

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MONTANA CORRECTLY CLAIMED
FEDERAL REIMBURSEMENT
FOR MOST MEDICAID
PHYSICIAN-ADMINISTERED DRUGS**

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Office of Inspector General

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EXECUTIVE SUMMARY

Montana claimed \$16,000 over 3 years in Federal reimbursement that was unallowable and \$116,000 that may have been unallowable because it did not comply with Federal Medicaid requirements for invoicing 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 for the drugs. States generally offset their Federal share of these rebates against their Medicaid expenditures. States invoice the manufacturers for rebates to reduce the cost of drugs to the program. However, a prior Office of Inspector General review found that States did not always invoice and collect all rebates due for drugs administered by physicians. For this audit, we reviewed the Montana Department of Public Health and Human Services (State agency), invoicing for rebates for physician-administered drugs for the period January 1, 2011, through December 31, 2013.

Our objective was to determine whether the State agency complied with Federal Medicaid requirements for invoicing 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 that is administered by 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 certain 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 physician-administered drugs and for 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 utilization data to invoice and collect rebates.

The State agency is responsible for paying claims, submitting invoices to manufacturers, and collecting Medicaid drug rebates for physician-administered drugs. The State agency uses its claim utilization data for physician-administered drugs, which it derives from claims submitted by providers, to invoice manufacturers quarterly and to maintain a record of rebate accounts receivable due from the manufacturers.

WHAT WE FOUND

Although the State agency generally complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs, it claimed unallowable Federal reimbursement for some of these drugs. The State agency did not invoice manufacturers for rebates associated with \$23,932 (\$15,940 Federal share) in physician-administered drugs. Of

this amount, \$19,363 (\$12,919 Federal share) was for single-source drugs, and \$4,569 (\$3,021 Federal share) was for top-20 multiple-source drugs. Because the State agency's internal controls did not always ensure that it invoiced manufacturers to secure rebates, the State agency improperly claimed Federal reimbursement for these single-source drugs and top-20 multiple-source drugs.

Further, the State agency did not submit the utilization data necessary to secure rebates for all other physician-administered drugs. Although the State agency generally collected the drug utilization data necessary to invoice the manufacturers for rebates associated with these claims, providers submitted claims totaling \$127,962 (\$84,802 Federal share) that did not have NDCs. We were unable to determine whether the State agency was required to invoice for rebates for these other physician-administered drug claims that did not have NDCs in the utilization data. Furthermore, under the Medicaid drug rebate program, claims totaling \$47,247 (\$31,354 Federal share), which contained NDCs, could have been eligible for rebates. Accordingly, we set aside these amounts and are recommending that the State agency work with CMS to determine (1) the unallowable portion of the \$127,962 (\$84,802 Federal share) of claims that were submitted without NDCs and (2) whether the remaining \$47,247 (\$31,354 Federal share) of claims could have been invoiced to the manufacturers for rebates.

WHAT WE RECOMMEND

We recommend that the State agency:

- refund to the Federal Government \$12,919 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement,
- refund to the Federal Government \$3,021 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement,
- work with CMS to determine:
 - the unallowable portion of \$84,802 (Federal share) for other claims for covered outpatient physician-administered drugs that were submitted without NDCs and that may have been ineligible for Federal reimbursement and refund that amount, and
 - whether the remaining \$31,354 (Federal share) of other physician-administered drug claims could have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims; and
- strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.

STATE AGENCY COMMENTS AND OUR RESPONSE

In written comments on our draft report, the State agency concurred with our first and second recommendations and with the first part of our third recommendation, and it described corrective actions that it had taken or planned to take in response to our fourth recommendation. The State agency did not concur with the second part of our third recommendation because, it said, certain statutory and regulatory provisions in the criteria do not specifically address other physician-administered drugs that were not single-source or top-20 multiple-source physician-administered drugs.

After reviewing the State agency's comments, we agree that the criteria do not specifically address other physician-administered drugs that were not single-source or top-20 multiple-source physician-administered drugs. Nevertheless, we set aside the \$31,354 (Federal share) associated with these claims because the State agency appears to have the necessary information available to invoice these claims for rebate under the Medicaid drug rebate program. We acknowledge that there are not specific criteria that require the State agency to invoice these other physician-administered drug claims, but the drug manufacturers would generally have been required to pay for the rebates had the State agency invoiced the manufacturers for these claims. Therefore, we continue to recommend that the State agency work with CMS to determine whether these drug claims could have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims.

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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 for the drugs. States generally offset their Federal share of these rebates against their Medicaid expenditures. States invoice the manufacturers for rebates to reduce the cost of drugs to the program. However, a prior Office of Inspector General review found that States did not always invoice and collect all rebates due for drugs administered by physicians.¹ (Appendix A lists previous reviews of the Medicaid drug rebate program.) For this audit, we reviewed the Montana Department of Public Health and Human Services (State agency), invoicing for rebates for physician-administered drugs for the period January 1, 2011, through December 31, 2013.

OBJECTIVE

Our objective was to determine whether the State agency complied with Federal Medicaid requirements for invoicing 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 that is administered by 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 invoicing manufacturers for rebates as described in section 1927 of the Act. To invoice for rebates, States capture drug utilization data that identifies, by NDC, the number of units of each drug for which the States reimbursed Medicaid providers and 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 24, 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 invoiced to the Medicaid program on a claim form using Healthcare Common Procedure Coding System (HCPCS) codes.³ For purposes of the Medicaid drug rebate program, physician-administered drugs are classified as either single-source or multiple-source.⁴

The Deficit Reduction Act of 2005 (DRA) amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs for all single-source physician-administered drugs and for the top 20 multiple-source physician-administered drugs.⁵ 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 DRA, many States did not collect rebates on physician-administered drugs if the drug claims did not contain NDCs. NDCs enable States to identify the drugs and their manufacturers and facilitate the collection of rebates for the drugs.

The State Agency's Medicaid Drug Rebate Program

The State agency is responsible for paying claims, submitting invoices to manufacturers, and collecting Medicaid drug rebates for physician-administered drugs. The State agency also requires all physician-administered drug claims to be submitted with the NDC of the product. The State agency uses its claim utilization data for physician-administered drugs, which it derives from claims submitted by providers, to invoice manufacturers quarterly and to maintain a record of rebate accounts receivable due from the manufacturers. The manufacturers then pay the rebates directly to the State agency.

³ HCPCS codes (sometimes referred to as J-Codes) are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

⁴ See, e.g., section 1927(a)(7) of the Act. In general terms, multiple-source drugs are covered outpatient drugs for which there are two or more drug products that are rated therapeutically equivalent by the FDA. See, e.g., section 1927(k)(7) of the Act. Multiple-source drugs stand in contrast to single-source drugs, which do not have therapeutic equivalents.

⁵ The term “top-20 multiple-source drugs” is drawn from a CMS classification and describes these drugs in terms of highest dollar volume of physician-administered drugs in Medicaid. The Act section 1927(a)(7)(B)(i).

HOW WE CONDUCTED THIS REVIEW

The State agency claimed \$23,976,995 (\$15,886,304 Federal share) for physician-administered drugs paid between January 1, 2011, and December 31, 2013.

We determined drug classifications by matching the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk.⁶ Additionally, we determined whether the HCPCS codes were published in CMS's top-20 multiple-source drug listing.

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.

FINDINGS

Although the State agency generally complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs, it claimed unallowable Federal reimbursement for some of these drugs. The State agency did not invoice manufacturers for rebates associated with \$23,932 (\$15,940 Federal share) in physician-administered drugs. Of this amount, \$19,363 (\$12,919 Federal share) was for single-source drugs, and \$4,569 (\$3,021 Federal share) was for top-20 multiple-source drugs. Because the State agency's internal controls did not always ensure that it invoiced manufacturers to secure rebates, the State agency improperly claimed Federal reimbursement for these single-source drugs and top-20 multiple-source drugs.

Further, the State agency did not submit the utilization data necessary to secure rebates for all other physician-administered drugs. Although the State agency generally collected the drug utilization data necessary to invoice the manufacturers for rebates associated with these claims, providers submitted claims totaling \$127,962 (\$84,802 Federal share) that did not have NDCs. We were unable to determine whether the State agency was required to invoice for rebates for these other physician-administered drug claims that did not have NDCs in the utilization data. Furthermore, under the Medicaid drug rebate program, claims totaling \$47,247 (\$31,354 Federal share), which contained NDCs, could have been eligible for rebates. Accordingly, we set aside these amounts and are recommending that the State agency work with CMS to determine (1) the unallowable portion of the \$127,962 (\$84,802 Federal share) of claims that were submitted

⁶ The Medicare Part B crosswalk is published quarterly by CMS and is based on published drug and biological pricing data and information submitted to CMS by manufacturers. It contains the payment amounts that will be used to pay for Part B covered drugs as well as the HCPCS codes associated with those drugs. CMS instructed States that they could use the crosswalk as a reference because HCPCS codes and NDCs are standardized codes used across health care programs.

without NDCs and (2) whether the remaining \$47,247 (\$31,354 Federal share) of claims could have been invoiced to the manufacturers for rebates.

FEDERAL AND STATE REQUIREMENTS AND STATE AGENCY GUIDANCE

The DRA 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)). To secure rebates, States are required to report certain information to manufacturers within 60 days after the end of each rebate period (the Act § 1927(b)(2)(A)). Federal regulations prohibit Federal reimbursement for physician-administered drugs for which a State has not required the submission of claims containing the NDCs (42 CFR § 447.520).

The Montana Department of Public Health and Human Services, *General Information for Providers: Medicaid and Other Medical Assistance Programs*, page 1.2, states: “Changes and updates to manuals are provided through provider notices and replacement pages, which are posted on the Montana Medicaid Provider Information website (<http://medicaidprovider.hhs.mt.gov/>).”

In addition, the *Montana Healthcare Programs Notice*, dated March 7, 2008, states:

The Federal Deficit Reduction Act of 2005 mandates that all State Medicaid Programs require the submission of National Drug Codes (NDCs) on claims submitted with certain procedure codes for physician-administered drugs

Effective April 1, 2008, Montana Medicaid will require all claims submitted for physician-administered drugs to include the NDC(s), the corresponding CPT/HCPCS code, and the units administered for each code.⁷

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

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES ON SOME SINGLE-SOURCE PHYSICIAN-ADMINISTERED DRUGS

The State agency improperly claimed Federal reimbursement of \$19,363 (\$12,919 Federal share) for single-source physician-administered drug claims for which it did not invoice manufacturers for rebates.

Because the State agency did not submit utilization data to the manufacturers to secure rebates, the State agency improperly claimed Federal reimbursement for these single-source physician-administered drugs.

⁷ Office of Inspector General note: The acronym “CPT” stands for Current Procedural Terminology, which is developed by the American Medical Association as a listing of descriptive terms and five-character identifying codes and modifiers for reporting medical services and procedures.

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES ON SOME TOP-20 MULTIPLE-SOURCE PHYSICIAN-ADMINISTERED DRUGS

The State agency improperly claimed Federal reimbursement of \$4,569 (\$3,021 Federal share) for top-20 multiple-source physician-administered drug claims for which it did not invoice manufacturers for rebates.

Before 2012, CMS provided the State agency, on a yearly basis, with a listing of top-20 multiple-source HCPCS codes and their respective NDCs. However, the State agency did not always submit the utilization data to the drug manufacturers for rebate purposes.

Because the State agency did not submit utilization data to the manufacturers to secure rebates, the State agency improperly claimed Federal reimbursement for these top-20 multiple-source physician-administered drugs.

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES ON OTHER PHYSICIAN-ADMINISTERED DRUGS

We were unable to determine whether, in some cases, the State agency was required to invoice for rebates for other physician-administered drug claims.

Although the State agency generally collected the drug utilization data necessary to invoice the manufacturers for rebates associated with other physician-administered drug claims, providers submitted some claims, totaling \$127,962 (\$84,802 Federal share), that did not have NDCs. For the claims that did not have NDCs in the utilization data, we were unable to determine whether the State agency improperly claimed Federal reimbursement for the physician-administered drugs associated with these claims. Furthermore, under the Medicaid drug rebate program, claims totaling \$47,247 (\$31,354 Federal share), which contained NDCs, could have been eligible for rebates. If the State agency would have invoiced these claims for rebate, the drug manufacturers would have been required to pay the rebates.

Accordingly, we set aside these amounts and are recommending that the State agency work with CMS to determine (1) the unallowable portion of the \$127,962 (\$84,802 Federal share) of the claims that were submitted without NDCs and (2) whether the remaining \$47,247 (\$31,354 Federal share) of other physician-administered drugs could have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims.

RECOMMENDATIONS

We recommend that the State agency:

- refund to the Federal Government \$12,919 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement,

- refund to the Federal Government \$3,021 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement,
- work with CMS to determine:
 - the unallowable portion of \$84,802 (Federal share) for other claims for outpatient physician-administered drugs that were submitted without NDCs and that may have been ineligible for Federal reimbursement and refund that amount, and
 - whether the remaining \$31,354 (Federal share) of other physician-administered drug claims could have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims; and
- strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency concurred with our first and second recommendations and with the first part of our third recommendation (that it work with CMS regarding the \$84,802 (Federal share) of the claims that were submitted without NDCs). Furthermore, the State agency described corrective actions that it had taken or planned to take in response to our fourth recommendation. The State agency did not concur with the second part of our third recommendation (that it work with CMS regarding the remaining \$31,354 (Federal share) of claims) because, it said, certain statutory and regulatory provisions in the criteria do not specifically address other physician-administered drugs that were not single-source or top-20 multiple-source physician-administered drugs.

The State agency's comments are included in their entirety as Appendix D.

OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing the State agency's comments, we agree that the criteria do not specifically address other physician-administered drugs that were not single-source or top-20 multiple-source physician-administered drugs. Nevertheless, we set aside the \$31,354 (Federal share) associated with these claims because the State agency appears to have the necessary information available to invoice these claims for rebate under the Medicaid drug rebate program. We acknowledge that there are not specific criteria that require the State agency to invoice these other physician-administered drug claims, but the drug manufacturers would generally have been required to pay for the rebates had the State agency invoiced the manufacturers for these claims. Therefore, we continue to recommend that the State agency work with CMS to determine whether these drug claims could have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims.

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>California Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	<u>A-09-14-02038</u>	1/07/16
<i>Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06056</u>	9/18/15
<i>Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06049</u>	7/22/15
<i>Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-06-12-00060</u>	5/04/15
<i>Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06051</u>	4/13/15
<i>Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-13-02037</u>	3/04/15
<i>Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<u>A-06-14-00031</u>	2/10/15
<i>The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-03-12-00205</u>	8/21/14
<i>Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-13-06040</u>	8/07/14
<i>Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs</i>	<u>A-09-12-02079</u>	4/30/14
<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>	4/24/14
<i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-03-12-00200</u>	11/26/13
<i>Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<u>A-06-12-00059</u>	9/19/13

Report Title	Report Number	Date Issued
<i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i>	<u>A-06-10-00011</u>	8/12/11
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	<u>OEI-03-09-00410</u>	6/24/11

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

The State agency claimed \$23,976,995 (\$15,886,304 Federal share) for physician-administered drugs paid between January 1, 2011, and December 31, 2013.

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 for reimbursing physician-administered drug claims and its process for claiming and obtaining Medicaid drug rebates for physician-administered drugs.

We conducted our audit work, which included contacting the State agency, from December 2014 to June 2015.

METHODOLOGY

To accomplish our objective, we took the following steps:

- We reviewed applicable Federal laws, regulations, and guidance pertaining to the Medicaid drug rebate program and physician-administered drugs.
- We interviewed CMS officials about the Federal requirements and guidance governing physician-administered drugs under the Medicaid drug rebate program.
- We reviewed State agency regulations and guidance to providers, including invoicing instructions for physician-administered drugs.
- We reviewed State agency policies and procedures for rebates for physician-administered drugs.
- We interviewed State agency personnel to gain an understanding of the administration of and controls over the Medicaid invoicing and rebate process for physician-administered drugs.
- We obtained listings of the CMS top-20 multiple-source physician-administered drugs, the Medicare Part B crosswalk, and the CMS Medicaid Drug File for our audit period.
- We obtained claim details from the State agency for all drug claims, including physician-administered drugs, for the period January 1, 2011, through December 31, 2013.

- We obtained the listing of 340B entities from the State agency.⁸
- We removed drug claims totaling \$23,777,854 (\$15,754,208 Federal share) that either were not eligible for a drug rebate or contained an NDC and were invoiced for rebate.
- We reviewed the remaining drug claims totaling \$199,141 (\$132,096 Federal share) to determine whether the State agency complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. Specifically:
 - We identified single-source drugs by matching the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk to identify the drug classification.
 - We identified the top 20 multiple-source drugs by matching the HCPCS code on the drug claim to the HCPCS code on CMS's top-20 multiple-source drug listing.
 - We identified other multiple-source drugs by matching the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk to identify the drug classification.
- We discussed the results of our review with State agency officials on September 15, 2015.

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.

⁸ Under the 340B drug pricing program (set forth in 42 U.S.C. § 256b), a 340B entity may purchase reduced-price covered outpatient drugs from manufacturers; examples of 340B entities are disproportionate share hospitals, which generally serve large numbers of low-income and/or uninsured patients, and State AIDS drug assistance programs. Drugs subject to discounts under the 340B drug pricing program are not subject to rebates under the Medicaid drug rebate program. Section 1927(j) of the Act and 42 U.S.C. § 256b(a)(5)(A).

APPENDIX C: FEDERAL AND STATE REQUIREMENTS AND STATE AGENCY GUIDANCE 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 (HHS) 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 DRA 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 DRA 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 collect the utilization and coding data described in section 1927(a)(7) of the Act.

Section 1927(a)(7) of the Act requires that States shall provide for the collection and submission of such utilization data and coding (such as J-codes and NDCs for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order 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. To secure rebates, States are required to report certain information to manufacturers within 60 days after the end of each rebate period (the Act § 1927(b)(2)(A)).

Section 1927(a)(7)(D) of the Act allowed HHS 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 specify 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 invoice a manufacturer for rebates (42 CFR § 447.520).

STATE AGENCY REQUIREMENTS AND GUIDANCE

The *Montana Healthcare Programs Notice*, dated March 7, 2008, states:

The Federal Deficit Reduction Act of 2005 mandates that all State Medicaid Programs require the submission of National Drug Codes (NDCs) on claims submitted with certain procedure codes for physician-administered drugs

Effective April 1, 2008, Montana Medicaid will require all claims submitted for physician-administered drugs to include the NDC(s), the corresponding CPT/HCPCS code, and the units administered for each code.

This requirement became effective April 1, 2008, and was thus in effect for our entire audit period.



Department of Public Health and Human Services

Health Resources Division ♦1400 E Broadway, PO Box 202951 ♦ Helena, MT 59620-2951 ♦ fax:444-1861

Steve Bullock, Governor

Richard H. Opper, Director

November 25, 2015

Department of Health and Human Services
Office of Inspector General, Office of Audit Services
Region VIII
Attn: Patrick J. Cogley
601 East 12th Street, Room 0429
Kansas City, MO 64106

Report Number: A-07-15-06062

Dear Mr. Cogley:

Thank you for your letter dated October 27, 2015, regarding the draft report entitled *Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs*. The Department has reviewed the draft report and has created a corrective action plan in regards to the findings and recommendations as follows.

OIG Recommendations

The draft report presented the Department with four recommendations.

1. Refund to the Federal Government \$12,919 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement.
2. Refund to the Federal Government \$3,021 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement.
3. Work with CMS to determine the unallowable portion of \$84,802 (Federal share) for other claims for outpatient physician-administered drugs that were submitted without NDCs and that may have been ineligible for Federal reimbursement and refund that amount, and whether the remaining \$31,354 (Federal share) of other physician-administered drug claims could have been invoiced to the manufacturers' to receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebate for those claims.
4. Strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.

Department Corrective Action Plan

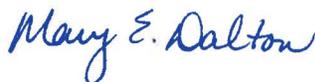
The Department concurs with the recommendations to refund the Federal Government \$12,919 for claims for single-source physician-administered drugs, and \$3,021 for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement. The Department will also work with CMS to determine if the unallowable portion of \$84,802 for outpatient physician-administered drugs that were submitted without NDCs are eligible for reimbursement.

The Department does not concur with the third recommendation regarding the remaining \$31,354 of other physician-administered drug claims that could have been invoiced to manufactures. CFR §447.520 FFP: *Conditions relating to physician administered drugs*, only addresses single source and the top-20 physician administered drugs. In addition, the Deficit Reduction Act of 2005 specifically addresses the Federal reimbursement requirements for single source and the top-20 physician administered drugs.

During the course of the audit, the Department identified two areas where improvements can be made to strengthen internal controls. The Department is conducting staff training on January 13, 2016, for all current and new rebate staff. In addition, the Department discovered two system issues which resulted in some of the audit findings. System change work orders were submitted to our fiscal agent on November 20, 2015 to resolve these issues, and will be implemented on May 18, 2016.

The Department is committed to providing a physician-administered drug program that offers the best value to our clients and the taxpayers. I look forward to your final report on this issue. Should you have any questions regarding this response please contact Dan Peterson, Allied Health Services Bureau Chief, at (406) 444-4144.

Sincerely,



Mary E. Dalton
State Medicaid Director

CC: Duane Preshinger, Health Resources Division Administrator
Becky Schlauch, Business and Financial Services Division Administrator
Dan Peterson, Health Resources Division
Beckie Beckert-Graham, Health Resources Division