

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

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

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# *Office of Inspector General*

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## EXECUTIVE SUMMARY

*Virginia did not bill manufacturers for some rebates for physician-administered drugs dispensed to enrollees of Medicaid managed-care organizations. As a result, Virginia did not collect an estimated \$2.9 million (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 Virginia Department of Medical Assistance Services, Division of Health Care Services (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 on provider claim lines. States must report drug rebates on the Form CMS-64.

In Virginia, 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, Virginia paid MCOs \$2,411,629,093 (\$1,238,462,930 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 manufacturers for rebates for drugs associated with the NDCs 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. The State agency estimated average rebates per claim billed to manufacturers, and we determined these estimates to be reasonable. We applied the estimates and determined that the State agency did not bill rebates of \$5,831,528 (\$2,915,764 Federal share) to manufacturers for physician-administered drug utilization without valid NDCs.

The State agency did not bill manufacturers for rebates for these drugs because the MCOs submitted utilization data to the State 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 implement edits in its Medicaid Management Information System to ensure that MCOs submitted valid NDCs. Therefore, the State did not obtain rebates for these drugs.

## **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 \$5,831,528 (\$2,915,764 Federal share) in rebates, and refunding the Federal share of rebates collected;
- implement Medicaid Management Information System edits to verify that NDCs are present and valid in all drug utilization data; and
- ensure that MCOs submit drug utilization data containing NDCs for all physician-administered drugs.

## **STATE AGENCY COMMENTS**

In written comments on our draft report, the State agency concurred with our recommendations and described corrective actions that it 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. 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.<sup>1</sup>

### OBJECTIVE

Our objective was to determine whether the Virginia Department of Medical Assistance Services, Division of Health Care Services (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.<sup>2</sup> 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

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

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

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(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)<sup>3</sup> 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

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<sup>3</sup> 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."

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(Form CMS-64.9R), which is part of the Form CMS-64. The expenditures, adjustments, and 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 Virginia, the State agency is responsible for billing and collecting Medicaid drug rebates for physician-administered drugs. The State agency contracts with Catamaran Corporation<sup>4</sup> (the contractor) to manage its drug rebate program. The State agency processes claim data in its Medicaid Management Information System (MMIS), which contains a field for NDCs associated with drug utilization submitted by MCOs. The State agency forwards the drug utilization to the contractor to bill the manufacturers. Manufacturers pay rebates directly to the State agency; the State agency then forwards the payment information 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 \$2,411,629,093 (\$1,238,462,930 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. From this information, we selected 74 NDCs representing drugs with high utilization that the State agency indicated had been invoiced for rebates. These 74 NDCs were associated with 8 manufacturers' drugs. After we verified that the drugs associated with the 74 selected NDCs had been 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, the State agency was unable to determine the amount it paid MCOs for physician-administered drugs. In 2013, the State agency billed \$8,735,947 (\$4,367,974 Federal share) in manufacturer rebates for certain MCO physician-administered drug utilization with valid NDCs. On the basis of this amount, the State estimated the average rebate per claim billed. We determined these estimates to be reasonable. We applied the estimates to the claim lines with missing or invalid NDCs to determine an estimated rebate amount for which the State agency did not bill.

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.

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<sup>4</sup> Formerly SXC Health Solutions.

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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 drugs associated with the NDCs 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. Using the State agency's estimated average rebates per claim billed to manufacturers, we determined that the State agency did not bill manufacturers for rebates totaling an estimated \$5,831,528 (\$2,915,764 Federal share).

### **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 Medicaid Memos, 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 the 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 150,965 physician-administered drug claim lines submitted by MCOs, and the State agency did not bill manufacturers for rebates for these drugs. We applied the State agency's estimates of average rebate per claim to the 150,965 claims

without valid NDCs and calculated that the State agency did not bill manufacturers for rebates totaling an estimated \$5,831,528<sup>5</sup> (\$2,915,764 Federal share).<sup>6</sup>

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 implement edits in its MMIS to ensure that MCOs submitted valid NDCs. Therefore, the State did not obtain rebates for these drugs.

## **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 \$5,831,528 (\$2,915,764 Federal share) in rebates, and refunding the Federal share of rebates collected;
- implement MMIS edits to verify that NDCs are present and valid in all drug utilization data; and
- ensure that MCOs submit drug utilization data containing NDCs for all physician-administered drugs.

## **OTHER MATTERS**

We identified an additional 32,342 claim lines that the State agency said it did not invoice for rebates because the NDC was not found in the CMS URA pricing file or because the manufacturer was not listed on the CMS labeler file that the State used to bill manufacturers for rebates during 2013. Because the drugs are not listed in the CMS files, the claim lines may not be covered outpatient drugs. Our objective did not require that we assess the completeness of the CMS URA pricing or labeler files. Therefore, we were unable to determine the extent to which these claim lines may have affected Federal reimbursement.

## **STATE AGENCY COMMENTS**

In written comments on our draft report, the State agency concurred with our recommendations and described corrective actions that it planned to take.

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

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<sup>5</sup> 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.

<sup>6</sup> 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. *Virginia Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations (A-03-15-00201)*

**APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS**

<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>California Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Some Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-09-15-02035</u></a>	12/8/16
<i>Kansas Correctly Invoiced Rebates to Manufacturers for Most Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-07-15-06060</u></a>	8/18/16
<i>Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-14-06057</u></a>	5/26/16
<i>Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-15-06063</u></a>	3/31/16
<i>South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-15-06059</u></a>	2/09/16
<i>Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-15-06062</u></a>	1/14/16
<i>North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-15-06058</u></a>	1/13/16
<i>California Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	<a href="#"><u>A-09-14-02038</u></a>	1/07/16
<i>Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-14-06056</u></a>	9/18/15
<i>States' Collection of Rebates for Drugs Paid Through Medicaid Managed Care Organizations Has Improved</i>	<a href="#"><u>OEI-05-14-00431</u></a>	9/16/15
<i>Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-14-06049</u></a>	7/22/15
<i>Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-06-12-00060</u></a>	5/04/15
<i>Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-14-06051</u></a>	4/13/15

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<i>Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#">A-09-13-02037</a>	3/04/15
<i>Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<a href="#">A-06-14-00031</a>	2/10/15
<i>The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-03-12-00205</a>	8/21/14
<i>Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-07-13-06040</a>	8/07/14
<i>Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-09-12-02079</a>	4/30/14
<i>Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	<a href="#">A-09-12-02080</a>	4/24/14
<i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-03-12-00200</a>	11/26/13
<i>Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<a href="#">A-06-12-00059</a>	9/19/13
<i>States' Collection of Rebates for Drugs Paid Through Medicaid Managed Care Organizations</i>	<a href="#">OEI-03-11-00480</a>	9/07/12
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	<a href="#">OEI-03-09-00410</a>	5/06/11

## APPENDIX B: AUDIT SCOPE AND METHODOLOGY

### SCOPE

We reviewed the Form CMS-64 and determined that the State agency paid MCOs \$2,411,629,093 (\$1,238,462,930 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 obtained from the State agency drug claim line information for the first quarter of 2013. From this information, we selected 74 NDCs representing drugs with high utilization that the State agency indicated had been invoiced for rebates. These 74 NDCs were associated with 8 manufacturers' drugs. After we verified that the drugs associated with the 74 selected NDCs had been invoiced for rebates, we requested and 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, the State agency was unable to determine the amount it paid MCOs for physician-administered drugs. In 2013, the State agency billed \$8,735,947 (\$4,367,974 Federal share) in manufacturer rebates for certain MCO physician-administered drug utilization with valid NDCs. On the basis of this amount, the State estimated the average rebate per claim billed. We determined these estimates to be reasonable. We applied the estimates to the claim lines with missing or invalid NDCs to determine an estimated rebate amount for which the State agency did not bill.

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 May 2016 and performed fieldwork at the State agency office in Richmond, Virginia.

### 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, issued to providers;
- reviewed State agency policies and procedures for rebates for physician-administered drugs and State agency contracts with 9 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;
- obtained from the State agency the amount of rebates collected for physician-administered drug utilization with valid NDCs;
- 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,
  - selecting, from the first quarter, drug claim line information for 74 NDCs that represented drugs with high utilization and that were associated with 8 manufacturers, and
  - reviewing copies of rebate invoices submitted to the 8 manufacturers 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 per claim rebate amounts for physician-administered drugs 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 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 data 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**

Virginia's Medicaid Memo dated May 31, 2007, informed physician providers participating in the Virginia Medical Assistance Programs that physician-administered drug claims with a date of service of July 1, 2007, or later will require the NDC. Virginia's Medicaid Memo dated April 2, 2008, informed hospitals and MCOs participating in the Virginia Medical Assistance Programs that outpatient hospital physician-administered drug claims with a date of July 1, 2008, or later will require an NDC.

Since July 1, 2012, Virginia's contracts with its MCOs have included provisions that required the MCOs to submit physician-administered drug utilization with a valid NDC.

## APPENDIX D: STATE AGENCY COMMENTS



# COMMONWEALTH of VIRGINIA

## Department of Medical Assistance Services

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November 10, 2016

Mr. Jason C. Jelen  
Regional Inspector General for Audit Services  
Office of Audit Services, Region III  
Public Ledger Building, Suite 316  
150 s. Independence Mall West  
Philadelphia, Pennsylvania 19106-3499

RE: Draft Audit Report Number A-03-15-00201

Dear Mr. Jelen:

The Department of Medical Assistance Services would like to thank the Office of Inspector General (OIG) for this opportunity to respond to the draft audit report number A-03-15-00201 entitled *Virginia Did Not Bill Manufacturers for Rebates for Some Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed Care Organizations*. This response will provide our comments with statements of concurrence or non-concurrence with each recommendation.

### **OIG Recommendation #1**

DMAS to work with CMS to resolve the drug utilization data without valid NDCs by determining the correct NDCs, billing for the estimated \$5,831,528 (\$2,915,764 Federal share) in rebates, and refunding the Federal share of rebates collected.

### **DMAS Response to OIG Recommendation #1**

We concur with the OIG recommendation that DMAS will work with CMS to achieve a satisfactory resolution for the uncollected rebates identified in the OIG audit.

### **OIG Recommendation #2**

DMAS to implement Medicaid Management Information System edits to verify that NDCs are present and valid in all drug utilization data.

## **DMAS Response to OIG Recommendation #2**

DMAS concurs with this recommendation. Based on the findings of the OIG audit, DMAS will implement encounter edits to identify physician administered drugs that are missing data elements needed for the collection of drug rebates. These edits will be in place by January 1, 2017.

## **OIG Recommendation #3**

DMAS to ensure that MCOs submit drug utilization data containing NDCs for all physician administered drugs.

## **DMAS Response to OIG recommendation #3**

DMAS concurs with this recommendation and will incorporate the edits established above into our existing MCO Compliance Monitoring Process. Encounters flagged with one of these edits will result in compliance penalties for the MCO. All deficient encounters will be tracked to ensure that the MCO re-submits the encounter with the required rebate elements.

If you have any questions, please do not hesitate to contact our Director of Internal Audit, Paul Kirtz at (804) 225-4162.

Sincerely,



Cynthia B. Jones

Cc: Dr. Kate Neuhausen  
Donna Proffitt  
Paul Kirtz