

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**CALIFORNIA CLAIMED UNALLOWABLE  
FEDERAL MEDICAID REIMBURSEMENT  
BY NOT BILLING MANUFACTURERS  
FOR REBATES FOR SOME  
PHYSICIAN-ADMINISTERED DRUGS**

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Inspector General

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# *Office of Inspector General*

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## EXECUTIVE SUMMARY

*California claimed \$4.4 million over three quarters between 2008 and 2010 in Federal reimbursement that was unallowable and \$27.3 million that may have been unallowable because it did not comply with Federal Medicaid requirements for billing manufacturers for rebates for some physician-administered drugs.*

### WHY WE DID THIS REVIEW

For a covered outpatient drug to be eligible for Federal reimbursement under the Medicaid program's drug rebate requirements, manufacturers must pay rebates to the States for the drugs. States generally offset 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.

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

### BACKGROUND

The Medicaid drug rebate program became effective in 1991 (the Social Security Act § 1927). For a covered outpatient drug to be eligible for Federal reimbursement under the program, the drug manufacturer must enter into a rebate agreement with the Centers for Medicare & Medicaid Services 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.

In California, the State agency is responsible for (1) paying claims and (2) billing and collecting Medicaid drug rebates for physician-administered drugs. The State agency uses a contractor to manage its drug rebate program. The contractor bills manufacturers by NDC for rebates and documents the payments received every quarter. On April 1, 2009, the State agency implemented an edit in its Medicaid Management Information System to deny claims for physician-administered drugs submitted without NDCs or valid NDCs.

### HOW WE CONDUCTED THIS REVIEW

Our audit covered \$237,533,773 of the State agency's fee-for-service claims for physician-administered drugs paid for the quarters April through June 2008, July through September 2009, and October through December 2010 (audit period). Of this paid amount, we reviewed

\$58,907,969 that was not billed for rebates. Of the remaining \$178,625,804 that was billed for rebates, we reviewed \$61,432,295 to verify that the claims were properly billed for rebates.

## **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. Of the \$61,432,295 in claims that we reviewed, associated with 26 NDCs and 21 manufacturers, the entire amount was properly billed for rebates. However, the State agency did not bill for rebates for claims for physician-administered drugs totaling \$58,907,969:

- The State agency did not capture NDCs (or, in some cases, did not capture valid NDCs) for claims totaling \$49,782,377 (\$26,193,351 Federal share). This amount consisted of \$2,723,165 (\$1,504,436 Federal share) for single-source and top-20 multiple-source drugs and \$47,059,212 (\$24,688,915 Federal share) for other drugs for which we were unable to determine whether billing for rebates was required. The State agency did not have an edit to ensure that NDCs or valid NDCs were submitted for physician-administered drugs before April 1, 2009. Even after the State agency implemented the edit on April 1, 2009, this edit did not ensure that NDCs or valid NDCs were captured for all claims for physician-administered drugs.
- The State agency had drug utilization data, with NDCs, for claims totaling \$9,125,592 (\$5,548,703 Federal share) but did not submit these data to bill manufacturers for and collect rebates for these physician-administered drugs. This amount consisted of \$4,788,781 (\$2,888,132 Federal share) for single-source drugs and top-20 multiple-source drugs and \$4,336,811 (\$2,660,571 Federal share) for other drugs for which we were unable to determine whether billing for rebates was required. The State agency did not submit the data to manufacturers because of inadequate oversight of the processes for rebate billing and collection.

Because the State agency did not bill manufacturers for and collect rebates for single-source and top-20 multiple-source physician-administered drugs, it improperly claimed \$4,392,568 of Federal reimbursement for these drugs. Because we could not determine whether the other drugs were required to be billed for rebates, we set aside \$27,349,486 (Federal share) for the Centers for Medicare & Medicaid Services' (CMS) resolution.

## **WHAT WE RECOMMEND**

We recommend that the State agency:

- refund to the Federal Government \$4,392,568 (Federal share) for claims for single-source and top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement;

- work with CMS to determine the unallowable portion of the \$27,349,486 (Federal share) for other claims for physician-administered drugs that were ineligible for Federal reimbursement and refund that amount;
- determine and refund the unallowable portion of Federal reimbursement for physician-administered drugs that were not billed for rebates beginning July 1, 2008, for quarters not included within our audit period;
- strengthen the NDC edit (implemented on April 1, 2009) to ensure that NDCs are captured and valid for all claims for physician-administered drugs; and
- improve oversight of the processes for rebate billing and collection to ensure submission to manufacturers of drug utilization data for claims 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 recommendation. Although the State agency acknowledged that it did not capture NDCs for claims, it disagreed with the refund amount until it can complete further analysis. The State agency provided information on corrective actions that it planned to take and stated that drug manufacturers should be invoiced for rebates by the end of calendar year 2016. The State agency agreed with our four remaining recommendations and described corrective actions that it had taken or planned to take.

After reviewing the State agency's comments, we maintain that our first recommendation is 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.

### OBJECTIVE

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

### BACKGROUND

#### Medicaid Drug Rebate Program

The Medicaid drug rebate program became effective in 1991 (the Social Security Act (the Act) § 1927). For a covered outpatient drug to be eligible for Federal reimbursement under the program, the drug's manufacturer must enter into a rebate agreement with 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 consists of 11 digits and 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, which contains a summary of actual Medicaid expenditures for each quarter and is used by CMS to reimburse States for the Federal share of Medicaid expenditures.

### **Physician-Administered Drugs**

Drugs administered by a physician are typically 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 the FDA.<sup>4</sup>

Before the Deficit Reduction Act of 2005, many States did not collect rebates on physician-administered drugs if the drug claims did not contain NDCs. NDCs allow States to identify drugs and their manufacturers and to facilitate the collection of drug rebates. The Deficit Reduction Act essentially amended section 1927 of the Act to require States to capture the necessary information, including NDCs, to bill manufacturers for rebates on physician-administered drugs. However, section 1927(a)(7) of the Act allowed CMS to delay some collection and submission requirements for States that demonstrated a need for additional time for implementation.

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

The State agency is responsible for (1) paying claims and (2) billing and collecting Medicaid drug rebates for physician-administered drugs.<sup>5</sup> The State agency uses a contractor to manage its

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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 March 17, 2015.

<sup>5</sup> Although section 1927(a)(7) of the Act specifically addresses rebates for single-source drugs and the 20 drugs with the highest dollar volume dispensed (the top 20 multiple-source drugs), State agency officials told us that they bill manufacturers for rebates on all physician-administered drugs (single-source drugs and all multiple-source drugs).

drug rebate program.<sup>6</sup> The contractor bills manufacturers by NDC for rebates and documents the payments received every quarter.

Before April 1, 2009, the State agency used its HCPCS-to-NDC crosswalk to assign NDCs to HCPCS codes for physician-administered drugs to bill manufacturers for and collect rebates. The State agency billed a drug for rebate only if the drug claim's HCPCS code was listed on the crosswalk.

On April 1, 2009, the State agency implemented an edit in its Medicaid Management Information System (MMIS) to deny claims for physician-administered drugs submitted without NDCs or valid NDCs.<sup>7</sup> Beginning on that date, the State agency identified physician-administered drugs eligible for rebates by relying on its MMIS and Rebate Accounting Information System to process a series of edits on NDCs submitted for physician-administered drugs and comparing the NDCs with the NDCs in a drug labeler file obtained from CMS.<sup>8</sup>

The State agency requested a waiver from CMS to meet the Deficit Reduction Act's requirement related to capturing NDCs for physician-administered drugs and the availability of Federal reimbursement for these drugs. CMS granted a 3-month extension through March 31, 2008, for claims for physician-administered drugs.

## **HOW WE CONDUCTED THIS REVIEW**

Our audit covered \$237,533,773 of the State agency's fee-for-service claims for physician-administered drugs paid for the quarters April through June 2008, July through September 2009, and October through December 2010 (audit period).<sup>9</sup> Of this paid amount, we reviewed \$58,907,969 that the State agency did not bill to manufacturers for the associated rebates. Of the remaining \$178,625,804 that was billed for rebates, we selected and reviewed claims that included 26 NDCs associated with 21 manufacturers (totaling \$61,432,295) to verify that the claims were properly billed 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

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<sup>6</sup> Hewlett Packard Enterprise Services, Inc., was the State agency's contractor from January 1, 2008, through September 30, 2010. Xerox was the State agency's contractor from October 1 through December 31, 2010. According to State agency officials, the contractors' responsibilities were the same.

<sup>7</sup> For physician-administered drugs paid from March 23, 2008, through March 31, 2009, the State agency hired Healthcare Management Systems, Inc., to obtain NDCs from providers. The State agency told us that this company obtained NDCs for some, but not all, claims.

<sup>8</sup> We refer to the drug labeler file used by the State agency to identify physician-administered drugs eligible for rebates as "the State's labeler file."

<sup>9</sup> We selected for review claims paid after the CMS waiver had ended but before the State agency's implementation of the April 1, 2009, edit (April through June 2008). We also selected for review claims paid after the implementation of this edit (July through September 2009 and October through December 2010) to confirm whether this edit captured NDCs.

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. Of the \$61,432,295 in claims that we reviewed, associated with 26 NDCs and 21 manufacturers, the entire amount was properly billed for rebates. However, the State agency did not bill for rebates for claims for physician-administered drugs totaling \$58,907,969:

- The State agency did not capture NDCs (or, in some cases, did not capture valid NDCs) for claims totaling \$49,782,377 (\$26,193,351 Federal share). This amount consisted of \$2,723,165 (\$1,504,436 Federal share) for single-source and top-20 multiple-source drugs and \$47,059,212 (\$24,688,915 Federal share) for other drugs for which we were unable to determine whether billing for rebates was required. The State agency did not have an edit to ensure that NDCs or valid NDCs were submitted for physician-administered drugs before April 1, 2009. Even after the State agency implemented the edit on April 1, 2009, this edit did not ensure that NDCs or valid NDCs were captured for all claims for physician-administered drugs.
- The State agency had drug utilization data, with NDCs, for claims totaling \$9,125,592 (\$5,548,703 Federal share) but did not submit these data to bill manufacturers for and collect rebates for these physician-administered drugs. This amount consisted of \$4,788,781 (\$2,888,132 Federal share) for single-source drugs and top-20 multiple-source drugs and \$4,336,811 (\$2,660,571 Federal share) for other drugs for which we were unable to determine whether billing for rebates was required. The State agency did not submit the data to manufacturers because of inadequate oversight of the processes for rebate billing and collection.

Because the State agency did not bill manufacturers for and collect rebates for single-source and top-20 multiple-source physician-administered drugs, it improperly claimed \$4,392,568 of Federal reimbursement for these drugs. Because we could not determine whether the other drugs were required to be billed for rebates, we set aside \$27,349,486 (Federal share) for CMS's resolution.<sup>10</sup>

## 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)). Federal regulations prohibit Federal

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<sup>10</sup> We could not determine whether the other drugs were required to be billed for rebates because the claims did not have NDCs or valid NDCs or the NDCs were not related to single-source or top-20 multiple-source drugs.

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

The State agency's Medi-Cal<sup>11</sup> update bulletin 407 for consolidated inpatient and outpatient services, dated August 2008, states that providers are encouraged to use NDCs and HCPCS codes for physician-administered drugs on all Medi-Cal claims. Claims with dates of service on or after April 1, 2009, that do not include a valid NDC paired with an HCPCS code will be denied. Appendix C contains Federal requirements and State guidance related to physician-administered drugs.

### **THE STATE AGENCY DID NOT ALWAYS CAPTURE NATIONAL DRUG CODES TO BILL MANUFACTURERS FOR REBATES FOR PHYSICIAN-ADMINISTERED DRUGS**

The State agency did not capture NDCs (or, in some cases, did not capture valid NDCs, such as NDCs with nonnumeric information) to bill manufacturers for rebates for physician-administered drugs totaling \$49,782,377. The claims that the State agency provided to us identified the drugs by HCPCS codes, which we used to classify the drug on each claim as single-source, top-20 multiple-source, or other. We determined that the State agency paid:

- \$1,856,039 (\$1,059,097 Federal share) for claims for single-source drugs,
- \$867,126 (\$445,339 Federal share) for claims for top-20 multiple-source drugs, and
- \$47,059,212 (\$24,688,915 Federal share) for other drugs for which we were unable to determine whether billing for rebates was required.<sup>12</sup>

As a result, the State agency improperly claimed Federal reimbursement of \$1,504,436 for single-source and top-20 multiple-source physician-administered drugs. Because we could not determine whether the other drugs were required to be billed for rebates, we set aside \$24,688,915 (Federal share) for CMS's resolution.

The State agency did not have an edit to ensure that NDCs or valid NDCs were submitted for physician-administered drugs before April 1, 2009. Even after the State agency implemented the edit on April 1, 2009, this edit did not ensure that NDCs or valid NDCs were captured for all claims for physician-administered drugs.

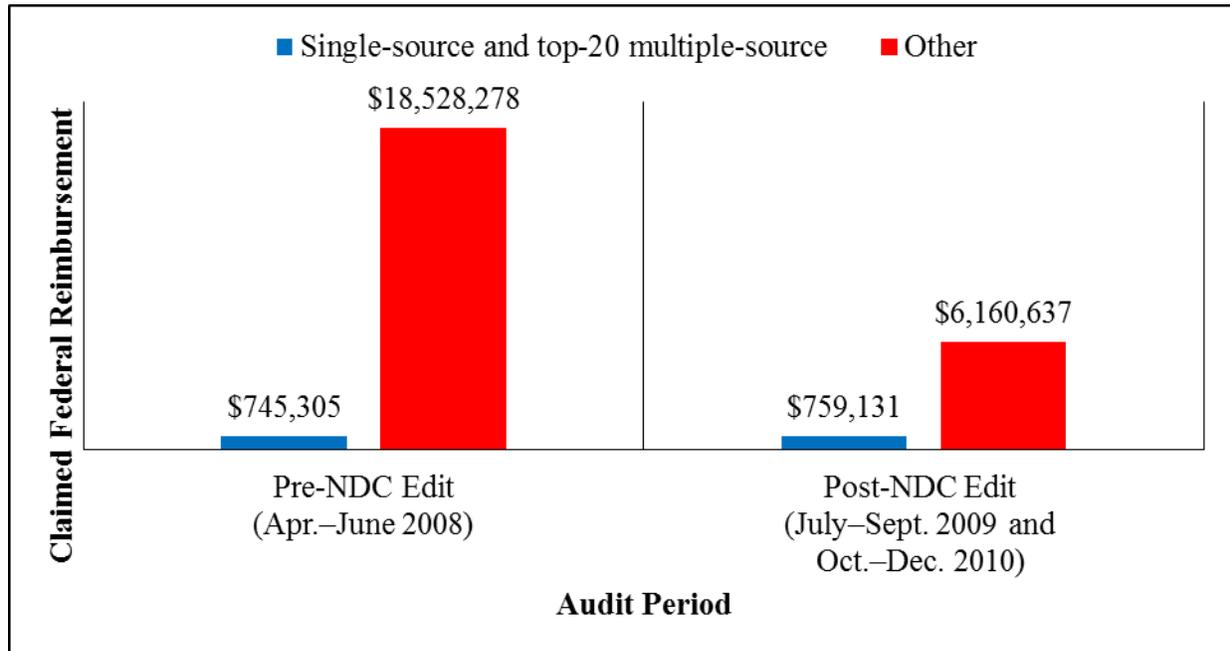
The figure on the following page shows the improperly claimed Federal reimbursement for physician-administered drugs for the portions of our audit period before and after the NDC edit was implemented.

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<sup>11</sup> In California, the Medicaid program is known as Medi-Cal.

<sup>12</sup> Without the NDCs or valid NDCs for these claims, we were unable to determine whether these were single-source drugs or top-20 multiple-source drugs.

**Figure: Federal Share of Claims for Physician-Administered Drugs Without National Drug Codes or With Invalid National Drug Codes That Were Not Billed for Rebates**



**THE STATE AGENCY DID NOT ALWAYS SUBMIT DRUG UTILIZATION DATA TO BILL MANUFACTURERS FOR AND COLLECT REBATES FOR PHYSICIAN-ADMINISTERED DRUGS**

The State agency had drug utilization data, with NDCs, for physician-administered drugs totaling \$9,125,592, but it did not submit these data to bill manufacturers for and collect rebates. Specifically, the State agency paid:

- \$4,748,695 (\$2,863,443 Federal share) for claims for single-source drugs,
- \$40,086 (\$24,689 Federal share) for claims for top-20 multiple-source drugs, and
- \$4,336,811 (\$2,660,571 Federal share) for claims for other drugs for which we were unable to determine whether billing for rebates was required.<sup>13</sup>

As a result, the State agency improperly claimed Federal reimbursement of \$2,888,132 for single-source and top-20 multiple-source drugs. Because we could not determine whether the other drugs were required to be billed for rebates, we set aside \$2,660,571 of Federal reimbursement for CMS’s resolution. The State agency did not submit the drug utilization data to manufacturers because of inadequate oversight of the processes for rebate billing and collection.

<sup>13</sup> The NDCs for these claims did not match single-source NDCs in CMS’s Medicaid Drug File or NDCs on CMS’s list of the top 20 multiple-source drugs. However, State agency officials told us that they bill manufacturers for rebates on all physician-administered drugs.

## RECOMMENDATIONS

We recommend that the State agency:

- refund to the Federal Government \$4,392,568 (Federal share) for claims for single-source and top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement;
- work with CMS to determine the unallowable portion of the \$27,349,486 (Federal share) for other claims for physician-administered drugs that were ineligible for Federal reimbursement and refund that amount;
- determine and refund the unallowable portion of Federal reimbursement for physician-administered drugs that were not billed for rebates beginning July 1, 2008, for quarters not included within our audit period;
- strengthen the NDC edit (implemented on April 1, 2009) to ensure that NDCs are captured and valid for all claims for physician-administered drugs; and
- improve oversight of the processes for rebate billing and collection to ensure submission to manufacturers of the drug utilization data for claims 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 recommendation. Although the State agency acknowledged that it did not capture NDCs for claims, it disagreed with the refund amount until it can complete further analysis. The State agency provided information on corrective actions that it planned to take and stated that drug manufacturers should be invoiced for rebates by the end of calendar year 2016. The State agency agreed with our four remaining recommendations and described corrective actions that it had taken or 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 recommendation is valid.

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

<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<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>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>	5/4/15
<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
<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>	3/4/15
<i>Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<a href="#"><u>A-06-14-00031</u></a>	2/10/15
<i>The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-03-12-00205</u></a>	8/21/14
<i>Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-13-06040</u></a>	8/7/14
<i>Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-09-12-02079</u></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="#"><u>A-09-12-02080</u></a>	4/24/14
<i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-03-12-00200</u></a>	11/26/13

<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<a href="#"><u>A-06-12-00059</u></a>	9/19/13
<i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i>	<a href="#"><u>A-06-10-00011</u></a>	8/12/11
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	<a href="#"><u>OEI-03-09-00410</u></a>	5/6/11

## APPENDIX B: AUDIT SCOPE AND METHODOLOGY

### SCOPE

Our audit covered \$237,533,773 of the State agency's fee-for-service claims for physician-administered drugs paid for the quarters April through June 2008, July through September 2009, and October through December 2010.<sup>14</sup> Of this paid amount, we reviewed \$58,907,969 that the State agency did not bill to manufacturers for the associated rebates. Of the remaining \$178,625,804 that was billed for rebates, we selected and reviewed claims that included 26 NDCs associated with 21 manufacturers (totaling \$61,432,295) to verify that the claims were properly billed for rebates.

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.

We conducted our audit from January 2014 to April 2015 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;
- interviewed CMS officials about the Federal laws, regulations, and guidance governing physician-administered drugs under the Medicaid drug rebate program;
- reviewed State guidance to providers, 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;
- obtained the CMS Medicaid Drug File for our audit period;

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<sup>14</sup> We selected for review claims paid after the CMS waiver had ended but before the State agency's implementation of the April 1, 2009, edit (April through June 2008). We also selected for review claims paid after the implementation of this edit (July through September 2009 and October through December 2010) to confirm whether this edit captured NDCs.

- obtained from the State agency the HCPCS-to-NDC crosswalk used to identify physician-administered drugs eligible for rebate before April 1, 2009;
- obtained from the State agency the State’s labeler file used to identify physician-administered drugs eligible for rebates beginning April 1, 2009;
- obtained from the State agency the claims paid during our audit period for physician-administered drugs;
- excluded from our review certain paid claims not eligible for rebates;
- identified the paid claims not billed for rebates that lacked NDCs or had invalid NDCs and:
  - matched HCPCS codes on the claims to the HCPCS codes on the Medicare Part B crosswalk to identify the NDCs associated with each HCPCS code and traced the resulting NDCs to CMS’s Medicaid Drug File to identify single-source drugs,<sup>15</sup>
  - matched the HCPCS codes on the claims to the HCPCS codes on CMS’s list of the top 20 multiple-source drugs to identify top-20 multiple-source drugs, and
  - classified the remaining claims as other drugs for which we were unable to determine whether billing for rebates was required;
- identified paid claims not billed for rebates that had NDCs and:
  - matched NDCs on the claims to the NDCs in CMS’s Medicaid Drug File to identify single-source drugs,
  - matched the NDCs on the claims to the NDCs on CMS’s list of the top 20 multiple-source drugs to identify top-20 multiple-source drugs, and
  - classified the remaining claims as other drugs for which we were unable to determine whether billing for rebates was required;
- identified the paid claims billed for rebates and:
  - selected 26 NDCs associated with 21 manufacturers<sup>16</sup> and
  - reviewed copies of rebate invoices submitted to the manufacturers to verify the billing of rebates by NDC for the selected NDCs; and

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<sup>15</sup> CMS instructed the States that they could use the Medicare Part B crosswalk as a reference because HCPCS codes and NDCs are standardized codes.

<sup>16</sup> These NDCs represented drugs that had high payment amounts and units of service or had high payment amounts per unit.

- 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 REQUIREMENTS AND STATE GUIDANCE RELATED TO PHYSICIAN-ADMINISTERED DRUGS**

### **FEDERAL LAWS**

Under the Medicaid program, States may provide coverage for outpatient drugs as an optional service (the Act § 1905(a)(12)). 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 capture 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 the NDC (§ 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)).

### **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>17</sup>

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<sup>17</sup> On November 15, 2010, CMS amended 42 CFR § 447.502 to remove the definition of "multiple-source drug" (75 Fed. Reg. 69591, 69592).

## **STATE GUIDANCE**

California's Medi-Cal Update Bulletin 407 for consolidated inpatient and outpatient services, dated August 2008, states that providers are encouraged to use the NDC and the HCPCS code for physician-administered drugs on all Medi-Cal claims. The bulletin also states: "Claims with dates of service on or after April 1, 2009 that do not meet the NDC reporting requirements to include a valid NDC paired with an HCPCS code, will result in claims being denied."

## 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  
San Francisco, CA 94103

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 Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Some Physician Administered Drugs*

DHCS appreciates the work performed by OIG and the opportunity to respond to the draft report. Please contact Ms. Sarah Hollister, Audit Coordinator, at [REDACTED] if you have any questions.

Sincerely,

[Jennifer Kent]

Jennifer Kent  
Director

Enclosure

cc: Karen Johnson, Chief Deputy Director

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**Department of Health Care Services Response to the OIG Report Entitled:  
*California Claimed Unallowable Federal Medicaid Reimbursement  
by Not Billing Manufacturers for Rebates for Some Physician-Administered  
Drugs***

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**Finding 1:** The State agency did not capture Nation Drug Code (NDCs) (or, in some cases, did not capture valid NDCs) for claims totaling \$49,782,377 (\$26,193,351 Federal share). This amount consisted of \$2,723,165 (\$1,504,436 Federal share) for single-source and top-20 multiple-source drugs and \$47,059,212 (\$24,688,915 Federal share) for other drugs for which we were unable to determine whether billing for rebates was required. The State agency did not have an edit to ensure that NDCs or valid NDCs were submitted for physician-administered drugs before April 1, 2009. Even after the State agency implemented the edit on April 1, 2009, this edit did not ensure that NDCs or valid NDCs were captured for all claims for physician-administered drugs.

Because the State agency did not bill manufacturers for and collect rebates for single-source and top-20 multiple-source physician-administered drugs, it improperly claimed \$4,392,568 of Federal reimbursement for these drugs. Because the OIG could not determine whether the other drugs were required to be billed for rebates, the OIG set aside \$27,349,486 (Federal share) for CMS's resolution

**Recommendation 1:** DHCS should refund to the Federal Government \$4,392,568 (Federal share) for claims for single-source and top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement.

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

While DHCS acknowledges the State did not capture NDCs for claims, DHCS disagrees with the amount to be refunded until further analysis can be completed. DHCS will review the list of claims that were identified by the OIG. Some of these claims may have already been invoiced for rebates. As the audit report stated, DHCS had contracted with HMS to collect unpaid rebates for claims without an NDC that had dates of service from January 1, 2008 through March 31, 2009. Any other claims that were identified but were not part of the HMS project will be reviewed and invoiced for rebates. In order to do so, it will be necessary to make system changes. DHCS is currently working on a system development notice (SDN) that should be implemented by the end of 2016 and retroactive to April 1, 2009. This system change will allow DHCS to invoice for many of the claims identified in the audit. Once the system change is implemented, DHCS will review the data to determine why the remaining claims were not invoiced. Once reasons are identified, additional system changes will be made to invoice for remaining claims. Drug manufacturers should be invoiced for rebates by the end of calendar year 2016.

**Recommendation 2:** DHCS should work with CMS to determine the unallowable portion of the \$27,349,486 (Federal share) for other claims for physician-administered drugs and refund that amount.

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

DHCS will review the list of claims to determine which are not rebate eligible and which may have already been invoiced as part of the HMS project. Once the review is completed, DHCS will work with CMS to determine which, if any of the unallowable portion should be returned. DHCS staff will need to review the claims, identify the cause of the error, implement system changes and work with CMS. Due to the exceptionally high number of claims involved (approximately 4-5 million), the review and analysis of the data will take time to complete, as will any required system changes necessary to fix any systemic problems identified as a result of the analysis. DHCS expects the work required to address this recommendation to be completed no later than the end of calendar year 2017.

**Recommendation 3:** DHCS should determine and refund the unallowable portion of Federal reimbursement for physician administered drugs that were not billed for rebates beginning July 1, 2008, for quarters not included within our audit period.

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

Please refer to the response to Finding 1, Recommendation 2. DHCS will address these quarters simultaneously with the other quarters that were part of the OIG audit. The methodology should be very similar and the unallowable portion, if any should be identifiable. DHCS will work with CMS to refund any amounts owed. Consistent with the response to Finding 1, Recommendation 2, the work required to address this recommendation should be completed no later than the end of calendar year 2017.

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**Finding 2: The State agency had drug utilization data, with NDCs, for claims totaling \$9,125,592 (\$5,548,703 Federal share) but did not submit these data to bill manufacturers for and collect rebates for these physician-administered drugs. This amount consisted of \$4,788,781 (\$2,888,132 Federal share) for single-source drugs and top-20 multiple source drugs and \$4,336,811 (\$2,660,571 Federal share) for other drugs for which we were unable to determine whether billing for rebates was required. The State agency did not submit the data to manufacturers because of inadequate oversight of the processes for billing and collection of rebates.**

**Recommendation 4:** DHCS should strengthen the NDC edit (implemented on April 1, 2009) to ensure that NDCs are captured and valid for all claims for physician-administered drugs.

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

As noted in the response to Finding 1, Recommendation 1, DHCS is working on an SDN that should be implemented by the end of 2016 and retroactive to April 1, 2009. The change will allow DHCS to invoice for many of the claims identified in the audit. This recommendation should be completed no later than the end of calendar year 2017, which will allow for the data to be reviewed to determine why the remaining claims were not invoiced. Once the system change is implemented, the data will be reviewed to determine why the remaining claims were not invoiced. Once reasons are identified, additional system changes may be required in order to invoice for remaining claims.

**Recommendation 5:** Improve oversight of the processes for billing and collection of rebates to ensure submission to manufacturers of drug utilization data for claims for physician administered drugs.

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

DHCS has edits in place, which requires many of the claims include an NDC with the procedure code or the claim is rejected for payment. As noted in the response to Finding 1, Recommendation 1, an SDN is to be implemented that will capture many of the claims which had not been invoiced for rebates. Many of these procedure codes are used for multiple purposes such as the Z7610 (Miscellaneous Drugs/Supplies). The Medi-Cal provider bulletin requires that an NDC be included when billing for drugs. Each claim's NDC must meet certain criteria in order to be included for rebates. DHCS will review rejected claims to determine the cause and make system changes as necessary. This review process should be done by the end of calendar year 2017, as an effective review cannot be done until the current SDN is implemented to determine which claims are still not being invoiced.