Department of Health and Human Services

**OFFICE OF INSPECTOR GENERAL**

# WYOMING CLAIMED UNALLOWABLE FEDERAL REIMBURSEMENT FOR SOME MEDICAID PHYSICIAN-ADMINISTERED DRUGS

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## EXECUTIVE SUMMARY

***Wyoming claimed $1.3 million over 3 years in Federal reimbursement that was unallowable and $93,000 that may have been unallowable because it did not comply with Federal Medicaid requirements for invoicing 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 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 Wyoming Department of Health, Division of Healthcare Financing (State agency), invoicing for rebates for physician-administered drugs for the period January 1, 2011, through December 31, 2013.

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 $2,613,862 ($1,306,931 Federal share) in physician-administered drugs. Of this amount, $2,327,828 ($1,163,914 Federal share) was for single-source drugs, and $286,034 ($143,017 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 $185,000 ($92,500 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 $438,552 ($219,276 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 $185,000 ($92,500 Federal share) of claims that were submitted without NDCs and (2) whether the remaining $438,552 ($219,276 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 $1,163,914 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;

- refund to the Federal Government $143,017 (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 $92,500 (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 $219,276 (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, 2013; and

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

## STATE AGENCY COMMENTS AND OUR RESPONSE

In written comments on our draft report, the State agency did not concur with our findings and disagreed with the monetary amounts specified in our draft report's first two recommendations. However, the State agency agreed to reprocess physician-administered drug claims and said that it would address any outstanding Federal match (that is, Federal share) that may be due.

The State agency based its nonconcurrence on three stated reasons: (1) that we had not removed from our calculations the physician-administered drug claims associated with all 340B facilities (entities that may under Federal statute purchase reduced-price covered outpatient drugs from manufacturers and whose drug claims are not eligible for rebates); (2) that manufacturers had not been given the required opportunity to make necessary adjustments and resolve disputes; and (3) that invoicing itself had not been finalized, which could result in inaccurate calculations of amounts due the Federal Government.

The State agency added that it was in the process of re-invoicing and reprocessing all physician-administered drug claims and that, with respect to our third and fourth recommendations, it would work with CMS to report the results of these efforts to identify an accurate Federal share. Finally, the State agency described corrective actions that it had taken or planned to take in response to our fifth recommendation.

The State agency followed up the transmittal of its written comments to us by separately providing us with an updated listing of 340B facilities that expanded upon the listing that the State agency had given to us during our audit. After reviewing the State agency's comments and that updated information, we adjusted our findings for this final report to account for the additional 340B providers that the State agency had now identified.

Other than this adjustment, though, we maintain that our findings and all recommendations as stated in this final report are valid. We recognize that the rebate process is fluid and ongoing, but as of the date we issued the draft report, the claims that are included in the findings' amounts had not been invoiced to the manufacturers. Part of this fluidity relates to manufacturers' disputes; however, this dispute process begins only after the invoices have been submitted to the manufacturers. Our findings indicated that invoices were not generated. Therefore, the dispute process would not yet have occurred. With respect to the physician-administered drug claims which the State agency has (since our issuance of the draft report) identified as being invoiced to manufacturers (and the related manufacturers' adjustments and disputes), the appropriate course of action is for the State agency to provide this information in detail to CMS during the audit resolution process after our issuance of this final 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 Wyoming Department of Health, Division of Healthcare Financing (State agency), invoicing for rebates for physician-administered drugs for the period January 1, 2011, through December 31, 2013.

## 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 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 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 the 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 section 1927(a)(7)(B)(i).

## HOW WE CONDUCTED THIS REVIEW

The State agency claimed $10,960,644 ($5,480,322 Federal share) for physician-administered drugs paid between January 1, 2011, and December 31, 2013.

We used the CMS Medicaid Drug File to determine whether the NDCs listed on the claims were classified as single-source drugs or multiple-source drugs. For claims submitted without an NDC, we matched the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk to identify the drug classification.[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 $2,613,862 ($1,306,931 Federal share) in physician-administered drugs. Of this amount, $2,327,828 ($1,163,914 Federal share) was for single-source drugs, and $286,034 ($143,017 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 $185,000 ($92,500 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 $438,552 ($219,276 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 $185,000 ($92,500 Federal share) of claims that

[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.

were submitted without NDCs and (2) whether the remaining $438,552 ($219,276 Federal share) of claims could have been invoiced to the manufacturers for rebates.

## FEDERAL AND STATE 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 *Wyoming Department of Health Public Health Insurance Program*, section 1.2, states that "Medicaid will update the manuals posted on the Medicaid/EqualityCare website.[7] Most of the changes come in the form of provider bulletins and Remittance Advice (RA) banners, although others may be newsletters or even letters from state officials" to communicate program policy change.

In addition, Wyoming's *EqualityCare News 07-001/07-013*, dated December 2007, states:

> … the Deficit Reduction Act of 2005 (DRA) made significant changes to the [Federal Medicaid drug rebate] program, including the requirement to invoice drug manufacturers for products administered in an *office, clinic, hospital, or other outpatient setting*.
>
> In order to meet the requirement of the DRA, state Medicaid programs must require their providers to report National Drug Codes (NDCs) on professional and institutional claims…. **With the publication of this bulletin, the requirement becomes effective for dates of service on and after March 1, 2008.** [Emphasis (in both quoted paragraphs) in original.]

Appendix C contains Federal and State requirements 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 $2,327,828 ($1,163,914 Federal share) for single-source physician-administered drug claims for which it did not invoice manufacturers for rebates.

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.

[7] Office of Inspector General note: In Wyoming, Medicaid is also called EqualityCare. Accordingly, the State agency's EqualityCare Web site is the online resource that contains Medicaid rules and guidance.

## 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 $286,034 ($143,017 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 $185,000 ($92,500 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 $438,552 ($219,276 Federal share), which contained NDCs, could have been eligible for rebates. If the State agency would have 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 $185,000 ($92,500 Federal share) of the claims that were submitted without NDCs and (2) whether the remaining $438,552 ($219,276 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 $1,163,914 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;

- refund to the Federal Government $143,017 (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 $92,500 (Federal share) for other claims for 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 $219,276 (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, 2013; 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 findings and disagreed with the monetary amounts specified in our draft report's first two recommendations. However, the State agency agreed to reprocess physician-administered drug claims and said that it would address any outstanding Federal match (that is, Federal share) that may be due.

The State agency offered three reasons why it did not concur with the amounts conveyed in our draft report's recommended refunds:

- The State agency said that when calculating claim details on physician-administered drugs (Appendix B), we had not removed all of the claims associated with all of the 340B facilities or entities.[8] (The State agency separately provided us detailed data on 340B facilities.)

- The State agency also said that drug manufacturers "… were not given the required opportunity to make necessary adjustments and disputes…. [M]anufacturers are allowed to dispute state utilization data per federal law."

[8] Under the 340B drug pricing program (set forth in 42 U.S.C. § 256b), a 340B entity may purchase reduced-price covered outpatient drugs from manufacturers; examples of 340B entities are disproportionate share hospitals, which generally serve large numbers of low-income and/or uninsured patients, and State AIDS drug assistance programs. Drugs subject to discounts under the 340B drug pricing program are not subject to rebates under the Medicaid drug rebate program. Section 1927(j) of the Act and 42 U.S.C. § 256(a)(5)(A).

- In addition, the State agency pointed out that invoicing to the manufacturers had not been finalized, "resulting in inaccurate Federal match liabilities."

The State agency added that it was in the process of re-invoicing and reprocessing all physician-administered drug claims and that, with respect to our third and fourth recommendations, it would work with CMS to report the results of these efforts to identify an accurate Federal share. Finally, the State agency described corrective actions that it had taken or planned to take in response to our fifth recommendation.

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

## OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing the State agency's comments and the updated listing of 340B facilities that it separately provided, we adjusted our findings for this final report to account for the 340B providers whose physician-administered drug claims we had not previously removed during our audit work. (The claims we removed were associated with newly identified 340B providers; one of these, for example, was located in a neighboring State (Utah) but furnished services to beneficiaries who lived in the State of Wyoming.) For this final report, we have removed the claims associated with these newly identified providers and adjusted the findings' amounts—that is, the amounts the State agency referred to as "Federal match liabilities"—accordingly.

Other than this adjustment, though, we maintain that our findings and all recommendations as stated in this final report are valid. We recognize that the rebate process is fluid and ongoing, but as of the date we issued the draft report, the claims that are included in the findings' amounts had not been invoiced to the manufacturers. Part of this fluidity relates to manufacturers' disputes; however, this dispute process begins only after the invoices have been submitted to the manufacturers. Our findings indicated that invoices were not generated. Therefore, the dispute process would not yet have occurred. With respect to the physician-administered drug claims which the State agency has (since our issuance of the draft report) identified as being invoiced to manufacturers (and the related manufacturers' adjustments and disputes), the appropriate course of action is for the State agency to provide this information in detail to CMS during the audit resolution process after our issuance of this final report.

## APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

| Report Title | Report Number | Date Issued |
|---|---|---|
| *South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs* | A-07-15-06059 | 2/09/16 |
| *Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs* | A-07-15-06062 | 1/14/16 |
| *North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs* | A-07-15-06058 | 1/13/16 |
| *California Claimed Unallowable Federal Medicaid Reimbursement by Not Billing manufacturers for Rebates for Some Physician-Administered Drugs* | A-09-14-02038 | 1/07/16 |
| *Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs* | A-07-14-06056 | 9/18/15 |
| *Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs* | A-07-14-06049 | 7/22/15 |
| *Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs* | A-06-12-00060 | 5/04/15 |
| *Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs* | A-07-14-06051 | 4/13/15 |
| *Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations* | A-09-13-02037 | 3/04/15 |
| *Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs* | A-06-14-00031 | 2/10/15 |
| *The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs* | A-03-12-00205 | 8/21/14 |
| *Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs* | A-07-13-06040 | 8/07/14 |
| *Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs* | A-09-12-02079 | 4/30/14 |

| Report Title | Report Number | Date Issued |
|---|---|---|
| *Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs* | A-09-12-02080 | 4/24/14 |
| *Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs* | A-03-12-00200 | 11/26/13 |
| *Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs* | A-06-12-00059 | 9/19/13 |
| *Nationwide Rollup Report for Medicaid Drug Rebate Collections* | A-06-10-00011 | 8/12/11 |
| *States' Collection of Medicaid Rebates for Physician-Administered Drugs* | OEI-03-09-00410 | 6/24/11 |

## APPENDIX B: AUDIT SCOPE AND METHODOLOGY

### SCOPE

The State agency claimed $10,960,644 ($5,480,322 Federal share) for physician-administered drugs paid between January 1, 2011, and December 31, 2013.

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 Cheyenne, Wyoming, from December 2014 to May 2015.

### 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, 2011, through December 31, 2013.
- We obtained the listing of 340B entities from the State agency.[9]

[9] See footnote 8.

- We removed drug claims totaling $7,723,230 ($3,861,615 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 $3,237,414 ($1,618,707 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 NDC on the drug claim to the NDC on CMS's Medicaid Drug File. For claims submitted without an NDC, we matched the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk to identify the drug classification.

    - 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 other multiple-source drugs by matching the NDC on the drug claim to the NDC on the CMS Medicaid Drug File. For claims submitted without an NDC, we matched the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk to identify the drug classification.

- We discussed the results of our review with State agency officials on July 13, 2015.

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

## APPENDIX C: FEDERAL AND STATE REQUIREMENTS 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 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.

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 REQUIREMENTS AND GUIDANCE

Wyoming's *EqualityCare News 07-001/07-013*, dated December 2007, states:

> … the Deficit Reduction Act of 2005 (DRA) made significant changes to the [Federal Medicaid drug rebate] program, including the requirement to invoice drug manufacturers for products administered in an *office, clinic, hospital, or other outpatient setting*.
>
> In order to meet the requirement of the DRA, state Medicaid programs must require their providers to report National Drug Codes (NDCs) on professional and institutional claims …. **With the publication of this bulletin, the requirement becomes effective for dates of service on and after March 1, 2008.** [Emphasis (in both quoted paragraphs) in original.]

This requirement became effective March 1, 2008, and was thus in effect for our entire audit period.

Wyoming Department of Health

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**Thomas O. Forslund, Director** **Governor Matthew H. Mead**

November 30, 2015

TG-2015-043

Mr. Patrick J. Cogley
Regional Inspector General for Audit Services
60 1 East 12 Street
Room 0429
Kansas City, MO 64106

Re: Report Number A-07-15-06063

Dear Mr. Cogley:

Wyoming Medicaid Division of Health Care Financing (DHCF) appreciates the opportunity to respond to the Department of Health and Human Services, Office of Inspector General (OIG) draft audit report titled "Wyoming Claimed Unallowable Federal Reimbursements for Some Medicaid Physician-Administered Drugs."

Wyoming Medicaid's response to the preliminary finding and recommendations identified in the draft audit report are listed below.

**Response to Finding (page 3):**

**Finding:**

"The State did not invoice manufacturers for rebates associated with $2,676,018 ($1,338,009 Federal share) in physician-administered drugs."

**DHCF does not concur with finding**

The DHCF does not concur with the State's liability for the Federal share for the following reasons:

- Claims for all 340B facilities were not removed
- Manufacturers were not given the required opportunity to make necessary adjustments and disputes
- Invoicing has not been finalized resulting in inaccurate Federal match liabilities

The OIG's figure for Federal match is not accurate based on the reasons stated above.

DHCF is re-invoicing and reprocessing all physician-administered claims, addressing the above bullet points and supplying the necessary rebate utilization data; however, manufacturers are allowed to dispute state utilization data per federal law.

This action will address any outstanding Federal match that may be due in an accurate and complete manner.

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**Recommendation (page 3):**

"refund to the Federal Government $1,194,974 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;"

The Federal share identified is inaccurate. Wyoming will refund the Federal share for un-invoiced claims for single-source physician-administered drugs after Manufacturers are afforded the opportunity to review utilization data and make Federally allowed adjustments and disputes.

**Recommendation (page 4):**

"refund to the Federal Government $143,035 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement;"

The Federal share identified is inaccurate. The state will refund the Federal share for un-invoiced claims for top-20 multiple-source physician-administered drugs after Wyoming reprocesses the claims, ensuring providers submit NDC information and Manufacturers are afforded the opportunity to review utilization data and make Federally allowed adjustments and disputes.

**Recommendation (page 4):**

"Work with CMS to determine:

- The unallowable portion of $92,596 (Federal share) for other claims for 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 $227,759 (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 manufactures' rebate for those claims;"

Wyoming will work with CMS to report results of re-invoicing and reprocessing claims to identify an accurate Federal share after Manufacturers are afforded the opportunity to review utilization data and make Federally allowed adjustments and disputes.

**Recommendation (page 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, 2013;"

Wyoming will work with CMS to report results of re-invoicing and reprocessing claims to identify an accurate Federal share.

**Recommendation (page 4):**

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

Wyoming maintains a focus on integrity and compliance. We appreciate the OIG's support of our compliance efforts and look forward to ensuring accurate Federal match figures are obtained and reported. The DHCF is actively working to strengthen controls and processes to ensure drug manufacturers are appropriately billed for physician-administered drug rebates. As of this date the following controls and processes have been implemented to ensure compliance to federal law, policies, and procedures:

- As of July 1, 2015 Wyoming required submission of NDCs for all outpatient physician-administered drug claims. The current Wyoming Fiscal Agent (Xerox) is required to obtain all missing or omitted NDCs on legacy outpatient physician-administered drug claims.

- Wyoming implemented a process to retro-invoice all outpatient physician-administered drug claims. The current Wyoming Fiscal Agent (Xerox) is required to make all physician-administered drug rebate invoicing corrections prior to June 30, 2016.
- Goold Health Systems (GHS) has been contracted as the Wyoming State Fiscal Agent for pharmacy services. GHS will be invoicing all rebates for physician-administered drugs effective July 1, 2016.

The Division of Healthcare Financing is prepared for on-going communications with the OIG until full accountability and accuracy is achieved for the audit finding and recommendations.

Sincerely,

Teri Green
State Medicaid Agent
Wyoming Department of Health

TG/mg

c: Lindsey Schilling, Provider Operations Administrator, Division of Healthcare Financing
Cori Cooper, Pharmacy Services Manager, Division of Healthcare Financing
Mark Gaskill, Quality Assurance Manager, Division of Healthcare Financing
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