Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

OREGON CLAIMED UNALLOWABLE FEDERAL MEDICAID REIMBURSEMENT BY NOT BILLING MANUFACTURERS FOR REBATES FOR SOME PHYSICIAN-ADMINISTERED DRUGS

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

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Deputy Inspector General

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A-09-12-02080

Office of Inspector General

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EXECUTIVE SUMMARY

During 2010, Oregon claimed Federal reimbursement of $2.3 million that was unallowable and $1.1 million that may have been unallowable because it did not comply with Federal Medicaid requirements for billing manufacturers for rebates for some 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 the Oregon Health Authority, Division of Medical Assistance Programs (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 Oregon, the State agency is responsible for billing and collecting Medicaid drug rebates for physician-administered drugs. The State agency contracts with a contractor to bill for rebates. The contractor uses the State agency's claim data for physician-administered drugs to bill manufacturers quarterly and to maintain a record of rebate accounts receivable due from the manufacturers. This review covers Medicaid fee-for-service claims for physician-administered drugs paid in calendar year (CY) 2010.

WHAT WE FOUND

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 $11,673,687 in paid claims reviewed, the State agency properly billed for rebates associated with $6,176,013. However, the State agency did not bill for rebates associated with $5,497,674:

- The State agency did not have NDCs (or, in some cases, did not have validated NDCs) to submit drug utilization data to bill rebates for claim lines totaling $3,705,827, consisting of $3,219,708 for claim lines that we identified for single-source drugs and $486,119 for claim lines that we identified for top-20 multiple-source drugs. As a result, the State agency improperly claimed reimbursement for $3,705,827 ($2,326,099 Federal share) for these claim lines.

- We were unable to determine the portion of $1,791,847 ($1,124,628 Federal share) for which the State agency may have improperly claimed reimbursement. This amount included claim lines for drugs for which there was insufficient information to determine whether the drugs were eligible for rebates.

The State agency did not always bill manufacturers for rebates because the State agency's Medicaid Management Information System (MMIS) did not have an edit to ensure that NDCs were present on drug claims or an edit to validate NDCs if submitted. State agency officials stated that they thought NDC edits would be included in the MMIS when it became operational in December 2008. However, the State agency informed us that it did not implement these edits until July 1, 2011. The State agency also informed us that in December 2012, it retroactively billed for rebates associated with claims for physician-administered drugs paid since July 1, 2011.

WHAT WE RECOMMEND

We recommend that the State agency:

- refund to the Federal Government $2,326,099 (Federal share) for claim lines for single-source and top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement;

- work with CMS to determine the portion of the $1,124,628 (Federal share) for other claim lines for physician-administered drugs that was ineligible for Federal reimbursement and refund that amount;

- work with CMS to determine and refund the unallowable Federal reimbursement for any physician-administered drugs claimed without NDCs and not billed for rebates before January 1, 2010, and after December 31, 2010;

- verify that the NDC edits implemented on July 1, 2011, ensure that NDCs are present and validated for payment on all drug claims; and

- ensure that all physician-administered drugs eligible for rebates are processed for rebates.

STATE AGENCY COMMENTS AND OUR RESPONSE

In written comments on our draft report, the State agency concurred with our first recommendation that it refund the Federal share for claim lines for single-source and top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement. However, the State agency did not concur with the refund amount and provided information on actions that it had taken since our audit. The State agency concurred with the four remaining recommendations and described corrective actions that it had taken or planned to take.

We did not audit the State agency's actions because they were after our audit period; therefore, we did not revise the refund amount in our first recommendation.

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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 the Oregon Health Authority, Division of Medical Assistance Programs (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. 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.

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]

The Deficit Reduction Act of 2005 amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs. To collect the rebates, States submit to the manufacturers the NDCs for single-source and the top 20 multiple-source physician-administered drugs. Beginning on January 1, 2007, CMS was responsible for publishing annually the list of the top 20 multiple-source drugs by HCPCS codes that had the highest dollar volume dispensed. Before the Deficit Reduction Act, 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.

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 physician-administered drugs. Since 2008, the State agency's Medicaid Management Information System (MMIS) has been able to store NDCs submitted by providers, but these provider-submitted NDCs were not validated (i.e., the NDCs were not checked for rebate eligibility) and were not used to bill for rebates. The State agency informed us that it did not implement NDC edits in the MMIS until July 1, 2011. These edits require an NDC to be present and valid on claims for physician-administered drugs and will deny payment for claims submitted without NDCs.[5]

[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] Denial of payment for claims submitted without NDCs applies to fee-for-service claims.

The State agency contracts with Hewlett Packard Enterprise Services (the contractor) to manage its drug rebate program.[6] During our audit period, the State agency did not rely on the NDCs submitted by providers; instead, the State agency used its contractor's proprietary HCPCS-to-NDC crosswalk to assign NDCs to HCPCS codes on some drug claim lines.[7] Using these assigned NDCs, the contractor identified the rebatable units, calculated the rebates due on the basis of CMS's unit rebate amount, and billed the manufacturers by NDC for rebates on drugs listed on its crosswalk.

The manufacturers pay the rebates directly to the State agency. The State agency forwards the payment information to the contractor, which posts the information in the State agency's MMIS. The contractor maintains accounts receivable information and works with manufacturers to resolve any unpaid rebates.[8]

HOW WE CONDUCTED THIS REVIEW

Our audit covered $17,317,044 of State agency fee-for-service claims for physician-administered drugs paid in calendar year (CY) 2010.[9] We excluded from our review $5,643,357 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).[10] Therefore, we reviewed $11,673,687 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 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.

[6] The contractor also manages the State agency's pharmacy drug-rebate processes; however, this review does not cover the pharmacy claim and rebate processes.

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

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

[9] We plan to review in a separate report the drug utilization data of Medicaid managed-care organizations for physician-administered drugs paid in CY 2010.

[10] 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)).

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 $11,673,687 in paid claims reviewed, the State agency properly billed for rebates associated with $6,176,013.[11] However, the State agency did not bill for rebates associated with $5,497,674:

- The State agency did not have NDCs (or, in some cases, did not have validated NDCs) to submit drug utilization data to bill rebates for claim lines totaling $3,705,827, consisting of $3,219,708 for claim lines that we identified for single-source drugs and $486,119 for claim lines that we identified for top-20 multiple-source drugs. As a result, the State agency improperly claimed reimbursement for $3,705,827 ($2,326,099 Federal share) for these claim lines.

- We were unable to determine the portion of $1,791,847 ($1,124,628 Federal share) for which the State agency may have improperly claimed reimbursement. This amount included claim lines for drugs for which there was insufficient information to determine whether the drugs were eligible for rebates.

The State agency did not always bill manufacturers for rebates because the State agency's MMIS did not have an edit to ensure that NDCs were present on drug claims or an edit to validate NDCs if submitted. State agency officials stated that they thought NDC edits would be included in the MMIS when it became operational in December 2008. However, the State agency informed us that it did not implement these edits until July 1, 2011. The State agency also informed us that in December 2012, it retroactively billed for rebates associated with claims for physician-administered drugs paid since July 1, 2011.

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).

Oregon's Medical-Surgical Services Administrative Rule 410-130-0180, dated July 1, 2009, requires both the NDC and HCPCS code on all claim forms for drug reimbursement. Through its information memorandum transmittals, the State agency notified providers to submit NDCs on claims for physician-administered drugs.

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

[11] We traced the $6,176,013 in claim lines to a rebate claim file that the contractor used to bill manufacturers for rebates.

THE STATE AGENCY DID NOT BILL MANUFACTURERS FOR REBATES AS REQUIRED FOR FEDERAL REIMBURSEMENT ON SOME PHYSICIAN-ADMINISTERED DRUGS

The State agency improperly claimed Federal reimbursement for $3,705,827 ($2,326,099 Federal share) for 23,332 claim lines for which it did not bill manufacturers for rebates. The State agency did not have NDCs for 77 percent of these claim lines because the State agency did not ensure that providers submitted NDCs for claims for physician-administered drugs. For the claim lines that had NDCs, the State agency did not validate the NDCs.

The claim lines that the State agency provided to us identified the drugs by HCPCS codes. We used CMS's Medicare Part B crosswalk to match the HCPCS codes to NDCs listed in the CMS Medicaid Drug File.[12] We determined that the State agency paid:

- $3,219,708 ($2,020,959 Federal share) for 3,342 claim lines for single-source drugs administered by physicians and

- $486,119 ($305,140 Federal share) for 19,990 claim lines for top-20 multiple-source drugs administered by physicians.

Because the State agency lacked NDCs for the majority of its drug utilization data and could not validate the NDCs that were available, it did not bill for rebates. We verified that these claim lines were not billed for rebates. As a result, $2,326,099 was not eligible for Federal reimbursement.

THE STATE AGENCY DID NOT BILL MANUFACTURERS FOR REBATES THAT MAY HAVE BEEN REQUIRED FOR FEDERAL REIMBURSEMENT ON OTHER PHYSICIAN-ADMINISTERED DRUGS

We were unable to determine whether the State agency improperly claimed Federal reimbursement for $1,791,847 ($1,124,628 Federal share) for 21,468 claim lines paid for physician-administered drugs because there was insufficient information to determine whether the drugs were eligible for rebates. The State agency did not have NDCs for 87 percent of these claim lines or did not validate the NDCs submitted. As a result, the State agency did not bill manufacturers for rebates.

- The State agency paid $1,610,145 ($1,010,577 Federal share) for 17,378 claim lines submitted for drugs for which the HCPCS codes had multiple NDCs. For example, for one claim line, one HCPCS code had five associated NDCs, of which only two NDCs were single-source drugs and eligible for rebates. Because the claim line did not have the specific NDC, it did not have sufficient information to determine whether the drug was eligible for rebate.

[12] CMS instructed States that they could use the Medicare Part B crosswalk as a reference because HCPCS codes and NDCs are standardized codes. We used this crosswalk to match the HCPCS codes to NDCs listed in the CMS Medicaid Drug File.

- The State agency paid $181,702 ($114,051 Federal share) for 4,090 claim lines submitted for drugs for which the HCPCS codes did not appear on CMS's Medicare Part B crosswalk or the contractor's crosswalk. Because the HCPCS codes did not appear on the crosswalks, we could not determine the NDCs. Therefore, we could not determine whether the drugs were eligible for rebate.

Accordingly, we set aside $1,791,847 ($1,124,628 Federal share) for CMS's resolution.

THE MEDICAID MANAGEMENT INFORMATION SYSTEM LACKED NATIONAL DRUG CODE EDITS

The State agency required providers to include NDCs on claims for physician-administered drugs. However, the providers did not submit NDCs for 82 percent of the claims in our review, and the State agency's MMIS did not have an edit to require the submission of NDCs. For claims submitted with NDCs, the MMIS did not have an edit to validate the NDCs.

The State agency informed us that it did not implement NDC edits until July 1, 2011. These edits require an NDC to be present and valid on claims for reimbursement for physician-administered drugs. The State agency also informed us that in December 2012, it retroactively billed for rebates associated with claims for physician-administered drugs paid since July 1, 2011. We did not verify the effectiveness of the NDC edits because the implementation date was after our audit period.

For some claims, we found that the contractor could have billed for rebates using its crosswalk. However, the State agency explained that these claims were not billed for rebates because of a lack of oversight. According to the State agency, it is working with its contractor to ensure that all rebates are billed.

RECOMMENDATIONS

We recommend that the State agency:

- refund to the Federal Government $2,326,099 (Federal share) for claim lines for single-source and top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement;
- work with CMS to determine the portion of the $1,124,628 (Federal share) for other claim lines for physician-administered drugs that was ineligible for Federal reimbursement and refund that amount;
- work with CMS to determine and refund the unallowable Federal reimbursement for any physician-administered drugs claimed without NDCs and not billed for rebates before January 1, 2010, and after December 31, 2010;
- verify that the NDC edits implemented on July 1, 2011, ensure that NDCs are present and validated for payment on all drug claims; and
- ensure that all physician-administered drugs eligible for rebates are processed for rebates.

STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the State agency concurred with our first recommendation that it refund the Federal share for claim lines for single-source and top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement. However, the State agency did not concur with the refund amount and provided information on actions that it had taken since our audit. The State agency concurred with the four remaining recommendations and described corrective actions that it had taken or planned to take. The State agency's comments are included in their entirety as Appendix E.

We did not audit the State agency's actions because they were after our audit period; therefore, we did not revise the refund amount in our first recommendation.

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-03-12-00200	November 2013
Nationwide Rollup Report for Medicaid Drug Rebate Collections	A-06-10-00011	August 2011
States' Collection of Medicaid Rebates for Physician-Administered Drugs	OEI-03-09-00410	June 2011
Follow-Up Audit of the Medicaid Drug Rebate Program in Oregon	A-09-07-00052	March 2008
Medicaid Rebates for Physician-Administered Drugs	OEI-03-02-00660	April 2004

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered $17,317,044 of State agency fee-for-service claims for physician-administered drugs paid in CY 2010. We excluded from our review $5,643,357 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 $11,673,687 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 September 2012 to July 2013 and performed fieldwork at the State agency office in Salem, Oregon.

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 rebates for physician-administered drugs;
- interviewed State agency and rebate 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 contractor used to identify rebate-eligible claims paid 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 contractor used to bill manufacturers for rebates associated with claims paid in CY 2010 for physician-administered drugs;

- identified the paid claim details for 44,800 claim lines that the State agency had not billed for rebates by:

    - excluding certain fee-for-service claim lines not eligible for rebates,

    - reviewing the remaining claim lines to determine whether they were eligible for rebates, and

    - verifying whether the claim lines eligible for rebates were billed for rebates;

- identified single-source and multiple-source drug claim lines by:

    - matching the HCPCS codes on the claim lines[13] to the HCPCS codes on the Medicare Part B and contractor crosswalks to identify the NDCs associated with each HCPCS code and

    - tracing the resulting NDCs to CMS's Medicaid Drug File to identify whether the drugs were single-source or multiple-source;

- identified top-20 multiple-source drug claim lines by tracing the HCPCS codes on the claim lines to the HCPCS codes on CMS's top-20 multiple-source drug list;

- identified claim lines that we could not determine to be single-source or multiple-source;[14] and

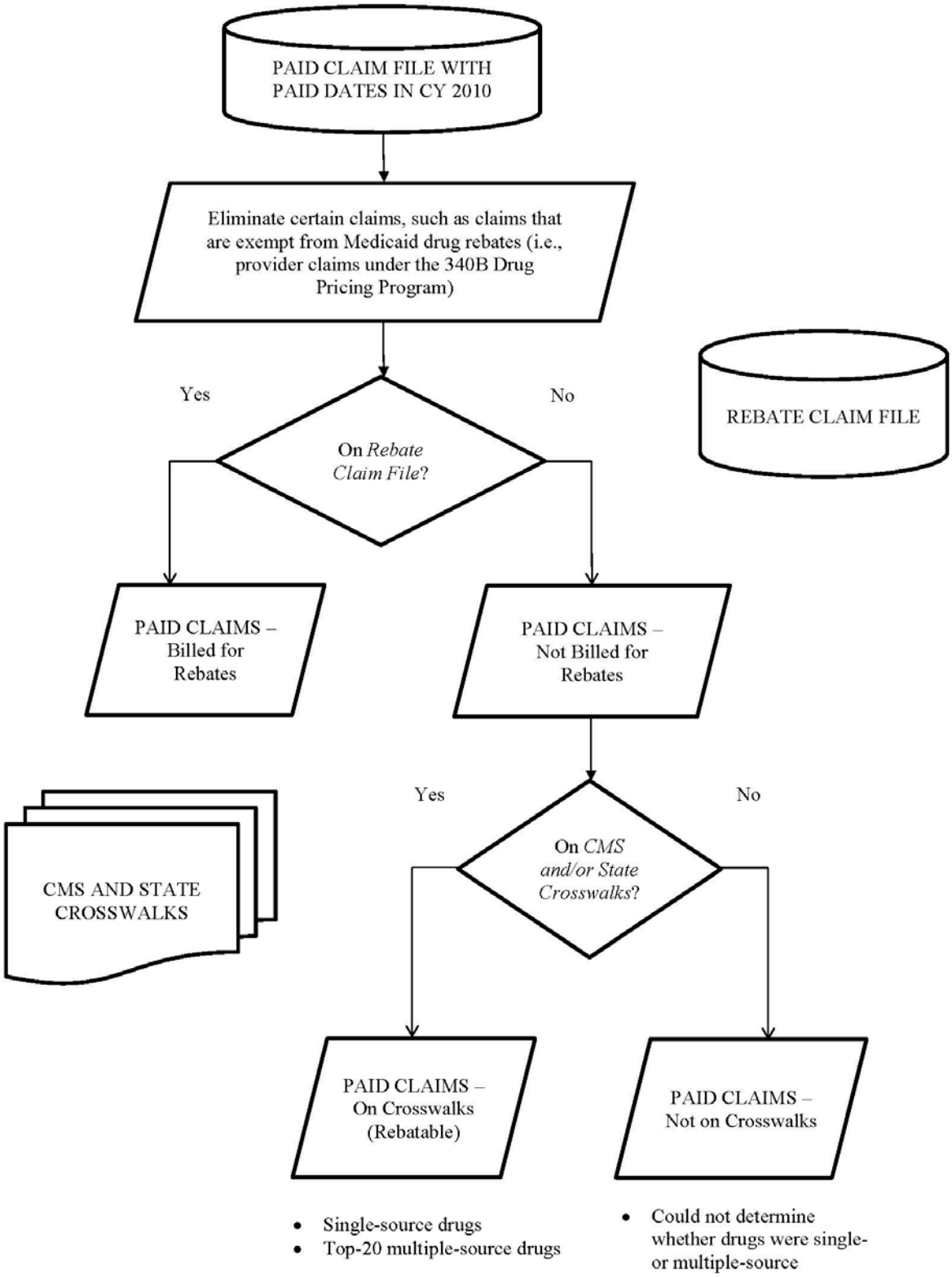
- discussed the results of our review with the State agency.

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.

[13] The majority of the claim lines had no NDCs, and the claim lines with NDCs were not validated or used to bill for rebates. Therefore, we used the Medicare Part B and contractor crosswalks to identify the associated NDCs for each of the claim lines.

[14] An HCPCS code may have several NDCs associated with it. Depending on the actual NDC reported, the drug may be classified as either single-source or multiple-source. The NDC is necessary to determine whether the drug is single-source or multiple-source. Because we could not determine the NDCs for these drugs, we could not determine whether the claim lines were eligible for rebates.

APPENDIX C: AUDIT METHODOLOGY FLOWCHART



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.

Section 1927(a)(7)(D) of the Act allowed the Secretary to delay any of the above requirements to prevent hardship to States that required additional time to implement the physician-administered drug reporting requirements.

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).[15]

[15] 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

Oregon's Medical-Surgical Services Administrative Rule 410-130-0180, dated July 1, 2009, states that drug reimbursement is made to practitioners only when the drug is administered by the practitioner in the office, the clinic, or home settings. Both the NDC number and HCPCS code are required on all claim forms.

Oregon's information memorandum transmittal (IM) 06-208 reminds providers of the requirement to include the NDC on all electronic claims for physician-administered drugs. It states: "The new [MMIS], scheduled to go online late in 2007, will automatically deny drug claims that don't include the NDC."

Oregon's IM 08-201 states that, effective January 1, 2009, NDCs are required on all drug claims. Before submitting a claim for a physician-administered drug, a provider should verify that the drug has an approved NDC and is rebatable.

Oregon's IM 10-153 states that, starting July 1, 2011, Oregon plans to deny fee-for-service claims for physician-administered drugs that do not include NDC information.

APPENDIX E: STATE AGENCY COMMENTS

OFFICE OF THE DIRECTOR
John A. Kitzhaber, MD, Governor

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February 12, 2014

Lori A. Ahlstrand
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Office of Audit Services, Region IX
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Oregon Health Authority
Medical Assistant Programs
Response to HHS OIG Draft Audit Report
Oregon Claimed Unallowable Federal Medicaid Reimbursement By Not Billing Manufacturers For Rebates For Some Physician-Administered Drugs.
Report: A-09-12-02080

Dear Ms. Ahlstrand:

The Oregon Health Authority (OHA) would like to thank the Office of Inspector General for this opportunity to respond to the draft audit report. The response will provide our general comments and then provide specific responses to the recommendations from the draft report.

OHA Comments:
In order to comply with the constantly changing Federal healthcare Laws and programs, as well as State legislative directives, OHA has to prioritize its Medicaid Management Information System (MMIS) programming resources based upon the monetary impact to the State agency. Oregon has a sincere interest in being good stewards of public expenditures. It is important to provide additional context around the findings stated in the report. Just prior to the audit period Oregon had been rolling out a new MMIS system that was expected to be readily configurable to implement much of the invoicing needs around drug rebate. However, the configuration of the system required additional programming that as stated needed to be prioritized. Due to competing priorities and projected monetary impacts OHA had to prioritize programming of these changes behind other higher impact items. As of July 1, 2011 the State agency has fully implemented National Drug Code (NDC) edits within MMIS. Furthermore, Oregon was a leader in configuring their MMIS to appropriately invoice for managed care drug utilization which spans from March 2010 to present. This invoicing change had a substantial monetary implication to Oregon's invoices to drug manufactures and in turn increased rebate revenue to the State and Federal government.

We would like to provide clarification around the OIG statement "However, the State agency explained that these claims were not billed for rebates because of a lack of oversight." A State representative did contact the OIG contact to clarify that this statement applied only to the Healthcare Common Procedure Coding System (HCPCS) code to NDC crosswalk used by the State's contractor to conduct invoicing. The OIG contact verified that this comment applied only to the oversight of the use of the contractor's proprietary crosswalk.

The Office of Inspector General has requested the State of Oregon respond to each of the recommendations contained in this report with a statement of concurrence or non-concurrence. The State agency responds as directed below.

OIG Recommendation #1
Refund to the Federal Government $2,326,099 (federal share) for claim lines for single source and top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement.

State Response to OIG Recommendation #1:
We concur with the recommendation that the Oregon Health Authority refund the federal share for single-source and top 20 multiple-source physician administered drug (PAD) claims that were ineligible for Federal reimbursement. However, we do not concur that the refund amount should be $2,326,099. Since the Exit conference, OHA has been able to identify claims with pertinent information required to submit invoices to respective drug manufacturers for rebates. OHA has initiated a process that will ensure that invoicing occurs for these identified claims and expect to have invoicing completed by the end of 2014. This process will include invoicing for rebates on claims from 2008 to present. We will ensure that appropriate payments are made and reported to CMS for rebate revenue received on all of the identified claims.

OIG Recommendation #2
Work with CMS to determine the portion of the $1,124, 628 (federal share) for other Physician-administered drugs that was ineligible for Federal reimbursement and refund that amount.

State Response to OIG Recommendation #2:
OHA concurs with the recommendation and will work with CMS to determine the portion of the $1,124,628 for other PAD claims that were ineligible for Federal reimbursement and refund that amount.

OIG Recommendation #3
Work with CMS to determine and refund the unallowable Federal reimbursement for physician-administered drugs claimed without NDCs and not billed for rebates before January 1, 2010 and after December 31st, 2010.

State Response to OIG Recommendation #3:
OHA concurs with the recommendation. Since the Exit conference we have conducted extensive analysis and have initiated a process that will identify claims that have pertinent information to invoice for rebates for claims paid in 2008 through present. These claims will lead to the State preparing appropriate invoices to drug manufacturers for rebate. At this time we have invoiced for

all eligible PAD claims from July 1, 2011 to present, this includes claims for both fee-for-service and managed care utilization. Additional retrospective analysis has been completed and invoicing for all remaining claims with pertinent information will be used to generate additional invoices to drug manufacturers for rebate by the end of 2014. As above, we will ensure that appropriate payments and reporting to CMS is complete on all of the identified claims.

OIG Recommendation #4:
Verify that the NDC edits implemented July 1, 2011, ensure that the NDCs are present and validated for payment on all drug claims.

State response to OIG Recommendation #4:
OHA concurs with this recommendation. We have conducted testing to ensure that the July 1, 2011 implemented NDC edits are functioning as required and do identify that a NDC is both present and valid on all drug claims. In an effort to provide additional certainty we will conduct this testing again to ensure these edits are continuing to function.

OIG Recommendation #5
Ensure that all physician-administered drugs eligible for rebates are processed for rebates.

State response to OIG Recommendation #5:
OHA concurs with this recommendation. We have, since the Exit conference, developed an extensive plan to address a retrospective invoicing solution required to ensure rebate eligible claims that have pertinent information needed for invoicing are indeed invoiced to drug manufacturers. For all other claims moving forward, we are confident that claims are subject to appropriate audits to ensure pertinent information is submitted with all drug claims, and utilized to ensure all drug claims are appropriately rebated as required.

Please feel free to contact me with questions or for additional information.

Sincerely,

/Tina Edlund/

Tina Edlund
Acting Director