

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

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

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**November 2017
A-05-16-00013**

Office of Inspector General

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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: November 2017

Report No. A-05-16-00013

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



Why OIG 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. 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 the Ohio Department of Medicaid (State agency) complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs.

How OIG Did This Review

Our review covered physician-administered drug claims paid by the State agency between January 1, 2012, and December 31, 2014.

We used the Centers for Medicare & Medicaid Services' (CMS) Medicare Part B crosswalk to identify, if possible, the National Drug Codes (NDCs) associated with each Healthcare Common Procedure Coding System (HCPCS) code listed on claims from providers. 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.

Ohio Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs

What OIG Found

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 manufacturers for rebates associated with \$3.6 million (\$2.3 million Federal share) in single-source and top-20 multiple-source physician-administered 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 drug utilization data necessary to secure rebates for other physician-administered drugs. These drugs were included in claims totaling \$6.2 million (\$4.0 million Federal share) that did not have NDCs and in claims totaling \$195,526 (\$128,057 Federal share) that contained NDCs.

In addition, the State agency invoiced manufacturers for rebates associated with \$30.5 million (\$20.0 million Federal share) in physician-administered drugs after the completion of our fieldwork.

What OIG Recommends and State Agency Comments

We recommend that the State agency refund to the Federal Government \$2.3 million (Federal share) for claims for single-source physician-administered drugs and for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement; work with CMS to determine the unallowable portion of \$4.0 million (Federal share) and \$128,057 (Federal share) for other claims for covered outpatient physician-administered drugs that were not invoiced for rebates and refund that amount; work with CMS to ensure that rebates associated with physician-administered drug claims totaling \$20.0 million (Federal share) that were invoiced after the completion of our fieldwork are appropriately reported to the Medicaid program; 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.

In written comments on our draft report, the State agency partially concurred with our first, second, and fifth recommendations; did not concur with part of our third recommendation; concurred with the other recommendations, and described corrective actions that it had taken or planned to take.

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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 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 Ohio Department of Medicaid's (State agency) invoicing for rebates for physician-administered drugs for the period January 1, 2012, through December 31, 2014 (audit period).

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

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.

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 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 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 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

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 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 § 1927(a)(7)(B)(i).

record of rebate accounts receivable due from the manufacturers. The manufacturers then pay the rebates directly to the State agency.

HOW WE CONDUCTED THIS REVIEW

Our review covered physician-administered drug claims paid by the State agency between January 1, 2012, and December 31, 2014.

We used CMS's Medicare Part B crosswalk to identify, if possible, the NDCs associated with each HCPCS code listed on claims from providers. We then used the CMS Medicaid Drug File to determine whether the identified NDCs were classified as single-source drugs or multiple-source drugs.⁶ 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. The State agency did not invoice manufacturers for rebates associated with \$3,573,638 (\$2,325,552 Federal share) in physician-administered drugs. Of this amount, \$2,171,716 (\$1,408,033 Federal share) was for single-source drugs, and \$1,401,922 (\$917,519 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 drug utilization data necessary to secure rebates for all other physician-administered drugs. The State agency generally did not collect the drug utilization data necessary to invoice the manufacturers for rebates associated with these claims. Providers submitted claims totaling \$6,164,138 (\$4,020,250 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

⁶ The Medicare Part B crosswalk is published quarterly by CMS and is based on published drug and biological pricing data and information submitted to CMS by manufacturers. It contains the payment amounts that will be used to pay for Part B covered drugs as well as the HCPCS codes associated with those drugs. 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.

utilization data. Furthermore, under the Medicaid drug rebate program, claims totaling \$195,526 (\$128,057 Federal share), which contained NDCs, could have been eligible for rebates.

In addition, the State agency invoiced manufacturers for rebates associated with \$30,463,044 (\$20,007,447 Federal share) in physician-administered drugs after the completion of our fieldwork. The State agency had not received or reported the rebates associated with these claims to the Medicaid program as of May 31, 2017.

FEDERAL 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).

Prior to our audit period, the State agency required all providers (except hospitals) to submit NDCs on claims for physician-administered drugs. After our audit period, the State agency required hospitals to submit NDCs on all outpatient physician-administered drug claims.

Appendix C contains Federal requirements and State agency guidance 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 \$2,171,716 (\$1,408,033 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 \$1,401,922 (\$917,519 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, 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.

The State agency generally did not collect the drug utilization data necessary to invoice the manufacturers for rebates associated with other physician-administered drug claims. Providers submitted claims, totaling \$6,164,138 (\$4,020,250 Federal share), that did not have NDCs. For these 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 \$195,526 (\$128,057 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.

THE STATE AGENCY INVOICED MANUFACTURERS FOR REBATES ON PHYSICIAN-ADMINISTERED DRUGS AFTER THE COMPLETION OF OUR FIELDWORK

The State agency had not invoiced manufacturers for rebates associated with \$30,463,044 (\$20,007,447 Federal share) in physician-administered drugs during our fieldwork. However, the State agency invoiced manufacturers for rebates associated with these Medicaid drug claims in May 2017, after the completion of our fieldwork. The State agency had not received or reported the rebates associated with these claims to the Medicaid program as of May 31, 2017.

RECOMMENDATIONS

We recommend that the State agency:

- refund to the Federal Government \$1,408,033 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;
- refund to the Federal Government \$917,519 (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 \$4,020,250 (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 \$128,057 (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 ensure that rebates associated with physician-administered drug claims totaling \$30,463,044 (\$20,007,447 Federal share) that were invoiced after the completion of our fieldwork are appropriately reported to the Medicaid program;
- 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 partially concurred with our first, second, and fifth recommendations; did not concur with the first part of our third recommendation; concurred with the remaining recommendations, and described corrective actions that it had taken or planned to take. These corrective actions include a plan to return the Federal share of additional rebate funds as they are received and a description of additional controls that were implemented to ensure that NDCs are included on drug claims and that all claims eligible for rebates are invoiced to manufacturers.

For our first and second recommendations, the State agency agreed that it was required to invoice manufacturers for rebates for physician-administered drugs but noted that the majority of the drug claims were Medicare crossover claims and that Medicare has not provided all information needed for rebates in the crossover process.

The State agency did not concur with the first part of our third recommendation (that it work with CMS regarding the \$4,020,250 (Federal share) of claims) because, it said, States were not required to collect NDCs or invoice for rebates for drugs that were not top-20 multiple-source physician-administered drugs.

For our fifth recommendation, the State agency stated that it had retained a new vendor for drug rebate operations and is working to determine whether additional rebates can be invoiced.

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 are valid. 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.

We acknowledge that the State agency has an obligation to reimburse providers for crossover claims, but 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. CMS issued guidance to Medicare providers that requires NDCs to be included on physician-administered drug crossover claims. In addition, CMS has acknowledged that some State Medicaid agencies have denied physician-administered drug crossover claims that were not submitted with proper NDCs or have developed the required information with physicians, outpatient hospitals, and clinic hospitals to invoice manufacturers for rebates. However, if the State agency can retroactively 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 in this report.

We agree that the Federal requirements do not specifically address other physician-administered drugs that were not single-source or top-20 multiple-source physician-administered drugs. Nevertheless, we set aside the \$4,020,250 (Federal share) associated with these claims because the claims did not have NDCs in the utilization data, and we were unable to determine whether the claims may have been for drugs that were single-source or top-20 multiple-source physician-administered drugs. If the State agency had invoiced these claims for rebate, the drug manufacturers would have been required to pay the rebates. Therefore, we continue to recommend that the State agency work with CMS to determine whether these drug claims may have been eligible for Federal reimbursement and refund that amount.

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<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>	9/12/17
<i>Iowa Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs of Medicaid Managed-Care Organizations</i>	<u>A-07-16-06065</u>	5/05/17
<i>Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-16-00014</u>	3/23/17
<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>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>	12/08/16
<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

Report Title	Report Number	Date Issued
<i>Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-14-06049	7/22/15
<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

Our review covered physician-administered drug claims paid by the State agency 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, which included some fieldwork at the State agency office in Columbus, Ohio, from December 2015 through April 2017.

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 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 drugs for the period January 1, 2012, through December 31, 2014.⁷

⁷ We did not review crossover claims for which the State agency could not identify the Medicaid portion claimed for only the physician-administered drugs.

- We obtained the listing of 340B entities from the State agency.⁸
- We removed drug claims, totaling \$93,851,847 (\$62,165,841 Federal share), that either were not eligible for a drug rebate (including the drug claims submitted by 340B entities) or contained an NDC and were invoiced for rebate.
- We reviewed the remaining drug claims, totaling \$40,396,346 (\$26,481,306 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 HCPCS code on the drug claim to the HCPCS code on CMS’s Medicare Part B crosswalk to identify, if possible, the NDCs associated with each HCPCS code listed on claims from providers. We used the CMS Medicaid Drug File to determine whether these NDCs were classified as single-source drugs.
 - 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 (ones that were not identified as single-source or as top-20 multiple-source drugs) as other outpatient physician-administered drugs.
- We reviewed drug claims that were invoiced after the completion of our fieldwork.
- We discussed the results of our review with State agency officials on April 14, 2017, and May 31, 2017.

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 Medicare/Medicaid disproportionate share hospitals, which generally serve large numbers of low-income and/or uninsured patients, and State AIDS drug-assistance programs.

APPENDIX C: FEDERAL 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 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 States to 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 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 for which a State has not required the submission of claims using codes that identify the drugs sufficiently for the State to invoice a manufacturer for rebates (42 CFR § 447.520).

STATE AGENCY GUIDANCE

The State agency, *Provider Information Release*, No. 10.11, dated May 16, 2011, states (page 1):

With the implementation of the Medicaid Information Technology System (MITS), the Office of Ohio Health Plans will require that National Drug Code (NDC) information be submitted on select medical claims that itemize drugs.

The NDC will be required at the detail level when a claim is submitted with a Healthcare Common Procedure Coding System (HCPCS) code that represents a drug. With the exception of hospital claims, federal law requires that any code for a drug covered by Medicaid must be submitted with the NDC.

Claims affected by this policy will be denied if the NDC information is missing or invalid.

The State agency, *Medicaid Information Technology Supplemental Release*, dated August 9, 2011, states (page 4): “National Drug Code (NDC) information must be submitted through the MITS Web Portal. The NDC must be reported at the detail level on all claims (other than hospital claims) for a procedure code that represents a drug (HCPCS codes in the J series, HCPCS codes in the Q or S series that represent drugs, or CPT codes in the 90281–90399 range).”

The State agency, *The Answer Key*, No. 3, dated August 16, 2011, states (page 1): “Professional claims for physician-administered medications and injectables must include an appropriate National Drug Code (NDC). Such claims submitted without an NDC will be denied, regardless of provider type.”

The State agency, *Hospital Handbook Transmittal Letter*, No. 3352-17-01, dated December 28, 2016, states (page 2): “Effective January 1, 2017, the Department is requiring HCPCS codes (J codes or Q codes) on outpatient claims be billed with the appropriate National Drug Code (NDC) when a valid NDC code is applicable.”



August 24, 2017

Sheri L. Fulcher
Regional Inspector General for Audit Services
Department of Health and Human Services
Office of Inspector General
233 North Michigan, Suite 1360
Chicago, IL 60601

Re: A-05-16-00013 Ohio Medicaid Physician-Administered Drug Rebate Audit

Dear Ms. Fulcher,

Thank you for the opportunity to respond to the draft report issued by the OIG regarding their review of Ohio's drug rebate process for Medicaid physician-administered drugs. The Ohio Department of Medicaid appreciates the OIG's comprehensive review of Ohio's process in invoicing and submitting payment for rebates for physician-administered drugs.

In the attached response to the draft report, ODM has provided a response for each recommendation made by the OIG in regards to this review.

If you have any questions or would like to discuss our responses further, please contact Angela Houck at (614) 752-3250 or angela.houck@medicaid.ohio.gov.

Sincerely,

/Michelle Horn/

Michelle Horn
CFO
Ohio Department of Medicaid

Ohio Department of Medicaid Responses:

Recommendation 1: OIG recommends that the State agency refund to the Federal Government \$1,408,033 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal Reimbursement.

State Response: The Ohio Department of Medicaid (ODM) partially concurs with this recommendation. ODM agrees that Section 1927(a)(7) of the Social Security Act requires the state to invoice manufacturers for rebates for single-source physician-administered drugs, and ODM did not invoice for rebates timely.

ODM notes that a majority of the single-source physician-administered drug claims identified by OIG are Medicare crossover claims. Medicaid programs are required by Section 1902(a)(10)(E) of the Social Security Act to pay cost sharing for Medicare crossover claims regardless of coverage availability through Medicaid,ⁱ so ODM disagrees that these claims are improper payments. Medicare has not passed all information needed for rebates in the crossover process, and ODM urges that CMS be required to collect and transmit all information needed for Medicaid rebates.

Of the OIG-identified claims for which ODM has not sent rebate invoices, 72% (4,913 claims) are Medicare crossover claims. ODM will continue to pursue rebates on the remaining 1,953 claims and refund the Federal Share of those rebates through the usual business processes.

Recommendation 2: OIG recommends that the State agency refund to the Federal Government \$917,519 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal Reimbursement.

State Response: ODM partially concurs with this recommendation. As noted in the response to Recommendation 1, ODM agrees that Section 1927(a)(7) of the Social Security Act requires the state to invoice manufacturers for rebates for the top 20 multiple-source physician-administered drugs, and ODM did not invoice for rebates timely.

As in Recommendation 1, ODM also notes that 59% (21,422 claims) of the top 20 multiple-source physician-administered drug claims identified by OIG are Medicare crossover claims. Medicaid programs are required by Section 1902(a)(10)(E) of the Social Security Act to pay cost sharing for Medicare crossover claims regardless of coverage availability through Medicaid,ⁱⁱ so ODM disagrees that these claims are improper payments. Medicare has not passed all information needed for rebates in the crossover process, and ODM urges that CMS be required to collect and transmit all information needed for Medicaid rebates.

ODM will reimburse the Federal Government for the Federal Share of the remaining, non-crossover claims, \$710,912.

Recommendation 3a: OIG recommends that the State agency work with CMS to determine the unallowable portion of \$4,020,250 (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.

State response: ODM does not concur with this recommendation. During the time period covered by this audit, states were not required to collect NDCs or invoice for rebates for drugs that were not in the top 20 multiple-source physician-administered drugs. ODM also notes that 77% (183,958 claims) of the claims identified by OIG are Medicare crossover claims that were not received from Medicare with all information necessary to invoice for rebates.

Recommendation 3b: OIG recommends that the State agency work with CMS to determine whether the remaining \$128,057 (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.

State response: ODM concurs with this recommendation. The state will review the remaining claims that were submitted with an NDC to determine whether rebates may be obtained from manufacturers.

Recommendation 4: OIG recommends that the State agency work with CMS to ensure that rebates associated with physician-administered drug claims totaling \$30,463,044 (\$20,007,447 Federal share) that were invoiced after the completion of our fieldwork are appropriately reported to the Medicaid program.

State response: ODM concurs with this recommendation. By June 30, \$13,008,584.63 (representing \$15,339,346.27 in Medicaid-paid amount) has been collected and reported to the Medicaid program through the CMS-64 financial report. As additional funds are received, the Federal share will be returned to the Federal government through this standard process.

Recommendation 5: OIG recommends that the State agency 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.

State response: ODM partially concurs with this recommendation. ODM has retained a new vendor for drug rebate operations and is working to determine whether additional rebates for this time period can be invoiced. As noted in previous recommendations, Medicare crossover claims do not consistently have all information needed to invoice for rebates. ODM suggests that OIG work with the Medicare program to ensure all required information is collected by CMS and passed on to states.

Recommendation 6: OIG recommends that the State agency strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.

State Response: ODM concurs with this recommendation and appreciates the opportunity to describe the additional controls that have been implemented. The Ohio Medicaid Information Technology System now requires a valid NDC to be submitted with every drug code, and uses a robust HCPCS to NDC crosswalk to ensure the NDC and HCPCS describe the same drug. This crosswalk was implemented July 1, 2017. Non-crossover claims without an NDC or with an NDC that does not match the HCPCS are denied.

In addition to the enhanced edits on claims processing, the state has changed vendors for drug rebate operations to a vendor that has a proven track record of collecting as many rebates as possible, and has robust systems in place to ensure all claims eligible for rebates are invoiced to the appropriate manufacturer.

ⁱ CMCS-MMCO-CM Informational Bulletin, "Payment of Medicare Cost Sharing for Qualified Medicare Beneficiaries (QMBs), available at <https://www.medicaid.gov/federal-policy-guidance/downloads/cib-06-07-2013.pdf>, retrieved August 22, 2017

ⁱⁱ CMCS-MMCO-CM Informational Bulletin, "Payment of Medicare Cost Sharing for Qualified Medicare Beneficiaries (QMBs), available at <https://www.medicaid.gov/federal-policy-guidance/downloads/cib-06-07-2013.pdf>, retrieved August 22, 2017