current processes for handling physician administered drug rebates that address the noted deficiencies and prevent their reoccurrence are presently in place under the new vendors.

The current rebate processor provides monthly NDC/JCode crosswalks of rebateable physician administered drugs for use in adjudication by the claims processing vendor. In the existing medical claims adjudication system, there are several edits that ensure NDCs are captured and appropriately processed. Claims immediately reject if a submitted NDC is invalid. Other system edits determine if an NDC is required for the JCode and will cause the claim to reject if the NDC is missing when required, if it is an invalid NDC, and verify that the NDC and JCode are associated with each other through the crosswalk provided by the rebate processor. If the NDC and JCode are not associated, the claim denies for payment. Denied claims are then researched to ensure that rebateable drugs have not been omitted on the rebate processor crosswalk.

- 4. OIG Finding:** The rebate contractor did not receive 4,755 claim lines totaling \$496,044 (\$342,555 Federal share) because NDCs were not present or valid NDCs were not captured. As a result, the rebate contractor did not bill manufacturers for rebates on the State agency's behalf.

OIG Recommendation: Ensure that all physician-administered drugs eligible for rebates are processed for rebates.

State Response: We concur with the finding and have initiated an action plan to implement the OIG's specific recommendation as follows:

As explained in the response above, with the change of claims adjudicator and rebate processor in 2010, the claims adjudication process was redesigned to ensure NDCs are captured for rebateable drugs. The rebate processor provides a monthly NDC/JCode crosswalk of rebateable physician administered drugs for use in adjudication by the claims processor. If an NDC is required, the system edits against this crosswalk to ensure that the

Ms. Lori A. Ahlstrand
March 26, 2014
Page 4

NDC and the JCode are associated with each other. If not, the claim detail will deny for payment. All paid claims are passed to the data warehouse and subsequently to the rebate processor. Denied claims are researched to ensure that there was not an omission of a rebateable drug on the rebate processor crosswalk.

If you have any questions regarding the Department's responses to these findings, please contact Lisa Hettinger, Chief, Bureau of Financial Operations at (208) 287-1141.

Sincerely,

/Paul J. Leary/

PAUL J. LEARY
Administrator

PJL/ksl