

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MINNESOTA DID NOT BILL
MANUFACTURERS FOR SOME REBATES
FOR DRUGS DISPENSED TO
ENROLLEES OF MEDICAID
MANAGED-CARE ORGANIZATIONS**

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Office of Inspector General

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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.

Report in Brief

Date: October 2020
Report No. A-05-17-00018

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why OIG Did This Audit

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. Previous OIG audits found that States did not always bill and collect all rebates due for drugs administered by physicians to enrollees of Medicaid managed-care organizations (MCOs).

Our objective was to determine whether Minnesota complied with Federal Medicaid requirements for billing manufacturers for rebates for drugs dispensed to MCO enrollees.

How OIG Did This Audit

We reviewed drug utilization data for both pharmacy and physician-administered drugs for Minnesota's MCOs from January through December 2016.

We identified MCO drug utilization data for drugs that were not billed for rebates and used drug files from the Centers for Medicare & Medicaid Services (CMS) to determine which drugs were eligible or may have been eligible for rebates. For these drugs, we calculated the rebate amount that Minnesota could have collected if it had billed these drugs for rebates.

Minnesota Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations

What OIG Found

Minnesota did not fully comply with Federal Medicaid requirements for billing manufacturers for rebates for drugs dispensed to MCO enrollees. Minnesota did not bill for and collect manufacturers' rebates that we calculated to be \$6.1 million (Federal share). Specifically, it did not bill for and collect manufacturers' rebates that we calculated to be (1) \$5.9 million (Federal share) for pharmacy drugs and for single-source and top-20 multiple-source physician-administered drugs that were eligible for rebates and (2) \$173,780 (Federal share) for physician-administered drugs that may have been eligible for rebates. Minnesota did not always bill for and collect manufacturers' rebates because Minnesota and its contractor did not identify all of the rebate-eligible drugs in the utilization data submitted by the MCOs.

What OIG Recommends and Minnesota Comments

We recommend that Minnesota (1) bill for and collect manufacturers' rebates for pharmacy drugs and for single-source and top-20 multiple-source physician-administered drugs that we calculated to be \$5.9 million (Federal share) and refund the Federal Government and (2) work with CMS to determine whether the non-top-20 multiple-source physician-administered drugs were eligible for rebates that we calculated to be \$173,780 (Federal share) and, if so, upon receipt of the rebates, refund the Federal share. We also make a recommendation related to pharmacy and physician-administered drugs that were not billed for rebates after our audit period and a procedural recommendation to ensure that all rebate-eligible drugs are properly identified and billed for rebate.

In written comments on our draft report, Minnesota agreed with our recommendations and said that all of the claims identified in the first two recommendations were put through the rebate process and Minnesota will return the Federal share of rebate payments. In addition, Minnesota described actions it has taken or plans to take to address our remaining recommendations.

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INTRODUCTION

WHY WE DID THIS AUDIT

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 rebates to reduce the cost of drugs to the program. However, previous Office of Inspector General (OIG) audits found that States did not always bill and collect all rebates due for drugs administered by physicians to enrollees of Medicaid managed-care organizations (MCOs). (Appendix B lists previous OIG reports related to the Medicaid drug rebate program.¹) For this audit, we reviewed the Minnesota Department of Human Services' (State agency's) billing of rebates for both pharmacy and physician-administered drugs dispensed to MCO enrollees.

OBJECTIVE

Our objective was to determine whether the State agency complied with Federal Medicaid requirements for billing manufacturers for rebates for drugs dispensed to MCO enrollees.

BACKGROUND

Pharmacy and Physician-Administered Drugs

Drugs may be provided to a beneficiary through a pharmacy or administered by a physician in an office or a hospital. Pharmacy drugs are typically billed to Medicaid using National Drug Codes (NDCs). A valid NDC is a unique identifier that represents a drug's specific manufacturer, product, and package size. Physician-administered drugs are typically billed to the Medicaid program on a claim form using Healthcare Common Procedure Coding System (HCPCS) codes.² Each HCPCS code may have more than one NDC.

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 manufacturer must enter into a rebate agreement administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. Manufacturer rebates are essentially shared between the States and the Federal Government to offset the cost of prescription drugs. CMS, the States, and drug manufacturers each have specific functions under the program.

¹ OIG performed similar audits for rebates due for drugs administered by physicians to fee-for-service enrollees. These audits are also listed in Appendix B.

² HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

Manufacturers are required to submit a list of all covered outpatient drugs to CMS and to report each drug's average manufacturer price and, where applicable, best price.³ On the basis of this information, CMS calculates a unit rebate amount for each drug (i.e., each NDC) and provides these amounts 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 NDC, unit type, units per package size, and product name.⁴

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(a)(7) of the Act. To bill for rebates, States must use drug utilization data that identify, by NDC, the number of units of each drug for which the States reimbursed Medicaid providers. The States must capture these drug utilization data 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.

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 (Form CMS-64), which contains a summary of actual Medicaid expenditures for each quarter and which CMS uses to reimburse States for the Federal share of Medicaid expenditures.

Federal Reimbursement to States for Payments to Medicaid Managed-Care Organizations

States use two primary models to pay for Medicaid services: fee-for-service and managed care. In the managed-care model, States contract with MCOs to make services available to enrolled Medicaid beneficiaries, usually in return for a predetermined periodic payment, known as a capitation payment. States pay MCOs for each covered individual regardless of whether the enrollee receives services during the relevant time (42 CFR § 438.2). MCOs use the capitation payments to pay claims for these services. Capitation payments may cover outpatient drugs, which include both pharmacy and physician-administered drugs.

To claim Federal reimbursement, States report capitation payments made to MCOs as MCO expenditures on the Form CMS-64. These expenditures are not identified by specific type of service (such as pharmacy drugs or physician-administered drugs). States must report adjustments to drug expenditures and drug rebates on the Form CMS-64. The expenditures, adjustments, and rebates do not distinguish between amounts related to pharmacy drugs and amounts related to physician-administered drugs.

³ Section 1927(b) of the Act and section II of the Medicaid rebate agreement.

⁴ The CMS Medicaid Drug File provides the product data for the active drugs that have been reported by participating drug manufacturers as of the most recent rebate reporting period under the Medicaid Drug Rebate Program.

States' Collection of Rebates for Pharmacy and Physician-Administered Drugs

To collect rebates for drugs, States submit to the manufacturers the drug utilization data containing NDCs for the drugs. NDCs enable States to identify the drugs and their manufacturers and facilitate the collection of rebates for the drugs. Before the Deficit Reduction Act of 2005 (DRA), many States did not collect rebates on physician-administered drugs if the drug claims did not contain NDCs. NDCs were more readily available for pharmacy drug claims because providers used NDCs to bill for pharmacy drugs.

The DRA amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs for all single-source and top-20 multiple-source drugs.⁵ 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).⁶ 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.⁷ 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.

Effective March 23, 2010, the Patient Protection and Affordable Care Act (ACA)⁸ requires manufacturers to pay rebates on covered outpatient drugs dispensed to MCO enrollees if the MCOs are responsible for coverage of such drugs. States typically require MCOs to submit NDCs to the State for covered outpatient drugs dispensed to eligible individuals. States must include the drug utilization data reported by MCOs when billing manufacturers for rebates. Pharmacy and physician-administered drugs dispensed to MCO enrollees are recorded in MCO drug utilization data on claim lines.

The State Agency's Medicaid Drug Rebate Program

In Minnesota, the State agency is responsible for billing and collecting Medicaid drug rebates for both pharmacy and physician-administered drugs. The State agency uses a drug rebate application system (Drug Rebate Analysis and Management System (DRAMS)) that is

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 § 1927(a)(7)(B)(i)).

⁶ Section 1927(k)(7) of the Act. Single-source drugs are commonly referred to as "brand-name" drugs.

⁷ Section 1927(k)(7) of the Act. According to the definition of "therapeutic equivalence" in the FDA glossary of terms, a therapeutically equivalent drug product may be substituted with another product to achieve the same clinical effect as the prescribed drug. Available online at <https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms>. Accessed on June 22, 2020.

⁸ P.L. No. 111-148 (Mar. 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010, P.L. No. 111-152 (Mar. 30, 2010).

administered by a contractor.⁹ The State agency uses the DRAMS to identify drug encounters eligible for rebate, invoice manufacturers quarterly, and maintain a record of rebate accounts receivable due from the manufacturers. The manufacturers then pay the rebates directly to the State agency.

The State agency requires MCOs to report the NDC and its corresponding information on submitted encounter claims. The MCO typically uses the claims to develop encounter data. Encounter data are the records of services delivered to Medicaid beneficiaries enrolled in MCOs. During calendar year 2016, the State agency required its MCOs to submit encounter data on a bi-weekly basis. When submitting encounter data, MCOs must populate all fields required by the State agency, including those required for drug rebate processing, because they provide the drug utilization data available from the MCOs. Submitted encounter data must pass all data quality edits before acceptance by the State agency. The State agency forwards the encounter data related to pharmacy and physician-administered drugs and fields necessary for rebate processing to the DRAMS, which uses the data to bill for drug rebates.

HOW WE CONDUCTED THIS AUDIT

We reviewed drug utilization data for both pharmacy¹⁰ and physician-administered drugs for Minnesota's eight MCOs from January 1 through December 31, 2016 (audit period).

We identified MCO drug utilization data for pharmacy and physician-administered drugs that were billed for rebates and tested the rebates billed by selecting 4 manufacturers associated with 754 NDCs and reviewing the supporting documentation.¹¹ We also identified MCO drug utilization data for pharmacy and physician-administered drugs that were not billed for rebates and determined which drugs were eligible or may have been eligible for rebates. For both pharmacy and physician-administered drugs with NDCs identified that were not billed for rebates, we calculated the amount of rebates that the State agency could have collected if it had billed these drugs for rebates.

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.

⁹ Xerox Business Services, LLC, was the State agency's contractor during the audit period.

¹⁰ We reviewed only February 2016 pharmacy drug utilization data.

¹¹ These four manufacturers included the manufacturer with the highest paid total for physician-administered drugs, the manufacturer with the highest paid total for pharmacy drugs, the manufacturer with the most invoiced physician-administered drug claim lines, and the manufacturer with the most invoiced pharmacy drug claim lines in our audit period.

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

FINDINGS

During our audit period, the State agency did not fully comply with Federal Medicaid requirements for billing manufacturers for rebates for drugs dispensed to MCO enrollees. The State agency did not bill for and collect manufacturers' rebates that we calculated to be \$12,146,175 (\$6,073,088 Federal share)¹² for some pharmacy and physician-administered drugs that were eligible or may have been eligible for rebates.

The State agency did not always bill for and collect manufacturers' rebates because the State agency and its contractor did not identify all of the rebate-eligible drugs in the utilization data submitted by the MCOs.

FEDERAL AND STATE REQUIREMENTS

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)(C)). Federal regulations prohibit Federal reimbursement for physician-administered drugs unless the States require the submission of claims containing NDCs (42 CFR § 447.520).

The ACA amended section 1927 of the Act, effective March 23, 2010, to specifically require manufacturers to pay rebates on covered outpatient drugs dispensed to MCO enrollees if the MCOs are responsible for coverage of such drugs. To bill for rebates, States must include information for drugs dispensed to individuals enrolled in MCOs when billing manufacturers for rebates (the Act §§ 1927(b)(1)(A) and (b)(2)(A)).

The ACA also amended section 1903 of the Act to specifically address the conditions of Federal reimbursement for covered outpatient drugs dispensed to MCO enrollees. Essentially, States must secure rebates for drugs dispensed through MCOs and require MCOs to submit to the State NDCs for drugs dispensed to eligible individuals (the Act § 1903(m)(2)(A)).

The contracts between the State agency and the MCOs require that the MCOs comply with all State and Federal laws and regulations, and implement any necessary changes in policies and procedures as required by the State agency (MCO contracts, Article 12). The contracts also state that MCOs participate in a quality assurance program that verifies timeliness,

¹² Section 2501(a) of the ACA modified section 1927(c)(1)(B) and added section 1927(b)(1)(C) which, effective January 1, 2010, increased the rebate amount due from manufacturers, with the difference between the previous amount and the increased amount credited to the Federal Government. We did not include this amount in our calculation of the Federal share because we did not have the information required to calculate the increased amount.

completeness, accuracy, and consistency of encounter data that is submitted to the State agency (MCO contracts, Article 3¹³).

Appendix C contains Federal and State requirements related to Medicaid drug rebates.

THE STATE AGENCY DID NOT BILL MANUFACTURERS FOR SOME REBATES FOR DRUGS DISPENSED THROUGH MEDICAID MANAGED-CARE ORGANIZATIONS

The State agency did not bill for and collect manufacturers' rebates for pharmacy and physician-administered drugs dispensed to MCO enrollees:

- For drugs that were eligible for rebates, the State agency did not bill for and collect rebates that we calculated to be \$11,798,615 (\$5,899,308 Federal share). This amount consisted of:
 - \$10,492,357 (\$5,246,179 Federal share) for single-source and top-20 multiple-source physician-administered drugs and
 - \$1,306,258 (\$653,129 Federal share) for pharmacy drugs.
- For non-top-20 multiple-source physician-administered drugs¹⁴ that may have been eligible for rebates, the State agency did not bill for and collect rebates that we calculated to be \$347,560 (\$173,780 Federal share).

In total, during our audit period the State agency did not bill for and collect manufacturers' rebates that we calculated to be \$12,146,175 (\$6,073,088 Federal share) for pharmacy and physician-administered drugs that were eligible or may have been eligible for rebates.

THE STATE AGENCY AND ITS CONTRACTOR DID NOT IDENTIFY ALL OF THE REBATE-ELIGIBLE DRUGS

The State agency did not always bill for and collect manufacturers' rebates because the State agency and its contractor did not identify all of the rebate-eligible drugs in the utilization data submitted by the MCOs.

Although the State agency submitted rebate-eligible drugs to DRAMS for invoicing, DRAMS excluded certain encounters due to a system error that incorrectly identified some providers as

¹³ MCO contracts have this listed in various sections; however, the Article remains the same.

¹⁴ The NDCs for these multiple-source drugs matched the NDCs in CMS's Medicaid Drug File but were not top-20 HCPCS codes. The State agency's obligation to bill for rebates for these drugs is unclear. Accordingly, we set aside this amount for CMS resolution.

340B providers;¹⁵ thus, the eligible drugs were never invoiced for rebate. In addition, DRAMS incorrectly identified some pharmacy and physician-administered drugs as being part of a bundled service, which would make the encounter ineligible for rebate.¹⁶ However, after further analysis, the State agency determined that such encounters were not part of a bundled service and could have been invoiced for rebate.

RECOMMENDATIONS

We recommend that the Minnesota Department of Human Services:

- bill for and collect manufacturers' rebates for pharmacy drugs and for single-source and top-20 multiple-source physician-administered drugs that we calculated to be \$5,899,308 (Federal share) and refund the Federal Government;
- work with CMS to determine whether the non-top-20 multiple-source physician-administered drugs were eligible for rebates that we calculated to be at least \$173,780 (Federal share) and, if so, upon receipt of the rebates, refund the Federal share of the rebates collected;
- work with CMS to ensure that all pharmacy and physician-administered drugs eligible for rebates after our audit period are processed for rebates; and
- work with the contractor to confirm that DRAMS is properly identifying drug rebate eligibility to ensure that all rebate-eligible pharmacy and physician-administered drugs are identified and billed for rebates.

In written comments on our draft report, the State agency agreed with our recommendations and said that all of the claims identified in the first two recommendations were put through the rebate process and that the State agency will return the Federal share of rebate payments. Regarding our third recommendation, the State agency stated that it is conducting an analysis of the claims that were subsequently excluded during the rebate process to confirm that the re-exclusion was appropriate. Regarding our last recommendation, the State agency said that it

¹⁵ 42 U.S.C. § 256b(a)(5)(A)(i) prohibits duplicate discounts; that is, manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. The 340B Drug Pricing Program is a Federal Government program created in 1992 that requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices. Examples of 340B entities are Medicare and Medicaid disproportionate share hospitals, which generally serve large numbers of low-income or uninsured patients, or both, and State AIDS drug-assistance programs.

¹⁶ By including a drug in the bundled payment rate, the drug is excluded from the definition of a "covered outpatient drug," as defined in section 1927(k)(3) of the Act and in regulations at 42 CFR § 447.502.

will continue to work with the contractor to confirm that the DRAMS is properly identifying drug rebate eligibility.

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

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed drug utilization data for both pharmacy¹⁷ and physician-administered drugs for Minnesota's MCOs from January 1 through December 31, 2016.

We identified MCO drug utilization data for pharmacy and physician-administered drugs that were billed for rebates and tested the rebates billed by selecting 4 manufacturers associated with 754 NDCs and reviewing the supporting documentation. We also identified MCO drug utilization data for pharmacy and physician-administered drugs that were not billed for rebates and determined which drugs were eligible or may have been eligible for rebates.

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

We performed fieldwork at the State agency's offices in St. Paul, Minnesota.

METHODOLOGY

To accomplish our objective, we:

- reviewed Federal laws, regulations, and guidance related to the Medicaid drug rebate program for both pharmacy and physician-administered drugs;
- reviewed State agency guidance to MCOs, including billing instructions for pharmacy and physician-administered drugs;
- interviewed State agency personnel to gain an understanding of the MCOs' roles and responsibilities for submitting drug utilization data to the State agency;
- interviewed State agency personnel to gain an understanding of the administration of and controls over the Medicaid billing and rebate process for pharmacy and physician-administered drugs;
- obtained listings of the CMS top-20 multiple-source physician-administered drugs and the CMS Medicaid Drug File for our audit period;
- obtained the list of 340B entities from the State agency;

¹⁷ We reviewed only February 2016 pharmacy drug utilization data.

- obtained from the State agency the drug utilization data for pharmacy and physician-administered drugs for the audit period;
- identified MCO drug utilization data for pharmacy and physician-administered drugs billed for rebates and tested the rebates by:
 - selecting 4 manufacturers associated with 754 NDCs invoiced in the first quarter of 2016 and
 - reviewing copies of rebate invoices submitted to the 4 manufacturers and the resultant remittances to verify the billing of rebates by NDC and receipt of rebates;
- excluded from our audit certain MCO drug utilization data for pharmacy and physician-administered drugs not eligible for rebates (including the drug encounters submitted by 340B entities);
- identified MCO drug utilization data for pharmacy and physician-administered drugs not billed for rebates and identified the drugs that were eligible or may have been eligible for rebates by:
 - matching the NDC on the drug encounter to the NDC on the CMS Medicaid Drug File,
 - identifying pharmacy drugs and single-source and top-20 multiple-source physician-administered drugs that were eligible for rebates, and
 - identifying other physician-administered drugs that may have been eligible for rebates;¹⁸
- calculated the amount of rebates that the State agency could have collected for pharmacy and physician-administered drugs with NDCs if it had billed these drugs for rebates;¹⁹
- identified physician-administered drugs with NDCs as single-source, top-20 multiple-source, or non-top-20 multiple-source by:

¹⁸ For drugs with NDCs identified, we were able to identify them as non-top-20 multiple-source drugs using the drugs' NDCs and HCPCS codes.

¹⁹ To calculate the amount of rebates due for a drug, we multiplied the number of drug units by the unit rebate amount for the NDC.

- matching the NDC on the drug encounter to the NDC on the CMS Medicaid Drug File to identify the drug category as either single-source or multiple-source and
- matching the HCPCS code on the drug encounter to the HCPCS code on CMS's top-20 multiple-source drug listing; and
- discussed the results of our audit with State agency officials.

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: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Vermont Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs</i>	<u>A-07-19-06086</u>	9/18/2020
<i>Maine Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs</i>	<u>A-07-18-06079</u>	9/14/2020
<i>Michigan Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-05-17-00017</u>	8/25/2020
<i>Alaska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-09-19-02001</u>	7/21/2020
<i>New York Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-02-18-01016</u>	4/7/2020
<i>New York Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-02-18-01011</u>	2/19/2020
<i>New Jersey Did Not Bill Manufacturers for Tens of Millions of Dollars in Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-02-16-01011</u>	8/30/2019
<i>Texas Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-06-17-04001</u>	8/21/2019
<i>Connecticut Claimed Unallowable Federal Reimbursement for Medicaid Physician-Administered Drugs That Were Not Invoiced to Manufacturers for Rebates</i>	<u>A-07-18-06078</u>	8/16/2019

Report Title	Report Number	Date Issued
<i>Illinois Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-18-00030</u>	6/18/2019
<i>New Jersey Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-02-16-01012</u>	5/9/2019
<i>Indiana Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-17-00038</u>	4/5/2019
<i>Arizona Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-16-02031</u>	2/16/2018
<i>Arkansas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-06-16-00018</u>	2/12/2018
<i>Nebraska Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-07-13-06046</u>	12/22/2017
<i>Texas Did Not Bill Manufacturers for Some Rebates for Pharmacy Drugs of Medicaid Managed-Care Organizations</i>	<u>A-06-16-00004</u>	12/12/2017
<i>Ohio Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-16-00013</u>	11/1/2017
<i>Hawaii Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-16-02029</u>	9/26/2017
<i>Washington State Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-16-02028</u>	9/26/2017

Report Title	Report Number	Date Issued
<i>Nevada Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-09-16-02027	9/12/2017
<i>Iowa Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs of Medicaid Managed-Care Organizations</i>	A-07-16-06065	5/5/2017
<i>Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-05-16-00014	3/23/2017
<i>Colorado Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-14-06050	1/5/2017
<i>Delaware Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-03-15-00202	12/30/2016
<i>Virginia Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-03-15-00201	12/22/2016
<i>California Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Some Medicaid Managed-Care Organizations</i>	A-09-15-02035	12/8/2016
<i>Kansas Correctly Invoiced Rebates to Manufacturers for Most Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-07-15-06060	8/18/2016
<i>Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-14-06057	5/26/2016
<i>Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-15-06063	3/31/2016

Report Title	Report Number	Date Issued
<i>South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-15-06059	2/9/2016
<i>Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	A-07-15-06062	1/14/2016
<i>North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	A-07-15-06058	1/13/2016
<i>California Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	A-09-14-02038	1/7/2016
<i>Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	A-07-14-06056	9/18/2015
<i>Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-14-06049	7/22/2015
<i>Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-06-12-00060	5/4/2015
<i>Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-14-06051	4/13/2015
<i>Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-09-13-02037	3/4/2015
<i>Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	A-06-14-00031	2/10/2015

Report Title	Report Number	Date Issued
<i>The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-03-12-00205	8/21/2014
<i>Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-13-06040	8/7/2014
<i>Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs</i>	A-09-12-02079	4/30/2014
<i>Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	A-09-12-02080	4/24/2014
<i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-03-12-00200	11/26/2013
<i>Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	A-06-12-00059	9/19/2013
<i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i>	A-06-10-00011	8/12/2011
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	OEI-03-09-00410	6/24/2011

APPENDIX C: FEDERAL AND STATE REQUIREMENTS RELATED TO MEDICAID DRUG REBATES

FEDERAL LAWS

Under the Medicaid program, States may provide coverage for outpatient drugs as an optional service (the Act § 1905(a)(12)). The Act provides for Federal financial participation (Federal share) in State expenditures for these drugs (§ 1903(a)).

The Medicaid drug rebate program, created by the Omnibus Budget Reconciliation Act of 1990 (which added section 1927 to the Act), became effective on January 1, 1991. A manufacturer 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)). Manufacturer rebates are essentially shared between the States and the Federal Government to offset the cost of prescription drugs (the Act § 1927(b)(1)(B)). 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 submit the utilization and coding data described in section 1927(a)(7) of the Act.

Section 1927(a)(7) of the Act requires States to provide for the collection and submission of such utilization data and coding (such as HCPCS codes and NDCs) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug 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 states that, effective January 1, 2007, the utilization data must be submitted using NDCs. 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 2501 of the ACA amended section 1927(b)(1)(A) of the Act to require that manufacturers pay rebates for covered outpatient drugs dispensed to individuals enrolled in an MCO if the MCO is responsible for coverage of such drugs. Section 2501 of the ACA also amended section 1927(b)(2)(A) to require that States submit information necessary to secure rebates from manufacturers for covered outpatient drugs dispensed through MCOs. In addition, section 2501 amended section 1903(m)(2)(A) to essentially extend the Medicaid rebate obligations to drugs dispensed through MCOs. Under this provision, payment is prohibited unless the MCO contracts provide that the Medicaid rebate obligations apply to drugs dispensed through MCOs and require the MCOs to submit to the State the drug utilization by NDCs for drugs dispensed to eligible individuals.

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 our 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).²⁰

STATE GUIDANCE

The contracts between the State agency and the MCOs require that the MCOs comply with all State and Federal laws and regulations and implement any necessary changes in policies and procedures as required by the State agency (MCO contracts, Article 12). The contract also states that MCOs participate in a quality assurance program that verifies timeliness, completeness, accuracy, and consistency of encounter data that is submitted to the State agency (MCO contracts, Article 3).

²⁰ On November 15, 2010, CMS amended 42 CFR § 447.502 to remove the definition of “multiple-source drug” (75 Fed. Reg. 69591, 69592).

APPENDIX D: STATE AGENCY COMMENTS



Minnesota Department of Human Services
Elmer L. Andersen Building
Commissioner Jodi Harpstead
Post Office Box 64998
St. Paul, Minnesota 55164-0998

September 17, 2020

Department of Health and Human Services
Office of Audit Services, Region V
Attn: Sheri L. Fulcher, Regional Inspector General for Audit Services
233 North Michigan Avenue, Suite 1360
Chicago, Illinois 60601

Dear Ms. Fulcher:

Thank you for providing an opportunity to comment on draft audit report A-05-17-00018 entitled *Minnesota Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations*. We recognize the importance of ongoing evaluation, review and quality improvement to ensure that Medicaid funds are used as efficiently as possible. To that end, this letter summarizes our efforts thus far, and further review being conducted.

I would like begin by expressing our appreciation for the collaborative and professional manner in which your staff conducted this audit. The federal Medicaid drug rebate program is extremely complicated, involves multiple information technology systems and federal regulatory agencies, and is constantly evolving based on changes to the federal law, regulations and guidance from the Centers for Medicare and Medicaid Services (CMS). The audit team operated independently, but thoroughly collaborated and engaged with our staff to understand the history and current state of the rebate program and ultimately identify issues that required modifications of our business practices.

The issues identified in this audit were primarily related to the fact that the Drug Rebate Administration and Management System (DRAMS) was excluding too many claims from the drug rebate process from providers that participate in the federal 340B program. This was due to differences in methods used to identify fee for service (FFS) and managed care organization (MCO) drug claims that should be excluded from the rebate process. This audit identified that the DRAMS is unable to accommodate two different methods for excluding 340B claims from the drug rebate process. As a result of this audit, the Department has aligned the 340B rebate exclusion policies for the FFS program to 340B exclusion policies applied to the MCO claims. This change occurred on July 1, 2019, and both programs now exclude 340B claims from the rebate process in the same manner.

In addition to aligning the FFS and MCO policies, the Department has also identified all claims that were incorrectly excluded from the rebate process and invoiced drug manufacturers for the drug rebates. This invoicing effort was not limited to claims from the audit time period and included any claims that were impacted as far back as 2010. These claims were included with the drug rebate invoices for the third calendar quarter of 2019.

We understand that operating an efficient rebate program is essential for ensuring our members retain access to pharmacy services through the Medical Assistance benefit. We are committed to working with your office and CMS to address all of the issues identified in this audit to ensure all Minnesotans have access to high quality healthcare.

Our responses to the specific recommendations are detailed below.

Recommendation #1. We recommend that the Minnesota Department of Human Services bill for and collect manufacturers' rebates for pharmacy drugs and for single-source and top-20 multiple-source physician-administered drugs that we calculated to be \$5,899,308 (Federal share) and refund the Federal Government.

Response to Recommendation #1: We agree with the recommendation. All of these claims were put through the rebate process and we will return the federal share of rebate payments we receive. We are also conducting an analysis of the claims that were subsequently excluded during the rebate process (e.g. drug claims that are zero paid and excluded because they are part of a bundled payment) to confirm that the re-exclusion was appropriate. If any of those claims are determined eligible for rebate, we will invoice the manufacturers and return the federal share of any rebate payments we receive.

Recommendation #2. We recommend that the Minnesota Department of Human Services work with CMS to determine whether the non-top-20 multiple-source physician-administered drugs were eligible for rebates that we calculated to be at least \$173,780 (Federal share) and, if so, upon receipt of the rebates, refund the Federal share of the rebates collected.

Response to Recommendation #2: We agree with the recommendation, however, the rebate program and DRAMS does not operate differently for drugs identified as top-20 vs. non-top-20 or single-source vs. multiple-source, so the process outlined in our response to #1 includes all drugs, not just top-20 or multiple-source. All of these claims were put through the rebate process and we will return the federal share of rebate payments we receive. We are also conducting an analysis of the claims that were subsequently excluded during the rebate process (e.g. drug claims that are zero paid and excluded because they are part of a bundled payment) to confirm that the re-exclusion was appropriate. If any of those claims are determined eligible for rebate, we will invoice the manufacturers and return the federal share of any rebate payments we receive.

Recommendation #3. We recommend that the Minnesota Department of Human Services work with CMS to ensure that all pharmacy and physician-administered drugs eligible for rebates after our audit period are processed for rebates.

Response to Recommendation #3: We agree with this recommendation. While the majority of claims that were incorrectly excluded have been put through the rebate process and invoiced to the manufacturers, the Department is also conducting an analysis of the claims that were subsequently excluded during the rebate process to confirm that the re-exclusion was appropriate. If any of those claims are determined eligible for rebate, we will invoice the manufacturers and return the federal share of any rebate payments we receive.

Recommendation #4. We recommend that the Minnesota Department of Human Services work with the contractor to confirm that DRAMS is properly identifying drug rebate eligibility to ensure that all rebate-eligible pharmacy and physician-administered drugs are identified and billed for rebates.

Response to Recommendation #4: We agree with this recommendation and will continue to work with the contractor to confirm that DRAMS is properly identifying drug rebate eligibility.

If you have any questions, comments or concerns about our response, please contact [REDACTED] Director of Internal Audits, at [REDACTED] or through e-mail at [REDACTED]

Sincerely,

/Jodi Harpstead/
Jodi Harpstead
Commissioner