

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

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

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EXECUTIVE SUMMARY

Colorado claimed \$6.5 million over 3 years in Federal reimbursement that was unallowable and \$1.3 million that may have been unallowable because it did not comply with Federal Medicaid requirements for invoicing manufacturers for rebates for 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 their Federal share of these rebates against their Medicaid expenditures. States invoice the manufacturers for rebates to reduce the cost of drugs to the program. However, a prior Office of Inspector General review found that States did not always invoice and collect all rebates due for drugs administered by physicians. For this audit, we reviewed the Colorado Department of Health Care Policy and Financing (State agency) invoicing for rebates for physician-administered drugs for the period January 1, 2010, through December 31, 2012.

Our objective was to determine whether the State agency complied with Federal Medicaid requirements for invoicing 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 manufacturer must enter into a rebate agreement that is administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. The Deficit Reduction Act of 2005 amended section 1927 of the Social Security Act to specifically address the collection of rebates on certain physician-administered drugs. To collect these rebates, States submit to the manufacturers the drug utilization data containing National Drug Codes (NDCs) for all single-source physician-administered drugs and for 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 invoice and collect rebates.

The State agency is responsible for paying claims, submitting invoices to manufacturers, and collecting Medicaid drug rebates for physician-administered drugs. The State agency uses its claim utilization data for physician-administered drugs, which it derives from claims submitted by providers, to invoice manufacturers quarterly and to maintain a record of rebate accounts receivable due from the manufacturers.

WHAT WE FOUND

The State agency did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. The State agency did not invoice manufacturers for rebates associated with \$13,053,115 (\$6,526,558 Federal share) in physician-

administered drugs. Of this amount, \$10,459,207 (\$5,229,604 Federal share) was for single-source drugs, and \$2,593,908 (\$1,296,954 Federal share) was for top-20 multiple-source drugs. Because the State agency's internal controls did not always ensure that it invoiced manufacturers to secure rebates, the State agency improperly claimed Federal reimbursement for these single-source drugs and top-20 multiple-source drugs.

Further, the State agency did not submit the utilization data necessary to secure rebates for all other physician-administered drugs. Although the State agency generally collected the drug utilization data necessary to invoice the manufacturers for rebates associated with these claims, providers submitted claims totaling \$2,587,392 (\$1,293,696 Federal share) that did not have NDCs. We were unable to determine whether the State agency was required to invoice for rebates for these other physician-administered drug claims that did not have NDCs in the utilization data. Furthermore, under the Medicaid drug rebate program, claims totaling \$634,686 (\$317,343 Federal share), which contained NDCs, could have been eligible for rebates. Accordingly, we set aside these amounts and are recommending that the State agency work with CMS to determine (1) the unallowable portion of the \$2,587,392 (\$1,293,696 Federal share) of claims that were submitted without NDCs and (2) whether the remaining \$634,686 (\$317,343 Federal share) of claims could have been invoiced to the manufacturers for rebates.

WHAT WE RECOMMEND

We recommend that the State agency:

- refund to the Federal Government \$5,229,604 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;
- refund to the Federal Government \$1,296,954 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement;
- work with CMS to determine:
 - the unallowable portion of \$1,293,696 (Federal share) for other claims for covered outpatient physician-administered drugs that were submitted without NDCs and that may have been ineligible for Federal reimbursement and refund that amount, and
 - whether the remaining \$317,343 (Federal share) of other physician-administered drug claims could have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims;
- work with CMS to determine and refund the unallowable portion of Federal reimbursement for physician-administered drugs that were not invoiced for rebates after December 31, 2012; and

- strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.

STATE AGENCY COMMENTS AND OUR RESPONSE

State Agency Comments

In written comments on our draft report, the State agency did not concur with our first two recommendations but concurred with our other three recommendations and described corrective actions it planned to take. For our first two recommendations, the State agency did not concur that it should refund the Federal share of single-source and top-20 claims that were ineligible for Federal reimbursement because it anticipated that all rebate-eligible drug units would be invoiced “so no Federal funds will need to be refunded to CMS.” The State agency said that it intended to begin invoicing, in the first quarter of 2017, for the drug rebates related to the claims we questioned, to bring the State into compliance with Federal requirements for reimbursement for physician-administered drugs. The State agency said that it would provide the Federal share of the collected rebates to CMS. The State agency added that in the event any rebate-eligible drug units could not be invoiced, it would work with CMS to determine whether funds should be refunded on the basis of the Federal share of the claim reimbursement or the Federal share of the uncollected rebate.

Our Response

After reviewing the State agency’s comments, we maintain that all of our findings and recommendations remain valid. We recognize that the drug rebate process is fluid and ongoing, but as of the date we issued our draft report, the claims that are included in our findings’ amounts had not been invoiced to the drug manufacturers to secure rebates. Both Federal requirements and State agency guidance specify that claims for physician-administered drugs must be submitted with NDCs; Federal requirements essentially preclude Federal reimbursement for such claims if they are not invoiced to the manufacturers for rebate. Furthermore, the State agency conceded in its written comments that it had not been in compliance with Federal requirements for reimbursement for these drugs.

Although we commend the State agency for the corrective actions it promised to implement going forward, we note that those planned actions do not relieve the State agency of its responsibility for the claims from our audit period that we questioned. Federal Medicaid requirements related to the collection of rebates for specified categories of physician-administered drugs are well established and provide a basis for disallowance of Federal reimbursement for such claims if they were not invoiced for rebate. However, if the State agency can retrospectively obtain the rebates from the manufacturers and offer to remit the Federal share of the rebates to CMS, then, during the audit resolution process, CMS as the cognizant operating division will decide how to adjust the overpayment amounts conveyed in this report.

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INTRODUCTION

WHY WE DID THIS REVIEW

For a covered outpatient drug to be eligible for Federal reimbursement under the Medicaid program's drug rebate requirements, manufacturers must pay rebates to the States for the drugs. States generally offset their Federal share of these rebates against their Medicaid expenditures. States invoice the manufacturers for rebates to reduce the cost of drugs to the program. However, a prior Office of Inspector General review found that States did not always invoice and collect all rebates due for drugs administered by physicians.¹ (Appendix A lists previous reviews of the Medicaid drug rebate program.) For this audit, we reviewed the Colorado Department of Health Care Policy and Financing (State agency) invoicing for rebates for physician-administered drugs for the period January 1, 2010, through December 31, 2012.

OBJECTIVE

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

BACKGROUND

Medicaid Drug Rebate Program

The Medicaid drug rebate program became effective in 1991 (the Social Security Act (the Act) § 1927). For a covered outpatient drug to be eligible for Federal reimbursement under the program, the drug's manufacturer must enter into a rebate agreement that is administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each have specific functions under the program.

Manufacturers are required to submit a list to CMS of all covered outpatient drugs and to report each drug's average manufacturer price and, where applicable, best price.² On the basis of this information, CMS calculates a unit rebate amount for each drug and provides the information to the States each quarter. Covered outpatient drugs reported by participating drug manufacturers are listed in the CMS Medicaid Drug File, which identifies drugs with such fields as National Drug Code (NDC), unit type, units per package size, and product name.

Section 1903(i)(10) of the Act prohibits Federal reimbursement for States that do not capture the information necessary for invoicing manufacturers for rebates as described in section 1927 of the Act. To invoice for rebates, States capture drug utilization data that identifies, by NDC, the number of units of each drug for which the States reimbursed Medicaid providers and report the information to the manufacturers (the Act § 1927(b)(2)(A)). The number of units is multiplied by the unit rebate amount to determine the actual rebate amount due from each manufacturer.

¹ *States' Collection of Medicaid Rebates for Physician-Administered Drugs* (OEI-03-09-00410), issued June 24, 2011.

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

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 invoiced to the Medicaid program on a claim form using Healthcare Common Procedure Coding System (HCPCS) codes.³ For purposes of the Medicaid drug rebate program, physician-administered drugs are classified as either single-source or multiple-source.⁴

The Deficit Reduction Act of 2005 (DRA) amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs for all single-source physician-administered drugs and for the top 20 multiple-source physician-administered drugs.⁵ Beginning January 1, 2007, CMS was responsible for publishing annually the list of the top 20 multiple-source drugs by HCPCS codes that had the highest dollar volume dispensed. Before the DRA, many States did not collect rebates on physician-administered drugs if the drug claims did not contain NDCs. NDCs enable States to identify the drugs and their manufacturers and facilitate the collection of rebates for the drugs.

The State Agency's Medicaid Drug Rebate Program

The State agency is responsible for paying claims, submitting invoices to manufacturers, and collecting Medicaid drug rebates for physician-administered drugs. The State agency also requires all physician-administered drug claims to be submitted with the NDC of the product. The State agency uses its claim utilization data for physician-administered drugs, which it derives from claims submitted by providers, to invoice manufacturers quarterly and to maintain a record of rebate accounts receivable due from the manufacturers. The manufacturers then pay the rebates directly to the State agency.

³ HCPCS codes (sometimes referred to as J-Codes) are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

⁴ See, e.g., section 1927(a)(7) of the Act. In general terms, multiple-source drugs are covered outpatient drugs for which there are two or more drug products that are rated therapeutically equivalent by FDA. See, e.g., section 1927(k)(7) of the Act. Multiple-source drugs stand in contrast to single-source drugs, which do not have therapeutic equivalents.

⁵ The term “top-20 multiple-source drugs” is drawn from a CMS classification and describes these drugs in terms of highest dollar volume of physician-administered drugs in Medicaid. The Act § 1927(a)(7)(B)(i).

HOW WE CONDUCTED THIS REVIEW

The State agency claimed \$70,189,960 (\$35,094,980 Federal share) for physician-administered drugs paid between January 1, 2010, and December 31, 2012.

We used CMS's Medicare Part B crosswalk to identify, if possible, the NDCs associated with each HCPCS code listed on claims from providers. We then used the CMS Medicaid Drug File to determine whether the identified NDCs were classified as single-source drugs or multiple-source drugs.⁶ Additionally, we determined whether the HCPCS codes were published in CMS's top-20 multiple-source drug listing.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix B contains the details of our audit scope and methodology.

FINDINGS

The State agency did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. The State agency did not invoice manufacturers for rebates associated with \$13,053,115 (\$6,526,558 Federal share) in physician-administered drugs. Of this amount, \$10,459,207 (\$5,229,604 Federal share) was for single-source drugs, and \$2,593,908 (\$1,296,954 Federal share) was for top-20 multiple-source drugs. Because the State agency's internal controls did not always ensure that it invoiced manufacturers to secure rebates, the State agency improperly claimed Federal reimbursement for these single-source drugs and top-20 multiple-source drugs.

Further, the State agency did not submit the utilization data necessary to secure rebates for all other physician-administered drugs. Although the State agency generally collected the drug utilization data necessary to invoice the manufacturers for rebates associated with these claims, providers submitted claims totaling \$2,587,392 (\$1,293,696 Federal share) that did not have NDCs. We were unable to determine whether the State agency was required to invoice for rebates for these other physician-administered drug claims that did not have NDCs in the utilization data. Furthermore, under the Medicaid drug rebate program, claims totaling \$634,686 (\$317,343 Federal share), which contained NDCs, could have been eligible for rebates. Accordingly, we set aside these amounts and are recommending that the State agency work with CMS to determine (1) the unallowable portion of the \$2,587,392 (\$1,293,696 Federal share) of

⁶ The Medicare Part B crosswalk is published quarterly by CMS and is based on published drug and biological pricing data and information submitted to CMS by manufacturers. It contains the payment amounts that will be used to pay for Part B covered drugs as well as the HCPCS codes associated with those drugs. CMS instructed States that they could use the crosswalk as a reference because HCPCS codes and NDCs are standardized codes used across health care programs.

claims that were submitted without NDCs and (2) whether the remaining \$634,686 (\$317,343 Federal share) of claims could have been invoiced to the manufacturers for rebates.

FEDERAL REQUIREMENTS AND STATE AGENCY GUIDANCE

The DRA amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs. States must capture NDCs for single-source and top-20 multiple-source drugs (the Act § 1927(a)(7)). To secure rebates, States are required to report certain information to manufacturers within 60 days after the end of each rebate period (the Act § 1927(b)(2)(A)). Federal regulations prohibit Federal reimbursement for physician-administered drugs for which a State has not required the submission of claims containing the NDCs (42 CFR § 447.520).

The State agency, *Colorado Provider Bulletin*, reference B1000274, dated January 2010, states (pages 4–5):

All physician, outpatient hospital, EPSDT [Early Periodic Screening, Diagnosis, and Treatment], and Medicare Part B crossover claims for physician-administered single-source and the 20 multiple-source drugs (as identified by the Centers for Medicare and Medicaid Services) must be submitted using both Healthcare Common Procedure Coding System (HCPCS) codes and National Drug Code (NDC) numbers.... Claims submitted for these drugs using only HCPCS codes or only NDC numbers will be denied. Claims submitted with NDC numbers that do not correspond to the correct HCPCS codes will also be denied.⁷

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

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES ON SOME SINGLE-SOURCE PHYSICIAN-ADMINISTERED DRUGS

The State agency improperly claimed Federal reimbursement of \$10,459,207 (\$5,229,604 Federal share) for single-source physician-administered drug claims for which it did not invoice manufacturers for rebates.

⁷ The term “crossover claims” applies to claims for certain beneficiaries who are eligible for both Medicare and Medicaid. CMS guidance states that State Medicaid programs are obligated to reimburse providers for Medicare cost-sharing amounts due for Qualified Medicare Beneficiaries (QMBs) according to the States’ CMS-approved cost-sharing payment methodology. QMBs are persons who are entitled to Medicare Part A and are eligible for Medicare Part B, have incomes below 100 percent of the Federal Poverty Level, and have been determined to be eligible for QMB status by their State Medicaid agencies. CMCS [Center for Medicaid and CHIP [Children’s Health Insurance Program] Services] – MMCO [Medicare-Medicaid Coordination Office] – CM [Center for Medicare] Informational Bulletin dated Jun. 7, 2013, subject: *Payment of Medicare Cost Sharing for Qualified Medicare Beneficiaries (QMBs) (June 7, 2013 Informational Bulletin)*; and MMCO – CMCS Informational Bulletin dated Jan. 6, 2012, subject: *Billing for Services Provided to Qualified Medicare Beneficiaries (QMBs)*.

Because the State agency did not submit utilization data to the manufacturers to secure rebates, the State agency improperly claimed Federal reimbursement for these single-source physician-administered drugs.

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES ON SOME TOP-20 MULTIPLE-SOURCE PHYSICIAN-ADMINISTERED DRUGS

The State agency improperly claimed Federal reimbursement of \$2,593,908 (\$1,296,954 Federal share) for top-20 multiple-source physician-administered drug claims for which it did not invoice manufacturers for rebates.

Before 2012, CMS provided the State agency, on a yearly basis, with a listing of top-20 multiple-source HCPCS codes and their respective NDCs. However, the State agency did not always submit the utilization data to the drug manufacturers for rebate purposes.

Because the State agency did not submit utilization data to the manufacturers to secure rebates, the State agency improperly claimed Federal reimbursement for these top-20 multiple-source physician-administered drugs.

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES ON OTHER PHYSICIAN-ADMINISTERED DRUGS

We were unable to determine whether, in some cases, the State agency was required to invoice for rebates for other physician-administered drug claims.

Although the State agency generally collected the drug utilization data necessary to invoice the manufacturers for rebates associated with other physician-administered drug claims, providers submitted some claims, totaling \$2,587,392 (\$1,293,696 Federal share), that did not have NDCs. For the claims that did not have NDCs in the utilization data, we were unable to determine whether the State agency improperly claimed Federal reimbursement for the physician-administered drugs associated with these claims. Furthermore, under the Medicaid drug rebate program, claims totaling \$634,686 (\$317,343 Federal share), which contained NDCs, could have been eligible for rebates. If the State agency had invoiced these claims for rebate, the drug manufacturers would have been required to pay the rebates.

Accordingly, we set aside these amounts and are recommending that the State agency work with CMS to determine (1) the unallowable portion of the \$2,587,392 (\$1,293,696 Federal share) of the claims that were submitted without NDCs and (2) whether the remaining \$634,686 (\$317,343 Federal share) of other physician-administered drug claims could have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims.

RECOMMENDATIONS

We recommend that the State agency:

- refund to the Federal Government \$5,229,604 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;
- refund to the Federal Government \$1,296,954 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement;
- work with CMS to determine:
 - the unallowable portion of \$1,293,696 (Federal share) for other claims for covered outpatient physician-administered drugs that were submitted without NDCs and that may have been ineligible for Federal reimbursement and refund that amount, and
 - whether the remaining \$317,343 (Federal share) of other physician-administered drug claims could have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims;
- work with CMS to determine and refund the unallowable portion of Federal reimbursement for physician-administered drugs that were not invoiced for rebates after December 31, 2012; and
- strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency did not concur with our first two recommendations but concurred with our other three recommendations and described corrective actions it planned to take. These corrective actions include the planned implementation (on October 31, 2016) of a new Medicaid Management Information System (MMIS) that “will require that *all* claims for physician-administered drugs include a National Drug Code (NDC) number[;] otherwise the claim will not pay” (emphasis added).

For our first two recommendations, the State agency did not concur that it should refund the Federal share of single-source and top-20 claims that were ineligible for Federal reimbursement because it anticipated that all rebate-eligible drug units would be invoiced “so no Federal funds will need to be refunded to CMS.” The State agency said that it intended to begin invoicing, in the first quarter of 2017, for the drug rebates related to the claims we questioned, to bring the State into compliance with Federal requirements for reimbursement for physician-administered drugs. The State agency said that it would provide the Federal share of the collected rebates to

CMS. The State agency added that in the event any rebate-eligible drug units could not be invoiced, it would work with CMS to determine whether funds should be refunded on the basis of the Federal share of the claim reimbursement or the Federal share of the uncollected rebate.

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

OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing the State agency's comments, we maintain that all of our findings and recommendations remain valid. We recognize that the drug rebate process is fluid and ongoing, but as of the date we issued our draft report, the claims that are included in our findings' amounts (claims that the State agency paid between January 1, 2010, and December 31, 2012; see Appendix B) had not been invoiced to the drug manufacturers to secure rebates.

Both Federal requirements and State agency guidance (Appendix C) specify that claims for physician-administered drugs must be submitted with NDCs; Federal requirements essentially preclude Federal reimbursement for such claims if they are not invoiced to the manufacturers for rebate. Furthermore, the State agency conceded in its written comments that it had not been in compliance with Federal requirements for reimbursement for these drugs.

Although we commend the State agency for the corrective actions it promised to implement going forward, we note that those planned actions—in particular, the planned October 31, 2016, implementation of a new MMIS—do not relieve the State agency of its responsibility for the claims it paid in calendar years 2010 through 2012 that we questioned. Federal Medicaid requirements related to the collection of rebates for specified categories of physician-administered drugs are well established and provide a basis for disallowance of Federal reimbursement for such claims if they are not invoiced for rebate. However, if the State agency can retrospectively obtain the rebates from the manufacturers and offer to remit the Federal share of the rebates to CMS, then, during the audit resolution process, CMS as the cognizant operating division will decide how to adjust the overpayment amounts conveyed in this report.

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Kansas Correctly Invoiced Rebates to Manufacturers for Most Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-07-15-06060</u>	8/18/16
<i>Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06057</u>	5/26/16
<i>Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06063</u>	3/31/16
<i>South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06059</u>	2/09/16
<i>Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06062</u>	1/14/16
<i>North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06058</u>	1/13/16
<i>California Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	<u>A-09-14-02038</u>	1/07/16
<i>Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06056</u>	9/18/15
<i>Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06049</u>	7/22/15
<i>Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-06-12-00060</u>	5/04/15
<i>Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06051</u>	4/13/15
<i>Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-13-02037</u>	3/04/15

Report Title	Report Number	Date Issued
<i>Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<u>A-06-14-00031</u>	2/10/15
<i>The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-03-12-00205</u>	8/21/14
<i>Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-13-06040</u>	8/07/14
<i>Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs</i>	<u>A-09-12-02079</u>	4/30/14
<i>Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	<u>A-09-12-02080</u>	4/24/14
<i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-03-12-00200</u>	11/26/13
<i>Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<u>A-06-12-00059</u>	9/19/13
<i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i>	<u>A-06-10-00011</u>	8/12/11
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	<u>OEI-03-09-00410</u>	6/24/11

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

The State agency claimed \$70,189,960 (\$35,094,980 Federal share) for physician-administered drugs paid between January 1, 2010, and December 31, 2012.

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

We conducted our audit work, which included contacting the State agency in Denver, Colorado, from October 2013 to May 2016.

METHODOLOGY

To accomplish our objective, we took the following steps:

- We reviewed applicable Federal laws, regulations, and guidance pertaining to the Medicaid drug rebate program and physician-administered drugs.
- We interviewed CMS officials about the Federal requirements and guidance governing physician-administered drugs under the Medicaid drug rebate program.
- We reviewed State agency regulations and guidance to providers, including invoicing instructions for physician-administered drugs.
- We reviewed State agency policies and procedures for rebates for physician-administered drugs.
- We interviewed State agency personnel to gain an understanding of the administration of and controls over the Medicaid invoicing and rebate process for physician-administered drugs.
- We obtained listings of the CMS top-20 multiple-source physician-administered drugs, the Medicare Part B crosswalk, and the CMS Medicaid Drug File for our audit period.
- We obtained claim details from the State agency for all drug claims, including physician-administered drugs, for the period January 1, 2010, through December 31, 2012.
- We removed drug claims totaling \$53,914,767 (\$26,957,383 Federal share) that either were not eligible for a drug rebate or contained an NDC and were invoiced for rebate.

- We reviewed the remaining drug claims totaling \$16,275,193 (\$8,137,597 Federal share) to determine whether the State agency complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. Specifically:
 - We identified single-source drugs by matching the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk to identify, if possible, the NDCs associated with each HCPCS code listed on claims from providers. We used the CMS Medicaid Drug File to determine whether these NDCs were classified as single-source drugs.
 - We identified the top 20 multiple-source drugs by matching the HCPCS code on the drug claim to the HCPCS code on CMS's top-20 multiple-source drug listing.
 - We identified the remaining drugs (ones that were not identified as single-source or as top-20 multiple-source drugs) as other outpatient physician-administered drugs.
- We discussed the results of our review with State agency officials on December 3, 2015, and May 19, 2016.

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 AGENCY GUIDANCE RELATED TO PHYSICIAN-ADMINISTERED DRUGS

FEDERAL LAWS

Under the Medicaid program, States may provide coverage for outpatient drugs as an optional service (the Act § 1905(a)(12)). Section 1903(a) of the Act provides for Federal financial participation (Federal share) in State expenditures for these drugs. The Medicaid drug rebate program, created by the Omnibus Budget Reconciliation Act of 1990 that added section 1927 to the Act, became effective on January 1, 1991. Manufacturers must enter into a rebate agreement with the Secretary of Health and Human Services (HHS) and pay rebates for States to receive Federal funding for the manufacturer's covered outpatient drugs dispensed to Medicaid patients (the Act § 1927(a)). Responsibility for the drug rebate program is shared among the drug manufacturers, CMS, and the States.

Section 6002 of the DRA added section 1927(a)(7) to the Act to require that States capture information necessary to secure rebates from manufacturers for certain covered outpatient drugs administered by a physician. In addition, section 6002 of the DRA amended section 1903(i)(10) of the Act to prohibit Medicaid Federal share for covered outpatient drugs administered by a physician unless the States collect the utilization and coding data described in section 1927(a)(7) of the Act.

Section 1927(a)(7) of the Act requires that States shall provide for the collection and submission of such utilization data and coding (such as J-codes and NDCs) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates for all single-source physician-administered drugs effective January 1, 2006, and for the top 20 multiple-source drugs effective January 1, 2008. Section 1927(a)(7)(C) of the Act stated that, effective January 1, 2007, the utilization data must be submitted using the NDC. To secure rebates, States are required to report certain information to manufacturers within 60 days after the end of each rebate period (the Act § 1927(b)(2)(A)).

Section 1927(a)(7)(D) of the Act allowed HHS to delay any of the above requirements to prevent hardship to States that required additional time to implement the physician-administered drug reporting requirements.

FEDERAL REGULATIONS

Federal regulations set conditions for States to obtain a Federal share for covered outpatient drugs administered by a physician and specify 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 invoice a manufacturer for rebates (42 CFR § 447.520).

STATE AGENCY GUIDANCE

The State agency, *Colorado Provider Bulletin*, reference B1000274, dated January 2010, states (pages 4–5):

Notice to All Providers Billing Physician-Administered Drugs

All physician, outpatient hospital, EPSDT, and Medicare Part B crossover claims for physician-administered single-source and the 20 multiple-source drugs (as identified by the Centers for Medicare and Medicaid Services) must be submitted using both Healthcare Common Procedure Coding System (HCPCS) codes and National Drug Code (NDC) numbers when using the electronic 837P (Professional) and 837I (Institutional) claim formats. Claims submitted for these drugs using only HCPCS codes or only NDC numbers will be denied. Claims submitted with NDC numbers that do not correspond to the correct HCPCS codes will also be denied.

The Department [i.e., the State agency] posts a list of the single-source and top 20 multiple-source drugs, and their corresponding NDCs and HCPCS, in the Billing Manuals section of the Department's Web site.

The State agency, *Colorado Provider Bulletin*, reference B1000281, dated March 2010, states (page 4):

Notice to All Providers Billing Physician-Administered Drugs

All physician, outpatient hospital, EPSDT, and Medicare Part B crossover claims for physician-administered single-source and the 20 multiple-source drugs, as identified by the CMS, must be submitted using both HCPCS codes and National Drug Code (NDC) numbers when using the electronic 837P (Professional) and 837I (Institutional) claim formats.

The Department posts a list of the single-source and top 20 multiple-source drugs, and their corresponding NDCs and HCPCS, in the Billing Manuals section of the Department's Web site. Claims submitted for these drugs using only HCPCS codes or only NDC numbers will be denied. Claims submitted with NDC numbers that do not correspond to the correct HCPCS codes will also be denied.



COLORADO
Department of Health Care
Policy & Financing

1570 Grant Street
Denver, CO 80203

October 6, 2016

Mr. Patrick J. Cogley
Regional Inspector General for Audit Services
Office of Audit Services, Region VII
601 E. 12th Street, Room 0429
Kansas City, MO 64106

Re: Report Number A-07-14-06050

Dear Mr. Cogley:

Enclosed is the Department of Health Care Policy and Financing's response to the U.S. Department of Health and Human Services, Office of Inspector General (OIG) draft report entitled *Colorado Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs*.

If you have any questions or need additional information, please contact Delora Hughes-Wise at 303-866-4155 or at delora.hughes-wise@state.co.us.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Donna Kellow', with a long horizontal flourish extending to the right.

Donna Kellow
Audits and Compliance Division Director

DK:dhw

Cc: Mr. Richard Allen, Associate Regional Administrator for
Medicaid & Children's Health Operations
Center for Medicare & Medicaid Services, Region VIII



Colorado Department of Health Care Policy and Financing
Response to OIG Report No. A-07-14-06050

**Colorado's Planned Improvements to Drug Rebate
Management System Meets Federal Requirements**

October 6, 2016

Recommendation 1:

Refund to the Federal Government \$5,229,604 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement.

Response:

The Department does not concur as we anticipate that all rebate-eligible drug units will be invoiced so no Federal funds will need to be refunded to CMS. The Department intends to begin invoicing for the drug rebates related to these claims in 1Q2017 in order to bring the Department into compliance with the Federal requirements for reimbursement for physician-administered drugs. The invoicing will be performed by a new vendor who will be providing an improved rebate management team and system. The Department will provide the Federal share of the collected rebates to CMS. In the event any rebate-eligible drug units cannot be invoiced, the Department will work with CMS to determine whether funds should be refunded based on the Federal share of the claim reimbursement or the Federal share of the uncollected rebate

Recommendation 2:

Refund to the Federal Government \$1,296,954 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement.

Response:

The Department does not concur as we anticipate that all rebate-eligible drug units will be invoiced so no Federal funds will need to be refunded to CMS. The Department intends to begin invoicing for the drug rebates related to these claims in 1Q2017 in order to bring the Department into compliance with the Federal requirements for reimbursement for physician-administered drugs. The invoicing will be performed by a new vendor who will be providing an improved rebate management team and system. The Department will provide the Federal share of the collected rebates to CMS. In the event any rebate-eligible drug units cannot be invoiced the Department will work with CMS to determine whether funds should be refunded based on the Federal share of the claim reimbursement or the Federal share of the uncollected rebate.

Recommendation 3a:

Work with CMS to determine the unallowable portion of \$1,293,696 (Federal share) for other claims for covered outpatient physician-administered drugs that were submitted without NDCs and that may have been ineligible for Federal reimbursement and refund that amount.

Response:

The Department concurs and will work with CMS to determine whether these claims include any rebate-eligible drug units and, if so, invoice them for rebates. The Department will provide the Federal share of the collected rebates to CMS. In the event any rebate-eligible drug units are identified but cannot be invoiced the Department will also work with CMS to determine whether

funds should be refunded based on the Federal share of the claim reimbursement or the Federal share of the uncollected rebate.

Recommendation 3b:

Work with CMS to determine whether the remaining \$317,343 (Federal share) of other physician-administered drug claims could have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims.

Response:

The Department concurs and will work with CMS to determine whether these claims include any rebate-eligible drug units and, if so, invoice them for rebates. The Department will provide the Federal share of the collected rebates to CMS. In the event any rebate-eligible drug units are identified but cannot be invoiced the Department will also work with CMS to determine whether funds should be refunded based on the Federal share of the claim reimbursement or the Federal share of the uncollected rebate.

Recommendation 4:

Work with CMS to determine and refund the unallowable portion of Federal reimbursement for physician-administered drugs that were not invoiced for rebates after December 31, 2012.

Response:

The Department concurs though we anticipate that all rebate-eligible drug units will be invoiced so no Federal funds will need to be refunded to CMS. The Department will provide the Federal share of the collected rebates to CMS. In the event any identified rebate-eligible drug units cannot be invoiced the Department will work with CMS to determine whether funds should be refunded based on the Federal share of the claim reimbursement or the Federal share of the uncollected rebate.

Recommendation 5:

Strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.

Response:

The Department concurs and is implementing a new Medicaid Management Information System (MMIS) on October 31, 2016 that will ensure rebate-eligible drug units for physician-administered drugs will be invoiced for rebates. The MMIS will require that all claims for physician-administered drugs include a National Drug Code (NDC) number otherwise the claim will not pay. Also, the physician-administered drug/NDC crosswalk will be significantly expanded and updated on a quarterly basis in the MMIS to ensure that the billed procedure code/NDC combinations are valid.