

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

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

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# *Office of Inspector General*

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## EXECUTIVE SUMMARY

*During 2010, California claimed an estimated \$7.3 million in Federal reimbursement that was unallowable and \$35.2 million that may have been unallowable because it did not comply with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs dispensed to enrollees of managed-care organizations.*

### 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 the Federal share of these rebates against their expenditures. States bill the manufacturers for rebates to reduce the cost of 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. For this audit, we reviewed the California Department of Health Care Services' (State agency) billing of rebates for physician-administered drugs dispensed to enrollees of Medicaid managed-care organizations (MCOs).

Our objective was to determine whether the State agency complied with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs dispensed to enrollees of MCOs.

### BACKGROUND

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

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. Physician-administered drugs may be covered by the capitation payment. Effective March 23, 2010, the Patient Protection and Affordable Care Act requires manufacturers to pay rebates on covered outpatient drugs dispensed to enrollees of MCOs if the MCOs are responsible for coverage of such drugs. MCOs have flexibility in which drugs are covered, regardless of whether the manufacturers of those drugs participate in the drug rebate program. 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 enrollees of MCOs are recorded in MCO drug utilization data or encounter data.

In California, the State agency is responsible for billing and collecting Medicaid drug rebates for physician-administered drugs. The State agency requires MCOs to submit drug utilization data for physician-administered drugs, which it uses to bill for drug rebates. The State agency also requires MCOs to submit encounter data, which it uses to develop capitation rates. Encounter data documents the records of services delivered to Medicaid beneficiaries. From April through December 2010, California's 28 MCOs served approximately 4 million Medicaid beneficiaries.

## **HOW WE CONDUCTED THIS REVIEW**

We reviewed drug utilization data or encounter data for physician-administered drugs for 20 of California's 28 MCOs from April 1 through December 31, 2010 (audit period). After assessment of the 28 MCOs' enrollment reports and discussions with State agency officials, we selected the 20 MCOs because they had the highest number of enrollees.

## **WHAT WE FOUND**

During our audit period, the State agency did not always comply with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs dispensed to enrollees of MCOs. For the 20 MCOs we reviewed, the State agency billed for rebates for physician-administered drugs dispensed by 7 MCOs. However, the State agency did not bill for rebates for physician-administered drugs dispensed by the remaining 13 MCOs.

After reviewing records for physician-administered drugs in the encounter data for the 13 MCOs, we estimated that the State agency paid \$157,157,582 (\$96,793,355 Federal share) for drugs that were eligible or may have been eligible for rebates. On the basis of this amount, we estimated that the State agency did not bill for and collect from manufacturers rebates of \$69,109,297 (\$42,564,416 Federal share):

- The State agency did not bill for and collect estimated rebates of \$11,862,655 (\$7,306,209 Federal share) for single-source and top-20 multiple-source physician-administered drugs.
- The State agency did not bill for and collect estimated rebates of \$656,698 (\$404,460 Federal share) for non-top-20 multiple-source physician-administered drugs with NDCs that may have been eligible for rebates and \$56,589,944 (\$34,853,747 Federal share) for other drugs without NDCs. Because we could not determine whether these drugs were eligible for rebates, we set aside for CMS resolution the estimated \$35,258,207 of Federal reimbursement.

The State agency did not always bill manufacturers for rebates because the 13 MCOs did not submit drug utilization data for physician-administered drugs. Although State agency guidance required MCOs to submit drug utilization data for physician-administered drugs, the State agency informed us that its MCO contracts did not have a rebate or NDC reporting requirement.

## **WHAT WE RECOMMEND**

We recommend that the State agency:

- bill for and collect from manufacturers rebates for single-source and top-20 multiple-source physician-administered drugs dispensed to enrollees of MCOs and refund to the Federal Government the estimated \$7,306,209 (Federal share);
- work with CMS to determine:
  - whether the non-top-20 multiple-source physician-administered drugs with NDCs were eligible for rebates and, if so, upon receipt of the rebates, refund the estimated \$404,460 (Federal share) and
  - the unallowable portion of the estimated \$34,853,747 (Federal share) for other physician-administered drugs without NDCs that were eligible for rebates and, upon receipt of the rebates, refund that amount;
- work with its MCOs to ensure submission of drug utilization data for physician-administered drugs dispensed to enrollees; and
- implement a rebate and NDC reporting requirement in its MCO contracts to ensure that all MCOs submit drug utilization data for physician-administered drugs.

## **STATE AGENCY COMMENTS AND OUR RESPONSE**

In written comments on our draft report, the State agency partially agreed with our first and second recommendations and agreed with our third and fourth recommendations. Although the State agency acknowledged that it did not invoice for some MCO physician-administered drugs, the State agency disagreed with the amounts identified in our first and second recommendations until it can complete further analysis. The State agency provided information on actions that it had taken or planned to take to address all of our recommendations.

After reviewing the State agency's comments, we maintain that all of our recommendations are valid.

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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 the Federal share of these rebates against their expenditures. States bill the manufacturers for rebates to reduce the cost of 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. (Appendix A lists previous OIG reports related to reviews of the Medicaid drug rebate program.) For this audit, we reviewed the California Department of Health Care Services' (State agency) billing of rebates for physician-administered drugs dispensed to enrollees of Medicaid managed-care organizations (MCOs).

### OBJECTIVE

Our objective was to determine whether the State agency complied with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs dispensed to enrollees of MCOs.

### 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 are essentially shared between the States and the Federal Government to 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>1</sup> 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. An NDC is a number that identifies a specific drug.

Section 1903(i)(10) of the Act prohibits Federal reimbursement for States that do not capture the information necessary for billing manufacturers for rebates as described in section 1927(a)(7) of the Act. To bill for rebates, States must capture drug utilization data that identify, by NDC, the number of units of each drug for which the States reimbursed Medicaid providers and must report the information to the manufacturers (the Act § 1927(b)(2)(A)). The number of units is

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<sup>1</sup> The Act § 1927(b) and the Medicaid rebate agreement (§ II).

multiplied by the unit rebate amount to determine the actual rebate amount due from each manufacturer.

States report drug rebate accounts receivable data to CMS on the Medicaid Drug Rebate Schedule. This schedule is part of the Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program report (Form CMS-64), which contains a summary of actual Medicaid expenditures for each quarter and is used by CMS to reimburse States for the Federal share of Medicaid expenditures.

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

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. States pay MCOs for each individual receiving services regardless of whether the enrollee receives services during the relevant time period (42 CFR § 438.2). Physician-administered drugs may be covered by the capitation payment.

To claim Federal reimbursement, States report capitation payments made to MCOs as MCO expenditures on the Form CMS-64. These expenditures are not identified by specific type of service (such as physician-administered drugs). States must report both decreasing adjustments to drug expenditures and drug rebates on the Form CMS-64.

### **Physician-Administered Drugs**

Drugs administered by a physician are typically billed to the Medicaid program on a claim form using Healthcare Common Procedure Coding System (HCPCS) codes.<sup>2</sup> For purposes of the Medicaid drug rebate program, single-source drugs are those covered outpatient drugs produced or distributed under an original new drug application approved by the Food and Drug Administration (FDA).<sup>3</sup> Multiple-source drugs are defined, in part, as those covered outpatient drugs that have at least one other drug rated as therapeutically equivalent by FDA.<sup>4</sup>

The Deficit Reduction Act of 2005 amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs for all single-source and the top 20 multiple-source drugs.<sup>5</sup> Beginning on January 1, 2007, CMS was responsible for publishing annually the list of the top 20 multiple-source drugs by HCPCS codes that had the highest dollar

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<sup>2</sup> HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

<sup>3</sup> Section 1927(k)(7) of the Act. Single-source drugs are commonly referred to as “brand-name” drugs.

<sup>4</sup> Section 1927(k)(7) of the Act. According to the definition of “therapeutic equivalence” in the FDA glossary of terms, a therapeutically equivalent drug product can be substituted with another product to achieve the same clinical effect as the prescribed drug. <http://www.fda.gov/drugs/informationondrugs/ucm079436.htm>. Accessed on May 3, 2016.

<sup>5</sup> 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)).

volume dispensed. Before the Deficit Reduction Act, many States did not collect rebates on physician-administered drugs if the drug claims did not contain NDCs. To collect rebates for drugs, States submit to the manufacturers the drug utilization data containing NDCs for the drugs. NDCs enable States to identify the drugs and their manufacturers and facilitate the collection of rebates for the drugs.

Effective March 23, 2010, the Patient Protection and Affordable Care Act (ACA)<sup>6</sup> requires manufacturers to pay rebates on covered outpatient drugs dispensed to enrollees of MCOs if the MCOs are responsible for coverage of such drugs. MCOs have flexibility in which drugs are covered, regardless of whether the manufacturers of those drugs participate in the drug rebate program.<sup>7</sup> 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 enrollees of MCOs are recorded in MCO drug utilization data or encounter data.

### **The State Agency's Medicaid Drug Rebate Program**

The State agency is responsible for billing for and collecting Medicaid drug rebates for physician-administered drugs.<sup>8</sup> The State agency uses a contractor to manage its drug rebate program.<sup>9</sup> The contractor loads MCO data into the rebate accounting information system and bills manufacturers by NDC for rebates.

Beginning December 1, 2010, the State agency required its MCOs to submit drug utilization data for physician-administered drugs, which it uses to bill for drug rebates. The State agency also required MCOs to submit encounter data, which it uses to develop capitation rates. Encounter data documents the records of services delivered to Medicaid beneficiaries.

From April through December 2010, California's 28 MCOs served approximately 4 million Medicaid beneficiaries.

### **HOW WE CONDUCTED THIS REVIEW**

We reviewed drug utilization data or encounter data for physician-administered drugs for 20 of California's 28 MCOs from April 1 through December 31, 2010 (audit period). After assessment of the 28 MCOs' enrollment reports and discussions with State agency officials, we selected the 20 MCOs because they had the highest number of enrollees.

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<sup>6</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).

<sup>7</sup> CMS State Medicaid Director Letter #10-019, Medicaid Prescription Drugs. <https://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD10019.pdf>. Accessed on July 7, 2016.

<sup>8</sup> Although section 1927(a)(7) of the Act specifically addresses rebates for single-source drugs and the top 20 multiple-source drugs, State agency officials told us that they bill manufacturers for rebates on all physician-administered drugs.

<sup>9</sup> Xerox was the State agency's contractor during the audit period.

We reviewed seven MCOs' drug utilization data for physician-administered drugs. The State agency used these data to bill for rebates. The remaining 13 MCOs did not submit drug utilization data for physician-administered drugs to the State agency.<sup>10</sup> Instead, these MCOs submitted only encounter data with records for physician-administered drugs. However, the State agency did not use these data to bill for rebates.<sup>11</sup>

Because the State agency's MCO expenditures were not identified by specific type of service (e.g., physician-administered drugs) on the Form CMS-64, we requested that the State agency estimate the amount that it paid the 13 MCOs for physician-administered drugs and the amount of uncollected rebates.<sup>12</sup> However, because the State agency did not provide the requested information, we proceeded with our own estimates. On the basis of the records for physician-administered drugs in the encounter data, we estimated the amount that the State agency paid the 13 MCOs for physician-administered drugs and the amount of uncollected rebates for drugs that were eligible or may have been eligible for rebates.

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

During our audit period, the State agency did not always comply with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs dispensed to enrollees of MCOs. For the 20 MCOs we reviewed, the State agency billed for rebates for physician-administered drugs dispensed by 7 MCOs.<sup>13</sup> However, the State agency did not bill for rebates for physician-administered drugs dispensed by the remaining 13 MCOs.

After reviewing records for physician-administered drugs in the encounter data for the 13 MCOs, we estimated that the State agency paid \$157,157,582 (\$96,793,355 Federal share) for drugs that

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<sup>10</sup> The State agency informed us that some MCOs submitted partial data, but the State agency could not use these data to bill manufacturers for rebates.

<sup>11</sup> The State agency used encounter data to develop capitation rates. To bill for rebates, the State agency used drug utilization data for physician-administered drugs.

<sup>12</sup> The State agency paid its MCOs on the basis of capitation rates, which covered physician-administered drugs. However, the State agency informed us that it did not know the portion of the capitation rate attributable to physician-administered drugs.

<sup>13</sup> We reviewed supporting documentation and found that physician-administered drugs dispensed were properly billed for rebates. We focused our review on the 13 MCOs that did not submit drug utilization data to the State agency to bill for rebates.

were eligible or may have been eligible for rebates.<sup>14</sup> On the basis of this amount, we estimated that the State agency did not bill for and collect from manufacturers rebates of \$69,109,297 (\$42,564,416 Federal share):

- The State agency did not bill for and collect estimated rebates of \$11,862,655 (\$7,306,209 Federal share) for single-source and top-20 multiple-source physician-administered drugs.
- The State agency did not bill for and collect estimated rebates of \$656,698 (\$404,460 Federal share) for non-top-20 multiple-source physician-administered drugs with NDCs that may have been eligible for rebates and \$56,589,944 (\$34,853,747 Federal share) for other drugs without NDCs. Because we could not determine whether these drugs were eligible for rebates, we set aside for CMS resolution the estimated \$35,258,207 of Federal reimbursement.

The State agency did not always bill manufacturers for rebates because the 13 MCOs did not submit drug utilization data for physician-administered drugs. Although State agency guidance required MCOs to submit drug utilization data for physician-administered drugs, the State agency informed us that its MCO contracts did not have a rebate or NDC reporting requirement.

## **FEDERAL REQUIREMENTS AND STATE GUIDANCE**

The Deficit Reduction Act 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)(C)).

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 enrollees of MCOs 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 enrollees of MCOs. Essentially, States must secure rebates for drugs dispensed through MCOs and require MCOs to submit NDCs to the States for drugs dispensed to eligible individuals in order for the State to bill for rebates (the Act § 1903(m)(2)(A)).

Federal regulations prohibit Federal reimbursement for physician-administered drugs unless the States require the submission of claims containing NDCs (42 CFR § 447.520).

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<sup>14</sup> We estimated the amount paid for only 70 percent of the drugs that were eligible or may have been eligible for rebates on the basis of the State agency's Medicaid fee-for-service (FFS) rate schedule. We were unable to estimate the amount paid for the remaining 30 percent of drugs because there were no rates available in the rate schedule. Therefore, we could not estimate the amount of uncollected rebates.

In a December 1, 2010, letter addressed to California's MCOs, the State agency informed its MCOs of the ACA's rebate requirements. To bill for and collect drug rebates for outpatient drugs dispensed to enrollees of MCOs, the State agency required its MCOs to submit drug utilization data for physician-administered drugs.

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

### **THE STATE AGENCY DID NOT ALWAYS BILL MANUFACTURERS FOR REBATES FOR PHYSICIAN-ADMINISTERED DRUGS DISPENSED THROUGH MEDICAID MANAGED-CARE ORGANIZATIONS**

We estimated that the State agency did not bill for and collect from manufacturers rebates of \$69,109,297 (\$42,564,416 Federal share) for (1) single-source and top-20 multiple-source physician-administered drugs and (2) non-top-20 multiple-source and other physician-administered drugs.

#### **The State Agency Did Not Bill for and Collect Rebates for Single-Source and Top-20 Multiple-Source Physician-Administered Drugs**

The State agency did not bill for and collect estimated rebates of \$10,710,877 (\$6,596,829 Federal share) for single-source physician-administered drugs and \$1,151,778 (\$709,380 Federal share) for top-20 multiple-source physician-administered drugs. As a result, the State agency improperly claimed an estimated \$11,862,655 (\$7,306,209 Federal share) for these drugs.

#### **The State Agency Did Not Bill for and Collect Rebates for Non-Top-20 Multiple-Source and Other Physician-Administered Drugs**

The State agency did not bill for and collect estimated rebates of \$656,698 (\$404,460 Federal share) for non-top-20 multiple-source physician-administered drugs with NDCs<sup>15</sup> that may have been eligible for rebates. We could not determine whether the State agency was required to bill for rebates for these drugs. If the State agency had billed these multiple-source drugs for rebates, the manufacturers would have been required to pay the rebates.

Furthermore, the State agency did not bill for and collect estimated rebates of \$56,589,944 (\$34,853,747 Federal share) for other physician-administered drugs without NDCs. We could not determine whether these drugs were required to be billed for rebates because they did not have NDCs.

Accordingly, we set aside for CMS resolution the estimated \$57,246,642 (\$35,258,207 Federal share) for non-top-20 multiple-source and other physician-administered drugs.

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<sup>15</sup> The NDCs for these multiple-source drugs matched the NDCs in the CMS Medicaid Drug File.

## **SOME MANAGED-CARE ORGANIZATIONS DID NOT SUBMIT TO THE STATE AGENCY DRUG UTILIZATION DATA FOR PHYSICIAN-ADMINISTERED DRUGS**

The State agency did not always bill manufacturers for rebates because 13 of the 20 MCOs did not submit drug utilization data for physician-administered drugs. The State agency informed us that the MCOs had difficulty creating these data for physician-administered drugs and that most MCOs did not have the resources to accommodate the drug utilization data format for physician-administered drugs. Although State agency guidance required MCOs to submit drug utilization data for physician-administered drugs, the State agency informed us that its MCO contracts did not have a rebate or NDC reporting requirement. The State agency informed us that it was testing a new format for submission of drug utilization data for physician-administered drugs and amending its MCO contracts to include a rebate and NDC reporting requirement.

### **RECOMMENDATIONS**

We recommend that the State agency:

- bill for and collect from manufacturers rebates for single-source and top-20 multiple-source physician-administered drugs dispensed to enrollees of MCOs and refund to the Federal Government the estimated \$7,306,209 (Federal share);
- work with CMS to determine:
  - whether the non-top-20 multiple-source physician-administered drugs with NDCs were eligible for rebates and, if so, upon receipt of the rebates, refund the estimated \$404,460 (Federal share) and
  - the unallowable portion of the estimated \$34,853,747 (Federal share) for other physician-administered drugs without NDCs that were eligible for rebates and, upon receipt of the rebates, refund that amount;
- work with its MCOs to ensure submission of drug utilization data for physician-administered drugs dispensed to enrollees; and
- implement a rebate and NDC reporting requirement in its MCO contracts to ensure that all MCOs submit drug utilization data for physician-administered drugs.

### **STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, the State agency partially agreed with our first and second recommendations and agreed with our third and fourth recommendations:

- Although the State agency acknowledged that it did not invoice for some MCO physician-administered drugs, the State agency disagreed with the amounts identified in our first and second recommendations until it can complete further analysis. The State

agency commented that it believed some of the drugs we identified were not eligible for rebates. The State agency provided information on actions that it planned to take to address these recommendations and stated that the estimated date of completion is September 2018.

- The State agency commented that it had already addressed our third recommendation and was in the process of addressing our fourth recommendation. The State agency provided information on actions that it had taken and planned to take to address these recommendations.

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

After reviewing the State agency's comments, we maintain that all of our recommendations are valid. During our review, we requested that the State agency estimate the amount that it paid the 13 MCOs for physician-administered drugs and the amount of uncollected rebates. However, because the State agency did not provide the estimated amounts, we proceeded with our own estimates. As part of the methodology for calculating our estimates, we identified the units associated with the drugs' HCPCS codes that were eligible or may have been eligible for rebates by using CMS's list of the top 20 multiple-source drugs and CMS's Medicare Part B crosswalk and Medicaid Drug File. Afterward, we priced these drugs using the State agency's Medicaid FFS rate schedule. Then, we determined the percentage of rebates that the State agency collected for FFS-prescribed drugs and the paid amount for FFS-prescribed drugs on the basis of the Form CMS-64, and we applied this percentage to our estimated amount paid for physician-administered drugs. We excluded from our review certain drugs not eligible for rebates.

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

<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<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>	8/18/2016
<i>Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-14-06057</u></a>	5/26/2016
<i>Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-15-06063</u></a>	3/31/2016
<i>South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-15-06059</u></a>	2/9/2016
<i>Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-15-06062</u></a>	1/14/2016
<i>North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-15-06058</u></a>	1/13/2016
<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>	1/7/2016
<i>Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-14-06056</u></a>	9/18/2015
<i>Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-14-06049</u></a>	7/22/2015
<i>Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-06-12-00060</u></a>	5/4/2015
<i>Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-14-06051</u></a>	4/13/2015
<i>Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-09-13-02037</u></a>	3/4/2015

<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<a href="#">A-06-14-000031</a>	2/10/2015
<i>The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-03-12-00205</a>	8/21/2014
<i>Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-07-13-06040</a>	8/7/2014
<i>Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-09-12-02079</a>	4/30/2014
<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>	4/24/2014
<i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-03-12-00200</a>	11/26/2013
<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>	9/19/2013
<i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i>	<a href="#">A-06-10-00011</a>	8/12/2011
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	<a href="#">OEI-03-09-00410</a>	5/6/2011

## **APPENDIX B: AUDIT SCOPE AND METHODOLOGY**

### **SCOPE**

We reviewed drug utilization data or encounter data for physician-administered drugs for 20 of California's 28 MCOs from April 1 through December 31, 2010. Specifically, we reviewed 7 MCOs' drug utilization data and the remaining 13 MCOs' encounter data because these MCOs did not submit drug utilization data for physician-administered drugs to the State agency.

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 and collection of Medicaid rebates for physician-administered drugs dispensed to enrollees of MCOs.

We conducted our audit from July 2015 to April 2016 and performed fieldwork at the State agency office in Sacramento, California.

### **METHODOLOGY**

To accomplish our objective, we:

- reviewed Federal laws, regulations, and guidance related to the Medicaid drug rebate program and physician-administered drugs;
- reviewed State guidance to MCOs, including billing instructions for physician-administered drugs;
- reviewed State agency policies and procedures for rebates for physician-administered drugs;
- interviewed State agency personnel to gain an understanding of the administration of and controls over the Medicaid billing and rebate process for physician-administered drugs;
- reviewed drug expenditures reported on the State agency's Form CMS-64;
- obtained CMS's list of the top 20 multiple-source drugs, the CMS Medicare Part B crosswalk,<sup>16</sup> and the CMS Medicaid Drug File;
- obtained from the State agency the Medicaid FFS rate schedule;

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<sup>16</sup> CMS instructed States that they could use the Medicare Part B crosswalk as a reference because HCPCS codes and NDCs are standardized codes.

- selected 20 MCOs for review on the basis of our assessment of the MCOs' enrollment reports<sup>17</sup> and discussion with State agency officials;<sup>18</sup>
- obtained from the State agency the drug utilization data for physician-administered drugs for 7 MCOs and the encounter data with records of physician-administered drugs for 13 MCOs; and
- excluded from our review certain drugs not eligible for rebates.

After identifying for the 7 MCOs the drug utilization data for physician-administered drugs billed for rebates, we:

- selected 24 NDCs<sup>19</sup> associated with 20 manufacturers and
- reviewed copies of rebate invoices submitted to the manufacturers to verify the billing of rebates by NDC for the selected NDCs.

After identifying for the remaining 13 MCOs the encounter data with records of physician-administered drugs not billed for rebates, we determined drugs that were eligible or may have been eligible for rebates. Specifically, we

- identified single-source drugs by matching the NDCs in the drug records to the NDCs in CMS's Medicaid Drug File and matched the HCPCS codes in the remaining drug records to the HCPCS codes in CMS's Medicare Part B crosswalk to identify the NDCs associated with each HCPCS code and traced the resulting NDCs to the NDCs in the Medicaid Drug File;
- identified top-20 multiple-source drugs by matching the NDCs in the drug records to the NDCs in CMS's list of the top 20 multiple-source drugs and matched the HCPCS codes in the remaining drug records to the HCPCS codes in CMS's list of top-20 multiple-source drugs for drug records in which the NDCs did not match CMS's list;
- identified non-top-20 multiple-source drugs by matching the NDCs in the drug records to the NDCs in CMS's Medicaid Drug File;
- identified other drugs without NDCs in the drug records for which we were unable to determine whether billing for rebates was required;

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<sup>17</sup> We selected MCOs with the highest number of enrollees.

<sup>18</sup> The State agency informed us of which MCOs submitted drug utilization data for physician-administered drugs for rebates.

<sup>19</sup> These NDCs represented drugs that had high payment amounts, high units of service, or high payment amounts per unit.

- estimated the amount that the State agency paid the 13 MCOs for physician-administered drugs;<sup>20</sup> and
- estimated the amount of uncollected rebates for physician-administered drugs dispensed by the 13 MCOs.<sup>21</sup>

We 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.

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<sup>20</sup> We requested that the State agency estimate the amount that it paid the 13 MCOs for physician-administered drugs and the amount of uncollected rebates. However, because the State agency did not provide the requested information, we proceeded with our own estimates. We identified the units associated with the drugs' HCPCS codes that were eligible or may have been eligible for rebates. Afterward, we priced these drugs using the State agency's Medicaid FFS rate schedule.

<sup>21</sup> We determined the percentage of rebates that the State agency collected for FFS-prescribed drugs and the paid amount for FFS-prescribed drugs on the basis of the Form CMS-64. We applied this percentage to our estimated amount paid for physician-administered drugs that were eligible or may have been eligible for rebates.

## **APPENDIX C: FEDERAL REQUIREMENTS AND STATE GUIDANCE RELATED TO PHYSICIAN-ADMINISTERED DRUGS**

### **FEDERAL LAW**

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

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)). Manufacturer rebates are essentially shared between the States and the Federal Government to offset the cost of prescription drugs (the Act § 1927(b)(1)(B)). Responsibility for the drug rebate program is shared among the drug manufacturers, CMS, and the States.

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 collect the utilization and coding data described in section 1927(a)(7) of the Act.

States must provide for the collection and submission of utilization and coding data necessary 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 (the Act § 1927(a)(7)). Effective January 1, 2007, the utilization data must be submitted using NDCs (§ 1927(a)(7)(C)). To bill for 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 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 section, payment is prohibited unless the MCO contracts provide that the Medicaid rebate obligations apply to drugs dispensed through MCOs and require the MCOs to submit to the State the drug utilization by NDCs 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).

Federal regulations in effect during most of our audit period defined a brand-name drug as a single-source or innovator multiple-source drug and, in a relevant part, a multiple-source drug as a covered outpatient drug for which there is at least one other drug product that is rated as therapeutically equivalent (42 CFR § 447.502).<sup>22</sup>

## **STATE GUIDANCE**

In a December 1, 2010, letter addressed to California's MCOs, the State agency informed its MCOs of the ACA's rebate requirements. To collect drug rebates for outpatient drugs dispensed to enrollees of MCOs, the State agency required its MCOs to submit drug utilization data for physician-administered drugs.

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<sup>22</sup> On November 15, 2010, CMS amended 42 CFR § 447.502 to remove the definition of "multiple-source drug" (75 Fed. Reg. 69591, 69592).

## APPENDIX D: STATE AGENCY COMMENTS



State of California—Health and Human Services Agency  
Department of Health Care Services



EDMUND G. BROWN JR.  
GOVERNOR

Ms. Lori A. Ahlstrand  
Regional Inspector General for Audit Services  
Office of Audit Services, Region IX  
90 – 7<sup>TH</sup> Street, Suite 3-650  
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Dear Ms. Ahlstrand

The California Department of Health Care Services (DHCS) has prepared its response to the U.S. Department of Health and Human Services, Office of Inspector General (OIG) draft report entitled, *California Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Some Medicaid Managed-Care Organizations*.

DHCS appreciates the work performed by the OIG and the opportunity to respond to the draft report. Please contact Ms. Sarah Hollister, External Audit Manager, at (916) 650-0298 if you have any questions.

Sincerely,

[Jennifer Kent]

Jennifer Kent  
Director

Enclosure

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Page 2

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**Department of Health Care Services Response to the OIG audit report  
entitled, *California Did Not Bill Manufacturers for Rebates for Physician  
Administered Drugs Dispensed to Enrollees of Some Medicaid Managed  
Care Organizations***

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**Finding #1:**                    **The State agency did not bill for and collect estimated rebates of \$11,862,655 (\$7,306,209 Federal) for single-source and top-20 multiple source physician administered drugs.**

**Recommendation 1:**       **DHCS should bill for and collect from manufacturers rebate for single-source and top-20 multiple source physician administered drugs dispensed to enrollees of MCOs and refund the Federal Government the estimated \$7,306,209 (Federal).**

**Response:**                    DHCS partially agrees with the recommendation.

While DHCS acknowledges the State did not invoice for some of the MCO physician-administered drug utilization during the audit period, DHCS disagrees with the amounts identified until further analysis can be completed. DHCS believes some of the utilization identified is not eligible for rebates. DHCS will review the encounter data used by the OIG and attempt to collect MCO rebates for both single-source and top-20 multiple source drugs by requiring MCOs to resubmit corrected encounter data containing NDCs that accurately reflect utilization.

Due to the significant amount of time involved in the resubmission of corrected encounter data and the subsequent rebate invoicing to manufacturers, the estimated date of completion is September 2018.

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**Finding #2:**                    **The State agency did not bill for and collect estimated rebates for \$656,698 (\$404,460 Federal) for non-top-20 multiple-source physician administered drugs with NDCs that may have been eligible for rebates and \$56,589,944 (\$34,853,747 Federal) for other drugs without NDCs. Because OIG could not determine whether these drugs were eligible for rebates, they set aside for CMS resolution the estimated \$35,258,207 of Federal reimbursement.**

**Recommendation 2:**       **DHCS should work with CMS to determine whether the non-top-20 multiple-source physician administered drugs with NDCs were eligible for rebates and, if so, upon receipt of the rebates, refund the estimated \$404,460 (Federal).**

**Response:**

DHCS partially agrees with the recommendation.

While DHCS acknowledges the State did not invoice for some of the MCO physician-administered drug utilization during the audit period, DHCS disagrees with the amounts identified until further analysis can be completed. DHCS believes some of the utilization identified is not eligible for rebates. DHCS will attempt to collect rebates for non-top-20 multiple source drugs by requiring MCOs to resubmit corrected encounter data containing NDCs that accurately reflect utilization. DHCS will also work with CMS to determine which of these drugs were or were not eligible for rebates.

Due to the significant amount of time involved in the resubmission of corrected encounter data, the subsequent rebate invoicing to manufacturers, and engagement until resolution with CMS, the estimated date of completion is September 2018.

**Recommendation 3: DHCS should work with CMS to refund the unallowable portion of the estimated \$34,853,747 (Federal) for other physician-administered drugs without NDCs that were eligible for rebates, and upon receipt of the rebates refund that amount.\***

DHCS partially agrees with the recommendation.

DHCS will work with CMS to determine the unallowable portion of FFP. However, due to the MCO physician administered drug services being a component of a capitated bundled rate, DHCS disagrees with the estimated unallowable federal portion identified in the recommendation until further analysis can be completed.

Due to the large amount of data that must be analyzed, the estimated date of completion is September 2018.

**Recommendation 4: DHCS should work with the MCOs to ensure submission of drug utilization data for physician-administered drugs dispensed to enrollees.**

**Response:**

DHCS agrees with the recommendation.

Medi-Cal managed care health plans (MCPs) are contractually obligated to submit encounter data to DHCS representing all health care services for which they have any financial liability. On November 12, 2014, DHCS transitioned to a new encounter reporting system which utilizes standardized transaction types—X12 837 Institutional, X12 837 Professional and NCPDP. Prior to this system transition, DHCS utilized proprietary encounter reporting formats that limited its ability to rebate for physician-administered drugs. Therefore, conversion to this new system ensures DHCS' ability to rebate for all applicable drug claims and

**\* OIG Note:** The State agency referred to the second part of our second recommendation as the third recommendation and renumbered the remaining recommendations.

encounters submitted by MCPs. Completion of Recommendation 3 has occurred.\*

**Recommendation 5:** **DHCS should implement a rebate and NDC reporting requirement in its MCO contracts to ensure that all MCOs submit drug utilization data for physician-administered drugs.**

**Response:** DHCS agrees with the recommendation.

DHCS drafted contract language specifically establishing requirements for MCPs to submit drug claims and encounters with all key data elements needed for rebate purposes.

This contract language is expected to be submitted to CMS no sooner than July 1, 2017.

\* **OIG Note:** The State agency referred to our third recommendation as shown in the report.