

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**NORTH CAROLINA DID NOT ALWAYS
INVOICE REBATES TO
MANUFACTURERS FOR PHYSICIAN-
ADMINISTERED DRUGS**

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Office of Inspector General

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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

Report in Brief

Date: February 2023

Report No. A-07-21-07002

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



Why OIG Did This Audit

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

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

How OIG Did This Audit

We reviewed claims for physician-administered drugs paid between January 2016 and December 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.

North Carolina Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs

What OIG Found

North Carolina did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. North Carolina did not invoice for, and collect from manufacturers, rebates associated with \$3.1 million (Federal share) in physician-administered drugs. Of this amount, \$2.3 million (Federal share) was for single-source drugs and \$734,000 (Federal share) was for top-20 multiple-source drugs. Further, we were unable to determine whether, in some cases, North Carolina was required to invoice for rebates for other multiple-source physician-administered drug claims. North Carolina did not invoice the manufacturers for rebates associated with claims totaling \$685,000 (Federal share) for these multiple-source drugs.

What OIG Recommends and North Carolina Comments

We recommend that North Carolina refund to the Federal Government \$2.3 million (Federal share) for claims for single-source physician-administered drugs and \$734,000 (Federal share) for claims for top-20 multiple-source physician-administered drugs. We also recommend that North Carolina work with CMS to determine the unallowable portion of \$685,000 (Federal share) for other claims for multiple-source physician-administered drugs that may have been ineligible for Federal reimbursement, refund that amount, and consider invoicing drug manufacturers for rebates for these drugs if CMS determines that the drug claims are allowable. In addition, we recommend that North Carolina 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 physician-administered drugs eligible for rebates are invoiced.

North Carolina agreed with all of our recommendations and described corrective actions that it had taken or planned to take. Specifically, North Carolina said that it would work with CMS to determine the amount, method, and timing of the refund, or pursue invoicing drug manufacturers for amounts determined to be allowable. North Carolina also said that it would review all physician-administered drug claims beginning January 1, 2020, through the present, and would work with CMS to determine any unallowable reimbursement and potential refund. Further, North Carolina said that it had reviewed procedures surrounding the physician-administered drug rebate process and would implement controls to mitigate the risks we identified.

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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 the Federal share of these rebates against their Medicaid expenditures. States invoice the manufacturers for rebates to reduce the cost of drugs to the program. However, 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 North Carolina Department of Health and Human Services, Division of Health Benefits's (State agency's) invoicing for rebates for physician-administered drugs for the period January 1, 2016, through December 31, 2019.

OBJECTIVE

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

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 the information to the States each quarter. Covered outpatient drugs reported by participating drug manufacturers are listed in the CMS Medicaid Drug File, which identifies drugs with such fields as National Drug Code (NDC), unit type, units per package size, and product name.

Section 1903(i)(10) of the Act prohibits Federal reimbursement for States that do not capture the information necessary for invoicing manufacturers for rebates as described in section 1927(a)(7) of the Act. To invoice for rebates, States capture drug utilization data that identifies,

¹ *States' Collection of Medicaid Rebates for Physician-Administered Drugs* (OEI-03-09-00410), issued June 24, 2011.

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

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.

Physician-Administered Drugs

Drugs administered by a physician are typically invoiced to the Medicaid program on a claim form using Healthcare Common Procedure Coding System (HCPCS) codes.³ For purposes of the Medicaid drug rebate program, 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 physician-administered drugs and for the top 20 multiple-source physician-administered 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 physician-administered 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 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 also requires the submission of NDCs on all claims with procedure codes for physician-administered drugs.⁶ The State agency uses its claim utilization data for physician-administered drugs, which it derives from claims submitted by providers, 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

The State agency claimed \$115,514,612 (\$77,439,470 Federal share) for physician-administered drugs paid between January 1, 2016, and December 31, 2019.

We used the CMS Medicaid Drug File to determine whether the NDCs listed on the claims were classified as single-source drugs or multiple-source drugs. For claims submitted without an NDC, we matched the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk to identify the drug classification.⁷ Additionally, we determined whether the HCPCS codes were published in CMS's top-20 multiple-source drug listing.

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 physician-administered drugs. The State agency did not invoice for, and collect from manufacturers, rebates associated with \$4.6 million (\$3.1 million Federal share) in physician-administered drugs.⁸ Of this amount, \$3.5 million (\$2.3 million Federal share) was for single-source drugs and \$1.1 million (\$734,000 Federal share) was for top-20

⁶ North Carolina Department of Health and Human Services, Division of Medical Assistance, Physician's Drug Program, Clinical Coverage Policy Number: 1B, Attachment A, Section H.7 (amended December 12, 2019).

⁷ 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)).

⁸ Specifically, the State agency did not invoice manufacturers for rebates associated with drug expenditures that totaled \$4,572,819 (\$3,058,102 Federal share).

multiple-source drugs.⁹ 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 drugs 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 \$1.0 million (\$685,000 Federal share) for these multiple-source drugs.¹⁰ Accordingly, we are recommending that the State agency work with CMS to determine the unallowable portion of the \$1.0 million (\$685,000 Federal share) of claims and consider invoicing drug manufacturers for rebates for these drugs if CMS determines that the drug claims are allowable.

FEDERAL AND STATE REQUIREMENTS

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

The North Carolina Department of Health and Human Services, Division of Medical Assistance, Physician's Drug Program, Clinical Coverage Policy Number: 1B, Attachment A, Section H.7 (amended December 12, 2019), states: "Effective with date of service December 28, 2007, providers shall bill all applicable drug products, including vaccines, with NDCs to comply with the Deficit Reduction Act of 2005."

Appendix C contains Federal and State requirements related to 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 \$3.5 million (\$2.3 million Federal share) for single-source physician-administered drug claims for which it did not invoice manufacturers for rebates.

⁹ Specifically, \$3,475,219 (\$2,324,567 Federal share) was for single-source drugs and \$1,097,600 (\$733,535 Federal share) was for top-20 multiple-source drugs.

¹⁰ Specifically, \$1,022,612 (\$684,731 Federal share) was for other multiple-source drugs.

Because the State agency's internal controls did not always ensure that it invoiced manufacturers to secure rebates for all single-source physician administered drugs, these claims were not eligible for Federal reimbursement.

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 \$1.1 million (\$734,000 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 to the drug manufacturers for rebate purposes.

Because the State agency's internal controls did not always ensure that it invoiced manufacturers to secure 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 MANUFACTURERS FOR REBATES ON OTHER MULTIPLE-SOURCE PHYSICIAN-ADMINISTERED DRUGS

We were unable to determine whether, in some cases, the State agency was required to invoice for rebates for other multiple-source physician-administered drug claims.

Although the State agency generally collected the drug utilization data necessary to invoice manufacturers for rebates associated with these multiple-source physician-administered drugs, the State agency did not invoice the manufacturers for rebates associated with these drugs, which were not identified as top-20 multiple-source drugs. Providers submitted claims totaling \$1.0 million (\$685,000 Federal share) that were not used to obtain Medicaid drug rebates. Under the Medicaid drug rebate program, these claims could have been eligible for rebates.

Accordingly, we set aside \$1.0 million (\$685,000 Federal share) for the remaining multiple-source drug claims and are recommending that the State agency 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.

RECOMMENDATIONS

We recommend that the North Carolina Department of Health and Human Services, Division of Health Benefits:

- refund to the Federal Government \$2,324,567 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;

- refund to the Federal Government \$733,535 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement;
- work with CMS to determine the unallowable portion of \$684,731 (Federal share) for other claims for multiple-source physician-administered drugs that may have been ineligible for Federal reimbursement, refund that amount, and consider invoicing drug manufacturers for rebates for these drugs if CMS determines that the drug claims are allowable;
- 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 physician-administered drugs eligible for rebates are invoiced.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency agreed with all of our recommendations and described corrective actions that it had taken or planned to take. Specifically, the State agency said that it would work with CMS to determine the amount, method, and timing of the refund, or pursue invoicing drug manufacturers for amounts determined to be allowable. The State agency also said that it would review all physician-administered drug claims beginning January 1, 2020, through the present, and would work with CMS to determine any unallowable reimbursement and potential refund. Further, the State agency said that it had reviewed procedures surrounding the physician-administered drug rebate process and would implement controls to mitigate the risks we identified.

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

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

The State agency claimed \$115,514,612 (\$77,439,470 Federal share) for physician-administered drugs paid between January 1, 2016, and December 31, 2019.

Our audit objective did not require an understanding or assessment of the complete internal control structure of the State agency. We limited our internal control review to obtaining an understanding of the State agency's processes for reimbursing physician-administered drug claims and its process for claiming and obtaining Medicaid drug rebates for physician-administered drugs.

We conducted our audit work, which included contacting the State agency in Raleigh, North Carolina, from December 2020 to November 2022.

METHODOLOGY

To accomplish our objective, we took the following steps:

- We reviewed applicable Federal laws, regulations, and guidance pertaining to the Medicaid drug rebate program and physician-administered drugs.
- We reviewed State agency requirements and guidance to providers, including invoicing instructions for physician-administered drugs.
- We reviewed State agency policies and procedures for rebates for physician-administered drugs.
- We interviewed State agency personnel to gain an understanding of the administration of and controls over the Medicaid invoicing and rebate process for physician-administered drugs.
- We obtained listings 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.
- We obtained claim details from the State agency for all physician-administered drugs for the period January 1, 2016, through December 31, 2019.

- We obtained the listing of 340B entities from the State agency.¹¹
- We removed drug claims totaling \$109,919,181 (\$73,696,637 Federal share) that either were not eligible for a drug rebate (including the drug claims submitted by 340B entities) or were invoiced for rebate.
- We reviewed the remaining drug claims totaling \$5,595,431 (\$3,742,834 Federal share) to determine whether the State agency complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs.
 - We identified single-source drugs based on the classification of the drugs in the CMS Medicaid Drug File. If necessary, we matched the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk to identify the NDCs associated with each HCPCS code listed on claims from providers.
 - We identified the top-20 multiple-source drugs by matching the HCPCS code on the drug claim to the HCPCS code on CMS's top-20 multiple-source drug listing.
 - We identified the remaining drugs as other outpatient physician-administered drugs. These drugs were not identified as single-source or as top-20 multiple-source drugs.
- We discussed the results of our audit with State agency officials on October 11, 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.

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

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Mississippi Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs</i>	<u>A-07-21-06101</u>	10/27/2022
<i>Tennessee Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-07-21-06096</u>	9/14/2022
<i>South Carolina Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs</i>	<u>A-07-21-07003</u>	8/10/2022
<i>Colorado Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-07-17-06075</u>	9/8/2021
<i>New Mexico Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-06-16-00001</u>	6/2/2021
<i>Massachusetts Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-06-18-04001</u>	10/22/2020
<i>Minnesota Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-05-17-00018</u>	10/21/2020
<i>Vermont Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs</i>	<u>A-07-19-06086</u>	9/18/2020
<i>Maine Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs</i>	<u>A-07-18-06079</u>	9/14/2020
<i>Michigan Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-05-17-00017</u>	8/25/2020
<i>Alaska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-09-19-02001</u>	7/21/2020
<i>New York Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-02-18-01016</u>	4/7/2020
<i>New York Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-02-18-01011</u>	2/19/2020
<i>New Jersey Did Not Bill Manufacturers for Tens of Millions of Dollars in Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-02-16-01011</u>	8/30/2019

Report Title	Report Number	Date Issued
<i>Texas Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-06-17-04001</u>	8/21/2019
<i>Connecticut Claimed Unallowable Federal Reimbursement for Medicaid Physician-Administered Drugs That Were Not Invoiced to Manufacturers for Rebates</i>	<u>A-07-18-06078</u>	8/16/2019
<i>Illinois Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-18-00030</u>	6/18/2019
<i>New Jersey Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-02-16-01012</u>	5/9/2019
<i>Indiana Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-17-00038</u>	4/5/2019
<i>Arizona Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-16-02031</u>	2/16/2018
<i>Arkansas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-06-16-00018</u>	2/12/2018
<i>Nebraska Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-07-13-06046</u>	12/22/2017
<i>Texas Did Not Bill Manufacturers for Some Rebates for Pharmacy Drugs of Medicaid Managed-Care Organizations</i>	<u>A-06-16-00004</u>	12/12/2017
<i>Ohio Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-16-00013</u>	11/1/2017
<i>Washington State Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-16-02028</u>	9/26/2017
<i>Hawaii Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-16-02029</u>	9/26/2017
<i>Nevada Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-16-02027</u>	9/12/2017
<i>Iowa Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs of Medicaid Managed-Care Organizations</i>	<u>A-07-16-06065</u>	5/5/2017

Report Title	Report Number	Date Issued
<i>Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-16-00014</u>	3/23/2017
<i>Colorado Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06050</u>	1/5/2017
<i>Delaware Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-03-15-00202</u>	12/30/2016
<i>Virginia Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-03-15-00201</u>	12/22/2016
<i>California Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Some Medicaid Managed-Care Organizations</i>	<u>A-09-15-02035</u>	12/8/2016
<i>Kansas Correctly Invoiced Rebates to Manufacturers for Most Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-07-15-06060</u>	8/18/2016
<i>Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06057</u>	5/26/2016
<i>Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06063</u>	3/31/2016
<i>South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06059</u>	2/9/2016
<i>Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06062</u>	1/14/2016
<i>North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06058</u>	1/13/2016
<i>California Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	<u>A-09-14-02038</u>	1/7/2016
<i>Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06056</u>	9/18/2015
<i>Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06049</u>	7/22/2015

Report Title	Report Number	Date Issued
<i>Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-06-12-00060</u>	5/4/2015
<i>Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06051</u>	4/13/2015
<i>Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-13-02037</u>	3/4/2015
<i>Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<u>A-06-14-00031</u>	2/10/2015
<i>The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-03-12-00205</u>	8/21/2014
<i>Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-13-06040</u>	8/7/2014
<i>Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs</i>	<u>A-09-12-02079</u>	4/30/2014
<i>Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	<u>A-09-12-02080</u>	4/24/2014
<i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-03-12-00200</u>	11/26/2013
<i>Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<u>A-06-12-00059</u>	9/19/2013
<i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i>	<u>A-06-10-00011</u>	8/12/2011
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	<u>OEI-03-09-00410</u>	6/24/2011

APPENDIX C: FEDERAL AND STATE REQUIREMENTS RELATED TO PHYSICIAN-ADMINISTERED DRUGS

FEDERAL LAWS

Under the Medicaid program, States may provide coverage for outpatient drugs as an optional service (the Act § 1905(a)(12)). Section 1903(a) of the Act provides for Federal financial participation (Federal share) in State expenditures for these drugs. The Medicaid drug rebate program, created by the Omnibus Budget Reconciliation Act of 1990 that added section 1927 to the Act, became effective on January 1, 1991. Manufacturers must enter into a rebate agreement with the U.S. 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 of HHS 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 bill a manufacturer for rebates (42 CFR § 447.520).

STATE REQUIREMENTS

The North Carolina Department of Health and Human Services, Division of Medical Assistance, Physician's Drug Program, Clinical Coverage Policy Number: 1B, Attachment A, Section H.7 (amended December 12, 2019), states: "Effective with date of service December 28, 2007, providers shall bill all applicable drug products, including vaccines, with NDCs to comply with the Deficit Reduction Act of 2005."



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**
Division of Health Benefits

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

DAVE RICHARD • Deputy Secretary, NC Medicaid

January 17, 2023

Department of Health and Human Services
Office of Inspector General
Attn: James Korn
Office of Audit Services, Region VII
601 East 12th Street, Room 0429
Kansas City, MO 64106

Re: Report Number A-07-21-07002

Dear Mr. Korn:

We have reviewed your draft report entitled *North Carolina Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs* (Report) covering the audit period January 1, 2016, through December 31, 2019. The Department agrees with the findings noted in the report. The following represents our response and corrective action plan to the Recommendations.

RECOMMENDATIONS

REFUND TO THE FEDERAL GOVERNMENT \$2,324,567 (FEDERAL SHARE) FOR CLAIMS FOR SINGLESOURCE PHYSICIAN-ADMINISTERED DRUGS THAT WERE INELIGIBLE FOR FEDERAL REIMBURSEMENT.

The Department agrees with the recommendation to refund excess funds to the Federal Government. The Department will work with CMS to determine the amount, method and timing of the refund.

REFUND TO THE FEDERAL GOVERNMENT \$733,535 (FEDERAL SHARE) FOR CLAIMS FOR TOP-20 MULTIPLE-SOURCE PHYSICIAN-ADMINISTERED DRUGS THAT WERE INELIGIBLE FOR FEDERAL REIMBURSEMENT.

The Department agrees with the recommendation to refund excess funds to the Federal Government. The Department will work with CMS to determine the amount, method and timing of the refund.

WORK WITH CMS TO DETERMINE THE UNALLOWABLE PORTION OF \$684,731 (FEDERAL SHARE) FOR OTHER CLAIMS FOR MULTIPLE-SOURCE PHYSICIAN-ADMINISTERED DRUGS THAT MAY HAVE BEEN INELIGIBLE FOR FEDERAL REIMBURSEMENT, REFUND THAT AMOUNT, AND CONSIDER INVOICING DRUG MANUFACTURERS FOR REBATES FOR THESE DRUGS IF CMS DETERMINES THAT THE DRUG CLAIMS ARE ALLOWABLE.

The Department agrees with the recommendation. The Department will work with CMS to address the claims identified in the \$684,731 questioned cost, identifying any unallowable amount and refunding that amount, or pursuing invoicing drug manufacturers for amounts determined to be allowable.

NC MEDICAID

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH BENEFITS

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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

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.

The Department agrees with the recommendation. The Department will perform a review of all PADP FFS claims beginning January 1, 2020, until present to identify any claims submitted with incorrect NDC and/or incorrect NDC/HCPCs combinations, which need to be corrected and/or recouped. The Department will work with CMS to determine any unallowable reimbursement and the method and timing of any necessary refund.

STRENGTHEN ITS INTERNAL CONTROLS TO ENSURE THAT ALL PHYSICIAN-ADMINISTERED DRUGS ELIGIBLE FOR REBATES ARE INVOICED.

The Department agrees with the recommendation. The Department has reviewed procedures surrounding the physician-administered drug rebate process, including the observations noted in this report and will implement controls to mitigate the risks identified.

We greatly appreciate the professionalism of your review staff and the opportunity to respond.

If you need any additional information, please contact Dennis Farley at (919) 500-2885.

Sincerely,

DocuSigned by:

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Dave Richard

cc: Kody H. Kinsley, Secretary
Jay Ludlam, Assistant Secretary, NC Medicaid
Shannon Dowler, Chief Medical Officer, NC Medicaid
Adam Levinson, Chief Financial Officer, NC Medicaid
Melanie Bush, Chief Operating Officer, NC Medicaid
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John E. Thompson, Director, Office of Compliance and Program Integrity, NC Medicaid
Sandy Terrell, Director of Clinical Policy, NC Medicaid
Angela Smith, Director of Pharmacy, NC Medicaid
Joel Mercer, Deputy Director, Finance & Accounting, NC Medicaid
Julie Cronin, General Counsel
Marjorie Donaldson, Chief Financial Officer
Laketha M. Miller, Controller
Jeffrey Grimes, Director, Office of the Internal Auditor
Lisa Allnutt, Manager, Risk Management, Compliance and Consulting