

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**TENNESSEE DID NOT ALWAYS
INVOICE REBATES TO
MANUFACTURERS FOR PHYSICIAN-
ADMINISTERED DRUGS DISPENSED
TO ENROLLEES OF MEDICAID
MANAGED-CARE ORGANIZATIONS**

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Office of Inspector General

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Report in Brief

Date: September 2022

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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. However, prior OIG audits found that States did not always invoice and collect all rebates due for drugs administered to Medicaid managed-care organizations' (MCOs') enrollees.

Our objective was to determine whether Tennessee complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs dispensed to MCO enrollees.

How OIG Did This Audit

We reviewed physician-administered drug claims totaling \$359.9 million that were paid by the MCOs between January 1, 2016, and December 31, 2019 (audit period).

We removed the physician-administered drug claims that were not eligible for rebate as part of the drug rebate program and worked with Tennessee to calculate the amounts of rebates that were associated with the remaining drugs and that were not invoiced.

Tennessee Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations

What OIG Found

Tennessee did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs dispensed to MCO enrollees. Tennessee did not invoice for, and collect from manufacturers, rebates totaling \$18.4 million (\$12.0 million Federal share) for physician-administered drugs dispensed to MCO enrollees. Of this amount, \$16.8 million (\$11.0 million Federal share) was for single-source and top-20 multiple-source drugs that were required to be rebated, and \$1.6 million (\$1.0 million Federal share) was for other multiple-source drugs that were eligible for rebates. In addition, Tennessee did not invoice for, and collect from manufacturers, \$43.3 million (\$28.4 million Federal share) in rebates for physician-administered drugs invoiced on crossover claims, for which beneficiaries are eligible for both Medicare and Medicaid services.

Although its policies required the collection of drug utilization data necessary to invoice for rebates on all claims, Tennessee's internal controls did not always ensure that the data were used to invoice manufacturers and collect rebates for physician-administered drugs dispensed to enrollees of MCOs.

What OIG Recommends and Tennessee Comments

We recommend that Tennessee: (1) invoice for and collect manufacturers' rebates and refund to the Federal Government \$11.0 million (Federal share) for single-source and top-20 multiple-source drugs; (2) work with the Centers for Medicare & Medicaid Services to determine the portion of the \$1.0 million (Federal share) for other multiple-source drugs that were eligible for rebate, invoice manufacturers, and refund the Federal share; (3) strengthen internal controls for non-crossover claims to ensure that all eligible physician-administered drugs are invoiced for rebate; and (4) consider revising its methodology going forward regarding payments for crossover claims.

Tennessee generally concurred with our first three recommendations and described corrective actions. Tennessee said that it had already invoiced manufacturers for over \$18.1 million and disputed \$334,425 in claims. We agreed with Tennessee, removed these claims from our findings, and adjusted the amount in our first two recommendations. Tennessee did not concur with our fourth recommendation, but said that it would consider our recommendation if it adjusts its crossover claim methodology in the future.

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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 for the drugs. States generally offset their Federal share of these rebates against their Medicaid expenditures. States invoice the manufacturers for rebates to reduce the cost of drugs to the program. However, prior Office of Inspector General (OIG) audits found that States did not always invoice and collect all rebates due for drugs administered to Medicaid managed-care organizations' (MCOs') enrollees. (Appendix B lists previous OIG audits and reviews of the Medicaid drug rebate program.¹) For this audit, we reviewed the Tennessee Department of Finance & Administration's (State agency's) invoicing for rebates for physician-administered drugs dispensed to MCO enrollees for the period January 1, 2016, through December 31, 2019.

OBJECTIVE

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

BACKGROUND

Medicaid Drug Rebate Program

The Medicaid drug rebate program became effective in 1991 (the Social Security Act (the Act) § 1927). For a covered outpatient drug to be eligible for Federal reimbursement under the program, the drug's manufacturer must enter into a rebate agreement that is administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each have specific functions under the program.

Manufacturers are required to submit a list to CMS of all covered outpatient drugs and to report each drug's average manufacturer price and, where applicable, best price.² On the basis of this information, CMS calculates a unit rebate amount for each drug and provides the information to the States each quarter. Covered outpatient drugs reported by participating drug manufacturers are listed in the CMS Medicaid Drug File, which identifies drugs with such fields as National Drug Code (NDC), unit type, units per package size, and product name.

Section 1903(i)(10) of the Act prohibits Federal reimbursement for States that do not capture the information necessary for invoicing manufacturers for rebates as described in section

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

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

1927(a)(7) of the Act. To invoice for rebates, States capture drug utilization data that identifies, by NDC, the number of units of each drug for which the States reimbursed Medicaid providers and report the information to the manufacturers (the Act § 1927(b)(2)(A)). The number of units is multiplied by the unit rebate amount to determine the actual rebate amount due from each manufacturer.

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

States use two primary models to pay for Medicaid services: fee-for-service (FFS) and managed care. In the managed-care model, States contract with MCOs to provide specific services to enrolled Medicaid beneficiaries (enrollees), 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 received services during the relevant time period (42 CFR § 438.2). MCOs use the capitation payments to pay provider claims for these services. Physician-administered drugs may be covered by the capitation payments.

To claim Federal reimbursement, States report capitation payments made to MCOs as MCO expenditures on the Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program (CMS-64 report). These expenditures are not identified by specific type or service (such as physician-administered drugs). When States receive drug rebates from manufacturers, the States must report the rebates as decreasing adjustments on the CMS-64 report. States report drug rebate accounts receivable data on the Medicaid Drug Rebate Schedule (Form CMS-64.9R), which is part of the CMS-64 report. CMS reimburses States for the Federal share of Medicaid expenditures reported on the CMS-64 report.

States' Collection of Rebates for Physician-Administered Drugs

Drugs administered by a physician are typically invoiced to the Medicaid program on a claim form using Healthcare Common Procedure Coding System (HCPCS) codes.³ 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 to 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.

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

³ HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies. The HCPCS codes associated with physician-administered drugs generally begin with a "J" and are referred to as J-Codes. These physician-administered drugs include injectable drugs that ordinarily cannot be self-administered, such as chemotherapy drugs, immunosuppressive drugs, and inhalation solutions.

multiple-source physician-administered drugs.⁴ 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).⁵ Multiple-source drugs are defined, in part, as those covered outpatient drugs that have at least one other drug rated as therapeutically equivalent by the FDA.⁶ 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 Affordable Care Act (ACA) required manufacturers to pay rebates on covered outpatient drugs dispensed to MCO enrollees if the MCOs are responsible for coverage of such drugs.⁷ Before the enactment of the ACA, drugs dispensed by Medicaid MCOs were excluded from the rebate requirements. States typically require MCOs to submit to the State agency NDCs for covered outpatient drugs dispensed to eligible individuals. MCOs submit to the State agency provider claim information, including claim lines for covered outpatient drugs. This information contains drug utilization data, which States must include when invoicing manufacturers for rebates.

The State Agency's Medicaid Drug Rebate Program

The State agency (which the State refers to as TennCare) is responsible for invoicing and collecting Medicaid drug rebates for physician-administered drugs. The State agency is required to submit drug utilization data to manufacturers, detailing drug usage by Medicaid beneficiaries, within 60 days of the end of each quarter.⁸ During our audit period, the State agency contracted with a pharmacy benefit manager (PBM) to handle the claims data.⁹ The PBM processed, invoiced, and collected Federal rebates through its rebate administration system, and assumed all responsibility for uncollected receivables. The PBM was also responsible for payment tracking and reconciliation as well as resolving disputes related to

⁴ 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)).

⁵ Section 1927(k)(7) of the Act. Single-source drugs are commonly referred to as “brand-name” drugs.

⁶ Section 1927(k)(7) of the Act. According to the definition of “therapeutically equivalent” in the FDA glossary of terms, a therapeutically equivalent drug product can be substituted for another product to achieve the same clinical effect as the prescribed drug.

⁷ 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. 23, 2010).

⁸ TennCare is Tennessee’s Medicaid program in which all Medicaid beneficiaries are enrolled in an MCO under a section 1115 waiver from CMS. However, certain physician-administered drugs for Medicaid beneficiaries are paid through FFS while others are paid by MCOs.

⁹ During our audit period, the State agency had two different pharmacy benefit managers: Magellan Medicaid Administration, Inc., initially and Optum Rx through a subsequent contract.

Federal rebates. The PBM housed historic quarterly rebate data in its rebate management system.

HOW WE CONDUCTED THIS AUDIT

We reviewed physician-administered drug claims totaling \$359,910,890 that were paid by the MCOs between January 1, 2016, and December 31, 2019 (audit period).

We used the quarterly CMS Medicaid Drug Rebate files and the Medicaid Drug Product files to determine whether the NDCs listed on the claims were classified as single-source drugs or multiple-source drugs. For claims submitted without an NDC, we matched the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk to identify the drug classification.¹⁰ Additionally, we determined whether the HCPCS codes were published in CMS's top-20 multiple-source drug list.

We removed claims for drugs that either were not eligible for rebates or were invoiced for rebates. For the remaining claims, we worked with the State agency to calculate the amounts of rebates that were not invoiced.

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 A contains the details of our audit scope and methodology.

FINDINGS

During our audit period, the State agency did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs dispensed to MCO enrollees. The State agency did not invoice for, and collect from manufacturers, rebates totaling \$18.4 million (\$12.0 million Federal share) for physician-

¹⁰ The Medicare Part B crosswalk is published quarterly by CMS and is based on drug and biological information submitted to CMS by manufacturers. CMS uses this information along with pricing data submitted by manufacturers to calculate a volume-weighted sales price for each HCPCS code, which becomes the basis for the reimbursement rate the State pays to providers for the following quarter. CMS instructed States that they could use the crosswalk as a reference because HCPCS codes and NDCs are standardized codes used across health care programs (State Medicaid Director Letter No. 06-016 (Jul. 11, 2006)). If the claim did not include the NDC, we used the Part B crosswalk to identify drug classifications for all the NDCs that map to the HCPCS code from the claim. Then we used the most conservative drug classification. For example, if a HCPCS code had NDCs with drug classifications of single-source and multiple-source, we categorized the claim as multiple-source.

administered drugs dispensed to MCO enrollees.¹¹ Of this amount, \$16.8 million (\$11.0 million Federal share) was for drugs that were required to be rebated.¹² In addition, the State agency did not invoice for rebates associated with \$1.6 million (\$1.0 million Federal share) in other multiple-source physician-administered drugs that were eligible for rebates.¹³

In addition, the State agency did not invoice for, and collect from manufacturers, \$43.3 million (\$28.4 million Federal share) in rebates for physician-administered drugs invoiced on crossover claims, for which beneficiaries are eligible for both Medicare and Medicaid services.¹⁴

Although its policies required the collection of drug utilization data necessary to invoice for rebates on all claims, the State agency's internal controls did not always ensure that the data were used to invoice manufacturers and collect rebates for physician-administered drugs dispensed to enrollees of MCOs.

FEDERAL 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)). To secure rebates, States are required to report certain information to manufacturers within 60 days after the end of each rebate period (the Act § 1927(b)(2)(A)). Federal regulations prohibit Federal reimbursement for physician-administered drugs for which a State has not required the submission of claims containing 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 invoice for rebates, States must include information for drugs dispensed to individuals enrolled in MCOs when invoicing 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

¹¹ Specifically, the State agency did not invoice manufacturers for rebates associated with drug expenditures that totaled \$18,382,022 (\$12,028,933 Federal share).

¹² Specifically, the State agency did not invoice manufacturers for rebates associated with drug expenditures that totaled \$16,805,782 (\$10,996,932 Federal share). This amount consisted of \$16,151,819 (\$10,569,221 Federal share) for single-source drugs and \$653,963 (\$427,711 Federal share) for top-20 multiple-source drugs.

¹³ Specifically, the State agency did not invoice manufacturers for rebates associated with drug expenditures that totaled \$1,576,240 (\$1,032,002 Federal share) for other multiple-source drugs.

¹⁴ Specifically, the State agency did not invoice manufacturers for rebates totaling \$43,280,999 (\$28,351,111 Federal share) for physician-administered drugs invoiced on crossover claims.

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)).

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

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES FOR PHYSICIAN-ADMINISTERED DRUGS DISPENSED TO ENROLLEES OF MEDICAID MANAGED-CARE ORGANIZATIONS

The State agency did not invoice for, and collect from manufacturers, rebates totaling \$18.4 million (\$12.0 million Federal share) for physician-administered drugs dispensed to MCO enrollees. Of this amount:

- \$16.8 million (\$11.0 million Federal share) was for drugs that were required to be rebated. Specifically, \$16.1 million (\$10.6 million Federal share) was for single-source drugs and \$654,000 (\$428,000 Federal share) was for top-20 multiple-source drugs. The State agency was required to rebate for single-source and top-20 multiple-source physician-administered drugs.
- \$1.6 million (\$1.0 million Federal share) was for other multiple-source drugs, which, although not *required* to be rebated like single-source and top-20 multiple-source drugs, were *eligible* for rebates. The State agency generally possessed sufficient information (such as NDCs) to invoice the manufactures for rebates for these drugs. If the State agency had invoiced these claims for rebate, the drug manufacturers would have been required to pay the rebates. Because there is no Federal requirement to invoice these claims for rebate, we are setting aside this amount for CMS resolution.

Although its policies require the collection of drug utilization data necessary to invoice for rebates on all claims, the State agency's internal controls did not always ensure that the data were used to invoice manufacturers and collect rebates for physician-administered drugs that were dispensed to enrollees of MCOs and that did not involve crossover claims.

While we were conducting our audit work (and after the December 31, 2019, close of our audit period), the State agency invoiced manufacturers for \$18.1 million (\$11.9 million Federal share) of the \$18.7 million in rebates discussed above. Of the \$18.1 million that the State agency invoiced to manufacturers, \$16.6 million (\$10.9 million Federal share) was for single-source and top-20 multiple-source drugs, and \$1.5 million (\$1.0 million Federal share) was for other multiple-source drugs.¹⁵

¹⁵ Specifically, the State agency invoiced manufacturers for \$18,139,391 (\$11,870,931 Federal share) while we were conducting our audit work. Of this amount, \$16,577,877 (\$10,848,521) was for single-source and top-20 multiple-source drugs, and \$1,561,514 (\$1,022,410 Federal share) was for other multiple-source drugs.

THE STATE AGENCY HAS AN OPPORTUNITY TO IMPROVE ITS PAYMENT METHODOLOGY FOR CROSSOVER CLAIMS TO OBTAIN REBATES FOR PHYSICIAN-ADMINISTERED DRUGS DISPENSED TO ENROLLEES OF MEDICAID MANAGED-CARE ORGANIZATIONS

The State agency did not invoice for, and collect from manufacturers, \$43.3 million (\$28.4 million Federal share) in rebates for physician-administered drugs invoiced on crossover claims. The term “crossover claims” refers to Medicaid claims for Federal reimbursement that involve beneficiaries who are eligible for both Medicare and Medicaid services (also known as “dual-eligible” beneficiaries). For crossover claims, health care providers invoice Medicare, which calculates its payment first and then submits an invoice containing any applicable coinsurance or deductible amounts to the State agency. After receiving crossover claims data from Medicare, the State agency calculates the payment it will make to the provider. However, the State agency has a payment methodology that resulted in it not paying any portion of the amount not covered by Medicare on any crossover claims during our audit period.

For example, an Eculizumab injection, along with other services, was administered to a dual-eligible beneficiary on July 12, 2016.¹⁶ For this claim, the provider submitted a claim to Medicare for reimbursement. Medicare paid \$49,250 for the claim and then submitted a claim to the State agency for \$2,576. The State agency calculated its share of the claim and determined that it would not pay any portion of the amount not covered by Medicare. However, if the State agency’s payment methodology had allowed a payment of even a nominal amount, the State agency could have collected \$16,889 (\$10,971 Federal share) for this claim.

In conformance to its payment methodology, the State agency does not pay for these crossover claims, which resulted in the State agency forgoing rebates for physician-administered drugs. We acknowledge that, according to the Act,¹⁷ the State agency was not required to make a payment on these crossover claims; however, we believe the State agency has an opportunity to improve its administration of the Medicaid drug rebate program insofar as crossover claims are concerned. If the payment methodology would have required the State agency to pay an amount on the cost-sharing of these crossover claims, the State agency could have invoiced for additional rebates totaling \$43.3 million (\$28.4 million Federal share) during our audit period.

¹⁶ Eculizumab is a monoclonal antibody used to treat a blood disorder that afflicts approximately 8,000 Americans each year.

¹⁷ “[A] State is not required to provide . . . payment for deductibles, coinsurance, or copayments for [M]edicare cost-sharing to the extent that payment . . . for the service would exceed the payment amount that otherwise would be made under the State plan . . . for such service” (the Act § 1902(n)(2)).

RECOMMENDATIONS

We recommend that the Tennessee Department of Finance & Administration:

- invoice for and collect manufacturers' rebates totaling \$16,805,782 (\$10,996,932 Federal share) for single-source and top-20 multiple-source physician-administered drugs and refund the Federal share of rebates collected;
- work with CMS to determine the portion of the \$1,032,002 (Federal share) for other multiple-source physician-administered drugs that were eligible for rebate, invoice the manufacturers for rebates for these drugs, and refund the Federal share;¹⁸
- strengthen internal controls for non-crossover claims to ensure that all eligible physician-administered drugs are invoiced for rebate in a timely manner; and
- consider revising its payment methodology going forward regarding payments for crossover claims, thereby to allow collection of manufacturers' rebates for associated physician-administered drugs.

STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the State agency generally concurred with our first three recommendations and described the actions it had taken or planned to take to address them. The State agency said that before we initiated this audit, it was already aware of the issues involving physician-administered drugs and was "working with its contractors to ensure that eligible rebates were appropriately invoiced and collected." In this regard, the State agency referred to language in our report (tied to our footnote 15) that it had already invoiced manufacturers for over \$18.1 million of the rebates that our draft report identified. "Outstanding rebates are expected to be invoiced to manufacturers in August 2022."

Additionally, although the State agency concurred with our first three recommendations, it disputed, and sent us detailed support for, \$334,425 in claims that, according to the State agency, should not have been included in our findings because they either were crossover claims or were submitted for 340B entities (footnote 20 in Appendix A).

With respect to our third recommendation, the State agency said that it "had already remedied this issue before the onset of the audit." Specifically, the State agency stated that in 2019 it

¹⁸ Of the combined \$12,028,933 (Federal share) (i.e., \$10,996,932 + \$1,032,002) referenced in the first two recommendations, the State agency invoiced drug manufacturers for rebates totaling \$11,870,931 (Federal share) while we were conducting our audit work (and after the December 31, 2019, close of our audit period). Of this combined amount that was invoiced to manufacturers while we were conducting our audit work, \$10,848,521 was for single-source and top-20 multiple-source drugs (first recommendation) and \$1,022,410 was for other multiple-source drugs (second recommendation).

competitively bid a new PBM contract that included rebate administration services and that also ensured that the new PBM would invoice outstanding historical claims.

The State agency did not concur with our fourth recommendation, noting that we did not identify a Federal requirement upon which to base this recommendation. The State agency also stated that adjusting its payment methodology to make crossover claims eligible for rebate could result in additional costs and might have further “policy implications on crossover claims as a whole.” Having said this, the State agency added that it would consider our recommendation if it adjusts its crossover claim payment methodology in the future.

The State agency’s comments appear in their entirety as Appendix D.

After reviewing the State agency’s comments, we revised our findings and adjusted the amounts conveyed in our first two recommendations. Specifically, after reviewing the State agency’s comments and evaluating the additional detailed support that it gave us regarding the claims for 340B entities, we revised our findings.¹⁹ As our report says and as the State agency mentioned in its written comments, the State agency invoiced manufacturers for \$18.1 million of the \$18.4 million that we identified; however, these claims were not billed until after the start of our fieldwork (footnote 15). We maintain that our findings and recommendations, as revised, are valid.

Regarding our fourth recommendation, we acknowledge that the State agency was not required to make a payment on these crossover claims and, because it did not make a payment on these claims, they were not eligible for rebate. However, we continue to believe that the State agency has an opportunity to improve its administration of the Medicaid drug rebate program insofar as crossover claims are concerned, and that it would be financially prudent to examine the costs and benefits of revising its payment methodology to secure additional rebates.

¹⁹ Although the State agency’s comments that said it disputed \$334,425 in claims, the State agency provided claims detailing \$334,455, which we used to adjust the amounts in the report.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed physician-administered drug claims that were paid by the MCOs between January 1, 2016, and December 31, 2019 (audit period). During our audit period, MCOs paid \$359,910,890 associated with physician-administered drugs dispensed to MCO enrollees.

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 procedures for and controls over invoicing for Medicaid rebates for physician-administered drugs.

We conducted our audit work, which included contacting the State agency in Nashville, Tennessee, from January 2021 to June 2022.

METHODOLOGY

To accomplish our objective, we took the following steps:

- We reviewed applicable Federal laws, regulations, and guidance pertaining to the Medicaid drug rebate program and physician-administered drugs.
- We reviewed State agency policies and procedures for rebates for physician-administered drugs.
- We interviewed State agency personnel to gain an understanding of the administration of and controls over the Medicaid rebate invoicing process for physician-administered drugs.
- We obtained lists of the CMS top-20 multiple-source physician-administered drugs, the Medicare Part B crosswalk (footnote 10), the CMS Medicaid Drug Rebate File, and the CMS Medicaid Drug Product File for our audit period.
- We obtained a list of 340B entities from the State agency.²⁰
- We obtained from the State agency a detailed list of physician-administered drug claims paid between January 1, 2016, through December 31, 2019. In response to this request,

²⁰ Under the 340B drug pricing program (set forth in 42 U.S.C. § 256b), a 340B entity may purchase reduced-price covered outpatient drugs from manufacturers; examples of 340B entities are disproportionate share hospitals, which generally serve large numbers of low-income and/or uninsured patients, and State AIDS drug assistance programs. Drugs subject to discounts under the 340B drug pricing program are not subject to rebates under the Medicaid drug rebate program. Section 1927(j) of the Act and 42 U.S.C. § 256(a)(5)(A).

the State agency provided data associated with claims totaling \$359,910,890. Specifically, we took the following steps:

- We identified single-source drugs based on the classification of the drugs in the quarterly CMS Medicaid Drug Rebate File and the CMS Medicaid Drug Product File. If the claims data did not include an NDC, we matched the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk to identify all of the NDCs associated with each HCPCS code. Because in each of these cases the NDC was unknown, we used the most conservative drug classification for the NDCs associated with the HCPCS code (footnote 10).
- We identified the top-20 multiple-source drugs by matching the HCPCS code on the drug claim to the HCPCS code on CMS's top-20 multiple-source drug list.
- We identified other multiple-source drugs eligible for rebate that were not single-source or top-20 multiple-source drugs.
- We followed up with State agency officials for an explanation of eligible claims that had not been invoiced for rebate.
- We worked with the State agency to determine the dollar amount of rebates not collected.
- We discussed the results of our audit with State agency officials on April 4, 2022.

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>South Carolina Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs</i>	<u>A-07-21-07003</u>	8/10/2022
<i>Colorado Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-07-17-06075</u>	9/8/2021
<i>New Mexico Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-06-16-00001</u>	6/2/2021
<i>Massachusetts Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-06-18-04001</u>	10/22/2020
<i>Minnesota Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-05-17-00018</u>	10/21/2020
<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

Report Title	Report Number	Date Issued
<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
<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>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>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>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

Report Title	Report Number	Date Issued
<i>Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-16-00014</u>	3/23/2017
<i>Colorado Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06050</u>	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>	<u>A-03-15-00202</u>	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>	<u>A-03-15-00201</u>	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>	<u>A-09-15-02035</u>	12/8/2016
<i>Kansas Correctly Invoiced Rebates to Manufacturers for Most Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-07-15-06060</u>	8/18/2016
<i>Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06057</u>	5/26/2016
<i>Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06063</u>	3/31/2016
<i>South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06059</u>	2/9/2016
<i>Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06062</u>	1/14/2016
<i>North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06058</u>	1/13/2016
<i>California Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	<u>A-09-14-02038</u>	1/7/2016
<i>Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06056</u>	9/18/2015

Report Title	Report Number	Date Issued
<i>Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06049</u>	7/22/2015
<i>Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-06-12-00060</u>	5/4/2015
<i>Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06051</u>	4/13/2015
<i>Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-13-02037</u>	3/4/2015
<i>Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<u>A-06-14-00031</u>	2/10/2015
<i>The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-03-12-00205</u>	8/21/2014
<i>Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-13-06040</u>	8/7/2014
<i>Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs</i>	<u>A-09-12-02079</u>	4/30/2014
<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 REQUIREMENTS AND STATE AGENCY GUIDANCE RELATED TO PHYSICIAN-ADMINISTERED DRUGS

FEDERAL LAWS

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

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

Section 1927(a)(7) of the Act requires that States shall provide for the collection and submission of such utilization data and coding for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates for all single-source physician-administered drugs effective January 1, 2006, and for the top 20 multiple-source drugs effective January 1, 2008.²¹ Section 1927(a)(7)(C) of the Act stated that, effective January 1, 2007, the utilization data must be submitted using the NDC. To secure rebates, States are required to report certain information to manufacturers within 60 days after the end of each rebate period (the Act § 1927(b)(2)(A)).

Section 2501 of the ACA amended section 1927(b)(1)(A) of the Act to require that manufacturers pay rebates on 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, each MCO contract must require that Medicaid rebates apply to drugs dispensed through the MCO. Section 2501

²¹ In general terms, multiple-source drugs are covered outpatient drugs for which there are two or more drug products that are rated therapeutically equivalent by the FDA. See, e.g., section 1927(k)(7) of the Act. Multiple-source drugs stand in contrast to single-source drugs, which do not have therapeutic equivalents. Further, 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)).

prohibits payment unless the MCO contracts require MCOs to submit to the State NDC drug utilization data for drugs dispensed to eligible individuals.

FEDERAL REGULATIONS AND GUIDANCE

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).

STATE AGENCY GUIDANCE

The purpose of the State agency's *TennCare Policy Manual* Number BTC-Pol-Enc-200701-001, dated September 7, 2012, is to clarify the State agency's position on the submission of encounters that must include the NDC for physician-administered drugs. Specifically, this policy states: "In conjunction with the DRA of 2005 and the ACA of 2010, TennCare requires all Physician Administered Drugs . . . to be reported using NDC codes in conjunction with Healthcare Common Procedure Coding System (HCPCS) codes (i.e. J Codes)."



Via Email

August 9, 2022

Dan Bittner
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Mr. Bittner –

The purpose of this letter is to provide the State of Tennessee’s management comments in response to HHS OIG’s recent audit of rebates for physician-administered drugs. Our comments are as follows:

OIG Recommendation #1 and #2:

- **Tennessee invoice for and collect manufacturers’ rebates totaling \$17,140,222 (\$11,215,118 Federal share) for single-source and top-20 multiple-source physician-administered drugs and refund the Federal share of rebates collected.**
- **Tennessee work with CMS to determine the portion of the \$1,032,011 (Federal share) for other multiple-source physician-administered drugs that were eligible for rebate, invoice the manufacturers for rebates for these drugs, and refund the Federal share.**

State Response:

The State concurs with these two recommendations. As discussed in the State’s response to recommendation #3 below, before OIG reached out to the State to initiate the audit, TennCare was already aware of the issue and working with its contractors to ensure that eligible rebates were appropriately invoiced and collected. As the OIG report explicitly acknowledges, TennCare had already invoiced manufacturers for \$18,139,391 million of the \$18,716,477 million in total rebates identified by OIG by the conclusion of this audit. This represents **96.9%** of the rebates identified by OIG. TennCare is currently working with its contracted Rebate Administrator to invoice and collect for the remaining rebates. Outstanding rebates are expected to be invoiced to manufacturers in August 2022.

However, TennCare does dispute OIG’s total amount of \$18,716,477 million in identified rebates. TennCare research has found \$334,424.76 in claims identified by OIG that either (1) were not rebate eligible because these claims were in fact crossover claims that were paid at zero or (2) were not rebate eligible as the claims were submitted by 340B registered entities. Thus, the total amount of eligible rebates should be \$18,382,052.24. The State can provide this additional claim information at the OIG’s convenience. Updating the above numbers based on this discrepancy, TennCare has already invoiced **98.7%** of eligible rebates for single source, top 20 multiple source drugs, and other multiple source drugs and begun collection for these rebates.

OIG Recommendation #3:

- **Tennessee strengthen internal controls for non-crossover claims to ensure that all eligible physician-administered drugs are invoiced for rebate in a timely manner; and**

State Response:

The State concurs with this recommendation; however, TennCare had already remedied this issue before the onset of the audit. In 2018, TennCare identified and began working to address enhanced rebate collection for physician-administered drugs. TennCare further permanently resolved this issue for future claims in 2019, over a year before OIG began work on this audit.

Specifically, beginning in 2018, TennCare attempted to work with its then Rebate Administrator to strengthen the source file mapping and validation necessary for the enhanced collection of rebates for physician-administered drugs. A contract dispute arose after TennCare sought to require this work and TennCare was ultimately unsuccessful in getting its Rebate Administrator to complete the project. Concurrently, in 2019 TennCare competitively bid a new PBM contract ("RFP") that included Rebate Administrator services. That RFP included updated language to ensure enhanced rebate collection for physician-administered drugs as well as an electronic rebate system of record that mapped according to all rebate eligible claims. This language also ensured outstanding historical claims would be invoiced by the new Rebate Administrator. Thus, while the State concurs with this recommendation, the issue was corrected prior to the audit and, as already noted in our comments, 98.7% of eligible historical rebates have since been invoiced to manufacturers.

OIG Recommendation #4:

- **Tennessee consider revising the payment methodology going forward regarding payments for crossover claims, thereby to allow collection of manufacturers' rebates for associated physician-administered drugs.**

State Response:

The State does not concur with this recommendation. OIG made no findings of noncompliance in this area and further failed to identify a federal requirement upon which to base this recommendation. While the State appreciates OIG's suggestion to revise the payment methodology for crossover claims, this cannot be done in a vacuum. OIG has identified \$43.3 million in rebates that could have been collected with a different methodology specific to physician-administered drugs; however, doing so would require revising the State's payment methodology upward, which could result in additional costs to the State as well as federal government. In addition, the State would have to consider the policy implications on crossover claims as a whole should it revise the payment methodology for only these services. That said, the State does commit to taking this recommendation into account should changes be made to TennCare's crossover claim methodologies in the future.

Please do not hesitate to reach out with any additional questions and we will promptly respond.

Sincerely,

/s/

Drew Staniewski
Deputy Director
Division of TennCare

CC (via email):

Natalie Alvarez, Office of Inspector General
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