Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

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

Inquiries about this report may be addressed to the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

Amy J. Frontz
Deputy Inspector General
for Audit Services

August 2024
A-07-22-07010

Office of Inspector General

https://oig.hhs.gov

The mission of the Office of Inspector General (OIG) is to provide objective oversight to promote the economy, efficiency, effectiveness, and integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of the people they serve. Established by Public Law No. 95-452, as amended, OIG carries out its mission through audits, investigations, and evaluations conducted by the following operating components:

Office of Audit Services. OAS provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. The audits examine the performance of HHS programs, funding recipients, and contractors in carrying out their respective responsibilities and provide independent assessments of HHS programs and operations to reduce waste, abuse, and mismanagement.

Office of Evaluation and Inspections. OEI's national evaluations provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. To promote impact, OEI reports also provide practical recommendations for improving program operations.

Office of Investigations. OI's criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs and operations often lead to criminal convictions, administrative sanctions, and civil monetary penalties. OI's nationwide network of investigators collaborates with the Department of Justice and other Federal, State, and local law enforcement authorities. OI works with public health entities to minimize adverse patient impacts following enforcement operations. OI also provides security and protection for the Secretary and other senior HHS officials.

Office of Counsel to the Inspector General. OCIG provides legal advice to OIG on HHS programs and OIG's internal operations. The law office also imposes exclusions and civil monetary penalties, monitors Corporate Integrity Agreements, and represents HHS's interests in False Claims Act cases. In addition, OCIG publishes advisory opinions, compliance program guidance documents, fraud alerts, and other resources regarding compliance considerations, the anti-kickback statute, and other OIG enforcement authorities.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC

at https://oig.hhs.gov

Section 8M of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG website.

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

August 2024 | A-07-22-07010

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

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.
- 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.
- This audit, one of a series of audits, determined whether South Carolina complied with Federal Medicaid requirements for invoicing manufacturers for physician-administered drugs dispensed to MCO enrollees.

What OIG Found

South Carolina did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs dispensed to MCO enrollees. South Carolina did not invoice for, and collect from manufacturers, rebates totaling $14.2 million (Federal share).

- Of this amount, $12.1 million (Federal share) was for single-source drugs and $65,691 (Federal share) was for top-20 multiple-source drugs.
- We also identified rebates totaling $1.9 million (Federal share) for other multiple-source drugs for which we were unable to determine whether, in some cases, the State was required to invoice for rebates.

What OIG Recommends

We recommend that South Carolina:

1. invoice for and collect manufacturers' rebates totaling $12.2 million (Federal share) for single-source and top-20 multiple-source physician-administered drugs and refund the Federal share;
2. work with CMS to determine whether the claims for other multiple-source physician-administered drugs, totaling $1.9 million (Federal share), were eligible for rebates and, if so, determine the rebates due for these drugs and, upon receipt of the rebates, refund the Federal share of the rebates collected;
3. ensure that all physician-administered drugs eligible for rebates after our audit period are processed for rebates; and
4. continue to review and strengthen its internal controls to ensure that, in line with South Carolina's existing policies, all physician-administered drugs eligible for rebates are invoiced.

South Carolina generally concurred with all of our recommendations and described corrective actions it had taken or planned to take.

TABLE OF CONTENTS

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 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. 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 South Carolina Department of Health and Human Services'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.[2]

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.[3] 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] OIG performed similar audits for rebates due for drugs administered by physicians to fee-for-service (FFS) as well as MCO enrollees. These audits are included in Appendix B. A previous OIG audit at South Carolina found that the State claimed unallowable Federal Medicaid reimbursement for some FFS physician-administered drugs.

[2] We selected this audit period to be consistent with the audit period in our previously issued South Carolina FFS report (A-07-21-07003; Appendix B).

[3] 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 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 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 Medicaid 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.[4] 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 for the top

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

20 multiple-source physician-administered drugs.[5] For purposes of the Medicaid drug rebate program, single-source drugs are those covered outpatient drugs produced or distributed under an original new drug application approved by the Food and Drug Administration (FDA). Multiple-source drugs are defined, in part, as those covered outpatient drugs that have at least one other drug related 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 provider claim information, including claim lines for covered outpatient drugs. This information conveys drug utilization data, which State must include when invoicing manufacturers for rebates.

The State Agency's Medicaid Drug Rebate Program

The State agency 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 enrollees, within 60 days of the end of each quarter. During our audit period, the State agency utilized a contractor to manage its drug rebate program. The contractor processed and invoiced Federal rebates through its rebate administration system. Manufacturers pay rebates directly to the State agency; the State agency then forwards the payment information to the contractor, which reconciles the payments received to the payments invoiced. The contractor forwards summarized invoice totals and details monthly payments data to the State agency. The State agency tracks invoice data for reporting purposes.

HOW WE CONDUCTED THIS AUDIT

We reviewed physician-administered drug claims paid by the MCOs that totaled $168,590,761 between January 1, 2016, and December 31, 2019 (audit period).

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

[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] Section 2501 of 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).

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.[8] Additionally, we determined whether the HCPCS codes were published in CMS's top-20 multiple-source drug listing.

We removed claims for drugs that either were not eligible for rebates or were invoiced for rebates. For the remaining physician-administered drug claims, totaling $45,244,489, 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 $19,892,535 ($14,151,294 Federal share) for physician-administered drugs dispensed to MCO enrollees.[9] Of this amount, $17,155,903 ($12,204,259 Federal share) was for drugs that were required to be rebated.[10] In addition, the State agency did not invoice for rebates associated with $2,736,632 ($1,947,035 Federal share) in other

[8] 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. 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.

[9] Of the $19,892,535 ($14,151,294 Federal share) we identified as not submitted for rebate, the State agency said that it had already invoiced, during our audit work, drug rebates totaling $17,128,012 ($12,181,484 Federal share). Of this amount, $14,847,083 ($10,559,104 Federal share) was for single-source and top-20 multiple-source drugs and $2,280,929 ($1,622,380 Federal share) was for other multiple-source drugs. We did not verify during our audit that the State agency had completed these actions.

[10] This amount consisted of $17,063,564 ($12,138,568 Federal share) for single-source drugs and $92,339 ($65,691 Federal share) for top-20 multiple-source drugs.

multiple-source physician-administered drugs which, although not required to be rebated like single-source and top-20 multiple-source drugs, were eligible for rebates.

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. During our audit, we briefed State agency officials on the results of our analysis, after which the State agency began to evaluate existing internal controls for the physician-administered drug claims and rebate process lifecycle. Based on its initial evaluation of internal controls, the State agency may decide to implement additional operational review processes to review claim information at each step in the drug claims and rebate process lifecycle, thereby to ensure that all eligible physician-administered drug claims paid by MCOs are invoiced to the drug manufacturers.

FEDERAL AND STATE REQUIREMENTS

The DRA amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs. States must capture NDCs for single-source and top-20 multiple-source drugs (the Act § 1927(a)(7)). To secure rebates, States are required to report certain information to manufacturers within 60 days after the end of each rebate period (the Act § 1927(b)(2)(A)). Federal regulations prohibit Federal reimbursement for physician-administered drugs for which a State has not required the submission of claims containing the NDCs (42 CFR § 447.520).

The 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 must secure rebates for drugs dispensed through MCOs and require MCOs to submit to the State NDCs for drugs dispensed to eligible individuals (the Act § 1903(m)(2)(A)).

The State agency publishes Medicaid bulletins to clarify and explain new and existing programs and policies for providers and other interested parties. The South Carolina Department of Health and Human Services Medicaid Bulletin (September 11, 2006) stated that for all drugs administered in an office, clinic, or other outpatient setting with dates of service on or after January 1, 2007, the State agency would:

> require providers billing for prescription drug products administered in an office or outpatient setting using a drug-related Healthcare Common Procedure Coding System (HCPCS) code to include the following data elements on all electronic,

> [South Carolina] Medicaid Web-Based Claims . . . and paper claim (*i.e.*, CMS-1500) submissions: National Drug Code (NDC) . . . each NDC must be an 11-digit code . . . unique to the manufacturer of the specific drug or product administered to the beneficiary.

Appendix C contains Federal and State requirements 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 $19,892,535 ($14,151,294 Federal share) for physician-administered drugs dispensed to MCO enrollees. Of this amount:

- $17,155,903 ($12,204,259 Federal share) was for drugs that were required to be rebated. Specifically, $17,063,564 ($12,138,568 Federal share) was for single-source drugs and $92,339 ($65,691 Federal share) was for top-20 multiple-source drugs.

- $2,736,632 ($1,947,035 Federal share) was for other multiple-source drugs. We were unable to determine whether, in some cases, the State agency was required to invoice for rebates for other multiple-source physician-administered drug claims. The State agency generally possessed sufficient information (such as NDCs) to invoice the manufacturers 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.

RECOMMENDATIONS

We recommend that the South Carolina Department of Health and Human Services:

- invoice for and collect manufacturers' rebates totaling $12,204,259 (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 whether the claims for other multiple-source physician-administered drugs, totaling $1,947,035 (Federal share), were eligible for rebates and, if so, determine the rebates due for these drugs and, upon receipt of the rebates, refund the Federal share of the rebates collected;

- ensure that all physician-administered drugs eligible for rebates after our audit period are processed for rebates; and

- continue to review and strengthen its internal controls to ensure that, in line with the State agency's existing policies, all physician-administered drugs eligible for rebates are invoiced.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency generally concurred with our recommendations and described corrective actions it had taken or planned to take.

For our first two recommendations, the State agency said that its rebate vendor, in August 2023, had invoiced manufacturers for $10,559,104 (Federal share) for single-source and top-20 multiple-source physician-administered drugs and $1,622,380 (Federal share) for other multiple-source physician-administered drugs. The State agency added that these actions were reflected on the September 2023 quarterly Form CMS-64R. The State agency also stated that the residual amounts of $1,645,155 (Federal share) for single-source and top-20 multiple-source physician-administered drugs, and $324,655 (Federal share) for other multiple-source physician-administered drugs, would be refunded to CMS through entries on the CMS-64 report "when instructed by CMS" to do so.

For our third recommendation, the State agency said it had determined that "MCOs did not consistently submit single ingredient claims and MCOs did not consistently submit an accurate paid date on claims." The State agency also said that its rebate vendor had implemented a policy to edit for a valid paid date and would continue to monitor for single ingredient claims.

For our fourth recommendation, the State agency said it had identified issues with the reference information it uses to identify physician-administered drugs requiring rebate. According to the State agency, the issues involve "inconsistent NDC and HCPCS crosswalk reference, invalid NDC and HCPCS combinations for MCO encounters, and lack of presence of NDC[s] on MCO encounters." The State agency added that it would emphasize, through policy and contractual terms, the requirements for MCO claim processing.

In addition, the State agency said that it is currently redesigning and implementing an enhanced Encounter Processing System "to improve and allow more robust adherence around NDC and HCPCS compliance for the acceptance of MCO encounters."

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

OFFICE OF INSPECTOR GENERAL RESPONSE

We commend the State agency for the corrective actions that it said it had taken or planned to take. We note, though, that the State agency's comments on our third recommendation did not directly address that recommendation. The State agency's comments on our third recommendation focused on the MCOs and the rebate vendor and spoke in terms of what the State agency called "single ingredient claims." When we separately queried the State agency

about the meaning of this term, the State agency explained that the term "single ingredient claims" refers to claims that are billed for only a single NDC. The State agency added that these claims do not involve compound drugs (i.e., medications that are tailored to the needs of an individual patient by combining, mixing, or altering ingredients).

In our judgment, single ingredient claims are therefore not the same as single-source drug claims. We acknowledge the State agency's statements that its rebate vendor had implemented a policy to edit for a valid paid date and that the State agency would monitor for single ingredient claims. We continue to recommend, however, that the State agency ensure that all physician-administered drugs eligible for rebates after our audit period are processed for rebates.

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 $168,590,761 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 Columbia, South Carolina.

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 requirements and guidance to providers, including invoicing instructions for physician-administered drugs.

- We reviewed State agency policies and procedures for rebates for physician-administered drugs.

- We interviewed State agency personnel to gain an understanding of the administration of and controls over the Medicaid invoicing and rebate process for physician-administered drugs.

- We obtained lists of the CMS top-20 multiple-source physician-administered drugs, the Medicare Part B crosswalk (footnote 8), 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, as drug claims associated with 340B entities are not eligible for rebate.[11]

- 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, the State agency provided data associated with claims totaling $168,590,761. We took the following steps:

    - We identified single-source drugs based on the classification of the drugs in the CMS Medicaid Drug File. If necessary, we matched the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk to identify the NDCs associated with each HCPCS code listed on claims from providers.

    - 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 the remaining drugs as other outpatient physician-administered drugs. These drugs were not identified as single-source or as top-20 multiple-source drugs.

- We removed drug claims paid by the MCOs totaling $123,346,272 that either were not eligible for a drug rebate or were invoiced for rebate.

- We reviewed the remaining drug claims paid by the MCOs totaling $45,244,489 to determine whether the State agency complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs.

- We discussed the results of our audit with State agency officials.

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

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

APPENDIX 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
Texas Did Not Bill Manufacturers for Some Rebates for Pharmacy Drugs of Medicaid Managed-Care Organizations	A-06-16-00004	12/12/2017
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 AND STATE REQUIREMENTS RELATED TO PHYSICIAN-ADMINISTERED DRUGS

FEDERAL REQUIREMENTS

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.[12] 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

[12] 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 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 State agency publishes Medicaid bulletins to clarify and explain new and existing programs and policies for providers and other interested parties. The South Carolina Department of Health and Human Services Medicaid Bulletin (September 11, 2006) states:

> To comply with Centers for Medicare and Medicaid Services (CMS) requirements related to the Deficit Reduction Act (DRA) of 2005, a change involving all drugs administered in an office/clinic or other outpatient setting will become effective with dates of service on or after January 1, 2007. The South Carolina Department of Health and Human Services (DHHS) will require providers billing for prescription drug products administered in an office or outpatient setting using a drug-related Healthcare Common Procedure Coding System (HCPCS) code to include the following data elements on all electronic, [South Carolina] Medicaid Web-Based Claims . . . and paper claim (*i.e.*, CMS-1500) submissions: National Drug Code (NDC) . . . each NDC must be an 11-digit code . . . unique to the manufacturer of the specific drug or product administered to the beneficiary.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
Healthy Connections MEDICAID

Henry McMaster GOVERNOR
Robert M. Kerr DIRECTOR
P.O. Box 8206 > Columbia, SC 29202
www.scdhhs.gov

July 29,2024

Re: Report Number A-07-22-07010

James I. Korn
Regional Inspector General for Audit Services
Department of Health & Human Services
Office of Inspector General
Office of Audit Services, Region VII
601 East 12th Street, Room 0429
Kansas City, MO 64106

Dear Mr. Korn:

The South Carolina Department of Health & Human Services (SCDHHS) has reviewed your draft report entitled "***South Carolina Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Managed-Care Organizations***". In general, SCDHHS concurs with each of the recommendations. As a result, we are offering the following corrective action(s) in response to these recommendations.

Recommendation #1 – Refund the Federal Government $17,155,903 million ($12,204,259 FFP) for single source and top-20 multiple-source physician-administered drugs and refund the Federal Share of rebates collected.

Corrective Action taken/planned – SCDHHS' drug rebate vendor, [redacted][13] has confirmed that $14,847,083 (10,559,104 FFP) has been invoiced to manufacturers in August 2023, which was reflected on the September 2023 CMS 64.9r report. The residual amount $2,308,819 ($1,645,155 FFP) will be refunded to the Federal Government via an entry to the CMS 64 when instructed by CMS.

Recommendation #2 – Work with CMS to determine the portion of the $2,736,632 ($1,947,035 FFP) for other multiple-source physician-administered drugs that were eligible for rebate, invoice the manufacturer for rebates for these drugs, and refund the Federal share.

Corrective Action taken/planned – SCDHHS' drug rebate vendor, [redacted] has confirmed that $2,280,930 ($1,622,380 FFP) has been invoiced to manufacturers in August 2023, which was reflected on the September 2023 quarterly CMS 64.9r report. The residual amount $455,702 ($324,655 FFP) will be refunded to the Federal Government via an entry to the CMS 64 when instructed by CMS.

Recommendation #3 – Ensure that all physician-administered drugs eligible for rebates after our audit period are processed for rebates.

[13] **Office of Inspector General Note—**The deleted text has been redacted because it is third-party information.

Corrective Action taken/planned – SCDHHS determined that MCOs did not consistently submit single ingredient claims and MCOs did not consistently submit an accurate paid date on claims. SCDHHS' drug rebate vendor has implemented a policy to edit for a valid paid date and will monitor for single ingredient claims.

Recommendation #4 – Continue to review and strengthen its internal controls to ensure that, in line with the State Agency's existing policies, all physician-administered drugs eligible for rebates are invoiced.

Corrective Action taken/planned – SCDHHS has identified issues with the reference information it utilizes for determining physician-administered drugs requiring rebate. The issues are related to inconsistent NDC and HCPCS crosswalk reference, invalid NDC and HCPCS combinations for MCO encounters, and lack of presence of NDC on MCO encounters. SCDHHS will reinforce through policy and contractual terms, the requirements for MCO claim processing to mitigate issues with encounter reporting submissions.

It should also be noted that SCDHHS is in the process of a full-scale redesign and implementation of a more advanced Encounter Processing System (EPS). The scope of the new EPS contains design and implementation of system functionalities to improve and allow more robust adherence around NDC and HCPCS compliance for the acceptance of MCO encounters.

We respectively request your positive consideration of these actions as a resolution to these findings. If you have questions or need additional information, please do not hesitate to call me at (803) 898-2504, or contact Cheryl Anderson at (803) 898-0730 or Cheryl.Anderson@SCDHHS.gov , or Milton German at (803) 898-1051 or German@SCDHHS.gov.

Sincerely,

/s/

Robert M. Kerr
Director