Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

SOUTH DAKOTA CLAIMED UNALLOWABLE FEDERAL REIMBURSEMENT FOR SOME MEDICAID PHYSICIAN-ADMINISTERED DRUGS

Inquiries about this report may be addressed to the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

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Office of Inspector General

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EXECUTIVE SUMMARY

South Dakota claimed $1.2 million over 3 years in Federal reimbursement that was unallowable and $40,000 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 South Dakota Department of Social Services (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 $2,086,423 ($1,206,454 Federal share) in physician-

administered drugs. Of this amount, $1,628,175 ($940,648 Federal share) was for single-source drugs, and $458,248 ($265,806 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 $66,858 ($39,813 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 $1,966,300 ($1,143,080 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 $66,858 ($39,813 Federal share) of claims that were submitted without NDCs and (2) whether the remaining $1,966,300 ($1,143,080 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 $940,648 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;

- refund to the Federal Government $265,806 (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 $39,813 (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 $1,143,080 (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 all of the amounts (recommended refunds to the Federal Government as well as funds set aside for resolution by CMS and the State agency) in our findings and recommendations. However, the State agency concurred in general terms that additional rebates could have been collected, and also described corrective actions that it had taken or planned to take.

Specifically, the State agency did not agree with the amounts of the refunds specified in our first three recommendations because, it said, the amounts were primarily related to Medicare crossover claims (which involve beneficiaries who are eligible for both Medicare and Medicaid). The State agency said that the Medicare program does not require NDC- or procedure-code-level detail necessary for States to facilitate the rebate process for drugs subject to rebate, and suggested that CMS should make Medicare requirements consistent with Medicaid requirements in mandating this level of detail. The State agency added that additional rebates could have been recovered had it received all necessary procedure codes and NDCs from Medicare crossover claims to facilitate the drug rebate submission process. The State agency also said that it has sought to recover those rebates directly from manufacturers after obtaining the information necessary to facilitate the process.

The State agency also stated that within the scope of its control, it had implemented "additional safeguards" requiring providers to include NDCs and procedure codes on all professional claims and would deny those claims for payment if this information is not contained in the crossover claims received from Medicare. The State agency also said that it is working to submit any claims eligible for rebate to the manufacturers for rebate purposes and that it would refund the applicable Federal share to CMS. In this context, the State agency concurred with our fourth recommendation and said that it would work with CMS to identify whether any portion of these crossover claims include drugs subject to rebate and that it would pursue rebates for those drugs as applicable.

After reviewing the State agency's comments, we maintain that all of our findings and recommendations are valid. The State agency pointed out that most of the claims identified in this report were crossover claims and did not contain NDCs in the utilization data. We agree with the State agency's remark, in its written comments, that the issue of crossover claims "… is common among many [State] Medicaid programs." In fact, we plan to address the challenges associated with States' processing of crossover claims, and identify possible ways in which States can more easily identify the NDCs associated with such physician-administered drug claims, in a separate report to CMS. However, unless CMS changes the Medicare requirements to mandate that providers include the NDCs on Medicare claims, the State agency will need to develop procedures for crossover claims at its level to comply with Medicaid drug rebate requirements. We commend the State agency as it has committed to implementing additional procedures to ensure that Medicaid drug rebates are collected for crossover claims.

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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 South Dakota Department of Social Services (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.

HOW WE CONDUCTED THIS REVIEW

The State agency claimed $8,718,302 ($5,067,666 Federal share) for physician-administered drugs paid between January 1, 2011, and December 31, 2013.

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[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).

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 $2,086,423 ($1,206,454 Federal share) in physician-administered drugs.[7] Of this amount, $1,628,175 ($940,648 Federal share) was for single-source drugs, and $458,248 ($265,806 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 $66,858 ($39,813 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 $1,966,300 ($1,143,080 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

[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.

[7] Most of these drug claims for single-source, top-20 multiple-source, and other physician-administered drugs were for crossover claims, which involve beneficiaries who are eligible for both Medicare and Medicaid. The majority of these claims are paid by Medicare and then sent to Medicaid for payment toward the Medicare deductible and coinsurance (within Medicaid program limits).

(1) the unallowable portion of the $66,858 ($39,813 Federal share) of claims that were submitted without NDCs and (2) whether the remaining $1,966,300 ($1,143,080 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).

In a letter to South Dakota Medicaid prescribing providers, issued on December 10, 2007, the State agency stated: "… all state Medicaid agencies require providers who use a drug-related Healthcare Common Procedure Coding System (HCPCS) J-code when billing prescription drug products to include the relevant National Drug Code (NDC) of the drug dispensed."

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 $1,628,175 ($940,648 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 $458,248 ($265,806 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 $66,858 ($39,813 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 $1,966,300 ($1,143,080 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 $66,858 ($39,813 Federal share) of the claims that were submitted without NDCs and (2) whether the remaining $1,966,300 ($1,143,080 Federal share) of other physician-administered drugs 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 $940,648 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;

- refund to the Federal Government $265,806 (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 $39,813 (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 $1,143,080 (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 all of the amounts (recommended refunds to the Federal Government as well as funds set aside for resolution by CMS and the State agency) in our findings and recommendations. However, the State agency concurred in general terms that additional rebates could have been collected, and also described corrective actions that it had taken or planned to take.

Specifically, the State agency did not agree with the amounts of the refunds specified in our first three recommendations because, it said, the amounts were primarily related to Medicare crossover claims (footnote 7). The State agency said that the Medicare program does not require NDC- or HCPCS-code-level detail necessary for States to facilitate the rebate process for drugs subject to rebate, and suggested that CMS should make Medicare requirements consistent with Medicaid requirements in mandating this level of detail. "While [the State agency] can require this information be included on the claim for Medicaid payment and has done so in its Medicaid Management Information System (MMIS), the primary payer, Medicare, should be consistent if Medicaid is charged with the drug rebate process for Medicare primary claims." The State agency added that additional rebates could have been recovered had it received all necessary HCPCS codes and NDCs from Medicare crossover claims to facilitate the drug rebate submission process. The State agency also said that it has sought to recover those rebates directly from manufacturers after obtaining the information necessary to facilitate the process.

The State agency also stated that within the scope of its control, it had implemented "additional safeguards" requiring providers to include NDCs and HCPCS codes on all professional claims and would deny those claims for payment if this information is not contained in the crossover claims received from Medicare. The State agency also said that it is working to submit any claims eligible for rebate to the manufacturers for rebate purposes and that it would refund the applicable Federal share to CMS. In this context, the State agency concurred with our fourth recommendation and said that it would work with CMS to identify whether any portion of these crossover claims include drugs subject to rebate and that it would pursue rebates for those drugs as applicable.

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, we maintain that all of our findings and recommendations are valid. The State agency pointed out that most of the claims identified in this report were crossover claims and did not contain NDCs in the utilization data. We agree

with the State agency's remark, in its written comments, that the issue of crossover claims "… is common among many [State] Medicaid programs." In fact, we plan to address the challenges associated with States' processing of crossover claims, and identify possible ways in which States can more easily identify the NDCs associated with such physician-administered drug claims, in a separate report to CMS. However, unless CMS changes the Medicare requirements to mandate that providers include the NDCs on Medicare claims, the State agency will need to develop procedures for crossover claims at its level to comply with Medicaid drug rebate requirements. We commend the State agency as it has committed to implementing additional procedures to ensure that Medicaid drug rebates are collected for crossover claims.

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs	A-07-15-06062	1/14/2016
North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs	A-07-15-06058	1/13/2016
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
Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs	A-09-12-02080	4/24/14

Report Title	Report Number	Date Issued
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 $8,718,302 ($5,067,666 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 Pierre, South Dakota, from December 2014 to August 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 $4,284,138 ($2,495,232 Federal share) that contained an NDC and were invoiced for rebate.

- We reviewed the remaining drug claims totaling $4,434,164 ($2,572,434 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 drug claims totaling $314,583 ($183,087 Federal share) that were not eligible for drug rebates.

- We discussed the results of our review with State agency officials on August 4, 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 *South Dakota Medical Assistance Program Pharmacy Manual*, Chapter II: Covered Services, issued July 2010, states: "The following items and services are not covered …. 11. Drugs manufactured by a firm that has not signed a rebate agreement with the United States Department of Health and Human Services…."

The *South Dakota Medical Assistance Program Pharmacy Manual*, Chapter III: Billing Instructions, issued July 2010, gives instructions to providers submitting claims for Medicaid prescription drugs. According to this guideline, the proper entry on the claim form for the data field for product or service identification is the NDC.

In a letter to South Dakota Medicaid prescribing providers, issued on December 10, 2007, the State agency stated: "…all state Medicaid agencies require providers who use a drug-related Healthcare Common Procedure Coding System (HCPCS) J-code when billing prescription drug products to include the relevant National Drug Code (NDC) of the drug dispensed."

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DSS
Strong Families - South Dakota's Foundation and Our Future

December 17, 2015

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

RE: Report No. A-07-15-06059:

Dear Mr. Cogley:

Thank you for the opportunity to provide a response to the review of physician administered drugs for the period January 1, 2011, through December 31, 2013. For ease of reference, the Department of Social Services has restated the recommendation, then provided the Departments' response.

The OIG draft report suggests that the State agency did not invoice manufacturers for rebates associated with $2,086,423 ($1,206,454 Federal share) in physician administered drugs. Further, the report suggest that the State agency did not submit the utilization data necessary to secure rebates for all other physician-administered drugs for claims totaling $66,858 ($39,813 Federal share) although the OIG was unable to determine whether the State agency was required to invoice for rebates for these drugs.

Furthermore, the report indicates that claims totaling $1,966,300 ($1,143,080 Federal share) which contained NDCs could have been eligible for rebates, although the OIG was unable to determine if these drugs were subject to rebate.

Accordingly, the OIG set aside these amounts and are recommending that the State agency work with CMS to determine (1) the unallowable portion of the $66,858 ($39,813 Federal share) of claims that were submitted without NDCs and (2) whether the remaining $1,966,300 ($1,143,080 Federal share) of claims could have been invoiced to the manufacturers for rebates.

Recommendation:

We recommend that the State agency:

Refund to the Federal Government $940,648 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement.
Refund to the Federal Government $265,806 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement;

DSS Response:

DSS outlined for the OIG that the claims and rebate amounts in question by the OIG are related to Medicare crossover claims related to individuals eligible for both Medicare and Medicaid. When individuals are eligible for both Medicare and Medicaid, Medicare is the primary payer and any coinsurance or deductible not covered by Medicare is sent to DSS Medicaid as a crossover claim. DSS Medicaid would reimburse the provider any coinsurance or deductible amounts allowable through Medicaid that were not paid by Medicare.

Medicare does not require the NDC and procedure code detail necessary for states, including South Dakota to facilitate the drug rebate process in the case where the drug is subject to rebate. Given that, DSS suggested that CMS require this information so that states, including South Dakota have the information necessary to facilitate the drug rebate process. While DSS can require this information be included on the claim for Medicaid payment and has done so in its Medicaid Management Information System (MMIS), the primary payer, Medicare, should be consistent if Medicaid is charged with the drug rebate process for Medicare primary claims. As seen in the OIG related reports from many other states, this issue is common among many Medicaid programs and is not unique to South Dakota.

In addition, DSS does not concur that the amounts accurately reflect the physician administered drugs subject to rebate related to Medicare crossover claims. DSS does concur, that due to the lack receiving all HCPC and NDC data elements from the Medicare crossover claim necessary to facilitate the drug rebate submission process, additional rebates could have been recovered. DSS has sought to recover those rebates directly from manufacturers after obtaining the necessary information from providers and other subsystems to facilitate the process.

As is the normal course of business, DSS will credit the federal government the appropriate share based on the applicable federal medical assistance percentage.

Recommendation:

We recommend that the State agency work with CMS to determine the unallowable portion of $39,813 (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 $1,143,080 (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.

DSS Response:

For the same reasons outlined in the first recommendation above, DSS does not concur the amounts listed in the report accurately reflect the amount of physician administered drugs subject to rebate. DSS does concur that it will work with CMS to identify if any portion of these claims include drugs subject to rebate and pursue rebates for those drugs as applicable.

Within the scope of DSS control, we have also added additional safe guards requiring providers including the HCPC code and the NDC code on all professional claims and will deny those claims for payment if this information is not contained in the crossover claim from Medicare. DSS is already working to submit any claims subject to rebate to the applicable manufacturer for rebate purposes and will refund the applicable federal portion to CMS.

The Department of Social Services encourages CMS require claims submitted though Medicare to include the NDC and procedure code. This would save time and effort of denying the submission and requesting the information from Medicare or the Medicaid provider.

Sincerely,

Brenda Tidball-Zeltinger
Deputy Secretary

Cc: Lynne Valenti, Secretary of DSS
Bill Regynski, Accounting and Financial Reporting Manager
Ann Schwartz, Deputy Director Medical Services
Lori Lawson, Deputy Director Medical Services