Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

ALABAMA DID NOT ALWAYS INVOICE REBATES TO MANUFACTURERS FOR PHARMACY AND PHYSICIAN-ADMINISTERED DRUGS

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Office of Inspector General

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Report in Brief
Date: September 2023
Report No. A-04-21-08090

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

Alabama Did Not Always Invoice Rebates to Manufacturers for Pharmacy and Physician-Administered Drugs

Why OIG Did This Audit

For a covered outpatient drug to be eligible for Federal reimbursement under the Medicaid program's drug rebate requirements, manufacturers must pay rebates to the States for the drugs. However, prior OIG audits found that States did not always invoice and collect all rebates due for drugs administered by pharmacies and physicians.

Our objective was to determine whether Alabama complied with Federal Medicaid requirements for invoicing manufacturers for rebates for pharmacy and physician-administered drugs.

How OIG Did This Audit

Our audit covered pharmacy and physician-administered drug claims that Alabama paid between January 1, 2016, and December 31, 2019.

We used the Centers for Medicare & Medicaid Services' (CMS's) Medicare Part B crosswalk and the CMS Medicaid Drug File to identify single-source and multiple-source drugs. In addition, we determined whether the Healthcare Common Procedure Coding System codes were published in CMS's top-20 multiple-source drug listing.

What OIG Found

Alabama did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for pharmacy and physician-administered drugs. Alabama did not invoice for, and collect from manufacturers, rebates associated with $21 million ($14.9 million Federal share) in single-source and $62,043 ($43,981 Federal share) in top-20 multiple-source physician-administered drug claims. Further, we were unable to determine whether, in some cases, Alabama was required to invoice for rebates for other multiple-source physician-administered drug claims. Alabama did not invoice the manufacturers for rebates associated with the claims totaling $410,454 ($290,455 Federal share) for these multiple-source drugs. Lastly, the OIG identified $6,568 ($4,719 Federal share) in single-source and $219,220 ($157,395 Federal share) in multiple-source pharmacy drug claims where Alabama did not collect a rebate from manufacturers.

What OIG Recommends and Alabama Comments

We recommend that Alabama refund to the Federal Government $14.9 million (Federal share) for claims for single-source physician-administered drugs and $43,981 (Federal share) for claims for top-20 multiple-source physician-administered drugs. We also recommend that Alabama work with CMS to determine and refund the unallowable portion of $290,455 (Federal share) for other claims for multiple-source physician-administered drugs that may have been ineligible for Federal reimbursement and consider invoicing drug manufacturers for rebates for those drug claims that CMS determines are allowable. Additionally, we recommend that Alabama complete the process for rebating pharmacy drugs totaling $6,568 ($4,719 Federal share) for single-source and $219,220 ($157,395 Federal share) for multiple-source drugs that it had not previously collected a rebate on or refund the Federal share. We also made two additional recommendations.

Alabama did not concur with our first four recommendations. However, they responded that they will be invoicing for, and collecting from manufacturers, rebates associated with the claims associated with each of the first four recommendations. They will be invoicing for these on the next available rebate cycle and plan to pay the Federal share on any rebate received. Alabama also responded that they would ensure rebate eligible physician-administered drugs are invoiced for rebates after December 31, 2019, and strengthen their internal controls.

The full report can be found at https://oig.hhs.gov/oas/reports/region4/42108090.asp.

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INTRODUCTION

WHY WE DID THIS AUDIT

For a covered outpatient drug to be eligible for Federal reimbursement under the Medicaid program's drug rebate requirements, manufacturers must pay rebates to the States for the drugs. States generally offset their Federal share of these rebates against their Medicaid expenditures. States invoice the manufacturers for rebates to reduce the cost of drugs to the program. However, a prior Office of Inspector General review found that States did not always invoice and collect all rebates due for drugs administered by physicians.[1] (Appendix B lists previous audits of the Medicaid drug rebate program.) For this audit, we reviewed the Alabama Medicaid Agency's (State agency's) invoicing for rebates for both pharmacy and physician-administered drugs for January 1, 2016, through December 31, 2019 (audit period).

OBJECTIVE

Our objective was to determine whether the State agency complied with Federal Medicaid requirements for invoicing manufacturers for rebates for pharmacy and 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 with the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each have specific functions under the program.

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

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

[1] *States' Collection of Medicaid Rebates for Physician-Administered Drugs* (OEI-03-09-00410), issued June 2011.

[2] Section 1927(b) of the Act.

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.

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 (Form CMS-64), 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.

Pharmacy and Physician-Administered Drugs

Drugs may be provided to a recipient through a pharmacy or administered by a physician in an office or a hospital. Pharmacy drugs are typically invoiced to Medicaid using NDCs. A valid NDC is a unique identifier that represents a drug's specific manufacturer, product, and package size. Physician-administered drugs are typically invoiced to the Medicaid program on a claim form using Healthcare Common Procedure Coding System (HCPCS) codes.[3] For purposes of the Medicaid drug rebate program, pharmacy and physician-administered drugs are classified as either single-source or multiple-source.[4]

The Deficit Reduction Act of 2005 (DRA) amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs for all single-source drugs and the top-20 multiple-source drugs.[5] Beginning on January 1, 2007, CMS was responsible for publishing an annual list of the top-20 multiple-source drugs by HCPCS codes that had the highest dollar volume dispensed. Before the DRA, many States did not collect rebates on physician-administered drugs if the drug claims did not contain NDCs. NDCs enable States to identify the drugs and their manufacturers and facilitate the collection of rebates for the drugs.

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

[4] See, e.g., the Act § 1927(a)(7). In general terms, multiple-source drugs are covered outpatient drugs for which there are two or more drug products that are rated as therapeutically equivalent by the Food and Drug Administration. See, e.g., the Act § 1927(k)(7). Multiple-source drugs stand in contrast to single-source drugs, which do not have therapeutic equivalents.

[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)).

The State Agency's Medicaid Drug Rebate Program

The State agency is responsible for paying claims, submitting invoices to manufacturers, and collecting Medicaid drug rebates for pharmacy and physician-administered drugs.

The State agency also requires the submission of NDCs on all claims with procedure codes for physician-administered drugs. The State agency uses its claim data for physician-administered drugs to invoice manufacturers quarterly and to maintain a record of rebate accounts receivable due from the manufacturers. The manufacturers then pay the rebates directly to the State agency.

HOW WE CONDUCTED THIS AUDIT

Our audit covered $3,431,301,000 ($2,436,609,951 Federal share) of pharmacy and physician-administered drug claims that the State agency paid during our audit period.

We obtained drug claim details from the State agency for pharmacy and physician-administered drug claims paid during our audit period. We then requested all drug claims that had been invoiced for rebates during our audit period. We removed claims for drugs that either were not eligible for rebates or were invoiced for rebates. We reviewed the remaining claims that were not invoiced for rebates. For claims submitted with NDCs, we used the CMS Medicaid Drug File to determine whether the NDCs listed on the claims were classified as single-source or multiple-source drugs. We identified the top-20 multiple-source drugs by matching the HCPCS code on each drug claim to the HCPCS code on the top-20 listing. We identified the remaining multiple-source drugs (those not identified as single-source drugs or top-20 multiple-source drugs) as other pharmacy and 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 A contains details of our audit scope and methodology.

FINDINGS

The State agency did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for pharmacy and physician-administered drugs. The State agency did not invoice for, and collect from manufacturers, rebates associated with $21,043,949 ($14,960,673 Federal share) in single-source and $62,043 ($43,981 Federal share) in top-20 multiple-source physician-administered drug claims. Because the State agency's internal controls did not always ensure that it invoiced manufacturers to secure rebates, the State

agency improperly claimed Federal reimbursement for these single-source and top-20 multiple-source drugs.

In addition, we were unable to determine in some cases whether the State agency was required to invoice for rebates for other multiple-source physician-administered drug claims. Although the State agency generally collected the drug utilization data necessary to invoice manufacturers for rebates associated with these drugs, the State agency did not invoice the manufacturers for rebates related to these claims, which totaled $410,454 ($290,455 Federal share). The State agency should work with CMS to determine the unallowable portion of the $410,454 ($290,455 Federal share) of claims and consider invoicing drug manufacturers for rebates for these drugs if CMS determines that the drug claims are allowable.

We also identified $6,568 ($4,719 Federal share) in single-source and $219,220 ($157,395 Federal share) in multiple-source pharmacy drug claims where the State agency did not collect a rebate from manufacturers.

State agency officials were unable to make a determination about the amount they should reimburse CMS until the rebate process was complete. However, State agency officials said they will invoice for, and collect from manufacturers, rebates associated with all the drug claims related to our findings. Because drug claims can only be invoiced for rebate quarterly, State agency officials estimate they can process these claims in the next available rebate cycle. The State agency has agreed to pay the Federal share of any rebate received.

FEDERAL REQUIREMENTS AND STATE AGENCY GUIDANCE

For payment to be available for covered outpatient drugs provided under Medicaid, manufacturers are required to enter into rebate agreements with the Secretary and pay quarterly rebates to State Medicaid agencies (the Act § 1927(a)(1) & (b)(1)).

In addition, 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 State agency created the *Alabama Medicaid Agency Pharmacy Services Division Physician Administered Drug NDC/HCPCS FAQ'S and Resource List*, which contains basic policy guidance and information regarding Alabama's Medicaid program. This policy guidance states:

> In 2008, the Alabama Medicaid Agency began requiring the NDC number for the top 20+ physician-administered multiple source drugs. Effective October 1, 2010, the NDC number will be mandatory on physician-administered

> drugs….Providers are required to submit their claims with the exact NDC that appears on the product administered….NDC's will be required on Medicare crossover claims for all applicable HCPCS codes on the list. The 11-digit NDC submitted must be the actual NDC number on the package or container from which the medicine was administered. As this process is to facilitate Medicaid drug rebates from manufacturers, providers are required to utilize drugs manufactured by companies who hold a federal rebate agreement. These NDCs will be the only ones Medicaid will cover for payment….claims without the proper NDC qualifier and NDC that are not currently included in the Medicaid Physician-Administered multi-source Top 20+ HCPCS drug listing will deny beginning October 1, 2010.

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

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES ON SOME SINGLE-SOURCE PHYSICIAN-ADMINISTERED DRUGS

The State agency improperly claimed Federal reimbursement of $21,043,949 million ($14,960,673 Federal share) for single-source physician-administered drug claims that it did not invoice to manufacturers for rebates.

Because the State agency did not invoice for rebates for all single-source physician-administered drugs, these claims were not eligible for Federal reimbursement. The State agency did not collect rebates for these claims for various reasons. Specifically, the State agency's claims processing system did not reject claims with invalid information in the HCPCS and NDC fields. Valid HCPCS and NDC combinations are required for processing rebates. In addition, the State agency's rebate processing system excluded other claims for rebate, but the State agency did not have sufficient controls to verify the exclusion reason. Lastly, the rebate processing system did not have sufficient controls to account for timing differences between the claim paid date and the subsequent CMS quarterly drug rebate file update. Officials said that they needed to perform additional research to ensure that all eligible physician-administered drug claims were being properly invoiced.

State agency officials were unable to determine the amount that they should reimburse CMS on this issue until the rebate process was complete. State agency officials estimated that they could process the drug claims associated with this finding during the next available rebate cycle. The State agency agreed to pay the Federal share of any rebate received.

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES ON SOME TOP-20 MULTIPLE-SOURCE PHYSICIAN-ADMINISTERED DRUGS

The State agency improperly claimed Federal reimbursement of $62,043 ($43,981 Federal share) for top-20 multiple-source drugs for which it did not invoice manufacturers for rebates.

CMS last provided the State agency with an annual listing of top-20 multiple-source HCPCS codes and their respective NDCs in 2011. We relied on this listing to identify top-20 multiple-source physician-administered drugs. However, the State agency did not always submit the utilization data for the drugs on the list to the drug manufacturers for rebate purposes.

Because the State agency did not invoice for rebates for all top-20 multiple-source physician-administered drugs, the related claims were not eligible for Federal reimbursement. The State agency did not collect rebates for these claims for the same reasons cited earlier: claims with invalid information in the HCPCS and NDC fields, the rebate processing system excluding some claims for rebate, and timing issues between the rebate processing system and CMS.

State agency officials were unable to determine the amount that they should reimburse CMS on this issue until the rebate process was complete. State agency officials estimated that they could process the drug claims associated with this finding during the next available rebate cycle. The State agency agreed to pay the Federal share of any rebate received.

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES ON OTHER PHYSICIAN-ADMINISTERED DRUGS

In some cases, we were unable to determine whether the State agency was required to invoice for rebates related to other pharmacy and physician-administered drug claims.

Although the State agency generally collected the drug utilization data necessary to invoice manufacturers for rebates associated with the claims for other multiple-source physician-administered drugs, it did not invoice the manufacturers for rebates totaling $410,454 (290,455 Federal share) that were associated with multiple-source physician-administered drugs. Providers submitted these claims, which were not used to obtain Medicaid drug rebates. Under the Medicaid drug rebate program, these claims could have been eligible for rebates. The State agency did not collect rebates for these claims for the same reasons cited earlier: claims with invalid information in the HCPCS and NDC fields, the rebate processing system excluding some claims for rebate, and timing issues between the rebate processing system and CMS.

Accordingly, we set aside $410,454 ($290,455 Federal share) for the remaining multiple-source drug claims. The State agency should work with CMS to determine the unallowable portion of these claims and consider invoicing drug manufacturers for rebates for these drugs if CMS determines that the drug claims are allowable.

State agency officials were unable to determine the amount that they should reimburse CMS on this issue until the rebate process was complete. State agency officials estimated that they could process the drug claims associated with this finding during the next available rebate cycle. The State agency agreed to pay the Federal share of any rebate received.

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES ON SOME SINGLE-SOURCE AND MULTIPLE-SOURCE PHARMACY DRUGS

The State agency did not collect rebates from manufacturers for claims totaling $6,568 ($4,719 Federal share) for single-source and $219,220 ($157,395 Federal share) for multiple-source pharmacy drugs. Specifically, these claims were not invoiced for rebate because State agency officials said they did not have a valid CMS Unit Rebate Amount (URA) provided for the claims' NDCs for the applicable year/quarter for each claim. Without a valid URA, the State agency was unable to invoice manufacturers for rebates on these pharmacy drugs. The State agency was unable to provide additional explanations before the issuance of the draft report.

State agency officials were unable to determine the amount that they should reimburse CMS on this issue until the rebate process was complete. State agency officials estimated that they could process the drug claims associated with this finding during the next available rebate cycle. The State agency agreed to pay the Federal share of any rebate received.

RECOMMENDATIONS

We recommend that the Alabama Medicaid Agency:

- refund to the Federal Government $14,960,673 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;

- refund to the Federal Government $43,981 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement;

- work with CMS to determine and refund the unallowable portion of $290,455 (Federal share) for other claims for multiple-source physician-administered drugs that may have been ineligible for Federal reimbursement and consider invoicing drug manufacturers for rebates for those drug claims that CMS determines are allowable;

- complete the process for rebating pharmacy drugs totaling $6,568 ($4,719 Federal share) for single-source and $219,220 ($157,395 Federal share) for multiple-source drugs that it had not previously collected a rebate on or refund the Federal share;

- work with CMS to determine and refund the unallowable portion of Federal reimbursement for physician-administered drugs that were not invoiced for rebates after December 31, 2019; and

- strengthen its internal controls to ensure that all pharmacy and physician-administered drugs eligible for rebates are invoiced.

STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, State agency officials said that they did not concur with our first four recommendations. However, State agency officials listed the steps it plans to take to invoice for, and collect from manufacturers, rebates associated with our findings for those four recommendations. The State agency agreed to take the actions we proposed in recommendations five and six.

STATE AGENCY COMMENTS TO OUR FIRST RECOMMENDATION

State agency officials did not concur with our first recommendation. However, they said that they planned to invoice for, and collect from manufacturers, rebates associated with the $14,960,673 (Federal share) in single-source physician-administered drug claims. According to State agency officials, this invoicing can only occur during a quarterly rebate cycle. The State agency estimates that it can process these claims in the next available rebate cycle. State agency officials also said that manufacturers would need time to pay the rebate owed and that the State agency would refund the Federal share of any rebate it received.

Office of Inspector General Response

We agree with the State agency's plan to process single-source physician-administered drug claims for rebate.

STATE AGENCY COMMENTS TO OUR SECOND RECOMMENDATION

State agency officials did not concur with our second recommendation. However, they said that they will be invoicing for, and collecting from manufacturers, rebates associated with the $43,981 (Federal share) in top-20 multiple-source physician-administered drug claims. According to State agency officials, this invoicing can only occur during a quarterly rebate cycle. The State agency estimates that it can process these claims in the next available rebate cycle. State agency officials also said that manufacturers would need time to pay the rebate owed and that the State agency would refund the Federal share of any rebate it received.

Office of Inspector General Response

We agree with the State agency's plan to process top-20 multiple-source physician-administered drug claims for rebate.

STATE AGENCY COMMENTS TO OUR THIRD RECOMMENDATION

State agency officials did not concur with our third recommendation. However, they said they will be invoicing for, and collecting from manufacturers, rebates associated with the $290,455 (Federal share) for other multiple-source physician-administered drug claims. According to State agency officials, this invoicing can only occur during a quarterly rebate cycle. The State agency estimates that it can process these claims in the next available rebate cycle. State agency officials also said that manufacturers would need time to pay the rebate owed and that the State agency would refund the Federal share of any rebate it received.

Office of Inspector General Response

We agree with the State agency's plan to process other multiple-source physician-administered drug claims for rebate.

STATE AGENCY COMMENTS TO OUR FOURTH RECOMMENDATION

State agency officials did not concur with our fourth recommendation. However, they said that they will be invoicing for, and collecting from manufacturers, rebates associated with the $6,568 ($4,719 Federal share) in single-source and $219,220 ($157,395 Federal share) in multiple-source pharmacy drug claims. According to State agency officials, this invoicing can only occur during a quarterly rebate cycle. The State agency estimates that it can process these claims in the next available rebate cycle. State agency officials also said that manufacturers would need time to pay the rebate owed and that the State agency would refund the Federal share of any rebate it received.

Office of Inspector General Response

We agree with the State agency's plan to process single-source and multi-source pharmacy drug claims for rebate.

STATE AGENCY COMMENTS TO OUR FIFTH AND SIXTH RECOMMENDATION

State agency officials said they would ensure rebate-eligible, physician-administered drugs are invoiced for rebates after December 31, 2019. The State agency will also pay the Federal share on all rebates received, and work to strengthen internal controls to ensure all pharmacy and physician-administered drugs eligible for rebates are invoiced, including internal retrospective audits.

Office of Inspector General Response

We agree with the State agency's plan to invoice and collect rebates for drug claims paid after December 31, 2019, and its plan to improve its internal controls so that all eligible drugs are properly rebated.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered $3,431,301,000 ($2,436,609,951 Federal share) of pharmacy and physician-administered drug claims that the State agency paid during our audit period (January 1, 2016, through December 31, 2019).

During our audit, we did not assess the overall internal control structure of the State agency. Rather, we limited our review to the State Agency's internal controls for compliance with Medicaid invoicing requirements for drug rebates. To evaluate these internal controls, we took the following steps:

- reviewed the State agency's code of ethics and organizational charts;
- reviewed the State agency's policies and procedures for rebate processing;
- reviewed the State agency's fiscal agent requirements; and
- discussed with State agency the causes of the identified errors.

We conducted our audit, which included contacting the State agency in Montgomery, Alabama from July 2021 through May 2023.

METHODOLOGY

To accomplish our objective, we took the following steps:

- We reviewed applicable Federal laws, regulations, and guidance about the Medicaid drug rebate program for both pharmacy and physician-administered drugs.
- We reviewed State agency policies and procedures for rebates for pharmacy and 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 pharmacy and physician-administered drugs.

- We obtained a listing of the CMS top-20 multiple-source physician-administered drugs, the Medicare Part B crosswalk, and the CMS Medicaid Drug File for our audit period.[6]

- We obtained drug claim details from the State agency for pharmacy and physician-administered drugs for the period January 1, 2016, through December 31, 2019.

- We obtained the listing of 340B entities from the State agency.[7]

- We removed duplicate drug claims, claims not eligible for a rebate, and claims that were properly invoiced for rebate.

- We reviewed the remaining claims for pharmacy and physician-administered drugs that were not invoiced for rebates and identified the following:

    - 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;

    - 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 listing; and

    - 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 discussed the results of our audit with State officials on May 8, 2023.

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.

[6] The Medicare Part B crosswalk is published quarterly by CMS and is based on drug and biological information manufacturers submitted to CMS. CMS uses this information along with pricing data manufacturers submitted to calculate a volume-weighted sales price for each HCPCS code, which becomes the basis for the reimbursement rate the States pay 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)).

[7] Under the 340B drug pricing program (set forth in 42 U.S.C § 256b), a 340B entity may purchase reduce-priced covered outpatient drugs from manufacturers. Examples of 340B entities include disproportionate share hospitals, which generally serve large numbers of low-income and 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
Kentucky Did Noy 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 Noy 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
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
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

Report Title	Report Number	Date Issued
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
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

Report Title	Report Number	Date Issued
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
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

Report Title	Report Number	Date Issued
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
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

Report Title	Report Number	Date Issued
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 AND STATE AGENCY GUIDANCE RELATED TO PHARMACY AND PHYSICIAN-ADMINISTERED DRUGS

FEDERAL LAWS

Under the Medicaid program, States may provide coverage for outpatient drugs as an optional service (the Act § 1905(a)(12)). Section 1903(a) of the Act provides for Federal financial participation (Federal share) in State expenditures for these drugs. The Medicaid drug rebate program, created by the Omnibus Budget Reconciliation Act of 1990 that added section 1927 to the Act, became effective on January 1, 1991. Manufacturers must enter into a rebate agreement with the Secretary of Health and Human Services (HHS) 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 to secure rebates for all single-source physician-administered drugs effective January 1, 2006, and for the top-20 multiple-source drugs effective January 1, 2008. Section 1927(a)(7)(C) of the Act states that, effective January 1, 2007, the utilization data must be submitted using 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)).

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 invoice a manufacturer for rebates (42 CFR § 447.520).

STATE AGENCY GUIDANCE

The State agency created the *Alabama Medicaid Agency Pharmacy Services Division Physician Administered Drug NDC/HCPCS FAQ'S and Resource List*, which contains basic policy guidance and information regarding Alabama's Medicaid program. This policy guidance states:

In 2008, the Alabama Medicaid Agency began requiring the NDC number for the top 20+ physician-administered multiple source drugs. Effective October 1, 2010, the NDC number will be mandatory on physician-administered drugs….Providers are required to submit their claims with the exact NDC that appears on the product administered….NDC's will be required on Medicare crossover claims for all applicable HCPCS codes on the list. The 11-digit NDC submitted must be the actual NDC number on the package or container from which the medicine was administered. As this process is to facilitate Medicaid drug rebates from manufacturers, providers are required to utilize drugs manufactured by companies who hold a federal rebate agreement. These NDCs will be the only ones Medicaid will cover for payment….claims without the proper NDC qualifier and NDC that are not currently included in the Medicaid Physician-Administered multi-source Top 20+ HCPCS drug listing will deny beginning October 1, 2010.

Alabama Medicaid Agency

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STEPHANIE MCGEE AZAR
Commissioner

July 20, 2023

Lori S. Pilcher
Regional Inspector General for Audit Services
Office of Audit Services, Region IV
Office of Inspector General
U.S. Department of Helaht and Human Services
61 Forsyth Street, SW, Suite 3T41
Atlanta, GA 30303

RE: Draft Audit Report Number: A-04-21-089090

Dear Ms. Pilcher:

The Alabama Medicaid Agency (Alabama Medicaid) welcomes the opportunity to comment on the recommendations contained in the draft report prepared by the Office of Inspector General (OIG) entitled, *Alabama Did Not Always Invoice Rebates to Manufacturers for Pharmacy and Physician-Administered Drugs.*

- **Recommendation 1:** Refund to the Federal Government $14,960,673 (Federal share) for claims for single source physician-administered drugs that were ineligible for Federal reimbursement.

  Alabama Medicaid response: Alabama Medicaid does not concur. The State agency will invoice for, and collect from manufacturers, rebates associated with $14,960,673 Federal share in single-source physician-administered drug claims. This invoicing can only occur during a rebate cycle which occurs quarterly. It is estimated the Agency can process these claims in the next available rebate cycle and time must be allowed for the manufacturers to pay the rebate owed. The State will pay the federal share on any rebate received.

- **Recommendation 2:** Refund to the Federal Government $43,981 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal Reimbursement.

  Alabama Medicaid response: Alabama Medicaid does not concur. The State agency will invoice for, and collect from manufacturers, rebates associated with $43,981 Federal share in top-20 multiple-source physician-administered drug claims. This invoicing can only occur during a rebate cycle which occurs quarterly. It is estimated the Agency can process these claims in the next available rebate cycle and time must be allowed for the manufacturers to pay the rebate owed. The State will pay the federal share on any rebate received.

- **Recommendation 3:** Work with CMS to determine and refund the unallowable portion of $290,455 (Federal share) for other claims for multiple-source physician-administered drugs that may have been ineligible for Federal reimbursement and consider invoicing drug manufacturers for rebates for those drug claims that CMS determines are allowable.

Alabama Medicaid response: Alabama Medicaid does not concur. The State agency will invoice for, and collect from manufacturers, rebates associated with $290,455 Federal share for multiple-source, physician-administered drugs. This invoicing can only occur during a rebate cycle which occurs quarterly. It is estimated the Agency can process these claims in the next available rebate cycle and time must be allowed for the manufacturers to pay the rebate owed. The State will pay the federal share on any rebate received.

- **Recommendation #4:** Complete the process for rebating pharmacy drugs totaling $6,568 ($4,719 Federal share) for single-source and $219,220 ($157,395 Federal share) for multiple-source drugs that it had not previously collected a rebate on or refund the Federal share.

  Alabama Medicaid response: Alabama Medicaid does not concur. The State agency will invoice for, and collect from manufacturers, rebates associated with $6,568 ($4,719 Federal share) in single-source and $219,220 ($157,395 Federal share) in multiple-source pharmacy drug claims. This invoicing can only occur during a rebate cycle which occurs quarterly. It is estimated the Agency can process these claims in the next available rebate cycle and time must be allowed for the manufacturers to pay the rebate owed. The State will pay the federal share on any rebate received.

- **Recommendation 5:** Work with CMS to determine and refund the unallowable portion of Federal reimbursement for physician-administered drugs that were not invoiced for rebates after December 31, 2019.

  Alabama Medicaid response: Alabama Medicaid will ensure rebate eligible physician-administered drugs are invoiced for rebates after December 31, 2019, following the procedure listed in the responses above. The State will pay the federal share on any rebate received.

- **Recommendation 6:** Strengthen its internal controls to ensure that all pharmacy and physician-administered drugs eligible for rebates are invoiced.

  Alabama Medicaid response: Alabama Medicaid will work to strengthen internal controls to ensure all pharmacy and physician-administered drugs eligible for rebates are invoiced, including internal retrospective audits.

Thank you again for the opportunity to respond to the recommendations contained in the Draft Report. Please let us know if we can provide you with any further information.

Sincerely,

Stephanie McGee Azar
Commissioner