Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

UTAH CLAIMED UNALLOWABLE FEDERAL REIMBURSEMENT FOR SOME MEDICAID PHYSICIAN-ADMINISTERED DRUGS

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Office of Inspector General

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EXECUTIVE SUMMARY

Utah claimed $4.4 million over 3 years in Federal reimbursement that was unallowable and $73,000 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 (OIG) review found that States did not always invoice and collect all rebates due for drugs administered by physicians. For this audit, we reviewed the Utah Department of Health, Division of Medicaid and Health 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 $6,187,741 ($4,387,284 Federal share) in physician-administered drugs. Of this amount, $5,189,057 ($3,678,539 Federal share) was for single-source drugs, and $998,684 ($708,745 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 $103,559 ($73,259 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 $1,589,937 ($1,128,492 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 $103,559 ($73,259 Federal share) of claims that were submitted without NDCs and (2) whether the remaining $1,589,937 ($1,128,492 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 $3,678,539 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;

- refund to the Federal Government $708,745 (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 $73,259 (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 $1,128,492 (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

State Agency Comments

In written comments on our draft report, the State agency concurred with the second part of our third recommendation and with our fourth and fifth recommendations. The State agency said that it has pursued and is pursuing rebates from manufacturers, but it did not concur with our first two recommendations or with the first part of our third recommendation. The State agency also described corrective actions that it had taken or planned to take to strengthen its internal controls.

The State agency cited three principal reasons for not concurring with some of our recommendations. First, the State agency pointed out that it requires providers to submit NDC-level detail with their claims for physician-administered drugs and stated that we misapplied Federal requirements when we recommended refunds of the Federal share of the claims that we identified as ineligible for Federal reimbursement. Second, the State agency said that although it continues to invoice manufacturers for rebates, it has determined that a number of the claims in question were either duplicate claims or Medicare crossover claims (which involve beneficiaries who are eligible for both Medicare and Medicaid). The State agency said that for these Medicare crossover claims, CMS guidelines specify that State Medicaid agencies do not have an option to deny coverage and must reimburse providers for the Medicare cost-sharing amount. Third, the State agency suggested that rather than recommending refunds of the Federal share of the claims in question, a "more fitting approach" would be for us to follow the lead of a similar OIG review of another State's Medicaid drug rebate program in which the recommendation was to set aside the amounts not billed for rebates for CMS resolution.

Our Response

After reviewing the State agency's comments, we adjusted some of the costs for this final report, where appropriate, to reflect the duplicate claims that the State agency had identified. Otherwise, we disagree with all three of the principal reasons the State agency gave for not concurring with some of our recommendations. Specifically, we disagree that we misapplied relevant Federal requirements and continue to recommend that the State agency refund the Federal share of the claims for single-source and top-20 multiple-source physician-administered drugs. Federal Medicaid requirements related to the collection of rebates for specified categories of physician-administered drugs are well established and permit the disallowance of Federal reimbursement for claims not invoiced for rebate. These requirements are separate from the requirements related to State Medicaid agencies' obligations to reimburse providers for cost-sharing amounts associated with Medicare crossover claims.

We agree with the State agency's remarks about certain issues surrounding crossover claims. We plan to address the challenges associated with States' processing of crossover claims, and identify ways in which States can more easily ensure the proper invoicing of these claims, in a separate report to CMS.

With respect to the physician-administered drug claims that the State agency has (since our exit conference) identified as being invoiced to manufacturers, 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. CMS may, at its discretion, determine that by returning the Federal share of recovered rebates, the State agency would not be required to refund the Federal share of the applicable drug claims.

With respect to the State agency's suggestion that we set aside, rather than disallow, the amounts not billed for rebates, the OIG review that the State agency cited was similar to this review in that it also involved physician-administered drugs. However, that review did not reflect the findings and recommendations identified during this review. Moreover, our recommendations in this report are consistent with recommendations in other related OIG reports. In light of all of these considerations, we continue to maintain that our findings and recommendations—as modified to reflect our removal of the duplicate claims discussed above—remain 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 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 (OIG) 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 Utah Department of Health, Division of Medicaid and Health 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

[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.

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. 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 $47,977,668 ($33,904,846 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 multi-source drugs.

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 $6,187,741 ($4,387,284 Federal share) in physician-administered drugs. Of this amount, $5,189,057 ($3,678,539 Federal share) was for single-source drugs, and $998,684 ($708,745 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 $103,559 ($73,259 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 $1,589,937 ($1,128,492

[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.

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 $103,559 ($73,259 Federal share) of claims that were submitted without NDCs and (2) whether the remaining $1,589,937 ($1,128,492 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 Utah Department of Health, *Medicaid Information Bulletin*, April 2008, stated that providers "billing physician-administered drugs … must report the NDC of the product." In addition, "[c]laims that do not include the NDC code will be denied for payment."

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 $5,189,057 ($3,678,539 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.

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 $998,684 ($708,745 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 $103,559 ($73,259 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 $1,589,937 ($1,128,492 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 $103,559 ($73,259 Federal share) of the claims that were submitted without NDCs and (2) whether the remaining $1,589,937 ($1,128,492 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 $3,678,539 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;

- refund to the Federal Government $708,745 (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 $73,259 (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 $1,128,492 (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 concurred with the second part of our third recommendation and with our fourth and fifth recommendations. The State agency said that it has pursued and is pursuing rebates from manufacturers, but it did not concur with our first two recommendations or with the first part of our third recommendation. The State agency also described corrective actions that it had taken or planned to take to strengthen its internal controls.

The State agency cited three principal reasons for not concurring with some of our recommendations:

- The State agency pointed out that it requires providers to submit NDC-level detail with their claims for physician-administered drugs and stated that we misapplied Federal requirements when we recommended refunds of the Federal share of the claims that we identified as ineligible for Federal reimbursement. Specifically, the State agency agreed that it is required by section 1927(a)(7) of the Act and 42 CFR § 447.520 to require providers to submit NDCs for physician-administered drugs, and it believes it has complied with these requirements. Therefore, the penalty contained in 42 CFR § 447.520, which may be imposed when a State does not require submission of the NDCs, is, according to the State agency, not applicable to the line items (claims) reviewed for this audit. The State agency added that it required providers to report NDCs and acknowledged that not all providers complied with this requirement.

- The State agency also stated that although it continues to invoice manufacturers for rebates, it has determined that a number of the claims in question were either duplicate claims or Medicare crossover claims.[7] The State agency said that for these Medicare

[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*

crossover claims, CMS guidelines have given State Medicaid agencies "clear direction" that they must reimburse providers for the Medicare cost-sharing amount "'*without regard to whether the costs incurred were for items and services for which medical assistance is otherwise available under the plan*.'"[8] The State agency said that accordingly, it does not have an option to deny coverage for these crossover claims.

- Finally, the State agency suggested that rather than recommending refunds of the Federal share of the claims in question, a "more fitting approach" would be for us to follow the lead of another OIG physician-administered drugs review of Idaho's Medicaid drug rebate program (A-09-12-02079; see Appendix A). The State agency said that the findings in that audit were "substantially similar" to our findings in this report and pointed out that we recommended that the amounts that Idaho did not bill for rebates be set aside for CMS resolution rather than refunded to the Federal Government.

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 adjusted some of the costs for this final report, where appropriate, to reflect the duplicate claims that the State agency had identified. Otherwise, we disagree with all three of the principal reasons the State agency gave for not concurring with some of our recommendations. Specifically:

- We disagree that we misapplied relevant Federal requirements and continue to recommend that the State agency refund the Federal share of the claims for single-source physician-administered drugs (our first recommendation) and top-20 multiple-source physician-administered drugs (our second recommendation) and that it work with CMS to determine the unallowable portion of the other claims for outpatient physician-administered drugs that were submitted without NDCs and refund that amount (the first part of our third recommendation). Federal Medicaid requirements related to the collection of rebates for single-source and top-20 multiple-source physician-administered drugs (both statutory and regulatory) are well established and permit the disallowance of Federal reimbursement for claims not invoiced for rebate.[9] These requirements are separate from the requirements related to State Medicaid agencies' obligations to reimburse providers for cost-sharing amounts associated with Medicare crossover claims.

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).*

[8] The State agency's written comments cite the Jun. 7, 2013, Informational Bulletin. The emphasis is in the original; the quoted phrase appears on pages 1 – 2 of that Informational Bulletin.

[9] For example, section 1903(i)(10) of the Act prohibits Medicaid Federal share for specified covered outpatient drugs administered by a physician unless the utilization and coding information required under section 1927(a)(7) is submitted.

We agree with the State agency's remarks about certain issues surrounding crossover claims. We plan to address the challenges associated with States' processing of crossover claims, and identify ways in which States can more easily ensure the proper invoicing of these claims, in a separate report to CMS.

- With respect to the physician-administered drug claims that the State agency has identified as being invoiced to manufacturers, 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. As of our exit conference with the State agency, these claims had not been invoiced to the manufacturers to receive rebates and therefore did not comply with Federal requirements. As part of the audit resolution process, CMS may, at its discretion, determine that by returning the Federal share of recovered rebates, the State agency would not be required to refund the Federal share of the applicable drug claims.

- With respect to the State agency's suggestion that we set aside, rather than disallow, the amounts not billed for rebates, the OIG review that the State agency cited (of Idaho's Medicaid drug rebate program) was similar to this review in that it also involved physician-administered drugs. However, that review did not reflect the findings and recommendations identified during this review. Moreover, our recommendations in this report are consistent with recommendations in other related OIG reports. (A complete list of OIG reports involving physician-administered drugs is contained in Appendix A.)

In light of all of these considerations, we continue to maintain that our findings and recommendations—as modified to reflect our removal of the duplicate claims discussed above—remain valid.

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-15-06063	3/31/16
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

Report Title	Report Number	Date Issued
Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs	A-09-12-02079	4/30/14
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 $47,977,668 ($33,904,846 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 Salt Lake City, Utah, from July 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 removed drug claims totaling $39,882,911 ($28,165,280 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 $8,094,757 ($5,739,566 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 in which the claim's NDC did not match to the Drug File, 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 in which the claim's NDC did not match to the Drug File, 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 removed additional drug claims totaling $213,520 ($150,532 Federal share) that were not eligible for drug rebates.

- We discussed the results of our review with State agency officials on May 28, 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 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 REQUIREMENTS AND STATE AGENCY GUIDANCE

The *Utah Medicaid Provider Manual*, section I, "General Information," states: "Fee-for-service providers must follow the scope of service, policies, procedures and processes in the Utah Medicaid Program Provider Manual and Medicaid Information Bulletins."

Through the Utah Department of Health, *Medicaid Information Bulletin,* April 2008, the State agency notified providers that:

> [t]he Deficit Reduction Act of 2005 (DRA) includes new provisions regarding state collection of data for the purpose of collecting Medicaid drug rebates from drug manufacturers for physician-administered drugs …. In order for Federal Financial Participation (FFP) to be available for these drugs, the state must provide collection and submission of utilization data in order to secure rebates. Since there are often several NDCs linked to a single Healthcare Common Procedure Coding System (HCPCS) code, the Centers for Medicare and Medicaid Services (CMS) deems that the use of NDC numbers is critical to correctly identify the drug and manufacturer in order to invoice and collect the rebates.
>
> Effective July 1, 2008, ESRD [end-stage renal disease] centers and outpatient hospital departments (excluding emergency rooms) billing physician-administered drugs with Revenue Code 0251, 0252, 0257-0259, 0634, or 0635 must report the NDC of the product …. Medicaid requires reporting the appropriate Revenue Code, HCPCS, and NDC relating to the physician-administered drug.

The Utah Department of Health, *Medicaid Information Bulletin*, April 2008, also specified that "[t]he NDC must be entered with 11 digits in a 5-4-2 digit format."

In addition, through the Utah Department of Health, *Medicaid Information Bulletin*, April 2008, the State agency notified providers that "[c]laims that do not include the NDC code will be denied for payment."

State of Utah

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Governor

SPENCER J. COX
Lieutenant Governor

Utah Department of Health

JOSEPH K. MINER, MD, MSPH, FACPM
Executive Director

Division of Medicaid and Health Financing

MICHAEL HALES
Deputy Director, Utah Department of Health
Director, Division of Medicaid and Health Financing

December 21, 2015

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

Dear Mr. Cogley:

Thank you for the opportunity to respond to the audit entitled *Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs* (Report # A-07-14-06057). We appreciate the effort and professionalism of you and your staff in this review. Likewise, our staff has spent time collecting information for your review, answering questions, and planning changes to improve the program. We believe that the results of our combined efforts will make a better, more efficient program.

We concur with some of the recommendations in this report. Our response describes the actions the State has already taken and those the State is planning to take in the future. The State is committed to the efficient and effective use of taxpayer funds and values the insight this report provides on areas that need improvement.

Sincerely,

Michael Hales
Deputy Director, Department of Health
Division Director, Medicaid and Health Financing

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Response to Recommendations

Recommendation 1:

We recommend that the State agency refund to the Federal Government $3,693,358 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement.

State Response:

The State does not concur with this recommendation. The State agrees that it is required by Section 1927(a)(7) to require providers to submit NDCs for physician-administered drugs. The State also agrees that this requirement to require providers to submit NDCs for those drugs is repeated in 42 CFR § 447.520 which also creates a penalty for states that do not require the submission of NDCs. The penalty created by that regulation for failure to require the submission of the NDCs is a loss of FFP.

The State has complied with this requirement as acknowledged on pages 4 and 11 of the draft audit. The April 2008 Medicaid Information Bulletin states the following: "Effective May 1, 2008, all HCPCS codes beginning with "J" and some "A, Q, K or S" codes that are associated with drugs (Codes available at http://health.utah.gov/medicaid/stplan/bcrp.htm) require reporting the NDC." Therefore the penalty contained in 42 CFR § 447.520, which may be imposed when a state does not require the submission of the NDCs, is not applicable to the line items in the audit. Although the State did require providers to report the NDC code, the State acknowledges that not all providers complied with this requirement.

The State acknowledges that Section 1927(b)(6) requires it to report the information to manufacturers no later than 60 days after the end of each rebate period. While the State has substantially complied with this requirement, there have been a limited number of instances when the State has not timely met this 60 day requirement. The State notes that Section 1927(b)(6) does not provide for a penalty if a state does not timely meet the 60 day billing date. The State is unable to find a federal regulation that provides for a penalty when a state does not timely meet the 60 day billing date required by Section 1927(b)(6).

The State believes it is a misapplication of law to impose a specific penalty tied to the failure of a state to require providers to submit NDCs contained in 42 CFR § 447.520 to a different requirement of billing manufacturers found in Section 1927(b)(6) because that Section does not contain authority to impose a penalty when a state does not timely comply with that Section.

Furthermore, the State has pursued and is pursing rebates, even in those limited circumstances when the bill is submitted to manufacturers beyond the 60 day deadline. As required, the State will return the federal share as the rebates are received. However, the State is not aware of a requirement to repay the federal share of the claim as recommended by the audit while also returning the federal share when rebates are recovered for the same line items.

The State believes the more fitting approach is the approach taken by HHS OIG in its recommendations to Idaho in the April 2014 audit entitled "Idaho did not bill manufacturers for rebates for some Medicaid physician-administered drugs." A-09-12-02079.

The findings in that audit are substantially similar to those findings in the Utah draft audit. These findings state that during "CY 2010, the State agency did not always comply with the Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs." See page 4 of the Idaho Audit. These findings are substantially similar to findings contained on page 3 of the Utah audit which provides that the "State agency did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs."

The Idaho findings state because the "State agency did not bill manufacturers for rebates associated with $2,636,804 ($1,825,685 Federal share), we are setting aside this amount for CMS resolution." See page 4 of the Idaho Audit. The approach taken by HHS OIG in Idaho is reasonable in light of the circumstances that the state was working with its contractor to bill manufacturers in circumstances where the Section 1927(b)(6) deadline was not met but the state still had collected the information and had the ability to still bill manufacturers.

Utah's situation is similar. Utah requires providers to submit NDC codes in compliance with Section 1927(a)(7) and has pursued drug rebates for claim lines identified in the audit as detailed below. Therefore, the same reasonable approach applied in Idaho should also be applied to Utah.

The State has completed invoicing for 4,859 of the 6,631 claim lines for single source drugs identified by the OIG for this audit. The 4,859 claim lines accounted for $4,536,509 ($3,216,385 Federal share estimate) of the proposed $5,210,162 ($3,693,358 Federal share estimate) overpayment.

Of the 1,732 claim lines for single source drugs, as identified by the OIG, for which the State has been unsuccessful, to date, in invoicing for the drug rebate, the State has identified that 715 claim lines, totaling $180,561 ($128,018 Federal share estimate) were Medicare crossovers. CMS has given the State clear direction that the state must reimburse providers for the Medicare cost sharing amount *"without regard to whether the costs incurred were for items and services for which medical assistance is otherwise available under the plan."*[1] CMS further clarifies "...a Medicaid agency's obligation to adjudicate and reimburse providers for QMB cost sharing exists even if the service or item is not covered by Medicaid, irrespective of whether the provider type is recognized in the State Plan and whether or not the QMB is eligible for coverage of Medicaid state plan services." As the State does not have an option to deny coverage for these single source claim lines, the State disagrees that these claim lines should be identified as containing ineligible payments.

[1] CMCS – MMCO – CM Information Bulletin: Payment of Medicare Cost Sharing for Qualified Medicare Beneficiaries (QMBs); June 7, 2013.

Furthermore, the State has identified that the OIG audit data for this recommendation contained numerous instances of multiple findings for the same claim lines. The data contained 1 instance where the same TCN and line number was counted as 3 separate errors and 38 additional instances where the same TCN and line number was counted as 2 separate errors. The following OIG IDs associated with this recommendation are involved with the duplicate findings:

Rec 1 OIG IDs Associated w Duplicate Findings			
1440	97048	177777	243630
8409	104404	178085	244918
8790	105138	184297	249439
10599	106376	186319	254709
17659	111317	189024	257835
31331	112521	190596	258859
33824	120142	191250	260174
38216	120294	214793	260840
38688	135754	219595	272436
40179	140759	222981	272881
43041	145731	223662	279287
49377	148393	225319	283037
68665	156607	226598	283178
73880	156817	228926	287063
77801	160245	230440	287743
81650	161785	231107	288934
82223	169776	232377	289138
87865	174215	235152	289544
92835	176679	239667	292030
96360	177329	241851	

Excluding the previously invoiced claim lines, Medicare crossover claim lines and duplicate findings for the same claim line, the State will continue to pursue drug rebates on the remaining 1,017 claim lines, totaling $471,987 ($334,639 Federal share estimate).

Recommendation 2:

We recommend that the State agency refund to the Federal Government $708,765 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement.

State Response:

The State does not concur with this recommendation. Please see the State's response to recommendation 1 for more detailed explanation as to why the State does not agree.

The State has completed invoicing 9,190 of the 11,509 claim lines for Top 20 multisource drugs identified by the OIG for this audit. The 9,190 claim lines accounted for $904,183 ($641,679 Federal share estimate) of the proposed $998,713 ($708,765 Federal share estimate) overpayment.

Of the 2,319 claim lines for Top 20 multisource drugs, as identified by the OIG, for which the State has been unsuccessful, to date, in invoicing for the drug rebate, the State has identified that 236 claim lines, totaling $2,713 ($1,926 Federal share estimate) were Medicare crossovers. As the State explained in its response to recommendation 1, because the State does not have an option to deny coverage for these Top 20 multisource claim lines, the State disagrees that these claim lines should be identified as containing ineligible payments.

The State would also like to highlight CMS commentary on the Top 20 multisource drugs. The CMS website: http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/state-prescription-drug-resources.html contains the following language:

> **Physician Administered Drugs**
>
> The Deficit Reduction Act of 2005 (DRA) requires States to collect Medicaid rebates for certain physician-administered drugs. Beginning January 1, 2006, States must collect utilization data for single source, physician-administered drugs in order to secure rebates for such drugs. Effective January 1, 2007, States must also collect National Drug Codes (NDC) for the 20 multiple source physician-administered drugs with the highest dollar volume in Medicaid. Beginning January 1, 2008, the DRA provides that States not collecting NDCs on these 20 drugs will not receive Federal matching payments for the drugs unless they receive a hardship waiver. For further information on this part of the DRA, please see the SMD letter on physician-administered drugs.
>
> We are proposing to stop publishing the "Top 20 multiple source physician-administered drugs" on the Medicaid.gov website. Previously, this listing was available for States to use when requiring providers to place National Drug Codes (NDCs) on claims for at least the top 20 multiple source drugs, in addition to all other physician-administered drugs.
>
> After a thorough search of the limited highest dollar volume Medicaid multiple source drugs, we discovered that most of the drugs were low-cost products and would not effectively represent a benefit to the States in rebate collection. Further, we believe the State impact in removing the top 20 listing will be minimal, as virtually all States do not limit NDC numbers on claims for only these drugs, but require NDC submission for all physician-administered drugs.

If you have comments on this proposal, please submit them to Joseph Fine at joseph.fine@cms.hhs.gov.

Furthermore, the State has identified that the OIG audit data for this recommendation contained two instances of multiple findings for the same claim lines. The following OIG IDs associated with this recommendation are involved with the duplicate findings:

Rec 2 OIG IDs Associated w Duplicate Findings			
90816	243311	252861	290764

While the State was able to identify that both of the duplicate errors impact the number of uninvoiced claim lines, one of the duplicate lines was a crossover claim. The State requests that the duplicate line be removed from the audit on that basis. The second claim accounted for $2 of the proposed overpayment.

Excluding the previously invoiced claim lines and the Medicare crossover claim lines, the State will continue to pursue drug rebates on the remaining 2,082 claim lines, totaling $91,790 ($65,171 Federal Share estimate).

Recommendation 3.1:

We recommend that the State agency work with CMS to determine the unallowable portion of $73,259 (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.

State Response:

The State does not concur with this recommendation for the following reasons. First, as previously mentioned in the State's response to recommendation 1, the state's policy *did* require providers to submit the NDC with the claim. Some providers did not comply with the State's policy. Second, of the 8,423 claim lines for drugs identified in this recommendation, for which the State has been unsuccessful, to date, in invoicing for the drug rebate, the State has identified that 588 claim lines, totaling $7,478 ($5,287 Federal share estimate) were Medicare crossovers. As the State explained in its response to recommendation 1, because the State does not have an option to deny coverage for these claim lines, the State disagrees that these claim lines should be identified as containing ineligible payments.

Recommendation 3.2:

We recommend that the State agency work with CMS to determine whether the remaining $1,128,492 (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.

State Response:

The State concurs with this recommendation. In fact, the State has already completed invoicing 31,389 of the 34,723 claim lines for drugs identified by the OIG for this recommendation. The 31,389 claim lines accounted for $1,502,974 ($1,067,112 Federal share estimate) of the $1,589,936 ($1,128,492 Federal share estimate) total dollars identified. The State will refund the Federal share of the manufacturers' rebates for these claims once the rebates are received from the manufacturers.

Recommendation 4:

We recommend that the State agency 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.

State Response:

The State concurs with this recommendation. While the State does not believe there to be additional uninvoiced claim lines, the State welcomes the opportunity to work with CMS to ensure all available drug rebates have been invoiced to manufacturers.

Recommendation 5:

We recommend that the State agency strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.

State Response:

The State concurs with this recommendation. The State has already taken a number of steps to ensure all claims for drug rebate eligible medications are invoiced for the drug rebate.

The first initiative the State has undertaken is to create, and implement, a NDC to HCPCS crosswalk for medical claims processing. If a provider submits a claim for an invalid NDC to HCPCS match then the claim will deny. This crosswalk ensures that the State only pays for active and rebatable drugs. The crosswalk was implemented on October 1, 2015.

The second initiative the State has pursued is contracting the operations of the drug rebate program to Goold Health Systems (GHS). Leveraging the expertise of GHS for day-to-day operations of the drug rebate program will ensure that the State invoices manufacturers for all rebate eligible claims. The contract is effective January 1, 2016.