

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MICHIGAN 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

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Report in Brief

Date: August 2020
Report No. A-05-17-00017

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 Michigan 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 Michigan'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. If the National Drug Code (NDC) was not listed on the drug encounter, we used a crosswalk to identify the NDC associated with each Healthcare Common Procedure Coding System (HCPCS) code listed. We calculated the rebate amount that Michigan could have collected for drugs with NDCs and the minimum rebate amount that Michigan could have collected for drugs without NDCs.

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

What OIG Found

Michigan did not fully comply with Federal Medicaid requirements for billing manufacturers for rebates for drugs dispensed to MCO enrollees. Michigan did not bill for and collect manufacturers' rebates that we calculated to be at least \$31.5 million (Federal share). Specifically, it did not bill for and collect manufacturers' rebates that we calculated to be at least (1) \$30 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) \$1.5 million (Federal share) for physician-administered drugs that may have been eligible for rebates that we set aside for CMS resolution. Michigan did not always bill for and collect manufacturers' rebates because Michigan and its contractor did not identify all of the rebate-eligible drugs in the utilization data submitted by the MCOs.

What OIG Recommends and Michigan Comments

We recommend that Michigan (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 at least \$30.0 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 and other physician-administered drugs without NDCs were eligible for rebates that we calculated to be at least \$1.5 million (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 improve the processes for determining drug rebate eligibility.

In written comments on our draft report, Michigan concurred with our first recommendation and said that it has billed manufacturers for rebates for claims related to the MCO pharmacy and physician-administered drugs identified in this report and has returned the Federal share to the Federal Government. In addition, Michigan described actions that it has taken or plans to take to address our remaining recommendations. We recognize the corrective actions Michigan has implemented or plans to implement to address our 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 Michigan Department of Health and 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

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.

to offset the cost of prescription drugs. CMS, the States, and drug manufacturers each have specific functions under the program.

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,

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.

adjustments, and rebates do not distinguish between amounts related to pharmacy drugs and amounts related to physician-administered drugs.

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.

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 April 6, 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).

The State Agency's Medicaid Drug Rebate Program

In Michigan, the State agency is responsible for billing and collecting Medicaid drug rebates for both pharmacy and physician-administered drugs. The State agency uses a contractor to manage its drug rebate program.⁹ Every quarter, the contractor bills manufacturers by NDC for rebates and reconciles the amounts billed with the manufacturers' payment collected by the State agency.

The State agency required providers dispensing outpatient drugs to MCO enrollees to report the NDC and its corresponding information for outpatient drugs on claims to the MCO. The MCO typically used 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 monthly 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 the fields necessary for rebate processing to the contractor, which uses the data to bill for drug rebates.

HOW WE CONDUCTED THIS AUDIT

We reviewed drug utilization data for both pharmacy and physician-administered drugs for Michigan's 11 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 486 NDCs and reviewing the supporting documentation.¹⁰ 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. However, for physician-administered drugs without NDCs identified, we calculated the minimum 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

⁹ Magellan Medicaid Administration was the State agency's contractor during the audit period.

¹⁰ 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 number of invoiced physician-administered drug claim lines, and the manufacturer with the most number of invoiced pharmacy drug claim lines in our audit period.

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 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 at least \$48,076,550 (\$31,491,236 Federal share)¹¹ 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 appropriately 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, statutes, regulations, and administrative procedures and implement any

¹¹ 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.

necessary changes in policies and procedures as required by the State agency. The contracts also state that MCOs must ensure that all encounter data are complete and accurate and must populate all fields required by the State agency, including, but not limited to, financial data for all encounters and fields required for billing manufacturers for rebates for drugs dispensed to MCO enrollees. On July 1, 2010, the State agency informed MCOs about the reporting requirements for the NDC and its corresponding information for outpatient drugs on (1) professional and institutional claim formats (used for physician-administered drugs) and (2) the pharmacy claim format.¹²

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 from manufacturers some 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 at least \$45,846,869 (\$30,031,147 Federal share). This amount consisted of:
 - \$14,260,192 (\$9,348,484 Federal share) for pharmacy drugs,
 - \$30,003,126 (\$19,645,316 Federal share) for single-source and top-20 multiple-source physician-administered drugs with NDCs, and
 - at least \$1,583,551 (\$1,037,347 Federal share) for single-source and top-20 multiple-source physician-administered drugs without NDCs.¹³
- For physician-administered drugs that may have been eligible for rebates, the State agency did not bill for and collect rebates that we calculated to be at least \$2,229,681 (\$1,460,089 Federal share). The amount that we set aside for CMS resolution consisted of:

¹² Michigan Department of Community Health Medical Services Administration Bulletin MSA 10-26 issued July 1, 2010. In 2015, Michigan Department of Health and Human Services, the current State agency, was created through a merger of the former Michigan Departments of Community Health and Human Services.

¹³ Even though these drugs did not have NDCs, we were able to identify single-source and top-20 multiple-source drugs by using the drugs' HCPCS codes.

- \$2,087,808 (\$1,367,105 Federal share) for non-top-20 multiple-source physician-administered drugs with NDCs¹⁴ and
- at least \$141,873 (\$92,984 Federal share) for physician-administered drugs without NDCs.¹⁵

In total, during our audit period the State agency did not bill for and collect manufacturers' rebates that we calculated to be at least \$48,076,550 (\$31,491,236 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 MCOs submitted drug utilization data, the State agency did not appropriately identify all of the rebate-eligible pharmacy and physician-administered drugs in the data. For example, for pharmacy drug encounters without a paid date, the State agency did not forward the encounters to the contractor even though the encounters were rebate-eligible when dispensed to MCO enrollees, regardless of when or whether the MCO paid for the drugs. The State agency also did not forward physician-administered drug utilization data that was missing certain fields, such as an Ambulatory Payment Classification code or NDC, to the contractor. The State agency's edits should have rejected and returned encounters with missing information to the MCO, but the edits were either ineffective or were bypassed, and the State agency accepted the drug encounters into its system. Because it accepted encounters with missing data fields, the State agency had trouble identifying the physician-administered drug encounters and did not always forward to the contractor the drug utilization data necessary for it to bill rebates.

Finally, the contractor did not use some of the drug utilization data that the State agency sent it to invoice the manufacturers even though the drugs were eligible for rebates. For example, the contractor did not invoice drug manufacturers for NDCs that were previously ineligible for Medicaid drug rebates because the drugs were withdrawn from the market, or expired but were re-introduced to the market and resumed Medicaid rebate eligibility before the drug encounter occurred.

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 is unclear. Accordingly, we set aside this amount for CMS resolution.

¹⁵ Because the drugs' HCPCS codes could not be used to determine whether the drugs were required to be billed for rebates, we set aside this amount for CMS resolution.

RECOMMENDATIONS

We recommend that the Michigan Department of Health and 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 at least \$30,031,147 (Federal share) and refund the Federal Government;
- work with CMS to determine whether the non-top-20 multiple-source physician-administered drugs and other physician-administered drugs without NDCs were eligible for rebates that we calculated to be at least \$1,460,089 (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
- improve the processes for determining drug rebate eligibility to ensure that all rebate-eligible pharmacy and physician-administered drugs contained in the drug utilization data submitted by the MCOs are identified and billed 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 and said that it has billed manufacturers for rebates for claims related to the MCO pharmacy and physician-administered drugs identified in this report and has returned the Federal share of rebates to the Federal Government.

In addition, the State agency described actions that it has taken or plans to take to address our remaining recommendations. The State agency commented that it will work with CMS to determine whether the drugs specified in the second recommendation were eligible for rebates and will submit those claims found eligible for rebate processing and return the Federal share as part of the standard process. Regarding our third recommendation, the State agency stated that it has submitted all historical claims dating back to 2010 that may have been excluded from rebates for the reasons identified during this audit. Regarding our last recommendation, the State agency described several changes it has made to rebate procedures and internal controls.

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

We recognize the corrective actions the State agency has implemented or plans to implement to address our recommendations. These corrective actions should improve the State agency's identification of rebate-eligible drugs in the utilization data submitted by the MCOs, and provide for the billing and collection of manufacturers' rebates for rebate-eligible drugs that the State agency did not previously identify.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed drug utilization data for both pharmacy and physician-administered drugs for Michigan'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 486 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 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 collection of Medicaid rebates for pharmacy and physician-administered drugs.

We performed fieldwork at the State agency's office in Lansing, Michigan.

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 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 lists of the CMS top-20 multiple-source physician-administered drugs, the Medicare Part B NDC-HCPCS crosswalk, and the CMS Medicaid Drug File for our audit period;

- obtained the list of 340B entities from the State agency;¹⁶
- 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 billed by:
 - selecting 4 manufacturers associated with 486 NDCs billed in the third 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,
 - matching the HCPCS code on the drug encounter without an NDC to the HCPCS code on CMS's Medicare Part B NDC-HCPCS crosswalk to identify, if possible, the NDC associated with each HCPCS code, and matching the associated NDC 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

¹⁶ 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 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.

- identifying other physician-administered drugs that may have been eligible for rebates;¹⁷
- obtained the Michigan Medicaid HCPCS-NDC crosswalk from the State agency;
- 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;¹⁸
- calculated the minimum amount of rebates that the State agency could have collected for physician-administered drugs without 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:
 - 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;
- used the HCPCS code to identify physician-administered drugs without NDCs as single-source or top-20 multiple-source by:
 - identifying the possible Michigan Medicaid NDCs associated with each HCPCS code and matching the associated NDC to the NDC on the CMS Medicaid Drug File to identify whether the drug category was single-source for all associated NDCs²⁰ and
 - matching the HCPCS code on the drug encounter to the HCPCS code on CMS's top-20 multiple-source drug listing; and

¹⁷ 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. For drugs without NDCs identified, we could not use the drugs' HCPCS codes to determine whether the drugs were required to be billed for rebates.

¹⁸ 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.

¹⁹ For each drug's HCPCS code, we multiplied the number of drug units by the unit rebate amount for each associated NDC to calculate the amounts of rebates due (each HCPCS code may have one or more NDCs). We summed the lowest amount of rebate due for each drug's HCPCS code, which yielded the minimum amount of rebates that the State agency could have collected.

²⁰ Some of the drugs' HCPCS codes could not be used to determine whether the drugs were required to be billed for rebates.

- 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>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
<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

Report Title	Report Number	Date Issued
<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
<i>Nevada Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-16-02027</u>	9/12/2017
<i>Iowa Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs of Medicaid Managed-Care Organizations</i>	<u>A-07-16-06065</u>	5/5/2017
<i>Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-16-00014</u>	3/23/2017

Report Title	Report Number	Date Issued
<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
<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

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>	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
<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

Report Title	Report Number	Date Issued
<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>	4/24/2014
<i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-03-12-00200</u>	11/26/2013
<i>Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<u>A-06-12-00059</u>	9/19/2013
<i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i>	<u>A-06-10-00011</u>	8/12/2011
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	<u>OEI-03-09-00410</u>	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 stated 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).²¹

STATE GUIDANCE

The contracts between the State agency and the MCOs require that the MCOs comply with all State and Federal laws, statutes, regulations, and administrative procedures and implement any necessary changes in policies and procedures as required by the State agency. The contract also states that MCOs must ensure that all encounter data is complete and accurate and must populate all fields required by the State agency, including, but not limited to, financial data for all encounters and fields required for the MCO pharmacy rebate.²² On July 1, 2010, the State agency informed MCOs about the reporting requirements for the NDC and its corresponding information for outpatient drugs on professional and institutional claim formats (used for physician-administered drugs) and pharmacy claim format.

²¹ On November 15, 2010, CMS amended 42 CFR § 447.502 to remove the definition of “multiple-source drug” (75 Fed. Reg. 69591, 69592).

²² MCO pharmacy rebate is the State agency’s terminology used to describe the rebates for covered outpatient drugs dispensed to MCO enrollees. The MCO pharmacy rebate is not limited to rebates for pharmacy drugs but includes rebates for physician-administered drugs.

APPENDIX D: STATE AGENCY COMMENTS



GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF HEALTH AND HUMAN SERVICES
LANSING

ROBERT GORDON
DIRECTOR

July 28, 2020

Ms. Sheri L. Fulcher
Regional Inspector General for Audit Services
Department of Health and Human Services
Office of Audit Services
233 North Michigan, Suite 1360
Chicago, IL 60601

Re: Report Number A-05-17-00017

Dear Ms. Fulcher:

Enclosed is the Michigan Department of Health and Human Services response to the draft report entitled "Michigan Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations" that covered the period of January 1, 2016 to December 31, 2016.

We appreciate the opportunity to review and comment on the report before it is released. If you have any questions regarding this response, please refer them to [REDACTED] at [REDACTED] or [REDACTED].

Sincerely,

/Robert Gordon/

Robert Gordon

RG:wb

Attachment

**Michigan's Billing of Manufacturers for Some Rebates for Drugs Dispensed
Through
Medicaid Managed-Care Organizations
(A-05-17-00017)**

Finding:

Michigan did not fully comply with Federal Medicaid requirements for billing manufacturers for rebates for drugs dispensed to Managed Care Organizations (MCO) enrollees. Michigan did not bill for and collect manufacturers' rebates that we calculated to be at least \$31.5 million (Federal share). Specifically, it did not bill for and collect manufacturers' rebates that we calculated to be at least (1) \$30 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) \$1.5 million (Federal share) for physician-administered drugs that may have been eligible for rebates that we set aside for Centers for Medicare and Medicaid (CMS) resolution. Michigan did not always bill for and collect manufacturers' rebates because Michigan and its contractor did not identify all of the rebate-eligible drugs in the utilization data submitted by the MCOs.

Recommendations:

We recommend that Michigan:

- (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 at least \$30.0 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 and other physician-administered drugs without National Drug Codes (NDC) were eligible for rebates that we calculated to be at least \$1.5 million (Federal share) and, if so, upon receipt of the rebates, refund the Federal share.
- (3) We also make a recommendation related to pharmacy and physician-administered drugs that were not billed for rebates after our audit period and
- (4) a procedural recommendation to improve the processes for determining drug rebate eligibility.

**Michigan's Billing of Manufacturers for Some Rebates for Drugs Dispensed
Through
Medicaid Managed-Care Organizations
(A-05-17-00017)**

Michigan Department of Health and Human Services (MDHHS) Response:

The Department:

- (1) concurs with this recommendation and has since submitted these claims for rebates and returned the Federal share to the Federal Government.
 - a. In 2018 quarter two, the Department billed manufacturers \$14,351,881.22 for 2016 claims related to the MCO pharmacy drugs identified in this report.
 - b. In 2019 quarter two, the Department billed manufacturers \$31,575,092.92 for 2016 claims related to the MCO physician-administered drugs identified in this report.
- (2) will work with CMS to determine whether non-top-20 multiple-source physician-administered drugs and other drugs without NDCs were eligible for rebates. If it is found that the claims are eligible for rebate, they will be submitted for rebate processing and return the Federal share as part of the standard process.
- (3) has submitted all historical claims (dating back to 2010) that may have been excluded from rebates for the reasons identified during this audit.
- (4) has made the following changes to rebate procedures and internal controls:
 - a. MCO pharmacy claim extracts were modified to include claims with zero paid amounts, null paid dates, and eligible claims from integrated care organizations.
 - b. MCO medical claim extracts were modified to include all institutional and professional claims for eligible drug products. Previously there was a defect in the extract logic which excluded professional claims from being sent for rebate.
 - c. The Department's rebate contractor has implemented controls to verify/validate all NDC/Labeler exclusions and monitor quarterly.
 - d. The Department has implemented internal controls to ensure that MCO claim extracts/loads are completed as expected.
 - e. The Department changed edits in the Medicaid Management Information System (MMIS) to reject MCO claims that do not have NDCs when NDCs are required.

Additional Details:

Integrated Care Organization (ICO) Claims

Prior to the audit, MDHHS was operating under the assumption that ICO claims were not rebate eligible. After receiving clarification from Health and Human Services/Centers for Medicare and Medicaid (HHS/CMS), rebate eligible ICO claims were sent for rebate and subsequently invoiced. All eligible claims from before/after the audit period were also sent for rebate as a part of this correction.

**Michigan's Billing of Manufacturers for Some Rebates for Drugs Dispensed
Through
Medicaid Managed-Care Organizations
(A-05-17-00017)**

Null Paid Date Claims

Prior to this audit, MDHHS was using paid date to determine which quarter the MCO claims should be invoiced in. Due to this, claims with null paid dates were excluded from rebate invoicing. After receiving clarification from HHS/CMS, the MCO rebate logic was changed to use date of service instead of date of payment. All claims with null paid dates (including those before/after the audit period) were sent for invoicing.

Zero Paid Amounts

Consistent with the Fee-For-Service Medicaid rebate program, the MCO Federal Rebate program was initially operationalized to exclude claims with zero paid amounts from rebate invoicing. After receiving clarification from HHS/CMS stating that MCO claims with zero paid amounts were rebate eligible due to capitation payments, the MCO rebate logic was modified. All claims with zero paid amounts (including those before/after the audit period) have since been included in the MCO Federal Medicaid rebate invoicing processes.

Claims without NDCs

Due to the incorrect assumption that claims with zero paid amounts were not eligible for MCO Federal Medicaid rebate invoicing, there was a bypass in the MMIS system initially which allowed MCO encounters without NDCs when the paid amount was zero. After receiving the clarification that claims with a zero paid amount were rebate eligible, MDHHS removed the NDC edit bypass and started rejecting for missing NDCs. The Department continues to research these claims to determine whether they were rebate eligible. If rebate eligible, all such claims (including those before and after the audit period) will be sent for rebate invoicing.

Professional Claims

A defect was discovered in the MCO medical claims extract that began unknowingly excluding professional outpatient drug claims from being sent for rebate invoicing during the audit period. After identifying the defect, all affected claims were sent for rebate invoicing as prior period adjustments.

Excluded NDCs/Labelers

The Department's rebate contractor was using a manual process to exclude non-participating manufacturers. Due to this manual process certain NDCs were added to the exclusion list and never removed, even when a labeler was reinstated. The contractor is currently working to implement an automated process to ensure NDCs will be added and removed from the exclusion list at the same time they are added/terminated from the Medicaid Drug Rebate Program.

**Michigan's Billing of Manufacturers for Some Rebates for Drugs Dispensed
Through
Medicaid Managed-Care Organizations
(A-05-17-00017)**

Until the automated process is implemented the contractor will audit the NDC exclusion list on a quarterly basis to ensure that all rebate eligible NDCs are invoiced. The Department has also implemented internal controls to monitor all exclusion reasons. All of the incorrectly excluded claims have now been invoiced (including claims from before/after the audit period). In accordance with and as part of standard operations and reporting, the Federal share along with any rebate offset amounts of rebate revenue paid to the State has been or shall continue to be refunded.