

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**WISCONSIN CLAIMED
UNALLOWABLE FEDERAL
REIMBURSEMENT FOR SOME
MEDICAID PHYSICIAN-
ADMINISTERED DRUGS**

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



Gloria L. Jarmon
Deputy Inspector General
for Audit Services

March 2017
A-05-16-00014

Office of Inspector General

<https://oig.hhs.gov>

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC
at <https://oig.hhs.gov>

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

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.

EXECUTIVE SUMMARY

Wisconsin claimed \$1.8 million over 3 years in Federal reimbursement that was unallowable and \$20,000 that may have been unallowable because it did not comply with Federal Medicaid requirements for invoicing manufacturers for rebates for some physician-administered drugs.

WHY WE DID THIS REVIEW

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. For this audit, we reviewed the Wisconsin Department of Health Services' (State agency) invoicing for rebates for physician-administered drugs for the period January 1, 2012, through December 31, 2014.

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

BACKGROUND

The Medicaid drug rebate program became effective in 1991 (the Social Security Act § 1927). For a covered outpatient drug to be eligible for Federal reimbursement under the program, the manufacturer must enter into a rebate agreement that is administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. The Deficit Reduction Act of 2005 amended section 1927 of the Social Security Act to specifically address the collection of rebates on certain physician-administered drugs. To collect these rebates, States submit to the manufacturers the drug utilization data containing National Drug Codes (NDCs) for all single-source physician-administered drugs and for the top-20 multiple-source physician-administered drugs. Federal reimbursement for covered outpatient drugs administered by a physician is not available to States that do not comply with Federal requirements for capturing NDCs to invoice and collect rebates.

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

WHAT WE FOUND

The State agency did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. Specifically, the State agency did

not invoice manufacturers for rebates associated with \$3,041,710 (\$1,831,378 Federal share) in physician-administered drugs. Of this amount, \$2,877,019 (\$1,732,222 Federal share) was for single-source drugs, and \$164,691 (\$99,156 Federal share) was for top-20 multiple-source drugs. 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, the State agency did not submit the utilization data necessary to secure rebates for all other physician-administered drugs. Although the State agency generally collected the drug utilization data necessary to invoice the manufacturers for rebates associated with these claims, providers submitted claims totaling \$32,602 (\$19,568 Federal share) that did not have NDCs. We were unable to determine whether the State agency was required to invoice for rebates for these other physician-administered drug claims that did not have NDCs in the utilization data. Furthermore, under the Medicaid drug rebate program, claims totaling \$169,537 (\$102,212 Federal share), which contained NDCs, could have been eligible for rebates. Accordingly, we set aside these amounts and are recommending that the State agency work with CMS to determine (1) the unallowable portion of the \$19,568 (Federal share) of claims that were submitted without NDCs and (2) whether the remaining \$102,212 (Federal share) of claims could have been invoiced to the manufacturers for rebates.

WHAT WE RECOMMEND

We recommend that the State agency:

- refund to the Federal Government \$1,732,222 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;
- refund to the Federal Government \$99,156 (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 \$19,568 (Federal share) for other claims for covered outpatient physician-administered drugs that were submitted without NDCs and that may have been ineligible for Federal reimbursement and refund that amount, and
 - whether the remaining \$102,212 (Federal share) of other physician-administered drug claims could have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims;

- 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, 2014; and
- strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.

STATE AGENCY COMMENTS AND OUR RESPONSE

State Agency Comments

In written comments on our draft report, the State agency did not completely concur with our first three recommendations but concurred with our other two recommendations and described corrective actions it planned to take. For our first three recommendations, the State agency said that, where possible, it has identified and corrected claim processing to allow it to complete invoicing manufacturers for rebate by March 1, 2017, on some of the claim lines identified as ineligible or that may have been ineligible. The State agency commented that this reduces the Federal share in the recommendations. The State agency said that it will refund the Federal share of the manufacturers' rebates for these invoiced claims when the rebates are received from the manufacturers. In addition, the State agency said that it will work with CMS to determine any additional Federal share amount required to be refunded.

Our Response

After reviewing the State agency's comments, we maintain that all of our findings and recommendations remain valid. We recognize that the drug rebate process is fluid and ongoing, but as of the date we issued our draft report, the claims that are included in our findings' amounts had not been invoiced to the drug manufacturers to secure rebates. Both Federal requirements and State agency guidance specify that claims for physician-administered drugs must be submitted with NDCs; Federal requirements essentially preclude Federal reimbursement for such claims if they are not invoiced to the manufacturers for rebate. Furthermore, the State agency acknowledged that not all providers complied with the requirement that claims for physician-administered drugs be submitted with NDCs during our audit period.

Although we commend the State agency for the corrective actions it plans to implement going forward, we note that those planned actions do not relieve the State agency of its responsibility for the claims from our audit period that we questioned. Federal Medicaid requirements related to the collection of rebates for specified categories of physician-administered drugs are well established and provide a basis for disallowance of Federal reimbursement for such claims if they were not invoiced for rebate. However, if the State agency can retrospectively obtain the rebates from the manufacturers and offer to remit the Federal share of the rebates to CMS, then, during the audit resolution process, CMS as the cognizant operating division will decide how to adjust the overpayment amounts conveyed in this report.

TABLE OF CONTENTS

INTRODUCTION	1
Why We Did This Review	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 Review.....	3
FINDINGS	3
Federal and State Requirements and State Agency Guidance	4
The State Agency Did Not Invoice Manufacturers for Rebates on Some Single-Source Physician-Administered Drugs	4
The State Agency Did Not Invoice Manufacturers for Rebates on Some Top-20 Multiple-Source Physician-Administered Drugs	4
The State Agency Did Not Invoice Manufacturers for Rebates on Other Physician-Administered Drugs	5
RECOMMENDATIONS	5
STATE AGENCY COMMENTS.....	6
OFFICE OF INSPECTOR GENERAL RESPONSE	6
APPENDIXES	
A: Related Office of Inspector General Reports.....	8
B: Audit Scope and Methodology.....	10
C: Federal and State Requirements and State Agency Guidance Related to Physician-Administered Drugs	12
D: State Agency Comments.....	14

INTRODUCTION

WHY WE DID THIS REVIEW

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 (OIG) review found that States did not always invoice and collect all rebates due for drugs administered by physicians.¹ (Appendix A lists previous reviews of the Medicaid drug rebate program.) For this audit, we reviewed the Wisconsin Department of Health Services' (State agency) invoicing for rebates for physician-administered drugs for the period January 1, 2012, through December 31, 2014.

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 that is administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each have specific functions under the program.

Manufacturers are required to submit a list to CMS of all covered outpatient drugs and to report each drug's average manufacturer price and, where applicable, best price.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 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

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.

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 Form CMS-64, Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program, 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. The State agency also requires all physician-administered drug claims to be submitted with the NDC of the product. 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.

³ HCPCS codes (sometimes referred to as J-Codes) are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

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

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 section 1927(a)(7)(B)(i).

HOW WE CONDUCTED THIS REVIEW

The State agency claimed \$158,330,902 (\$110,504,977 Federal share) for physician-administered drugs paid between January 1, 2012, and December 31, 2014.

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.

We used CMS's Medicare Part B crosswalk to identify, if possible, the NDCs associated with each HCPCS code listed on claims from providers.⁶ We then used the CMS Medicaid Drug File to determine whether the identified NDCs were classified as single-source drugs or multiple-source drugs. 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 B 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. Specifically, the State agency did not invoice manufacturers for rebates associated with \$3,041,710 (\$1,831,378 Federal share) in physician-administered drugs. Of this amount, \$2,877,019 (\$1,732,222 Federal share) was for single-source drugs, and \$164,691 (\$99,156 Federal share) was for top-20 multiple-source drugs. 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, the State agency did not submit the utilization data necessary to secure rebates for all other physician-administered drugs. Although the State agency generally collected the drug utilization data necessary to invoice the manufacturers for rebates associated with these claims, providers submitted claims totaling \$32,602 (\$19,568 Federal share) that did not have NDCs. We were unable to determine whether the State agency was required to invoice for rebates for these other physician-administered drug claims that did not have NDCs in the utilization data. Furthermore, under the Medicaid drug rebate program, claims totaling \$169,537 (\$102,212 Federal share), which contained NDCs, could have been eligible for rebates. Accordingly, we set aside these amounts and are recommending that the State agency work with CMS to determine (1) the unallowable portion of the \$19,568 (Federal share) of claims that were

⁶ 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.

submitted without NDCs and (2) whether the remaining \$102,212 (Federal share) of claims could have been invoiced to the manufacturers for rebates.

FEDERAL AND STATE REQUIREMENTS AND STATE AGENCY GUIDANCE

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).

In a July 2008 policy update to Wisconsin Medicaid providers, the State agency stated: “ForwardHealth⁷ will require that NDCs be indicated on claims for all physician-administered drugs to identify the drugs and invoice a manufacturer for rebates, track utilization, and receive federal funds.... If an NDC is not indicated on a claim submitted to ForwardHealth, or if the NDC indicated is invalid, the claim will be denied.”

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 \$2,877,019 (\$1,732,222 Federal share) for single-source physician-administered drug claims for which it did not invoice manufacturers for rebates.

Because the State agency did not submit utilization data to the manufacturers to secure rebates, the State agency improperly claimed Federal reimbursement for these 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 improperly claimed Federal reimbursement of \$164,691 (\$99,156 Federal share) for top-20 multiple-source physician-administered drug claims for which it did not invoice manufacturers for rebates.

Before 2012, CMS provided the State agency, on a yearly basis, with a 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 submit utilization data to the manufacturers to secure rebates,

⁷ ForwardHealth interChange is the claims processing system for Wisconsin Medicaid.

the State agency improperly claimed Federal reimbursement for these top-20 multiple-source physician-administered drugs.

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 other physician-administered drug claims.

Although the State agency generally collected the drug utilization data necessary to invoice the manufacturers for rebates associated with other physician-administered drug claims, providers submitted some claims, totaling \$32,602 (\$19,568 Federal share), that did not have NDCs. For the claims that did not have NDCs in the utilization data, we were unable to determine whether the State agency improperly claimed Federal reimbursement for the physician-administered drugs associated with these claims. Furthermore, under the Medicaid drug rebate program, claims totaling \$169,537 (\$102,212 Federal share), which contained NDCs, could have been eligible for rebates. If the State agency had invoiced these claims for rebate, the drug manufacturers would have been required to pay the rebates.

Accordingly, we set aside these amounts and are recommending that the State agency work with CMS to determine (1) the unallowable portion of the \$19,568 (Federal share) of the claims that were submitted without NDCs and (2) whether the remaining \$102,212 (Federal share) of other physician-administered drugs could have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims.

RECOMMENDATIONS

We recommend that the State agency:

- refund to the Federal Government \$1,732,222 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;
- refund to the Federal Government \$99,156 (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 \$19,568 (Federal share) for other claims for covered outpatient physician-administered drugs that were submitted without NDCs and that may have been ineligible for Federal reimbursement and refund that amount, and
 - whether the remaining \$102,212 (Federal share) of other physician-administered drug claims could have been invoiced to the manufacturers to receive rebates

and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims;

- 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, 2014; 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 did not completely concur with our first three recommendations but concurred with our other two recommendations and described corrective actions it planned to take. These corrective actions include plans to review current processes to identify any possible areas of improvement with physician-administered drug claim processing, such as possible enhancements to its NDC to HCPCS crosswalk.

For our first three recommendations, the State agency said that, where possible, it has identified and corrected claim processing to allow it to complete invoicing manufacturers for rebates by March 1, 2017, on some of the claim lines identified as ineligible or that may have been ineligible. The State agency commented that this reduces the Federal share in the recommendations. The State agency said that it will refund the Federal share of the manufacturers' rebates for these invoiced claims when the rebates are received from the manufacturers. In addition, the State agency said that it will work with CMS to determine any additional Federal share amount required to be refunded.

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

OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing the State agency's comments, we maintain that all of our findings and recommendations remain valid. We recognize that the drug rebate process is fluid and ongoing, but as of the date we issued our draft report, the claims that are included in our finding amounts (claims that the State agency paid between January 1, 2012, and December 31, 2014; see Appendix B) had not been invoiced to the drug manufacturers to secure rebates.

Both Federal requirements and State agency guidance (Appendix C) specify that claims for physician-administered drugs must be submitted with NDCs; Federal requirements essentially preclude Federal reimbursement for such claims if they are not invoiced to the manufacturers for rebate. Furthermore, the State agency acknowledged that not all providers complied with the requirement that claims for physician-administered drugs be submitted with NDCs during our audit period.

Although we commend the State agency for the corrective actions it plans to implement going forward, we note that those planned actions do not relieve the State agency of its responsibility

for the claims it paid in calendar years 2012 through 2014 that we questioned. Federal Medicaid requirements related to the collection of rebates for specified categories of physician-administered drugs are well established and provide a basis for disallowance of Federal reimbursement for such claims if they are not invoiced for rebate. However, if the State agency can retrospectively obtain the rebates from the manufacturers and offer to remit the Federal share of the rebates to CMS, then, during the audit resolution process, CMS as the cognizant operating division will decide how to adjust the overpayment amounts conveyed in this report.

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Colorado Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06050</u>	1/05/17
<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>	12/30/16
<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>	12/22/16
<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>	12/8/16
<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>	8/18/16
<i>Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06057</u>	5/26/16
<i>Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06063</u>	3/31/16
<i>South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06059</u>	2/09/16
<i>Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06062</u>	1/14/16
<i>North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06058</u>	1/13/16
<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>	1/07/16
<i>Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06056</u>	9/18/15
<i>Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06049</u>	7/22/15

Report Title	Report Number	Date Issued
<i>Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-06-12-00060	5/04/15
<i>Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-14-06051	4/13/15
<i>Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-09-13-02037	3/04/15
<i>Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	A-06-14-00031	2/10/15
<i>The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-03-12-00205	8/21/14
<i>Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-13-06040	8/07/14
<i>Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs</i>	A-09-12-02079	4/30/14
<i>Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	A-09-12-02080	4/24/14
<i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-03-12-00200	11/26/13
<i>Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	A-06-12-00059	9/19/13
<i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i>	A-06-10-00011	8/12/11
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	OEI-03-09-00410	6/24/11

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

The State agency claimed \$158,330,902 (\$110,504,977 Federal share) for physician-administered drugs paid between January 1, 2012, and December 31, 2014.

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 Madison, Wisconsin, from December 2015 to September 2016.

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 interviewed CMS officials about the Federal requirements and guidance governing physician-administered drugs under the Medicaid drug rebate program.
- We reviewed State agency regulations 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 drug claims for the period January 1, 2012, through December 31, 2014.

- We obtained the listing of 340B entities from the State agency.⁸
- We removed drug claims totaling \$155,087,053 (\$108,551,819 Federal share) that either were not eligible for a drug rebate or contained an NDC and were invoiced for rebate.
- We reviewed the remaining drug claims totaling \$3,243,849 (\$1,953,158 Federal share) to determine whether the State agency complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. Specifically:
 - We identified single-source drugs by matching the NDC on the drug claim to the NDC on CMS's Medicaid Drug File. For claims submitted without NDCs, 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.
 - 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 other multiple-source drugs by matching the NDC on the drug claim to the NDC on CMS's Medicaid Drug File. For claims submitted without NDCs, 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.
- We discussed the results of our review with State agency officials on October 27, 2016.

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.

⁸ Under the 340B drug pricing program (set forth in 42 U.S.C. § 256b), a 340B entity may purchase reduced-price covered outpatient drugs from manufacturers. Examples of 340B entities are disproportionate share hospitals, which generally serve large numbers of low-income and/or uninsured patients, and State AIDS drug assistance programs. Drugs subject to discounts under the 340B drug pricing program are not subject to rebates under the Medicaid drug rebate program. Section 1927(j) of the Act and 42 U.S.C. § 256b(a)(5)(A).

APPENDIX C: FEDERAL AND STATE REQUIREMENTS AND STATE AGENCY GUIDANCE 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 the U.S. Department 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 (such as J-codes and NDCs) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug to secure rebates for all single-source physician-administered drugs effective January 1, 2006, and for the top-20 multiple-source drugs effective January 1, 2008. Section 1927(a)(7)(C) of the Act 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 specify that no Federal share is available for physician-administered drugs for which a State has not required the submission of claims using codes that identify the drugs sufficiently for the State to invoice a manufacturer for rebates (42 CFR § 447.520).

STATE AGENCY REQUIREMENTS AND GUIDANCE

Wisconsin Administrative Code DHS 108.02(4) states: “The department shall publish provider handbooks, bulletins and periodic updates to inform providers of changes in state or federal law, policy, reimbursement rates and formulas, departmental interpretation, and procedural directives such as billing and prior authorization procedures, specific reimbursement changes and items of general information”

Wisconsin Administrative Code DHS 106.03(3)(b)1 states: “To be considered for payment, a correct and complete claim or adjustment shall be received”

Wisconsin Administrative Code DHS 106.03(3)(b)3 states: “To ensure that submissions are correct and there is appropriate follow-up of all claims, providers shall follow the claims preparation and submission instructions in provider handbooks and bulletins issued by the department.”

The ForwardHealth Update No. 2008-126, dated July 2008, states:

With the implementation of ForwardHealth interChange in October 2008, providers will be required to comply with requirements of the federal Deficit Reduction Act of 2005 (DRA) and submit National Drug Codes (NDCs) with Healthcare Common Procedure Coding System (HCPCS) and select *Current Procedural Terminology* (CPT) procedure codes on claims for physician-administered drugs. Section 1927(a)(7)(B) of the Social Security Act requires NDCs to be indicated on all claims submitted to ForwardHealth, including Medicare crossover claims

ForwardHealth will require that NDCs be indicated on claims for all physician-administered drugs to identify the drugs and invoice a manufacturer for rebates, track utilization, and receive federal funds. States that do not collect NDCs with HCPCS and CPT procedure codes on claims for physician-administered drugs will not receive federal funds for those claims. ForwardHealth cannot claim a rebate or federal funds if the NDC submitted on a claim is incorrect or invalid or if an NDC is not indicated.

If an NDC is not indicated on a claim submitted to ForwardHealth, or if the NDC indicated is invalid, the claim will be denied.

APPENDIX D: STATE AGENCY COMMENTS



State of Wisconsin Department of Health Services

Scott Walker, Governor
Linda Seemeyer, Secretary

February 13, 2017

Ms. Sheri Fulcher
Regional Inspector General for Audit Services
Office of Audit Services, Region V
233 North Michigan, Suite 1360
Chicago, IL 60601

Dear Ms. Fulcher:

The Wisconsin Department of Health Services (DHS) has prepared its response to the U.S. Department of Health and Human Services, Office of Inspector General (OIG) draft report entitled “Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician- Administered Drugs.” The cover letter, dated December 15, 2016, requested that DHS provide written comments, including the status of actions taken or planned in response to report recommendations.

DHS appreciates the opportunity to respond to the draft report and the work performed by the OIG. If you have any questions or require additional information, please contact Dale Crapp, Audit Coordinator, at (608) 266-9365 or by e-mail at Dale.Crapp@dhs.wisconsin.gov.

Sincerely,

/Linda Seemeyer/

Linda Seemeyer
Secretary

Enclosure: Final_A-05-16-100014_Response.pdf

cc: David Markulin, Assistant Regional Inspector for Audit Services, OIG
Brian Ritchie, Assistant Inspector General for Audit Services, OIG
Laura Behnke, Senior Auditor, OIG
Michael Heifetz, DHS Medicaid Director, DMS
Rachel Curran-Henry, DHS/DMS
Kimberly Smithers, DHS/DMS
Kim Wohler, DHS/DMS
Amy McDowell, DHS/DES
Robert Halverson, DHS/DES
Laurie Palchik, DHS/DES
Dale Crapp, DHS/DES

Wisconsin Department of Health Services
Response to Report Number A-05-16-00014
U.S. Department of Health and Human Services Office of Inspector General Report:
Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs

Response Summary

Beginning with the passage of the deficit Reduction Act of 2005 (DRA) that required states to begin collecting rebates on physician-administered drugs, the Wisconsin Department of Health Services (DHS) has worked vigorously to develop, monitor, and strengthen system processes and controls to ensure manufacturers are appropriately invoiced for eligible physician-administered drug claims.

DHS acknowledges that it is required by Section 1927(a)(7) of the Social Security Act to require providers to submit NDCs for physician-administered drugs and that Federal regulation 42 CFR § 447.520 also creates a penalty for the loss of Federal Financial Participation (FFP) for states that do not require the submission of NDCs.

DHS has complied with requiring providers to submit NDCs for physician-administered drugs as acknowledged on pages 4 and 12 of the draft audit. The July 2008 ForwardHealth Update 2008-126 to Wisconsin Medicaid Providers states: "Providers will be required to comply with requirements of the federal deficit Reduction Act of 2005 (DRA) and submit National Drug Codes (NDCs) with Healthcare Common Procedure Coding System (HCPCS) and select Current Procedural Terminology (CPT) procedure codes on claims for physician-administered drugs." DHS acknowledges that most but not all providers complied with this requirement during the audit period.

DHS recognizes that the OIG audit process is a beneficial practice to assist with identifying additional areas of opportunity for improvement, allowing us to continue strengthening our policies and processes around physician-administered drug claims. DHS will also work with the Centers for Medicare & Medicaid Services (CMS) to determine Federal share amounts that are required to be refunded.

Detailed responses addressing each of the recommendations outlined in the report are provided below:

1. **DHHS-OIG Recommendation to DHS:** *Refund to the Federal Government \$1,732,222 (Federal Share) for claims for single-source physician-administered drugs that were ineligible for federal reimbursement.*

DHS Response: The State does not completely concur with this recommendation.

Where possible the State has identified and corrected claim processing to allow us to complete invoicing manufacturers for rebate by March 1, 2017 on claim lines accounting for \$580,485 of the \$2,877,019 (\$1,732, 222 Federal share estimate) dollars associated with claims identified as single-source physician-administered drugs. This reduces the

Wisconsin Department of Health Services
Response to Report Number A-05-16-00014
U.S. Department of Health and Human Services Office of Inspector General Report:
Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs

Federal share examined in this category to a Federal share estimate of \$1,377,921. The State will refund the Federal share of the manufacturers' rebates for these invoiced claims once the rebates are received from the manufacturers. In addition, the State will work with CMS to determine any additional Federal share amounts required to be refunded.

2. **DHHS-OIG Recommendation to DHS:** *Refund to the Federal Government \$99,156 (Federal Share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for federal reimbursement.*

DHS Response: The State does not completely concur with this recommendation.

Where possible the State has identified and corrected claim processing to allow us to complete invoicing manufacturers for rebate by March 1, 2017 on claim lines accounting for \$6,675 of the \$164,691 (\$99,156 Federal share estimate) dollars associated with claims identified as Top-20 physician-administered drugs. This reduces the Federal share examined in this category to a Federal share estimate of \$94,809. The State will refund the Federal share of the manufacturers' rebates for these invoiced claims once the rebates are received from the manufacturers. In addition, the State will work with CMS to determine any additional Federal share amounts required to be refunded.

3. **DHHS-OIG Recommendation to DHS:** *Work with CMS to determine the unallowable portion of \$19,568 (Federal share) for other claims for covered outpatient physician-administered drugs that were submitted without NDCs and that may have been ineligible for federal Reimbursement and refund that amount, and whether the remaining \$102,212 (federal Share) of other physician-administered drug claims could have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, refund the federal share of the manufacturers' rebates for those claims.*

DHS Response: The State does not completely concur with this recommendation.

Where possible the State has identified and corrected claims processing to allow us to complete invoicing of manufacturers for rebate by March 1, 2017 on claim lines accounting for \$117,937 of the \$202,139 (\$102,212 and \$19,568 Federal share estimate) dollars associated with claims identified as "other" with and without NDCs. This reduces the Federal share examined in this category to a Federal share estimate of \$50,528. The State will refund the Federal share of the manufacturers' rebates for these invoiced claims once the rebates are received from the manufacturers. In addition, the State will work with CMS to determine any additional Federal share amounts required to be refunded.

4. **DHHS-OIG Recommendation to DHS:** *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, 2014.*

Wisconsin Department of Health Services
Response to Report Number A-05-16-00014
U.S. Department of Health and Human Services Office of Inspector General Report:
Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs

DHS Response: The State concurs with this recommendation.

The State will use the information acquired within this audit to review physician-administered drug claims processed after December 31, 2014 to ensure all physician-administered drugs eligible for rebates are invoiced. If necessary, the State will work with CMS to determine any Federal share amounts required to be refunded.

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

DHS Response: The State concurs with this recommendation.

The State acknowledges that the OIG audit process is beneficial to help identify key areas of additional opportunity for improvements, which allows us to further strengthen our policies and processes around physician-administered drug claims. The State plans to review current processes to identify any possible areas of improvement with physician-administered drug claim processing. In particular, the State is reviewing possible enhancements to our NDC to HCPCS crosswalk for claims processing, which would allow for more timely updates and help ensure all physician-administered drug claims are able to contain the appropriate data necessary for successfully invoicing of manufacturer rebates.