Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

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

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March 2023
A-04-21-08089

Office of Inspector General

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Report in Brief
Date: March 2023
Report No. A-04-21-08089

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

Georgia 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 Georgia 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 Georgia paid between April 1, 2018, and December 31, 2019.

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

What OIG Found

Georgia did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for pharmacy and physician-administered drugs. Georgia did not invoice for, and collect from manufacturers, rebates associated with $953,067 ($644,802 Federal share) in single-source and $13,785 ($9,325 Federal share) in top-20 multiple-source physician-administered drug claims. Further, we were unable to determine whether, in some cases, Georgia was required to invoice for rebates for other multiple-source physician-administered drug claims. Georgia did not invoice the manufacturers for rebates associated with the claims totaling $78,013 ($52,837 Federal share) for these multiple-source drugs. Additionally, the OIG identified $1.8 million ($1.2 million Federal share) in single-source and $526,240 ($360,454 Federal share) in multiple-source pharmacy drug claims that were not rebated for prior to our audit.

What OIG Recommends and Georgia Comments

We recommend that Georgia refund to the Federal Government $644,802 (Federal share) for claims for single-source physician-administered drugs and $9,325 (Federal share) for claims for top-20 multiple-source physician-administered drugs. We also recommend that Georgia work with CMS to determine and refund the unallowable portion of $52,837 (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. We also made three additional recommendations.

Georgia concurred with four of our recommendations. In addition, it acknowledged the two remaining findings but did not agree with the total amount of Federal reimbursement. For our first recommendation, Georgia requested that the OIG lower the amount of the recommendation by $44,938 (Federal share) to reflect claims identified by Georgia as not eligible for a rebate. We agreed to reduce this recommendation by the amount requested. For recommendation four, Georgia requested to reduce this recommendation due to the rebate process being completed while the audit was ongoing. Because we identified this issue during our audit but it was completed before issuance of the report, we maintain our finding until the processing of these claims can be validated by CMS. We maintain that our other findings and recommendations remain valid.

The full report can be found at https://oig.hhs.gov/oas/reports/region4/42108089.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 Georgia Department of Community Health's (State agency's) invoicing for rebates for both pharmacy and physician-administered drugs for April 1, 2018, 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 beneficiary 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 annually the 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.

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

[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 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)).

agency contracted with an outside vendor (the contractor), to manage its drug rebate program during our audit period.

The contractor works in conjunction with the State agency's claims processors to gather drug utilization data and transfer these data to the rebate-processing system. Using these data, the contractor invoiced manufacturers for rebates quarterly. Also, the contractor maintained accounts receivable information and worked with manufacturers to resolve any unpaid rebates.

HOW WE CONDUCTED THIS AUDIT

Our audit covered $1,557,654,964 ($1,056,211,868 Federal share) of pharmacy and physician-administered drug claims that were paid by the State agency 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 that the contractor provide us with 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 the 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 nor collect from manufacturers the rebates associated with $953,067 ($644,802 Federal share) in single-source and $13,785 ($9,325 Federal share) in top-20

multiple-source physician-administered drug claims.[6] 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.

Further, 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. 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 associated with the claims totaling $78,013 ($52,837 Federal share) for these multiple-source drugs. The State agency should work with CMS to determine the unallowable portion of the $78,013 ($52,837 Federal share) of claims and consider invoicing drug manufacturers for rebates for these drugs if CMS determines that the drug claims are allowable.

Lastly, the OIG identified $1.8 million ($1.2 million Federal share) in single-source and $526,240 ($360,454 Federal share) in multiple-source pharmacy drug claims that were not rebated.[7]

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)).

Additionally, 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 publishes the *Part II Policies and Procedures for Providers' Administered Drug List* (PADL) manual, which contains basic policy and information regarding Georgia's Medicaid program. This manual states:

[6] Specifically, the State agency did not invoice manufacturers for rebates associated with drug expenditures that totaled $966,852 ($654,127 Federal share). Of the physician-administered drug claims amount, $953,067 ($644,802 Federal share) was for single-source drugs and $13,785 ($9,325 Federal share) was for top-20 multiple-source drugs.

[7] Specifically, the State agency did not invoice manufacturers for rebates associated with single-source, pharmacy drug expenditures that totaled $1,811,523 ($1,240,894 Federal share).

> Effective January 1, 2007, and pursuant to the Congressional Budget Reconciliation Act of 2006, practitioners are required to bill/report injectable drugs administered in offices and outpatient facilities using the manufacturers' 11-digit National Drug Code (NDC) numbers with the preceding N4 qualifiers and/or HCPCS/CPT [Current Procedural Terminology] codes. . . . Billing should include the total number of units contained therein and as listed in the PADL manual, these are generally not billed per vial. Claims for injectable drugs received for processing without the NDC numbers and/or HCPCS/CPT codes or with conflicting or invalid numbers or codes will result in denials.

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 $953,067 ($644,802 Federal share) for single-source physician-administered drug claims for which it did not invoice 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. Based on its initial evaluation after the State agency was made aware of our analysis, the State agency determined that additional operational review processes would likely be necessary to review claim information at each step in the claim and rebate process lifecycle, in order to ensure that all eligible physician-administered drug claims are invoiced to the drug manufacturers. For example, the State agency would need to have a process in place to contact providers when they submit claims with invalid HCPCS and NDC combinations.[8]

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 $13,785 ($9,325 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 upon this listing in order 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.

[8] All physician-administered claims should include a valid combination of HCPCS codes and NDC's for the State agency to obtain a manufacturer's rebate.

Because the State agency did not invoice for rebates for all top-20 multiple-source physician-administered drugs, the claims that were not invoiced for rebates were not eligible for Federal reimbursement. The State agency did not invoice these claims for rebate because providers submitted claims with invalid information in the HCPCS and NDC fields needed for processing rebates.

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

We were unable to determine whether, in some cases, the State agency was required to invoice for rebates on 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, the State agency did not invoice the manufacturers for rebates associated with multiple-source physician-administered drugs totaling $78,013 ($52,837 Federal share). 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 invoice these claims for rebate because providers submitted claims with invalid information in the HCPCS and NDC fields needed for processing rebates.

Accordingly, we set aside $78,013 ($52,837 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.

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

The State agency did not invoice manufacturers for rebates on claims totaling $1.8 million ($1.2 million Federal share) for single-source and $526,240 ($360,454 Federal share) for multiple-source pharmacy drugs. Specifically, these claims were never submitted to the contractor for a rebate because the State agency's automated system incorrectly omitted a day's worth of claims due to inadequate logic in its initial implementation.

Once the State agency was made aware of this system logic issue, it began to evaluate its existing internal controls for the pharmacy drug rebate process lifecycle and started the rebate process for claims omitted. Before completion of the final report, the contractor stated the automated system oversight was isolated and will not reoccur based on updates to system logic, that controls were established to validate claims received from source vendors, and that the rebate processing for the pharmacy drug claims that were originally omitted was completed.

RECOMMENDATIONS

We recommend that the Georgia Department of Community Health:

- refund to the Federal Government $644,802 (Federal share) for single-source physician-administered drug claims that were ineligible for Federal reimbursement;

- refund to the Federal Government $9,325 (Federal share) for top-20 multiple-source physician-administered drug claims that were ineligible for Federal reimbursement;

- work with CMS to determine and refund the unallowable portion of $52,837 (Federal share) for other multiple-source physician-administered drug claims 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 drug claims totaling $1,240,894 (Federal share) for single-source and $360,454 (Federal share) for multiple-source drugs that it had not previously sent for invoicing or refund the Federal share;

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

- 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, the State agency concurred with four of our recommendations. The State agency also acknowledged the two remaining findings but did not agree with the total amount of Federal reimbursement.

STATE AGENCY COMMENTS TO OUR FIRST RECOMMENDATION

The State agency acknowledged this finding but did not agree that the $1 million ($690,000 Federal share) Federal reimbursement was improperly claimed. The State agency said that $66,398 ($44,800 Federal share) of claims were for vaccines that are not classified as covered outpatient drugs and are excluded from the Medicaid Drug Rebate Program (MDRP). The State agency also identified $203 ($138 Federal share) in claims that were paid for drugs with NDCs terminated from the MDRP. The rebate termination date was reported by CMS after the paid and service dates on both claims. Because these termination dates are retroactive, the State agency does not believe preventative measures are possible. Given this information, the State agency requested that OIG lower the amount of our recommendation by $66,602 ($44,938

Federal share). The State agency said it will refund the Federal share of rebates owed for the claims that are not eligible for rebates.

Office of Inspector General Response

After reviewing the State agency's comments and additional documentation provided, we agree and have adjusted the dollar amount in our first recommendation. In addition, we acknowledge that the State agency and its drug rebate vendor took steps to prepare submissions of invoices to drug manufacturers for eligible physician-administered drug claims that we had either questioned or set aside for CMS adjudication. Other than adjusting the dollar amount, however, we maintain that this recommendation is valid, and we reiterate that the State agency should continue to work with CMS until this process is complete.

STATE AGENCY COMMENTS TO OUR SECOND RECOMMENDATION

The State agency acknowledged this finding and said that as of November 2022, claims that are eligible for rebate collection are being reprocessed for invoicing. The State agency plans to complete the invoicing process during the February 2023 invoicing cycle and refund the Federal share of rebates owed.

Office of Inspector General Response

We maintain that our recommendation remains valid and that the State agency should continue to work with CMS until the correction process is complete.

STATE AGENCY COMMENTS TO OUR THIRD RECOMMENDATION

The State agency acknowledged this finding and said that as of November 2022, claims that are eligible for rebate collection were being reprocessed for invoicing. The State agency plans to complete the invoicing process during the February 2023 invoicing cycle and refund the Federal share of rebates owed.

Office of Inspector General Response

We maintain that our recommendation remains valid and that the State agency should continue to work with CMS until the correction process is complete.

STATE AGENCY COMMENTS TO OUR FOURTH RECOMMENDATION

The State agency agrees to complete the process for rebating. It said the error was an isolated event and occurred when the automated system of the Pharmacy Benefits Manager's contractor omitted a day's worth of claims, which resulted in those claims not being submitted to the rebate contractor for invoicing. However, the State agency disagrees with the OIG's recommended payment amount. It said the amount represents pharmacy claim

reimbursements, not those associated to rebate dollars. The State agency said it has invoiced eligible pharmacy claims associated with the omitted day, which total $1,259,773 in rebates.

OIG Response

We were unable to confirm before this report's issuance that the State agency had completed the rebating process. We could also not confirm that the State agency implemented new controls to ensure the system error was isolated and would not occur again. We will maintain our recommendation until all of the claims have been reprocessed and that refunds for the subsequent rebates can be validated by CMS.

STATE AGENCY COMMENTS TO OUR FIFTH AND SIXTH RECOMMENDATIONS

The State agency did not mention recommendations five and six in its response to our draft report. However, it stated that it has since taken steps to address these recommendations by processing physician-administered drug rebates and implementing additional internal controls related to our first three recommendations. For example, the State agency said that the rebate contractor discovered the specific cause related to the processing of claims for physician-administered drugs and is developing a solution to rectify the issue within the limitations of the HCPCS-NDC conversion file. Once the process of implementing additional controls is complete, the State agency said the rebate contractor will update its policies and procedures. In addition, the State agency identified an issue within the claims systems edits that allowed claims to be paid with active rebate termination dates. The State agency updated the system in April 2022 to deny these claims.

OIG Response

For recommendations five and six, we were unable to confirm before this report's issuance that the State agency had implemented the additional controls and system updates mentioned. We support the actions the State agency is taking and reiterate these recommendations.

See Appendix D for the State agency's comments on our draft report.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered $1,557,654,964 ($1,056,211,868 Federal share) of pharmacy and physician-administered drug claims that were paid by the State agency during our audit period (April 1, 2018, 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:

- reviewed the State agency's standards of conduct and organizational charts;
- reviewed the State agency's standard operating policies and procedures for rebate processing, claim exclusion, and dispute resolution;
- reviewed the State agency's agreement with the contractor as well as supplemental performance guarantees; and
- discussed with State agency the causes of the identified errors.

We conducted our audit, which included contacting the State agency in Atlanta, Georgia, from March 2021 through September 2022.

METHODOLOGY

To accomplish our objective, we took the following steps:

- We reviewed applicable Federal laws, regulations, and guidance pertaining to the Medicaid drug rebate program 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.[9]

- We obtained drug claim details from the State agency for pharmacy and physician-administered drugs for the period April 1, 2018, through December 31, 2019.

- We obtained the listing of 340B entities from the State agency.[10]

- 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:

    - 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 August 10, 2022.

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

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

[10] Under the 340B drug pricing program (set forth in 42 U.S.C § 256b), a 340B entity may purchase reduce-price covered outpatient drugs from manufacturers; examples of 340B entities are 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
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
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

Report Title	Report Number	Date Issued
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
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

Report Title	Report Number	Date Issued
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
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

Report Title	Report Number	Date Issued
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
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 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. 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 1927(a)(7)(D) of the Act allowed HHS to delay any of the above requirements to prevent hardship to States that required additional time to implement the physician-administered drug reporting requirements.

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 REQUIREMENTS

The State agency publishes a policy manual for the Medicaid program. The PADL manual contains basic information regarding Georgia's fee for service (FFS) Medicaid and PeachCare for Kids programs and should be used in conjunction with the *Policies and Procedures Manual for Medicaid and PeachCare for Kids Part I*, the *Part II Policies and Procedures Manual for Physician Services*, and other applicable program manuals.[11] The PADL manual is reviewed and updated quarterly.

The PADL manual states:

> Effective January 1, 2007, and pursuant to the Congressional Budget Reconciliation Act of 2006, practitioners are required to bill/report injectable drugs administered in offices and outpatient facilities using the manufacturers' 11-digit National Drug Code (NDC) numbers with the preceding N4 qualifiers and/or HCPCS/CPT codes. Providers may now bill for the full contents of a single dose vial (SDV) of an injectable medication so that the unused amount is also reimbursed. Billing should include the total number of units contained therein and as listed in the PADL, these are generally not billed per vial. Claims for injectable drugs received for processing without the NDC numbers and/or HCPCS/CPT codes or with conflicting or invalid numbers or codes will result in denials.

The State agency provided additional clarification on July 1, 2010: "Hospitals, dialysis facilities, and Federally Qualified Health Centers (FQHC) billing injectable drugs administered in outpatient facilities must submit claims using both, the NDC numbers and the HCPCS/CPT codes when submitting electronically or in hardcopy on the UB Claim form."

[11] The PeachCare for Kids program is a comprehensive health care program for uninsured children living in Georgia. Its authority derives from the Children's Health Insurance Program (Title XXI of the Act). Established in Georgia in 1998, it was reauthorized in 2018 for another 10-year period.

GEORGIA DEPARTMENT
OF COMMUNITY HEALTH

Brian P. Kemp, Governor | Caylee Noggle, Commissioner

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December 2022

Report Number: A-04-24-08089

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

Dear Lori Pilcher,

Enclosed below is the Georgia Department of Community Health (DCH), Medical Assistance Plans (MAP) division, response to the Department of Health and Human Services (HHS), Office of Inspector General (OIG) draft report.

Thank you,

peter d'alba Digitally signed by peter d'alba Date: 2022.12.19 11:09:58 -05'00'

Peter D'Alba, Pharm.D.
Director of Pharmacy, Medical Assistance Plans
Georgia Department of Community Health

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

The State agency improperly claimed Federal reimbursement of $1.0 million ($690,000 Federal share) for single-source physician-administered drug claims for which it did not invoice 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. Based on its initial evaluation after the State agency was made aware of our analysis, the State agency determined that additional operational review processes would likely be necessary to review claim information at each step in the claim and rebate process lifecycle, in order to ensure that all eligible physician-administered drug claims are invoiced to the drug manufacturers. For example, the State agency would need to have a process in place to contact providers when they submit claims with invalid HCPCS and NDC combinations.

[1] The Georgia Department of Community Health (DCH) acknowledges this finding but does not agree with the total amount of $1.0 million ($690,000 Federal Share) Federal reimbursement being improperly claimed.

[2] The Department found 656 paid vaccine claims included in this assessment for a total amount of $66,398.25. Vaccines are not classified as covered outpatient drugs, therefore, are excluded from the Medicaid Drug Rebate Program (MDRP). Section 2713 of the PHS Act requires group health plans or group health insurance coverage for routine immunizations. (§ 54.9815-2713(a)(1)(ii) - Coverage of Preventive Health Services)

[3] Additionally, there were two claims paid for by the State on NDC's terminated from the MDRP. The rebate termination date was reported by CMS after the paid and service dates on both claims. The total reimbursement amount for these claims was $203.42. Preventable measures may not be possible for this issue due to the termination dates being retro effective. Notification timeliness for termination dates is imperative to the State to avoid paid claims for drugs that are no longer eligible for rebates.

[4] Given the information above, DCH respectfully requests the reimbursement amount defined as improperly claimed be reduced by $66,601.67.

Regarding the additional findings for this section:

[5] The Rebate Contractor discovered the specific cause related to the physician-administered drugs and is in the development of a solution to rectify the issue within the limitations of the HCPCS-NDC conversion file. Once the enhanced process has been completed, the Rebate Contractor will update their policies and procedures accordingly. **($859,353.63; #1422 "Y" Claims; Single-Source)**

[6] Furthermore, the Department identified an issue within the claims system edits which allowed claims to pay with an active rebate termination date on file. Upon realization, the issue was swiftly rectified, and the system edits were updated to deny all claims for NDC's with an active drug rebate termination date moving forward, effective 04/21/2022. **($93,713.51; #278 "Y" Claims; Single-Source)**

[7] The claims which are eligible for rebate collection are currently being reprocessed for invoicing as of November 2022. Our goal will be to complete the invoicing process during the February 2023 invoicing cycle. DCH will refund the Federal share of rebates owed for the claims not eligible for rebates.

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

The State agency improperly claimed Federal reimbursement of $13,785 ($9,325 Federal share) for top 20 multi-source drugs for which it did not invoice manufacturers for rebates. CMS last provided the State agency with an annual listing of top 20 multi-source HCPCS codes and their respective NDCs in 2011. We relied upon this listing in order to identify top 20 multi-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 multi-source physician-administered drugs, the claims that were not invoiced for rebates were not eligible for Federal reimbursement. The State agency did not invoice these claims for rebate because providers submitted claims with invalid information in the HCPCS and NDC fields needed for processing rebates.

[8] (Issue as described above.) The Rebate Contractor discovered the specific cause related to the physician-administered drugs and is in the development of a solution to rectify the issue within the limitations of the HCPCS-NDC conversion file. Once the enhanced process has been completed, the Rebate Contractor will update their policies and procedures accordingly. **($9,298; #1,155 "Top 20 Claims"; Multi-Source)**

[9] (Issue as described above.) Furthermore, the Department identified an issue within the claims system edits which allowed claims to pay with an active rebate termination date on file. Upon realization, the issue was swiftly rectified, and the system edits were updated to deny all claims for NDC's with an active drug rebate termination date moving forward, effective 04/21/2022. **($4,487.15; #461 "Top 20 Claims"; Multi-Source)**

[10] The claims which are eligible for rebate collection are currently being reprocessed for invoicing as of November 2022. Our goal will be to complete the invoicing process during the February 2023 invoicing cycle. DCH will refund the Federal share of rebates owed for the claims not eligible for rebates.

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

We were unable to determine whether, in some cases, the State agency was required to invoice for rebates for claims for other pharmacy and physician-administered drugs. 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, the State agency did not invoice the manufacturers for rebates associated with multiple-source physician-administered drugs totaling $78,013 ($52,837 Federal share). 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 invoice these claims for rebate because providers submitted claims with invalid information in the HCPCS and NDC fields needed for processing rebates.

Accordingly, we set aside $78,013 ($52,837 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.

[11] (Issue as described above.) The Rebate Contractor discovered the specific cause related to the physician-administered drugs and is in the development of a solution to rectify the issue within the limitations of the HCPCS-NDC conversion file. Once the enhanced process has been completed, the Rebate Contractor will update their policies and procedures accordingly. **($69,530.87; #5,756 "N" Claims; Multi-Source)**

[12] (Issue as described above.) Furthermore, the Department identified an issue within the claims system edits which allowed claims to pay with an active rebate termination date on file. Upon realization, the issue was swiftly rectified, and the system edits were updated to deny all claims for NDC's with an active drug rebate termination date moving forward, effective 04/21/2022. **($8,479.38; #427 "N" Claims; Multi-Source)**

[13] The claims which are eligible for rebate collection are currently being reprocessed for invoicing as of November 2022. Our goal will be to complete the invoicing process during the February 2023 invoicing cycle. DCH will refund the Federal share of rebates owed for the claims not eligible for rebates.

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

The State agency did not invoice manufacturers for rebates totaling $1.8 million in pharmacy reimbursement ($1.2 million Federal share) for single-source and $526,240 ($360,454 Federal share) for multiple-source drugs. Specifically, these claims were never submitted to the Rebate contractor because the State agency's automated system incorrectly omitted a day's worth of claims due to inadequate logic in its initial implementation.

Once the State agency was made aware of this system logic issue, it began to evaluate its existing internal controls for the pharmacy drug rebate process lifecycle. The automated system oversight was isolated and, based on updates made to the system logic, will not recur. The contractor has established controls to validate claims received from source vendors, and the State agency is in the process of correcting its initial oversight by sending to the contractor pharmacy drug claims that it had not previously sent for invoicing. This process is ongoing as of issuance of this report.

[14] DCH agrees that there was an isolated event where DCH PBM contractor automated system omitted a day's worth of claims resulting in claims not being submitted to the rebate contractor for invoicing. However, DCH disagrees with the financials associated with this finding, $1.8M ($1.2M federal share) for single source and $526,240 ($360,454 federal share) for multiple source pharmacy drugs totaling $$2,326,240 ($1,560,454 federal share). The amounts stated in this finding represent pharmacy claim reimbursements and not amounts associated to rebate dollars. DCH has already invoiced (2022Q3 invoice cycle) eligible pharmacy claims associated with the omitted day which totaled $1,259,772.76 in rebates.

[15] The Rebate Contractor now has controls in place to validate claim files received from source vendors. The omitted days' worth of claims identified were submitted to the Rebate Contractor for inclusion with the November 2022 invoices which have now been completed.

[16] In addition, the PBM Contractor confirmed the system error related to this isolated incident has not occurred henceforth and reiterated, would not.