

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**DELAWARE DID NOT BILL
MANUFACTURERS FOR SOME REBATES
FOR PHYSICIAN-ADMINISTERED DRUGS
DISPENSED TO ENROLLEES OF
MEDICAID MANAGED-CARE
ORGANIZATIONS**

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EXECUTIVE SUMMARY

Delaware did not bill manufacturers for some rebates for physician-administered drugs dispensed to enrollees of Medicaid managed-care organizations. As a result, Delaware did not collect an estimated \$127,000 (Federal share) in rebates.

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. States bill the manufacturers for the rebates to reduce the cost of the drugs to the program. However, previous Office of Inspector General reviews found that States did not always bill and collect all rebates due for drugs administered by physicians to enrollees of Medicaid managed-care organizations (MCOs).

Our objective was to determine whether the Delaware Department of Health and Social Services, Division of Medicaid and Medical Assistance (State agency), complied with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs dispensed to MCO enrollees.

BACKGROUND

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 administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. Manufacturer rebates offset the cost of prescription drugs.

States contract with MCOs to provide specific services to enrolled Medicaid beneficiaries, usually in return for a predetermined periodic payment known as a capitation payment. The capitation payment may cover physician-administered drugs. To claim Federal reimbursement, States report to CMS the capitation payments made to MCOs as MCO expenditures on the Form CMS-64; these expenditures are not identified by specific type of service.

The Deficit Reduction Act of 2005 amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs. To collect rebates for drugs, States submit to the manufacturer the drug utilization data containing National Drug Codes (NDCs) for the drugs. States that do not comply with Federal requirements relating to capturing NDCs to bill and collect rebates are not eligible to receive Federal reimbursement for covered outpatient drugs administered by a physician.

Effective March 23, 2010, the Patient Protection and Affordable Care Act requires manufacturers to pay rebates on covered outpatient drugs dispensed to MCO enrollees if the MCOs are responsible for coverage of such drugs. States typically require MCOs to submit NDCs to the State for covered outpatient drugs dispensed to eligible individuals. States must include the drug utilization data reported by MCOs when billing manufacturers for rebates. Physician-

administered drugs dispensed to MCO enrollees are recorded in the MCO drug utilization data in provider claim lines. States must report drug rebates on the Form CMS-64.

In Delaware, the State agency is responsible for billing and collecting Medicaid drug rebates for physician-administered drugs. The State agency contracts with a contractor to manage its drug rebate program. In calendar year 2013, Delaware paid MCOs \$1,176,744,247 (\$655,393,376 Federal share), which included expenditures for physician-administered drugs. Our audit covered the State agency's MCO drug utilization data for physician-administered drugs from January through December 2013 (audit period).

WHAT WE FOUND

The State agency did not fully comply with Federal Medicaid requirements for billing manufacturers for some rebates for physician-administered drugs dispensed to MCO enrollees. The State agency properly billed for most rebates for MCO drug utilization in our judgmental sample. However, the State agency did not have valid NDCs for other drug utilization data submitted by MCOs for physician-administered drugs, and the State agency did not bill manufacturers for rebates for these drugs. We estimate that the State agency did not bill manufacturers for rebates totaling \$230,045 (\$126,524 Federal share). We did not have enough information to determine an estimate for some of the utilization.

The State agency did not bill manufacturers for rebates for this utilization because the MCOs submitted this utilization data to the State without valid NDC information. Although the State required MCOs to submit valid NDCs for all physician-administered drug utilization, the State agency did not ensure that MCOs submitted utilization with valid NDC information. Therefore, the State did not obtain rebates for this utilization.

WHAT WE RECOMMEND

We recommend that the State agency:

- work with CMS to resolve the drug utilization data without valid NDCs by determining the correct NDCs, billing manufacturers for the estimated \$230,045 (\$126,524 Federal share) in rebates, and refunding the Federal share of rebates collected;
- work with CMS to resolve the drug utilization without valid NDCs for which we were not able to determine an estimate by determining the correct NDCs and rebates due, billing manufacturers for the rebates, and refunding the Federal share of rebates collected; and
- ensure that MCOs submit drug utilization data containing NDCs for all physician-administered drugs.

STATE AGENCY COMMENTS AND OUR RESPONSE

In written comments on our draft report, the State agency did not concur with our first and second recommendations but did concur with our third recommendation. The State agency commented that it has no reasonable means for researching and identifying the specific products

and NDCs for our first and second recommendations because the MCO that submitted most of the utilization data without valid NDCs is no longer contracted with the State. However, during our audit period, the State agency's contract with MCOs provided for access to records to support claims for at least 5 years after the claim was submitted. As such, we maintain that our first and second recommendations are valid. The State agency provided information on actions it planned to take to address our third recommendation.

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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. States bill the manufacturers for the rebates to reduce the cost of the drugs to the program. However, previous Office of Inspector General (OIG) reviews found that States did not always bill and collect all rebates due for drugs administered by physicians to enrollees of Medicaid managed-care organizations (MCOs). Appendix A lists previous OIG reviews of the Medicaid drug rebate program.¹

OBJECTIVE

Our objective was to determine whether the Delaware Department of Health and Social Services, Division of Medicaid and Medical Assistance (State agency), complied with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs dispensed to MCO enrollees.

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 administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. Manufacturer rebates offset the cost of prescription drugs. 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 (URA) for each drug and provides these amounts to the States each quarter. Covered outpatient drugs reported by participating drug manufacturers are listed in the CMS Medicaid drug product data 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 to bill manufacturers for rebates as described in section 1927(a)(7) of the Act. To bill for rebates, States must use drug utilization data that identifies, by NDC, the number of units of each drug for which the States reimbursed Medicaid providers. The States must capture this drug utilization data and report the information to the manufacturers

¹ OIG performed similar reviews for rebates due for drugs administered by physicians to fee-for-service enrollees. These reviews are included in this appendix.

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

(the Act § 1927(b)(2)(A)). The number of units is multiplied by the URA to determine the actual rebate amount due from each manufacturer.

Federal Reimbursement to States for Payments to Medicaid Managed-Care Organizations

States use two primary models to pay for Medicaid services: fee-for-service and managed care. In the managed-care model, States contract with MCOs to provide services to enrolled Medicaid beneficiaries, usually in return for a predetermined periodic payment known as a capitation payment. States pay MCOs for each covered individual regardless of whether the enrollee received services during the relevant time period (42 CFR § 438.2). MCOs use the capitation payments to pay provider claims for these services. Capitation payments may cover outpatient drugs, which can include both drugs dispensed to patients at pharmacies and drugs dispensed by a physician.

To claim Federal reimbursement, States report capitation payments made to MCOs as MCO expenditures on the Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program (Form CMS-64). These expenditures are not identified by specific type of service. CMS reimburses States for the Federal share of Medicaid expenditures reported on the Form CMS-64.

Physician-Administered Drugs

The Deficit Reduction Act of 2005 amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs. To collect rebates for drugs, States submit to the manufacturers the drug utilization data containing NDCs for the drugs. A valid NDC is a unique identifier that represents a drug's specific manufacturer, product, and package size. NDCs allow States to identify drugs and manufacturers to pay drug rebates. States that do not comply with Federal requirements relating to capturing NDCs to bill and collect rebates are not eligible to receive Federal reimbursement for covered outpatient drugs administered by a physician.

Effective March 23, 2010, the Patient Protection and Affordable Care Act (ACA)³ required manufacturers to pay rebates on covered outpatient drugs dispensed to MCO enrollees if the MCOs are responsible for coverage of such drugs. States typically require MCOs to submit to the State agency NDCs for covered outpatient drugs dispensed to eligible individuals. MCOs submit to the State agency provider claim information including claim lines for covered outpatient drugs. This information includes drug utilization data, which States must include when billing manufacturers for rebates. Physician-administered drugs dispensed to MCO enrollees are recorded in MCO drug utilization data.

States must report adjustments to drug expenditures and drug rebates on the Form CMS-64. States report drug rebate accounts receivable data on the Medicaid Drug Rebate Schedule (Form CMS-64.9R), which is part of the Form CMS-64. The expenditures, adjustments, and

³ P.L. No. 111-148 (Mar. 23, 2010) as amended by the Health Care and Education Reconciliation Act of 2010; P.L. No. 111-152 (Mar. 30, 2010), collectively referred to as "ACA".

rebates do not distinguish between amounts related to pharmacy drugs and amounts related to physician-administered drugs.

The State Agency's Medicaid Drug Rebate Program

In Delaware, the State agency is responsible for billing and collecting Medicaid drug rebates for physician-administered drugs. The State agency contracts with HP Enterprise Services, LLC (the contractor) to process its Medicaid claims and manage its drug rebate program. The contractor processes claim data for the State agency in its Medicaid Management Information System (MMIS), which contains a field for NDCs associated with drug utilization submitted by MCOs. The contractor bills the manufacturer for rebates. Manufacturers pay rebates directly to the contractor, which reconciles the payments to the rebate invoices. The contractor maintains accounts receivable information and works with manufacturers to resolve any unpaid rebates.

HOW WE CONDUCTED THIS REVIEW

We reviewed the Form CMS-64 and determined that the State agency paid MCOs \$1,176,744,247 (\$655,393,376 Federal share) in calendar year (CY) 2013. This total included expenditures for physician-administered drugs. Our audit covered the State agency's MCO drug utilization data for physician-administered drugs from January through December 2013 (audit period).

We obtained from the State agency drug claim line information for the first quarter of 2013. We reconciled this drug claim line information to summary drug utilization information that the State indicated it had invoiced for rebates. After we verified that the utilization for the first quarter of 2013 was invoiced for rebates, we reviewed the drug claim line information from 2013 that the State indicated it did not invoice for rebates due to missing or invalid NDCs.

Because the State agency's MCO expenditures were not identified by specific type of service, we requested that the State agency estimate the amount it paid MCOs for physician-administered drugs. The State agency estimated that it paid MCOs \$15 million for physician-administered drugs in 2013. We requested that the State agency estimate the amount of rebates not collected for physician-administered drugs as a result of claim lines with missing or invalid NDCs. The State agency provided a partial estimate; we determined this estimate to be reasonable. In addition, we calculated average rebates per claim received by the State agency for the first quarter of 2013 and applied these amounts to some of the remaining claim lines with missing or invalid NDCs to determine an estimated rebate amount for which the State agency did not bill. We were not able to apply the estimates to the remaining claim lines with missing or invalid NDCs because the claim lines did not contain enough information.

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.

FINDING

The State agency did not fully comply with Federal Medicaid requirements for billing manufacturers for some rebates for physician-administered drugs dispensed to MCO enrollees. The State agency properly billed manufacturers for rebates for most drugs in our judgmental sample. However, the State agency did not have valid NDCs for other drug utilization data submitted by MCOs for physician-administered drugs, and the State agency did not bill manufacturers for rebates for these drugs. We estimate that the State agency did not bill manufacturers for rebates totaling \$230,045 (\$126,524 Federal share). We did not have enough information to determine an estimate for some of the utilization.

FEDERAL AND STATE REQUIREMENTS

The ACA amended section 1927 of the Act, effective March 23, 2010, to specifically require manufacturers to pay rebates on covered outpatient drugs dispensed to MCO enrollees if the MCOs are responsible for coverage of such drugs. To bill for rebates, States must include information for drugs dispensed to individuals enrolled in MCOs when billing manufacturers for rebates (the Act §§ 1927(b)(1)(A) and (b)(2)(A)).

The ACA also amended section 1903 of the Act to specifically address the conditions of Federal reimbursement for covered outpatient drugs dispensed to MCO enrollees. Essentially, States must secure rebates for drugs dispensed through MCOs and require MCOs to submit to the State NDCs for drugs dispensed to eligible individuals (the Act § 1903(m)(2)(A)).

Federal regulations prohibit Federal reimbursement for physician-administered drugs unless the States require that submitted claims contain NDCs (42 CFR § 447.520).

Through its Provider Alerts and Medicaid Alerts, the State agency notified providers to submit NDCs on claims for physician-administered drugs. In addition, through its contracts with MCOs, the State agency required MCOs to include NDCs in their physician-administered drug utilization data.

Appendix C contains Federal and State requirements related to physician-administered drugs.

THE STATE AGENCY DID NOT BILL MANUFACTURERS FOR SOME REBATES FOR PHYSICIAN-ADMINISTERED DRUGS DISPENSED TO ENROLLEES OF MEDICAID MANAGED-CARE ORGANIZATIONS

The State agency did not have NDCs for 27,971 physician-administered drug claim lines submitted by MCOs, and the State agency did not bill manufacturers for rebates for these drugs. Using the claim line information, the State estimated it did not bill manufacturers for rebates

totaling \$205,388⁴ (\$112,963 Federal share⁵) for 2,125 of the 27,971 claim lines. We determined this estimate to be reasonable. The State did not provide an estimate for the remaining 25,846 claim lines without a valid NDC. Of the remaining claim lines without a valid NDC, we estimated that the State did not bill manufacturers for rebates totaling \$24,657 (\$13,561 Federal share) for 15,542 claim lines without valid NDCs. We were not able to provide an estimate for the remaining 10,304 claim lines without valid NDCs because the claim lines did not contain enough information.

The State agency did not bill manufacturers for rebates for these drugs because the MCOs submitted to the State utilization data with a blank NDC field or an invalid NDC. Although the State required MCOs to submit valid NDCs for all physician-administered drug utilization, the State agency did not ensure that MCOs submitted utilization with valid NDC information. The State agency stated that utilization data submitted without valid NDCs was reported back to the MCO for correction. However, the State did not track this process, and not all of the utilization was corrected. Therefore, the State agency did not obtain rebates for this utilization.

RECOMMENDATIONS

We recommend that the State agency:

- work with CMS to resolve the drug utilization data without valid NDCs by determining the correct NDCs, billing manufacturers for the estimated \$230,045 (\$126,524 Federal share) in rebates, and refunding the Federal share of rebates collected;
- work with CMS to resolve the drug utilization without valid NDCs for which we were not able to determine an estimate by determining the correct NDCs and rebates due, billing manufacturers for the rebates, and refunding the Federal share of rebates collected; and
- ensure that MCOs submit drug utilization data containing NDCs for all physician-administered drugs.

STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the State agency did not concur with our first and second recommendations but did concur with our third recommendation.

- The State agency commented that the majority of the drug utilization data without valid NDCs is from a MCO that no longer has a current contract with the State. As a result, it

⁴ Because rebates vary according to the specific NDC billed, the State agency will have to identify the correct NDCs before determining the precise rebate amount.

⁵ Section 2501(a)(2) of the ACA modified section 1927(c)(1)(B) and added section 1927(b)(1)(C) which, effective January 1, 2010, increased the rebate amount due from manufacturers, with the difference between the previous amount and the increased amount credited to the Federal Government. We did not include this amount in our calculation of the Federal share because we did not have the information required to calculate the increased amount.

has no reasonable means for researching and identifying the specific products and correct NDCs for our first and second recommendations.

- The State agency concurred with our third recommendation and provided information on actions that it planned to take.

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

After reviewing the State agency's comments we maintain that our first and second recommendations are valid. According to the State's contract with its MCOs as amended in April 2012, Section 12.8 Records Retention states that "the Contractor shall retain medical, financial, and other supporting records relating to each claim for service paid under this contract with the State for not less than five (5) years after the claim is submitted. In the event that this Contract is terminated, the Contractor's records shall remain subject to the DMAP [Delaware Medical Assistance Program] regulations.... The Contractor must have written policies and procedures for storing this information so that it can be easily retrieved if necessary as per the terms of this contract." As such MCOs that contracted with the State during our audit period should be able to provide the information required for the State agency to work with CMS to resolve the drug utilization data without NDCs. Therefore, we maintain our recommendation that the State agency work with CMS to resolve the drug utilization data without valid NDCs as stated in our first and second recommendations.

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

| Report Title | Report Number | Date Issued |
|---|--|--------------------|
| <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> | 12/08/16 |
| <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 |
| <i>States' Collection of Rebates for Drugs Paid Through Medicaid Managed Care Organizations Has Improved</i> | <u>OEI-05-14-00431</u> | 9/16/15 |
| <i>Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i> | <u>A-07-14-06049</u> | 7/22/15 |
| <i>Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i> | <u>A-06-12-00060</u> | 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 | 03/04/15 |
| <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>States' Collection of Rebates for Drugs Paid Through Medicaid Managed Care Organizations</i> | OEI-03-11-00480 | 9/07/12 |
| <i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i> | OEI-03-09-00410 | 5/06/11 |

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed the Form CMS-64 and determined that the State agency paid MCOs \$1,176,744,247 (\$655,393,376 Federal share) in CY 2013. This total included expenditures for physician-administered drugs. Our audit covered the State agency's MCO drug utilization data for physician-administered drugs from January through December 2013.

We reconciled summary drug utilization information for the first quarter of 2013 that the State indicated it invoiced for rebates to drug claim line information for the first quarter of 2013. After we verified that the utilization for the first quarter of 2013 was invoiced for rebates, we reviewed drug claim line information from 2013 that the State indicated it did not invoice for rebates.

Because the State agency's MCO expenditures were not identified by specific type of service, we requested that the State agency estimate the amount it paid MCOs for physician-administered drugs. The State agency estimated that it paid MCOs \$15 million for physician-administered drugs in 2013. We requested that the State agency estimate the amount of rebates not collected for physician-administered drugs as a result of claim lines with missing or invalid NDCs. The State agency provided a partial estimate; we determined this estimate to be reasonable. In addition, we calculated average rebates per claim received by the State agency for the first quarter of 2013 and applied these amounts to some of the remaining claim lines with missing or invalid NDCs to determine an estimated rebate amount for which the State agency did not bill. We were not able to apply the estimates to the remaining claim lines with missing or invalid NDCs because the claim lines did not contain enough information.

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

We conducted our audit from March 2015 to September 2016 and performed fieldwork at the State agency office in New Castle, Delaware.

METHODOLOGY

To accomplish our objective, we:

- reviewed Federal laws, regulations, and guidance pertaining to the Medicaid drug rebate program and physician-administered drugs;
- reviewed State requirements, including billing instructions for physician-administered drugs;
- reviewed State agency policies and procedures for rebates for physician-administered drugs and State agency contracts with two MCOs;

- interviewed State agency and rebate contractor personnel to gain an understanding of the administration of and controls over the Medicaid rebate billing process for physician-administered drugs;
- reviewed the State agency's Form CMS-64 to identify MCO expenditures;
- tested the billing of rebates by:
 - obtaining from the State agency the first quarter CY 2013 summary MCO drug utilization information submitted to manufacturers for rebates for physician-administered drugs,
 - obtaining from the State agency the first quarter CY 2013 MCO claim line data for physician-administered drugs, and
 - reconciling the first quarter CY 2013 summary MCO drug utilization information to the first quarter CY 2013 MCO claim line data to verify the billing of rebates by NDC;
- obtained from the State agency the MCO claim line information for physician-administered drugs paid in CY 2013 without valid NDCs and not invoiced for rebates;
- obtained from the State agency the estimated rebate amounts not collected for some physician-administered drugs not invoiced in 2013;
- reviewed the State agency's methodology for calculating this estimate and determined whether the estimate was reasonable;
- estimated the amount of rebates not collected for the remaining physician-administered drug utilization without valid NDCs; and
- discussed the results of our review with State agency officials.

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

FEDERAL LAWS

Under the Medicaid program, States may provide coverage for outpatient drugs as an optional service (the Act § 1905(a)(12)). Section 1903(a) of the Act provides for Federal financial participation (Federal share) in State expenditures for these drugs.

The Medicaid drug rebate program, created by the Omnibus Budget Reconciliation Act of 1990 (which added section 1927 to the Act), became effective on January 1, 1991. A manufacturer must enter into a rebate agreement with the Secretary of Health and Human Services 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.

States must provide for the collection and submission of utilization and coding data necessary to secure rebates for certain physician-administered drugs (the Act § 1927(a)(7)). States must submit the utilization using NDCs (the Act § 1927(a)(7)(C)).

Section 6002 of the Deficit Reduction Act of 2005 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 Deficit Reduction Act 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 submit the utilization and coding data described in section 1927(a)(7) of the Act.

Section 2501 of the ACA amended section 1927(b)(1)(A) of the Act to require that manufacturers pay rebates for covered outpatient drugs dispensed to individuals enrolled in an MCO if the MCO is responsible for coverage of such drugs. Section 2501 of the ACA also amended section 1927(b)(2)(A) to require that States submit information necessary to secure rebates from manufacturers for covered outpatient drugs dispensed through MCOs. In addition, section 2501 amended section 1903(m)(2)(A) to essentially extend the Medicaid rebate obligations to drugs dispensed through MCOs. Under this provision, each MCO contract must require that Medicaid rebates apply to drugs dispensed through the MCO. Section 2501 prohibits payment unless the MCO contracts require MCOs to submit to the State NDC drug utilization data for drugs dispensed to eligible individuals.

FEDERAL REGULATIONS

Federal regulations set conditions for States to obtain a Federal share for covered outpatient drugs administered by a physician and specifically state that no Federal share is available for physician-administered drugs for which a State has not required the submission of claims using codes that identify the drugs sufficiently for the State to bill a manufacturer for rebates (42 CFR § 447.520).

STATE REQUIREMENTS AND GUIDANCE

Delaware's Medicaid Alert dated January 29, 2007, informed physician providers participating in the Delaware Medical Assistance Programs that physician-administered drug claims with a date of service of March 24, 2007, or later will require the NDC.

Delaware's Provider Alert dated June 6, 2008, informed hospital providers participating in the Delaware Medical Assistance Programs that physician-administered drug claims with a date of service of July 1, 2008, or later will require the NDC.

Delaware's contracts with its MCOs, as amended in April 2012, include provisions that require MCOs to submit physician-administered drug utilization with a valid NDC.

APPENDIX D: STATE AGENCY COMMENTS



**DELAWARE HEALTH
AND SOCIAL SERVICES**

DIVISION OF
MEDICAID & MEDICAL ASSISTANCE

OFFICE OF THE DIRECTOR

December 14, 2016

Jason Jelen
Regional Inspector General for Audit Services
Office of Audit Services, Region III
Public Ledger Building, Suite 316
150 S. Independence Mall West
Philadelphia, PA 19106

Dear Mr. Jelen

Thank you for sharing the draft report entitled *Delaware Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations (A-03-15-00202)*. Please find our response to your recommendations below.

Recommendation #1: Work with CMS to resolve the drug utilization data without valid NDCs by determining the correct NDCs, billing the manufacturers for the estimated \$230,045 in rebates, and refunding the Federal share of rebates collected.

DMMA does not concur. The majority of the encounters were submitted by a managed care organization that has not been contracted with Delaware Medicaid for two years. We have no reasonable means of researching and identifying the specific products and correct NDCs.

Recommendation #2: Work with CMS to resolve the drug utilization without valid NDCs for which we were not able to determine an estimate by determining the correct NDCs and rebates due, billing the manufacturers for the rebates and refunding the Federal share of rebates collected.

DMMA does not concur. The majority of the encounters were submitted by a managed care organization that has not been contracted with Delaware Medicaid for two years. We have no reasonable means of researching and identifying the specific products and correct NDCs.

Recommendation #3: Ensure that MCOs submit drug utilization data containing NDCs for all physician administered drugs.

DMMA concurs. We will continue to monitor the accuracy of the MCO encounters for physician administered drugs. Monthly rates of acceptance of these specific encounters will be shared with each plan. Request for a corrective action plan from the MCO staff will be requested if the acceptance rate falls below 95% approval. The contract with the MCOs specifically notes that any outpatient drug must be from a CMS rebate participating labeler.

P.O. BOX 906 • NEW CASTLE • DELAWARE • 19720 • TELEPHONE: (302) 255-9500

DMMA appreciates the work performed by the OIG and efforts to collaborate with the State during review of the data. Please contact Mr. William McGonegal, Chief of Program Integrity, at 302-255-9542 if you have any questions.

Sincerely,

A handwritten signature in blue ink, appearing to read "Stephen M. Groff".

Stephen M. Groff
Director

cc: Lisa Zimmerman, Deputy Director
William McGonegal, Chief of Program Integrity
Cynthia Denmark, Pharmacy Director