Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

STATE AGENCIES COULD BE OBTAINING HUNDREDS OF MILLIONS IN ADDITIONAL MEDICAID REBATES ASSOCIATED WITH PHYSICIAN-ADMINISTERED DRUGS

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Report in Brief
Date: May 2024
Report No. A-07-23-06111

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

State Agencies Could Be Obtaining Hundreds of Millions in Additional Medicaid Rebates Associated With Physician-Administered Drugs

Why OIG Did This Audit

Generally, for a covered outpatient drug to be eligible for Federal reimbursement under the Medicaid program, manufacturers must pay rebates to the States for drugs under the Medicaid drug rebate program. OIG has conducted a series of audits to examine whether Medicaid State agencies (State agencies) properly invoiced for, and collected, rebates for physician-administered drugs. This report provides the Centers for Medicare & Medicaid Services (CMS) with a summary of the results of our previous OIG reports and identifies potential issues that, if addressed, could bring about significant reductions in costs to the Medicaid program as a result of renewed efforts to collect rebates for physician-administered drugs.

Our objective was to summarize the results from our previous audits of individual State agencies that determined whether the State agencies complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs.

How OIG Did This Audit

We reviewed each of our 57 previous OIG audits of the Medicaid drug rebate program and summarized the results of those audits for this report. Our 57 previous audits covered physician-administered drug costs that the State agencies claimed for Federal reimbursement. Those audits covered audit periods that ranged from 3 months to 5 years in length, with the earliest audit period beginning on April 1, 2008, and the most recent audit period ending on December 31, 2020.

What OIG Found

Our 57 previous audits of individual State agencies, which we summarize for this report, determined that the State agencies generally did not comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs and that, in the aggregate, the State agencies could have invoiced for hundreds of millions of dollars in additional rebates. State agencies could have invoiced and obtained rebates from the manufacturers for $225.7 million (Federal share) for physician-administered drugs reimbursed on a fee-for-service basis, and should have collected additional rebates associated with $236.2 million (Federal share) for physician-administered drugs administered to Medicaid managed-care organization enrollees. Furthermore, some State agencies had opportunities to obtain additional rebates for physician-administered drugs beyond those that are required by Federal law. The State agencies generally lacked internal controls, to include policies and procedures, to provide for the collection of adequate and sufficient data to enable the State agencies to collect all rebates for eligible physician-administered drugs.

What OIG Recommends and CMS Comments

We recommend that CMS work with the State agencies to implement internal controls, including policies and procedures, to collect information to facilitate the collection of all rebates for eligible physician-administered drugs; issue finalized guidance to clarify and reinforce the requirement that rebates should be collected for all required physician-administered drugs; and work with and encourage the State agencies to maximize the amount of rebates that can be obtained when feasible, including invoicing for and obtaining rebates in cases when the rebates may not be required.

CMS concurred with our first and third recommendations and described corrective actions. CMS said that States had implemented about 70 percent of the recommendations we made to them in our previous audits, and added that it would continue to provide guidance and technical assistance to the States, to include working with the States on their implementation of internal controls. For our second recommendation, CMS referred to the issuance in May 2023 of a proposed rule that, if finalized, would allow States to invoice for and obtain rebates for all multiple-source physician-administered drugs that are covered outpatient drugs. We believe that the actions that CMS described, when fully executed, should resolve our second recommendation.

The full report can be found on the OIG website.

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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 drugs. States generally offset the Federal share of these rebates against their Medicaid expenditures. States invoice the manufacturers for rebates to reduce the cost of drugs to the program. The Office of Inspector General (OIG) has conducted a series of audits to examine whether Medicaid State agencies (State agencies) properly invoiced for, and collected, rebates for physician-administered drugs in accordance with Federal Medicaid requirements. Specifically, in those audits we examined whether physician-administered drugs, when administered as part of a fee-for-service (FFS) program or through one or more Medicaid managed-care organizations (MCOs), were properly invoiced and collected.

Accordingly, this report provides the Centers for Medicare & Medicaid Services (CMS) with a summary of the results of our previous OIG reports and identifies potential issues that, if addressed, could bring about significant reductions in costs to the Medicaid program as a result of renewed efforts to collect rebates for physician-administered drugs. Our previous OIG audits are listed in Appendix B.

OBJECTIVE

Our objective was to summarize the results from our previous audits of individual State agencies that determined whether the State agencies complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs.

BACKGROUND

Medicaid Drug Rebate Program

The Medicaid drug rebate program became effective in 1991 (the Social Security Act (the Act) § 1927). For a covered outpatient drug to be eligible for Federal reimbursement under the program, the drug's manufacturer must enter into a rebate agreement that is administered by 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.[1] 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

[1] Section 1927(b) of the Act and section II of the Medicaid rebate agreement.

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 (also referred to as "Federal financial participation" or "Federal matching funds") for States that do not capture the information necessary for invoicing manufacturers for rebates as described in section 1927(a)(7) of the Act. To invoice for rebates, States: (1) capture drug utilization data that identifies, by NDC, the number of units of each drug for which the States reimbursed Medicaid providers, and (2) report the information to the manufacturers (the Act § 1927(b)(2)(A)). In general, 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 report, which contains a summary of actual Medicaid expenditures for each quarter and is used by CMS to reimburse States for the Federal share of Medicaid expenditures.

Medicaid Coverage of Physician-Administered Drugs

States pay for Medicaid services through an FFS program, a managed-care program, or both. Under an FFS structure, the State pays providers directly for each covered service received by an individual enrolled in Medicaid (enrollee). Under a managed-care structure, States contract with MCOs to provide specific services to 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.[2]

States' Collection of Rebates for Physician-Administered Drugs

Drugs administered by a physician are generally invoiced on a claim form using Healthcare Common Procedure Coding System (HCPCS) codes.[3] To collect rebates for drugs, States collect the necessary information (from the MCOs if applicable) and submit to the manufacturers the drug utilization data (based on NDCs) for the drugs identified in the data. NDCs enable States to identify the physician-administered drug, including the manufacturer, to facilitate the

[2] Prepaid inpatient health plans and prepaid ambulatory health plans also cover physician-administered drugs (42 CFR § 438.3(s)).

[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.

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 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 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) 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. In the wake of the enactment of the ACA, States typically require MCOs to submit to the State agency NDCs for covered outpatient drugs dispensed to eligible enrollees. Accordingly, MCOs submit to the State agency provider claim information that includes claim lines for covered outpatient drugs. This information conveys drug utilization data, which States must include when invoicing manufacturers for rebates.

The State Agencies' Medicaid Drug Rebate Programs

Whether the Medicaid services are provided on an FFS or managed-care basis, State agencies are responsible for invoicing and collecting Medicaid drug rebates for physician-administered drugs. The State agencies are required to collect and submit drug utilization data to manufacturers, detailing drug usage by Medicaid enrollees, within 60 days of the end of each quarter.

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[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.

[6] 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)(A)(i) of the Act. Multiple-source drugs stand in contrast to single-source drugs, which do not have therapeutic equivalents. Furthermore, 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)). According to the definition of "therapeutic equivalence" in the Drugs@FDA glossary of terms, a therapeutically equivalent drug product can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product. Drug products are considered to be therapeutically equivalent only if they meet certain criteria established by the FDA.

[7] Section 2501, the Patient Protection and Affordable Care Act of 2010, 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).

Most State agencies have contracted with fiscal agents to manage the claims data. In each of these cases, the fiscal agent processed, invoiced, and collected Federal rebates through its rebate administration system. Generally, manufacturers pay rebates directly to the State agencies; the State agencies then forward the payment information to the fiscal agent, which reconciles the payments made by the manufacturers (to the States) to the rebate amounts invoiced to the manufacturers. The fiscal agent also maintains the accounts receivable information for the State agency's Medicaid drug rebate system and works with manufacturers to resolve any unpaid rebates.

HOW WE CONDUCTED THIS AUDIT

We reviewed each of our 57 previous OIG audits of the Medicaid drug rebate program (Appendix B) and summarized the results of those audits for this report. Our 57 previous audits covered physician-administered drug costs that the State agencies claimed for Federal reimbursement. Those audits covered audit periods that ranged from 3 months to 5 years in length, with the earliest audit period beginning on April 1, 2008, and the most recent audit period ending on December 31, 2020.[8]

For each of the audits whose results we summarized in this report, 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.[9] Additionally, we determined whether the HCPCS codes were published in CMS's top-20 multiple-source drug list.

For each of these audits, we removed claims for drugs that either were not eligible for rebates or had already been invoiced for rebates.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[8] As shown in Appendix B, several States were audited in both their FFS and MCO programs. For that reason, this report speaks in terms of more than 50 OIG audits. See also footnote 10 later in this report.

[9] 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)).

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

FINDINGS

Our previous audits of individual State agencies, which we summarize for this report, determined that the State agencies generally did not comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. Specifically, our 57 previous audits identified the extent to which State agencies could have invoiced and obtained rebates from the manufacturers but did not do so. Furthermore, our previous audits determined that, in the aggregate, the State agencies could have invoiced for hundreds of millions of dollars in additional rebates. Specifically:

- For the 35 State agencies in which we audited physician-administered drugs reimbursed on an FFS basis, 33 State agencies did not appropriately invoice and obtain rebates for all required physician-administered drugs.

- For the 22 State agencies in which we audited physician-administered drugs administered to MCO enrollees, none of the 22 State agencies appropriately invoiced and obtained rebates for all required physician-administered drugs.[10]

These previous audits determined that these State agencies could have invoiced and obtained rebates from the manufacturers for an additional $362.3 million ($225.7 million Federal share) for physician-administered drugs reimbursed on an FFS basis, and should have collected additional rebates associated with $392.8 million ($236.2 million Federal share) for physician-administered drugs administered to MCO enrollees.

Furthermore, some State agencies had opportunities to obtain additional rebates for physician-administered drugs beyond those that are required by Federal law. In this respect, we identified the following:

- State agencies could have obtained additional rebates if they had directly paid for physician-administered drugs that were associated with crossover claims.[11]

- In addition, one State agency did not invoice manufacturers for physician-administered drugs dispensed at non-critical access hospitals that billed Medicaid for covered outpatient drugs at no more than the hospital's purchasing costs.

[10] As of the preparation of this report, we have conducted audits of physician-administered drugs in a total of 46 States and the District of Columbia. For 10 of these States, we have conducted separate audits that examined rebates for physician-administered drugs administered both on an FFS basis and to MCO enrollees.

[11] The term "crossover claims" refers to Medicaid claims for Federal reimbursement that involve enrollees who are eligible for both Medicare and Medicaid services (also known as "dual-eligible" enrollees). 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.

Most State agencies had policies that generally required the collection of drug utilization data necessary to invoice for the required rebates on physician-administered drug claims. However, the State agencies generally lacked internal controls, to include policies and procedures, to provide for the collection of adequate and sufficient data to enable the State agencies to collect all rebates for eligible physician-administered drugs. In their written comments on our previous audits' draft reports, State agencies generally agreed with our recommendations to improve their controls and repay any overpayments, or said that they would work to obtain rebates for the physician-administered drug claims that we had identified.

Additionally, State agencies' abilities to administer their programs could have been enhanced if CMS had clarified the guidance that the Medicaid drug rebate program furnishes with respect to physician-administered drugs. Although section 1927(a)(7) of the Act requires (effective January 1, 2008) that States provide for the collection and submission of drug utilization data and coding information for the top 20 multiple-source drugs (footnote 6), CMS did not provide the States with an updated list of the top 20 multiple-source drugs from 2011 to 2021.[12] Our previous audits reported that some State agencies appeared to have been confused as to which multiple-source drugs are required to be invoiced for rebates. Accordingly, more precise guidance that clarifies what physician-administered drugs are required to be rebated would assist State agencies in complying with Federal requirements pertaining to the Medicaid drug rebate program.

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).

In addition, section 6002 of the DRA amended section 1903(i)(10) of the Act to prohibit a Medicaid Federal share (that is, Federal reimbursement) 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.

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

[12] Section 1927(a)(7)(B)(i) of the Act states that the Secretary of Health and Human Services (the Secretary) "may modify such list [of top-20 multiple-source drugs] from year to year to reflect changes" in dollar volume of physician-administered drugs dispensed.

information for drugs dispensed to individuals enrolled in MCOs when invoicing manufacturers for rebates (the Act §§ 1927(b)(1)(A) and (b)(2)(A)).

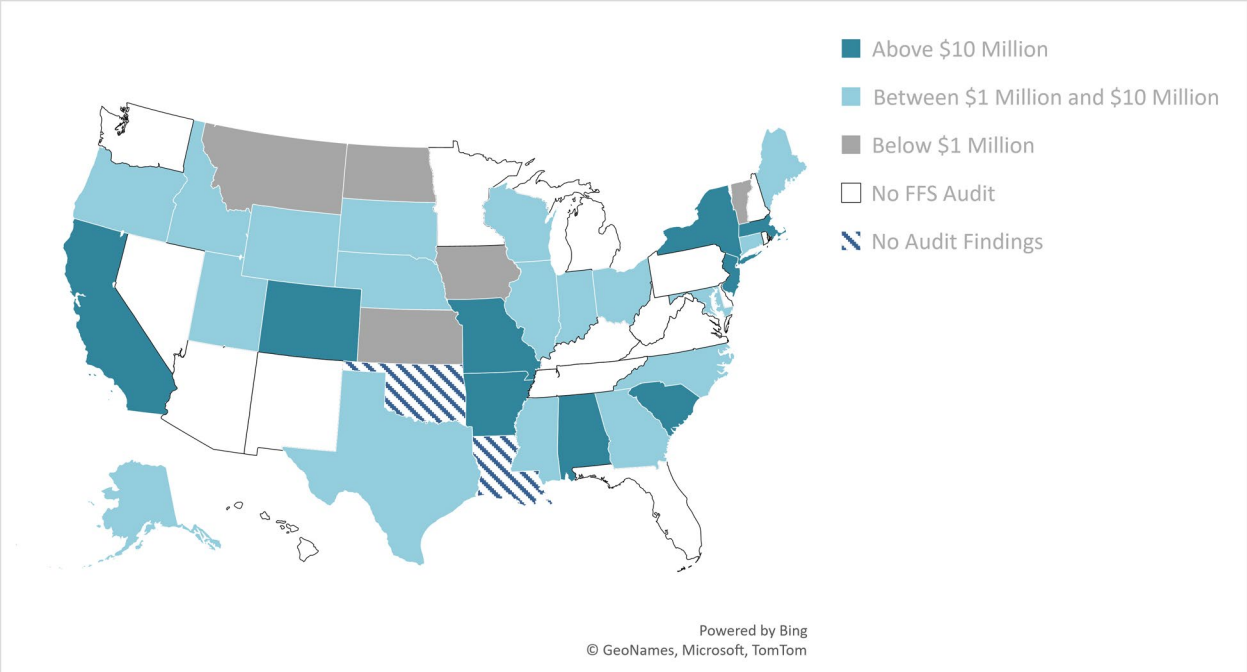
The ACA also amended section 1903 of the Act to specifically address the conditions of Federal reimbursement for covered outpatient drugs dispensed to MCO enrollees. Essentially, States must secure rebates for drugs dispensed through MCOs and require MCOs to submit to the State NDCs for drugs dispensed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

Appendix C contains details on these Federal requirements related to physician-administered drugs.

STATE AGENCIES DID NOT INVOICE MANUFACTURERS FOR REBATES ASSOCIATED WITH PHYSICIAN-ADMINISTERED DRUGS REIMBURSED ON A FEE-FOR-SERVICE BASIS

For the 35 State agencies in which we audited physician-administered drugs reimbursed on an FFS basis, 33 State agencies did not appropriately invoice and obtain rebates for all required physician-administered drugs. The State agencies did not invoice for, and collect from manufacturers, rebates associated with all single-source physician-administered drugs and top-20 multiple-source drugs. Furthermore, most State agencies did not always invoice and obtain rebates for other multiple-source physician-administered drug claims that were not included on the list of top-20 multiple-source drugs. Accordingly, these State agencies could have claimed additional rebates totaling $362.3 million ($225.7 million Federal share) in total drug costs for their particular audit periods. Figure 1 on the following page identifies the States that we audited and the range, by State, of the total physician-administered drug costs that were not invoiced for rebates.

Figure 1: Total Costs Associated With Physician-Administered Drugs Reimbursed on a Fee-for-Service Basis That Were Not Invoiced for Rebates



In general, these State agencies could have invoiced and obtained rebates for these physician-administered drugs; accordingly, in our previous audits, we generally recommended that the State agencies: (1) refund the overpayments for the single-source and top-20 multiple-source physician-administered drug claims that were not invoiced to the drug manufacturers for rebate and (2) work with CMS to determine the unallowable portions for the remaining other multiple-source drugs. We discuss each of these categories of physician-administered drugs (reimbursed on an FFS basis) below.

Drug Rebates for Single-Source Physician-Administered Drugs

For the 33 State agencies that did not appropriately invoice and obtain rebates for all required physician-administered drugs reimbursed on an FFS basis, our previous audits determined that the State agencies improperly claimed Federal reimbursement of $216.4 million ($139.6 million Federal share) for their particular audit periods for single-source physician-administered drug claims.

Because the State agencies did not invoice manufacturers for rebates for these single-source drugs, these claims were not eligible for Federal reimbursement.

Drug Rebates for Top-20 Multiple-Source Physician-Administered Drugs

For the 33 State agencies that did not appropriately invoice and obtain rebates for all required physician-administered drugs reimbursed on an FFS basis, our previous audits determined that the State agencies improperly claimed Federal reimbursement of $17.8 million ($11.0 million Federal share) for top-20 multiple-source physician-administered drug claims.

Because the State agencies did not invoice manufacturers for rebates for these top-20 multiple-source drugs, these claims were not eligible for Federal reimbursement.

Drug Rebates for Other Multiple-Source Physician-Administered Drugs

For the 33 State agencies that did not appropriately invoice and obtain rebates for all required physician-administered drugs reimbursed on an FFS basis, our previous audits identified other multiple-source physician-administered drugs claims for which we were unable to determine whether the State agencies were required to invoice for rebates.[13, 14] The State agencies potentially should have rebated for these other multiple-source physician-administered drugs.

Although most of the 33 State agencies collected the drug utilization data necessary to invoice manufacturers for rebates associated with these other multiple-source physician-administered drugs, the State agencies did not always invoice the manufacturers for the associated rebates. Providers submitted claims totaling $128.1 million ($75.1 million Federal share) that the State agencies did not use to obtain Medicaid drug rebates. Under the Medicaid drug rebate program, these claims would have been eligible for rebates.

Accordingly, our previous audits of these 33 State agencies generally did not question the costs associated with these other multiple-source drugs and recommended that the State agencies: (1) work with CMS to determine the unallowable portion of these claims and (2) consider

[13] In this report and our previous audit reports, we use the term "other multiple-source physician-administered drugs" to refer to those drugs that are not either single-source or top-20 multiple-source physician-administered drugs.

[14] During our audits, we were unable to definitively determine that these drugs were required to be invoiced for rebates given the wording of the Act § 1927(a)(7)(B) and CMS's select publishing of top 20 lists. When we began our series of audits of physician-administered drugs, some CMS officials conveyed that all physician-administered drugs claims, including those for other multiple-source physician-administered drugs, should be invoiced for rebates. However, formal guidance to States addressing this issue was not published and States continued to express confusion as to whether they were required to collect information for and invoice other multiple-source drugs. For these reasons, our previous audit reports consistently stated that we were unable to determine whether the State agencies were required to invoice for these rebates. However, CMS proposed a new rule in May 2023 (footnote 18 later in this report) addressing the invoicing of rebates for physician-administered drugs. According to CMS, "the proposed regulation would specify to States that they should invoice for rebates for all multiple source PADs [physician-administered drugs] that are CODs [Covered Outpatient Drugs], and not limit such rebate invoicing to the top 20 high dollar volume list." 88 Fed. Reg. 34238, 34276 (May 26, 2023).

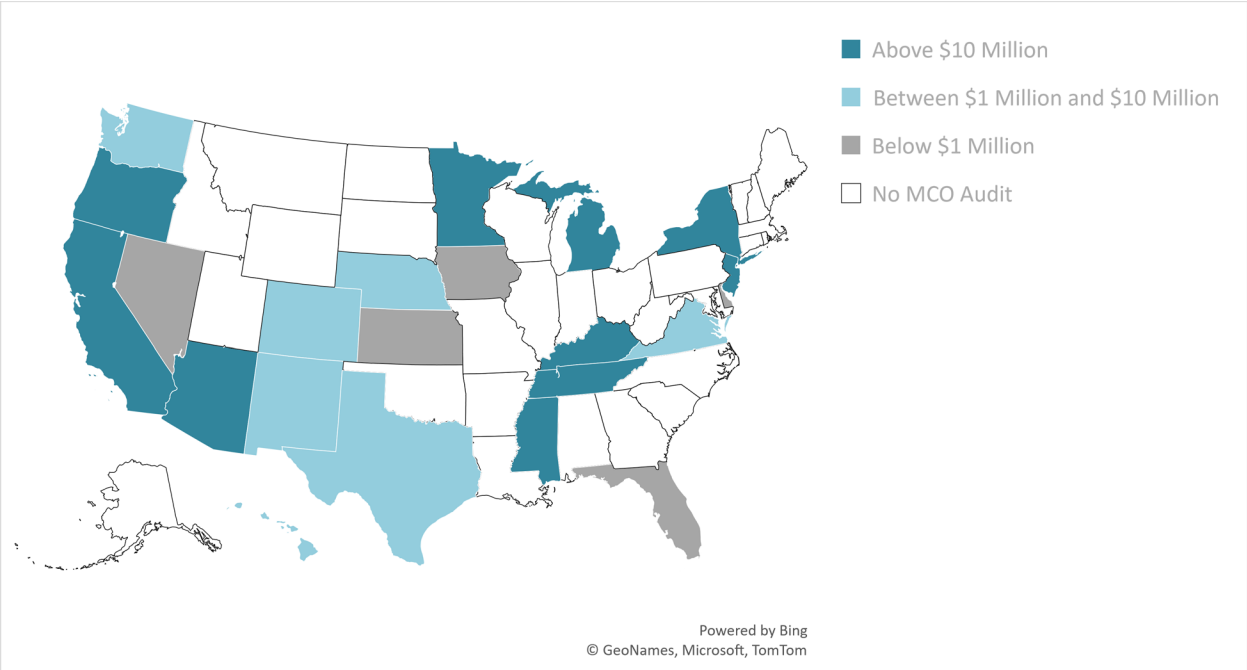
invoicing drug manufacturers for rebates for these drugs if CMS determines that the drug claims are allowable.

Although most State agencies had policies that required the collection of drug utilization data necessary to invoice for rebates on all physician-administered drug claims, State agencies did not always use the collected data to invoice manufacturers and collect rebates for physician-administered drugs.

STATE AGENCIES DID NOT INVOICE MANUFACTURERS FOR REBATES FOR PHYSICIAN-ADMINISTERED DRUGS ADMINISTERED TO MEDICAID MANAGED-CARE ORGANIZATION ENROLLEES

For the 22 State agencies in which we audited physician-administered drugs administered to MCO enrollees, none of the 22 State agencies appropriately invoiced and obtained rebates for all required physician-administered drugs (footnote 10). The 22 State agencies did not invoice for, and collect from manufacturers, rebates totaling $392.8 million ($236.2 million Federal share) for physician-administered drugs dispensed to MCO enrollees during the relevant audit periods. Figure 2 identifies the States that we audited and the range of these uncollected rebates by State.

Figure 2: Total Rebate Amounts Associated With Physician-Administered Drugs Administered to Medicaid Managed-Care Organization Enrollees That Were Not Invoiced for Rebates



SOME STATE AGENCIES COULD HAVE OBTAINED ADDITIONAL REBATES, BEYOND THOSE REQUIRED BY FEDERAL LAW, FOR PHYSICIAN-ADMINISTERED DRUGS

Our previous audits also identified that some State agencies had opportunities to obtain additional rebates for physician-administered drugs beyond those that are required by Federal law. These opportunities involved physician-administered drugs associated with indirectly paid drug claims (two State agencies) and physician-administered drugs administered at non-critical access hospitals (one State agency), as explained below.

Indirectly Paid Physician-Administered Drugs

Physician-administered drugs are eligible for a rebate as long as the drug meets the definition of a covered outpatient drug. The statute contains language that limits the definition of covered outpatient drugs to exclude drugs that are billed as part of a bundled service (the Act § 1927(k)(3)). This means that if a State agency does not directly pay for a drug, it cannot invoice for a rebate.

Our previous audits identified two State agencies that did not pay directly for physician-administered drugs associated with crossover claims. The term "crossover claims" refers to Medicaid claims for Federal reimbursement that involve individuals who are eligible for both Medicare and Medicaid services (also known as "dual-eligible enrollees") (footnote 11). 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. As part of the invoice process for crossover claims, Medicare submits two sets of data for these services: (1) the line-item level, which shows each individual service, such as physician-administered drugs, and (2) the header level, which consolidates the services to show a combined total amount for all the services on the claims. For a claim to be eligible for rebate, the State agency must make a payment for the physician-administered drug(s) at the line-item level. After receiving crossover claims data from Medicare, the State agency calculates the payment it will make to the provider.[15]

[15] Under § 1902(n)(2) of the Act, "[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 . . . ." We acknowledge that, according to the Act, the State agencies were not required to make a payment on these crossover claims; however, we believe that the State agencies had an opportunity to improve their administration of the Medicaid drug rebate program insofar as crossover claims are concerned.

Our previous audits identified two State agencies that paid the crossover claims at the header level, which made those claims ineligible for rebates. As a result, the States were not eligible for additional physician-administered rebates totaling $90 million ($64 million Federal share).[16]

Physician-Administered Drugs Dispensed at Non-Critical Access Hospitals

The Act § 1927(j)(2) directs State Medicaid plans to exempt certain hospitals (including non-critical access hospitals, among others) from rebate requirements as long as the hospitals bill Medicaid for covered outpatient drugs at no more than the "hospital's purchasing costs of covered outpatient drugs (as determined under the State plan)."

Our previous audits identified one State agency that did not invoice manufacturers for physician-administered drugs dispensed at non-critical access hospitals, whose reimbursement was limited to their purchasing costs. Although not required to do so, the State agency could have invoiced drug manufacturers for rebates totaling $17.3 million ($10.8 million Federal share) for these physician-administered drugs.[17]

STATE AGENCIES GENERALLY LACKED INTERNAL CONTROLS

Our previous audits determined that most State agencies had policies that generally required the collection of drug utilization data necessary to invoice for the required rebates on physician-administered drug claims. However, the State agencies generally lacked internal controls, to include policies and procedures, to provide for the collection of adequate and sufficient data to enable the State agencies to collect all rebates for eligible physician-administered drugs. Furthermore, some State agencies' policies and procedures could have been adjusted to provide for the invoicing of additional physician-administered drugs for the purposes of increasing the amount of rebates invoiced and potentially providing additional cost savings to their Medicaid programs.

In their written comments on our previous audits' draft reports, State agencies generally agreed with our recommendations to improve their controls and repay any overpayments, or said that they would work to obtain rebates for the physician-administered drug claims that we had identified. Thus, some State agencies have opportunities to increase the amounts of physician-administered drug rebates that they receive.

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[16] Specifically, the State agencies did not invoice manufacturers for rebates totaling $89,980,450 ($63,962,562 Federal share) for physician-administered drugs invoiced on crossover claims. See *Mississippi Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs* (A-07-21-06101) and *Tennessee Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations* (A-07-21-06096) (Appendix B).

[17] Specifically, $17,272,850 ($10,801,067 Federal share) was for physician-administered drug claims at non-critical access hospitals. Critical access hospitals are small facilities that give limited inpatient hospital services to people in rural areas and receive cost-based reimbursement. See *Maine Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs* (A-07-18-06079) (Appendix B).

NEED FOR CLARIFIED CMS GUIDANCE REGARDING TOP-20 MULTIPLE-SOURCE PHYSICIAN-ADMINISTERED DRUGS

State agencies' abilities to administer their programs could have been enhanced if CMS had clarified the guidance that the Medicaid drug rebate program furnishes with respect to physician-administered drugs. CMS could have issued clarified guidance that all multiple-source physician-administered drugs should be invoiced for rebates. Instead, CMS did not update the list of top-20 multiple-source drugs for 10 years, which appears to have contributed to the confusion that some State agencies experienced regarding which multiple-source drugs are required to be invoiced for rebates. As such, some State agencies revealed that they were unsure whether they could obtain rebates for other multiple-source physician-administered drugs that did not appear on the list of top-20 multiple-source drugs.

In particular, section 1927(a)(7) of the Act requires (effective January 1, 2008) that States provide for the collection and submission of drug utilization data and coding information for the top 20 multiple-source drugs (footnote 6). Specifically, section 1927(a)(7)(B)(i) of the Act required publication of a list of the 20 multiple-source physician-administered determined to have the highest dollar volume of physician-administered drugs dispensed under Medicaid. This section of the Act included provisions that the list may be modified from year to year to reflect changes in volume of these multiple-source drugs (footnote 12). CMS published lists of the top-20 multiple-source drugs (with respective HCPCS codes and NDCs) in 2006, 2009, 2010, and 2011 and then not again until 2021. (We relied on this list to identify top-20 multiple-source physician-administered drugs; Appendix A.)

The results of our previous audits raise the possibility that during the periods covered by our previous audits, the 2011 list may not have accurately reflected the highest dollar volume of physician-administered drugs dispensed under Medicaid over the years. Because top-20 multiple-source drugs are required to be invoiced for rebates, the possibility existed that the continued use of the 2011 list—and the absence of any updated lists in the 10 succeeding years—may have resulted in a missed opportunity for additional savings for the Medicaid drug rebate program.

Furthermore, our previous 57 audits revealed that the absence of an updated list of top-20 multiple-source drugs may have created confusion (which some State agencies expressed to us during our previous audits) as to which other multiple-source drugs are required to be invoiced for rebates—or whether they can be invoiced for rebates. Although CMS did not publish (during our previous audit periods) formal guidance to the State agencies addressing the need to invoice these physician-administered drugs for rebate, CMS officials have communicated to us that generally all multiple-source physician-administered drugs should be invoiced for rebates (footnote 13).

Recently—after the audit periods of our 57 previous audits—CMS proposed a new rule (in May 2023), which has not been finalized, that specifies that all multiple-source physician-

administered drugs that are covered outpatient drugs—not just the top-20 multiple-source drugs—are to be invoiced for rebates.[18]

CONCLUSION

The State agencies we audited (Appendix B) could have invoiced for, and collected from manufacturers, substantial amounts of additional rebates for physician-administered drugs. Additionally, some State agencies have further opportunities to significantly increase the amounts of physician-administered drug rebates beyond those required by Federal law. Accordingly, more precise guidance from CMS that clarifies what physician-administered drugs are required to be rebated would assist State agencies in complying with Federal requirements pertaining to the Medicaid drug rebate program.

RECOMMENDATIONS

We recommend that the Centers for Medicare & Medicaid Services:

- work with the State agencies to implement internal controls, including policies and procedures, to collect NDCs, in order to facilitate the collection of all rebates for eligible physician-administered drugs;

- issue finalized guidance regarding multiple-source physician-administered drugs, to clarify and reinforce the requirement that rebates should be collected for all required physician-administered drugs; and

- work with and encourage the State agencies to maximize the amount of physician-administered drug rebates that can be obtained when feasible, including invoicing for and obtaining rebates in cases when the rebates may not be required.

CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CMS concurred with our first and third recommendations and described corrective actions it had taken or planned to take. CMS also referred to the issuance of a proposed rule which, if finalized, would in CMS's view address our second recommendation.

For our first recommendation, CMS stated that out of the total of 263 recommendations that we had made to States in our previous 57 OIG audits, the States had, as of March 2024, fully

[18] 88 Fed. Reg. 34238, 34276 (May 26, 2023). In addition, in the proposed rule, CMS states that it is "proposing at § 447.520(b) a State require providers to submit claims for all covered outpatient drug single source and multisource physician-administered drugs using NDC numbers to collect FFP [Federal financial participation] and secure rebates. . . ." Furthermore, CMS is "proposing at § 447.520(c) to continue to publish the top 20 list of multiple source PADs on an annual basis, as statutorily required, but it is [CMS's] expectation that States would invoice rebates for all multiple source physician-administered drugs that are CODs."

implemented approximately 70 percent of those recommendations. CMS also said that it would continue to: work with States "to ensure the remaining recommendations are implemented," provide guidance and technical assistance to States regarding the collection of rebates for physician-administered drugs, and work with States "to ensure that they have implemented appropriate internal controls." For our third recommendation, CMS said that it would provide information to States on ways to maximize the amounts of physician-administered drug rebates that they can obtain. CMS also noted, though, that it "does not have the authority to require [S]tates to obtain additional rebates for [physician-administered drugs] for which there is no [Medicaid drug rebate program] statutory requirement."

For our second recommendation, CMS referred to the issuance of the proposed rule that we discuss just above our "Conclusion" section (footnotes 14 and 18). CMS stated that this rule, if finalized, would specify that States should invoice for rebates for all multiple-source physician-administered drugs that are covered outpatient drugs, not just those that are on the list of the top 20 multiple-source physician-administered drugs. CMS stated: "This proposal, if finalized, would reduce the administrative burden of monitoring any revisions to the list of the top 20 multiple source" physician-administered drugs, while also allowing States to obtain rebates for all physician-administered drugs that are covered outpatient drugs. CMS added that it believed that this proposed rule, if finalized, would address our second recommendation. We believe that the actions that CMS described, when fully executed, should resolve our second recommendation.

CMS also provided technical comments, which we addressed as appropriate. CMS's comments, excluding technical comments, are included as Appendix F.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed each of our 57 previous OIG audits of the Medicaid drug rebate program (Appendix B) and summarized the results of those audits for this report. Our 57 previous audits reviewed physician-administered drug costs that the State agencies claimed for Federal reimbursement. Those audits covered audit periods that ranged from 3 months to 5 years in length, with the earlier audit period beginning on April 1, 2008, and the most recent audit period ending on December 31, 2020 (footnote 8).

Our audit objective did not require an understanding or assessment of the complete internal control structures of the State agencies. We limited our internal control reviews to obtaining an understanding of each State agency's procedures for and controls over invoicing for rebates for physician-administered drugs.

METHODOLOGY

To accomplish our objectives in our previous audits, we generally 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 each State agency's policies and procedures for rebates for physician-administered drugs.

- We interviewed personnel from each of the State agencies to gain an understanding of the administration of and controls over their Medicaid rebate invoicing processes for physician-administered drugs.

- We obtained lists of the CMS top-20 multiple-source physician-administered drugs, the Medicare Part B crosswalk (footnote 9), the CMS Medicaid Drug Rebate File, and the CMS Medicaid Drug Product File for each of our audit periods.

- We obtained a list of 340B entities from each State agency.[19]

- We obtained, from each of the State agencies, a detailed list of physician-administered drug claims paid (the exact date range depended on the particular audit period). In

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

response to this request, the State agencies provided data associated with these claims. Thereafter, 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.

- We identified the top-20 multiple-source drugs (footnote 6) 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 then compiled information on the issues previously reported for this report, including our previous discussions with CMS, and discussed the results of our audits with CMS officials on August 17, 2023. This report culminates our longstanding efforts to convey recommendations that CMS could address to increase the State agencies' compliance with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
Mississippi Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-07-21-06103	10/18/2023
Alabama Did Not Always Invoice Rebates to Manufacturers for Pharmacy and Physician-Administered Drugs	A-04-21-08090	9/21/2023
Kentucky Did Not Always Invoice Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-04-22-07102	9/12/2023
Georgia Did Not Always Invoice Rebates to Manufacturers for Pharmacy and Physician-Administered Drugs	A-04-21-08089	3/13/2023
Florida Did Not Invoice Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-04-21-07098	3/3/2023
North Carolina Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs	A-07-21-07002	2/7/2023
Mississippi Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs	A-07-21-06101	10/27/2022
Tennessee Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-07-21-06096	9/14/2022
South Carolina Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs	A-07-21-07003	8/10/2022
Colorado Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-07-17-06075	9/8/2021
New Mexico Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-06-16-00001	6/2/2021
Massachusetts Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-06-18-04001	10/22/2020

Report Title	Report Number	Date Issued
Minnesota Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-05-17-00018	10/21/2020
Vermont Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs	A-07-19-06086	9/18/2020
Maine Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs	A-07-18-06079	9/14/2020
Michigan Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-05-17-00017	8/25/2020
Alaska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-09-19-02001	7/21/2020
New York Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-02-18-01016	4/7/2020
New York Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-02-18-01011	2/19/2020
New Jersey Did Not Bill Manufacturers for Tens of Millions of Dollars in Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-02-16-01011	8/30/2019
Texas Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-06-17-04001	8/21/2019
Connecticut Claimed Unallowable Federal Reimbursement for Medicaid Physician-Administered Drugs That Were Not Invoiced to Manufacturers for Rebates	A-07-18-06078	8/16/2019
Illinois Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-05-18-00030	6/18/2019
New Jersey Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-02-16-01012	5/9/2019
Indiana Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-05-17-00038	4/5/2019
Arizona Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-09-16-02031	2/16/2018

Report Title	Report Number	Date Issued
Arkansas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-06-16-00018	2/12/2018
Nebraska Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-07-13-06046	12/22/2017
Ohio Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-05-16-00013	11/1/2017
Washington State Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-09-16-02028	9/26/2017
Hawaii Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-09-16-02029	9/26/2017
Nevada Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-09-16-02027	9/12/2017
Iowa Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs of Medicaid Managed-Care Organizations	A-07-16-06065	5/5/2017
Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-05-16-00014	3/23/2017
Colorado Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-14-06050	1/5/2017
Delaware Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-03-15-00202	12/30/2016
Virginia Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-03-15-00201	12/22/2016
California Did Not Bill Manufacturers for Rebates For Physician-Administered Drugs Dispensed to Enrollees of Some Medicaid Managed-Care Organizations	A-09-15-02035	12/8/2016

Report Title	Report Number	Date Issued
Kansas Correctly Invoiced Rebates to Manufacturers for Most Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-07-15-06060	8/18/2016
Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-14-06057	5/26/2016
Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-15-06063	3/31/2016
South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-15-06059	2/9/2016
Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs	A-07-15-06062	1/14/2016
North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs	A-07-15-06058	1/13/2016
California Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs	A-09-14-02038	1/7/2016
Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs	A-07-14-06056	9/18/2015
Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-14-06049	7/22/2015
Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-06-12-00060	5/4/2015
Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-14-06051	4/13/2015
Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-09-13-02037	3/4/2015
Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs	A-06-14-00031	2/10/2015
The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-03-12-00205	8/21/2014

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

APPENDIX C: FEDERAL REQUIREMENTS RELATED TO PHYSICIAN-ADMINISTERED DRUGS

FEDERAL LAWS

Under the Medicaid program, States may provide coverage for outpatient drugs as an optional service (the Act § 1905(a)(12)). Section 1903(a) of the Act provides for Federal financial participation (Federal share) in State expenditures for these drugs. The Medicaid drug rebate program, created by the Omnibus Budget Reconciliation Act of 1990 that added section 1927 to the Act, became effective on January 1, 1991. Manufacturers must enter into a rebate agreement with the Secretary and pay rebates for States to receive Federal funding for the manufacturer's covered outpatient drugs dispensed to Medicaid enrollees (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 (that is, Federal reimbursement) 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 (footnote 6). 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)).

To invoice for rebates, States: (1) capture drug utilization data that identifies, by NDC, the number of units of each drug for which the States reimbursed Medicaid providers, and (2) report the information to the manufacturers (the Act § 1927(b)(2)(A)). In general, the number of units is multiplied by the unit rebate amount to determine the actual rebate amount due from each manufacturer.

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).

APPENDIX D: FEE-FOR-SERVICE PHYSICIAN-ADMINISTERED DRUGS: FINDINGS BY STATE

State	Single-Source Drugs		Top-20 Multiple-Source Drugs		Other Drugs[20]	
	Total Amount	Federal Share	Total Amount	Federal Share	Total Amount	Federal Share
Alabama	$21,043,949	$14,960,673	$62,043	$43,981	$410,454	$290,455
Alaska	1,541,303	939,361	115,712	73,892	307,495	188,681
Arkansas	12,080,550	8,516,758	1,949,188	1,375,598	2,056,289	1,449,533
California	6,604,734	3,922,540	907,212	470,028	51,396,023	27,349,486
Colorado	10,459,207	5,229,604	2,593,908	1,296,954	3,222,078	1,611,039
Connecticut	2,130,774	1,065,387	92,420	46,210	5,536,232	2,768,116
District of Columbia	2,740,774	2,129,738	342,197	262,801	1,264,058	983,125
Georgia	953,067	644,802	13,785	9,325	78,013	52,837
Idaho*	-	-	-	-	2,636,804	1,825,685
Illinois	7,605,067	4,032,568	63,591	32,620	503,950	258,640
Indiana	1,027,426	695,070	22,809	15,350	211,553	142,339
Iowa	228,958	155,296	27,947	18,593	176,044	111,485
Kansas	84,636	48,661	7,438	4,307	64,800	37,585
Louisiana†	-	-	-	-	-	-
Maine	6,387,953	4,004,984	441,135	276,229	962,771	605,768
Maryland	5,646,233	3,404,316	139,239	84,389	3,556,969	2,303,377
Massachusetts‡	21,000,000	10,518,114	1,800,000	882,892	9,881,068	4,937,428
Mississippi	1,086,744	820,732	524,561	395,621	1,328,776	1,001,849
Missouri	48,993,427	34,181,807	960,763	656,150	19,166,132	13,225,151
Montana	19,363	12,919	4,569	3,021	175,209	116,156
Nebraska	3,376,414	2,015,620	738,293	441,011	1,460,514	869,291
New Jersey	9,658,584	7,578,002	693,339	561,937	1,452,617	1,116,999
New York‡	5,900,000	3,197,404	270,592	146,672	5,500,000	3,055,167
North Carolina	3,475,219	2,324,567	1,097,600	733,535	1,022,612	684,731
North Dakota	136,738	78,006	1,356	730	521,406	302,512
Ohio	2,171,716	1,408,033	1,401,922	917,519	6,359,664	4,148,307
Oklahoma	-	-	-	-	-	-
Oregon	3,219,708	2,020,959	486,119	305,140	1,791,847	1,124,628
South Carolina	20,044,673	14,281,626	339,070	241,533	1,863,119	1,328,195
South Dakota	1,628,175	940,648	458,248	265,806	2,033,158	1,182,893
Texas	6,105,755	3,554,771	672,174	391,339	529,063	308,021
Utah	5,189,057	3,678,539	998,684	708,745	1,693,496	1,201,751
Vermont	658,442	357,706	87,204	47,389	144,576	78,363
Wisconsin	2,877,019	1,732,222	164,691	99,156	202,139	121,780
Wyoming	2,327,828	1,163,914	286,034	143,017	623,552	311,776
Totals	**$216,403,493**	**$139,615,347**	**$17,763,843**	**$10,951,490**	**$128,132,481**	**$75,093,149**

* This audit did not separately identify the drugs associated with single-source or top-20 multiple-source drugs. Therefore, for classification, we listed the amounts as other multiple-source drugs. These costs could have been attributed to all of the categories.

† This audit examined both FFS and MCO, but we classified as FFS as that was the majority of what we audited.

‡ Some of the amounts in these reports were rounded.

[20] This category captures all other findings, including multiple-source and those without NDCs.

APPENDIX E: MEDICAID MANAGED-CARE ORGANIZATION PHYSICIAN-ADMINISTERED DRUGS: FINDINGS BY STATE

State	Physician-administered Drugs	
	Total Amount	**Federal Share**
Arizona	$36,659,237	$25,634,628
California	69,109,297	42,564,416
Colorado	2,049,124	1,024,562
Delaware	230,045	126,524
Florida	98,335	59,898
Hawaii	3,250,408	1,690,115
Iowa	708,938	401,240
Kansas	63,491	35,949
Kentucky	21,578,898	15,491,320
Michigan	33,816,358	22,142,752
Minnesota	10,839,917	5,419,959
Mississippi	13,707,201	10,388,764
Nebraska	1,869,876	1,065,264
Nevada[*]	520,137	327,624
New Jersey[*]	138,347,944	75,530,290
New Mexico	1,636,448	1,189,861
New York[†]	21,032,098	10,885,620
Oregon	3,049,462	1,914,462
Tennessee	18,382,022	12,028,934
Texas	4,415,704	2,569,499
Virginia	5,831,528	2,915,764
Washington	5,640,490	2,820,336
Totals	**$392,836,958**	**$236,227,781**

[*] The amounts include physician-administered and pharmacy drugs, which may be provided to an enrollee through a pharmacy or administered by a physician in an office or a hospital. This report is summarizing the issues that we identified that were associated with physician-administered drugs exclusively.

[†] Some of the amounts in the report were rounded.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

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Washington, DC 20201

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FROM: Chiquita Brooks-LaSure
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SUBJECT: Office of Inspector General (OIG) Draft Report: State Agencies Could Be Obtaining Hundreds of Millions in Additional Medicaid Rebates Associated With Physician-Administered Drugs (A-07-23-06111)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report. CMS is committed to promoting the efficient operation of the Medicaid Drug Rebate Program (MDRP).

Under the Medicaid program, states may provide coverage of prescription drugs as an optional benefit under section 1905(a)(12) of the Social Security Act (the Act), and all states currently provide coverage for outpatient prescription drugs to the majority of eligible individuals. When states provide medical assistance for covered outpatient drugs (CODs) they must comply with the requirements of section 1927 the Act, which governs the MDRP and payment for CODs. With limited exceptions, if a prescription drug manufacturer wants payment to be available under Medicaid, the manufacturer must participate in the MDRP and agree to pay rebates. Drug manufacturers pay rebates directly to states on a quarterly basis, and the rebates are then shared between both states and the federal government to help offset the overall cost of prescription drugs under the Medicaid program. Physician-administered drugs (PADs) are types of outpatient prescription drugs that must be administered by a health care professional, such as prescription drugs that need to be injected. Generally, PADs are considered CODs and manufacturer rebates can be collected.

National Drug Codes (NDCs) are needed to bill manufacturers for rebates as they identify the specific manufacturer, product, and package size. However, in the past, many PADs were classified by Healthcare Common Procedure Coding System (HCPCS) codes, which grouped together different manufacturers of the same drug within the same code, and as a result could not be used to bill for rebates. To address this issue, and to increase the rebates being invoiced by states for PADs, the Deficit Reduction Act (DRA) of 2005 (P.L. 109-171) added sections 1927(a)(7) and 1903(i)(10)(C) to the Act. These changes required that states begin collecting and submitting utilization data for all PADs that were produced and distributed by a single manufacturer, or single source PADs, as well as for certain high-cost PADs that were produced and distributed by two or more manufacturers, or multiple source PADs. States also needed to require providers to submit claims for all single source and certain high-cost multiple source PADs using NDCs. If states were not collecting NDCs, and not submitting the appropriate utilization data where required under the new DRA provisions, states would be foregoing

available rebates and Federal matching funds would not be available. To identify the high-cost PADs covered by these new requirements, CMS was required to publish a list of the 20 multiple source PADs with the highest dollar volume in the Medicaid program. CMS published this initial list in 2006 and has made periodic updates to the list as needed, with the most recent update having been made in 2021.

In May 2023, CMS issued a proposed rule that, if finalized, would specify that states should invoice for rebates for all multiple source PADs that are CODs, not just those that are on the list of the top 20 multiple source PADs.[1] This proposal, if finalized, would reduce the administrative burden of monitoring any revisions to the list of the top 20 multiple source PADs, while also allowing states to obtain rebates for all PADs that are CODs. CMS also included a proposal that, if finalized, would require that states ensure that providers submit claims for all PADs that are CODs using NDCs. These proposals, if finalized, would ensure that states are able to obtain the required rebates so that they can most effectively operate their programs and enhance access to necessary prescription medications. CMS is committed to enhancing MDRP operations, as well as working with states to increase the efficiency and economy of their overall operations and resources.

The OIG's recommendations and CMS's responses are below.

OIG Recommendation 1

Work with the State agencies to implement internal controls, including policies and procedures, to collect NDCs, in order to facilitate the collection of all rebates for eligible physician-administered drugs.

CMS Response 1

CMS concurs with this recommendation. CMS will continue to provide guidance and technical assistance to states regarding the collection of manufacturer rebates for PADs and will continue to work with states to ensure that they have implemented appropriate internal controls. Across the OIG's 57 prior state audits, a total of 263 recommendations were made to 46 states. Many of these recommendations focused on improving internal controls to ensure the collection of rebates for all eligible PADs. Following the issuance of these prior state audits, CMS has worked closely with the states to ensure that the OIG's recommendations are implemented. As of March 2024, states have fully implemented approximately 70% of the OIG's prior recommendations, and CMS will continue working with states to ensure the remaining recommendations are implemented.

OIG Recommendation 2

Issue finalized guidance regarding multiple-source physician-administered drugs, to clarify and reinforce the requirement that rebates should be collected for all required physician-administered drugs.

CMS Response 2

As noted above, in May 2023, CMS issued a proposed rule that, if finalized, would specify that states should invoice for rebates for all multiple source PADs that are CODs, not just those that are on the list

[1] *Federal Register*: Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program; Proposed Rule (88 FR 34238) (May 26, 2023)

of the top 20 multiple source PADs.[2] If finalized, CMS believes this proposal will address the OIG's recommendation.

OIG Recommendation 3

Work with and encourage the State agencies to maximize the amount of physician-administered drug rebates that can be obtained when feasible, including invoicing for and obtaining rebates in cases when the rebates may not be required.

CMS Response 3

CMS concurs with this recommendation. CMS will provide information to states on ways to maximize the amount of PAD drug rebates that could be obtained; however, CMS does not have the authority to require states to obtain additional rebates for PADs for which there is no MDRP statutory requirement.

[2] *Federal Register*: Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program; Proposed Rule (88 FR 34238) (May 26, 2023)