

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**VERMONT 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: September 2020
Report No. A-07-19-06086

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, a prior OIG review found that States did not always invoice and collect all rebates due for drugs administered by physicians.

Our objective was to determine whether Vermont 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 2013 and December 2017.

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

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

What OIG Found

Vermont did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. Vermont did not invoice for, and collect from manufacturers, rebates associated with \$483,458 (Federal share) in physician-administered drugs. Of this amount, \$357,706 (Federal share) was for single-source drugs and \$47,389 (Federal share) was for top-20 multiple-source drugs. Further, we were unable to determine whether, in some cases, Vermont was required to invoice for rebates for other multiple-source physician-administered drug claims. Vermont did not invoice the manufacturers for rebates associated with claims totaling \$78,363 (Federal share) for these multi-source drugs.

What OIG Recommends and Vermont's Comments

We recommend that Vermont refund to the Federal Government \$357,706 (Federal share) for claims for single-source physician-administered drugs and \$47,389 (Federal share) for claims for top-20 multiple-source physician-administered drugs. We also recommend that Vermont work with CMS to determine the unallowable portion of \$78,363 (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 Vermont 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, 2017, and strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.

Vermont concurred with all of our findings and recommendations and described corrective actions that it planned to take to address them. Vermont described three main areas involving missed rebates and estimated that it would complete its corrective action plan for two of those areas before May 2021. Vermont said that the third area involved issues with National Drug Codes (NDCs) and added that it had already identified and remedied these issues in 2018 so that all claims with a date of service of January 1, 2019, or later were being denied payment unless a valid NDC was present.

TABLE OF CONTENTS

INTRODUCTION.....	1
Why We Did This Audit.....	1
Objective	1
Background	1
Medicaid Drug Rebate Program	1
Physician-Administered Drugs.....	2
The State Agency’s Medicaid Drug Rebate Program	2
How We Conducted This Audit.....	3
FINDINGS	3
Federal and State Requirements	4
The State Agency Did Not Invoice Manufacturers for Rebates on Some Single-Source Physician-Administered Drugs.....	5
The State Agency Did Not Invoice Manufacturers for Rebates on Some Top-20 Multiple-Source Physician-Administered Drugs.....	5
The State Agency Did Not Invoice Manufacturers for Rebates on Other Multiple-Source Physician-Administered Drugs	5
RECOMMENDATIONS.....	6
STATE AGENCY COMMENTS.....	6
APPENDICES	
A: Audit Scope and Methodology.....	7
B: Related Office of Inspector General Reports.....	9
C: Federal and State Requirements Related to Physician-Administered Drugs	13
D: State Agency Comments	15

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 Vermont Agency of Human Services, Department of Vermont Health Access' (State agency's), invoicing for rebates for physician-administered drugs for the period January 1, 2013, through December 31, 2017.

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 National Drug Codes (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 \$29,463,853 (\$16,033,211 Federal share) for physician-administered drugs paid between January 1, 2013, and December 31, 2017.

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 \$890,000 (\$483,000 Federal share) in physician-administered drugs.⁸ Of this amount, \$658,000 (\$358,000 Federal share) was for

⁶ Department of Vermont Health Access, Health Access Advisory, Volume XXIII, number 23 (January 2008).

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.

⁸ Specifically, the State agency did not invoice manufacturers for rebates associated with drug expenditures that totaled \$890,221 (\$483,458 Federal share).

single-source drugs and \$87,000 (\$47,000 Federal share) was for top-20 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 \$145,000 (\$78,000 Federal share) for these multi-source drugs.¹⁰ Accordingly, we are recommending that the State agency work with CMS to determine the unallowable portion of the \$145,000 (\$78,000 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 State agency publishes advisories to clarify and explain new and existing programs and policies for providers and other interested parties. The Department of Vermont Health Access, Medical Assistance Program, Health Access Advisory, volume XXIII, number 23 (January 2008), states:

In November 2007 [the State agency] announced that the collection and submission of data on all drugs dispensed or administered other than by a pharmacy would be required. This is a program change that is a result of the Deficit Reduction Act of 2005. The purpose of this is to allow for the collection of Medicaid drug rebates from manufacturers on all drugs dispensed in any outpatient setting as required by § 1927 of the Social Security Act. . . . In order to collect rebates from the correct manufacturers, [the State agency] will require data elements at the detail level in addition to the HCPCS codes.

⁹ Specifically, \$658,442 (\$357,706 Federal share) was for single-source drugs and \$87,204 (\$47,389 Federal share) was for top-20 multiple-source drugs.

¹⁰ Specifically, \$144,576 (\$78,363 Federal share) was for other multiple-source drugs.

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 \$658,000 (\$358,000 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.

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 \$87,000 (\$47,000 Federal share) for top-20 multiple-source drugs for which it did not invoice manufacturers for rebates.

Before 2012, CMS provided the State agency with an annual listing of top-20 multiple-source HCPCS codes and their respective NDCs. However, the State agency did not always submit the utilization data to the drug manufacturers for rebate purposes.

Because the State agency did not invoice for rebates for all top-20 multiple-source physician-administered drugs, the 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 \$145,000 (\$78,000 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 \$145,000 (\$78,000 Federal share) for the remaining multi-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 Vermont Agency of Human Services, Department of Vermont Health Access:

- refund to the Federal Government \$357,706 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;
- refund to the Federal Government \$47,389 (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 \$78,363 (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, 2017; 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 concurred with all of our findings and recommendations and described corrective actions that it planned to take to address them. The State agency described “three main areas where,” it said, “rebates are being missed.” For two of these areas, the State agency estimated that it would complete its corrective action plan before May 2021. The State agency said that the third area involved issues with NDCs and added that it had “already identified and remedied [these issues] in 2018 so that all claims with a date of service 1/1/2019 or later are being denied payment unless a valid NDC is present.” The State agency’s comments appear in their entirety as Appendix D.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

The State agency claimed \$29,463,853 (\$16,033,211 Federal share) for physician-administered drugs paid between January 1, 2013, and December 31, 2017.

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 Waterbury, Vermont, from March 2019 to June 2020.

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, 2013, through December 31, 2017.

- We obtained the listing of 340B entities from the State agency.¹¹
- We removed drug claims totaling \$19,939,905 (\$10,838,510 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 \$9,523,948 (\$5,194,701 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 May 11, 2020.

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>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
<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

Report Title	Report Number	Date Issued
<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
<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

Report Title	Report Number	Date Issued
<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
<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

Report Title	Report Number	Date Issued
<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 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 bill a manufacturer for rebates (42 CFR § 447.520).

STATE REQUIREMENTS

The State agency publishes Health Access Advisories to clarify and explain new and existing programs and policies for providers and other interested parties. The Department of Vermont Health Access, Health Access Advisory, Volume XXIII, number 23 (January 2008), states:

In November 2007 [the State agency] announced that the collection and submission of data on all drugs dispensed or administered other than by a pharmacy would be required. This is a program change that is a result of the Deficit Reduction Act of 2005. The purpose of this is to allow for the collection of Medicaid drug rebates from manufacturers on all drugs dispensed in any outpatient setting as required by § 1927 of the Social Security Act. . . . In order to collect rebates from the correct manufacturers, [the State agency] will require data elements at the detail level in addition to the HCPCS codes. These elements are the 11 digit [NDC] number, the Unit of Measurement Qualifier code, and the unit quantity. These must be reported on paper and electronic submissions of all outpatient claims. The NDC billing requirement will apply to all details where HCPCS reporting is required.



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August 30, 2020

Patrick J. Cogley
 Regional Inspector General for Audit Services
 Office of Audit Services, Region VII
 601 East 12th Street, Room 0429
 Kansas City, MO 64106

Re: Report Number: A-07-19-06086

Dear Mr. Cogley,

Thank you for sharing the draft report, *Vermont Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs*. The Department of Vermont Health Access, DVHA within Vermont Agency of Human Services, AHS concurs with the findings, *The State Agency did not invoice manufacturers for rebates on some single-source physician-administered drugs; The State Agency did not invoice manufacturers for rebates on some Top-20 multiple-source physician-administered drugs; The State Agency did not invoice manufactures for rebates on other multiple-source physician-administered drugs.*

We have identified three main areas where rebates are being missed. One is related to the data feed between the Fiscal Agent and the PBM where not all claims are being properly captured and provided to the PBM for rebate processing. The second area of concern is that some PAD claims are not being loaded into the rebate management system because the paid date does not align with the cycle date of the file. The third reason is attributable to a subset of claims not having NDCs present on the claim, the NDC was not valid on the date or service, or the NDC was not linked that HCPCS code in the crosswalk and therefore was not able to be rebated. This third set of issues DVHA had already identified and remedied in 2018 so that all claims with a date of service 1/1/2019 or later are being denied payment unless a valid NDC is present. DVHA is working diligently to correct the two deficiencies listed above that contributed to rebates being



missed on some PADs. Estimated time to complete the Corrective Action Plan CAP is prior to the first quarter 2021 Rebate Cycle (May 2021).

Recommendation 1 - Refund to the Federal Government \$357,706 (Federal share) for claims for single source physician-administered drugs that were ineligible for Federal reimbursement.

Management Corrective Action: DVHA concurs. DVHA will work with the Centers for Medicare and Medicaid Services (CMS) to refund the federal share the quarter in which this report is final. Once DVHA successfully invoices the rebatable claims identified in the audit, DVHA will retain the federal share of any monies previously remitted.

Recommendation 2 - Refund to the Federal Government \$47,389 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement.

Management Corrective Action: DVHA concurs. DVHA will work with the Centers for Medicare and Medicaid Services (CMS) to refund the federal share the quarter in which this report is final. Once DVHA successfully invoices the rebatable claims identified in the audit, DVHA will retain the federal share of any monies previously remitted.

Recommendation 3 - Work with CMS to determine the unallowable portion of \$78,363 (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.

Management Corrective Action: DVHA concurs. DVHA will work with the Centers for Medicare and Medicaid Services (CMS) to refund the federal share the quarter in which this report is final. Once DVHA successfully invoices the rebatable claims identified in the audit, DVHA will retain the federal share of any monies previously remitted.

Recommendation 4 - 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, 2017.

Management Corrective Action: DVHA concurs. An analysis of claims after December 31, 2017 will be conducted to identify any rebate-eligible unrebated PAD claims and DVHA will work with CMS to refund any unallowable amounts.



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Recommendation 5 - Strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.

Management Corrective Action: DVHA concurs. DVHA is rigorously working to identify all issues related to rebate-eligible non-rebated PADs as described above, and will assure that all rebatable PADs are properly identified, and that edits are in place to prevent non-rebatable PADs from processing for payment. Once we put in place the Corrective Action Plan, we will institute a quarterly review to ensure that all physician-administered drugs eligible for rebates are invoiced.

DVHA appreciates the work performed by the OIG and the opportunity to respond to the draft report. We wish to express our appreciation for the professionalism throughout the audit process.

Sincerely

A handwritten signature in black ink, appearing to read "Cory Gustafson", written over a thin red horizontal line.

Cory Gustafson, DVHA Commissioner

cc:

Ms. Charlie Arnold, Acting Director Audit & Review Branch

Dan Bittner, Assistant Regional Inspector General for Audit Services,

Anne Petrow, DVHA Program Compliance & Oversight Director

