Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

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

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Inspector General

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Office of Inspector General

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EXECUTIVE SUMMARY

Missouri claimed $34.8 million over 3 years in Federal reimbursement that was unallowable and $13.2 million that may have been unallowable because it did not comply with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs.

WHY WE DID THIS REVIEW

For a covered outpatient drug to be eligible for Federal reimbursement under the Medicaid program's drug rebate requirements, manufacturers must pay rebates to the States, and States generally must offset their Federal share of these rebates against their Medicaid expenditures. States bill the manufacturers for rebates to reduce the cost of drugs to the program. However, recent Office of Inspector General reviews found that States did not always bill and collect all rebates due for drugs administered by physicians. For this audit, we reviewed the Missouri Department of Social Services (DSS), MO HealthNet Division's (State agency's), billing for rebates for physician-administered drugs for the period January 1, 2009, through December 31, 2011.

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

BACKGROUND

The Medicaid drug rebate program became effective in 1991 (the Social Security Act, § 1927). For a covered outpatient drug to be eligible for Federal reimbursement under the program, the manufacturer must enter into a rebate agreement with the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. The Deficit Reduction Act of 2005 (DRA) 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 bill 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 bill 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 billing manufacturers for rebates for physician-administered drugs. The State agency did not collect the

NDCs (from claims submitted by providers) that were required for it to invoice manufacturers for rebates associated with $49,954,190 ($34,837,957 Federal share) in physician-administered drugs. Of this amount, $48,993,427 ($34,181,807 Federal share) was for single-source drugs, and $960,763 ($656,150 Federal share) was for top-20 multiple-source drugs. Because the State agency did not obtain NDC-level detail on the claims and did not submit utilization data to the manufacturers to collect rebates, the State agency improperly claimed Federal reimbursement for these single-source drugs and top-20 multiple-source drugs.

The State agency did not capture the utilization and coding data necessary to collect rebates for all physician-administered drugs. Without the NDCs, we were unable to determine whether the State agency improperly claimed Federal reimbursement for an additional $19,166,132 ($13,225,151 Federal share) for other physician-administered drug claims that may have included single-source drugs.

The State agency required providers to include NDCs on all physician-administered drug claims, and the State agency notified providers that it would deny claims that did not include NDCs. However, the State agency did not have a system edit in place to reject all of the claims submitted without NDCs. As a result, the State agency did not collect the drug utilization data necessary to bill the manufacturers for rebates associated with these physician-administered drug claims, and the claims were therefore ineligible for Federal reimbursement.

WHAT WE RECOMMEND

We recommend that the State agency:

- refund to the Federal Government $34,181,807 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement,

- refund to the Federal Government $656,150 (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 the $13,225,151 (Federal share) for other claims for outpatient physician-administered drugs that were ineligible for Federal reimbursement and refund that amount,

- work with CMS to determine and refund the unallowable Federal reimbursement for physician-administered drugs claimed without NDCs and not billed for rebates after December 31, 2011, and

- update its system edits to reject claims for all physician-administered drugs that do not include NDCs in order to improve the State's ability to ensure that all such drugs eligible for drug rebates are invoiced.

DEPARTMENT OF SOCIAL SERVICES COMMENTS AND OUR RESPONSE

In written comments on our draft report, DSS did not concur with any of our recommendations. DSS said that the requirements for the collection of rebates on physician-administered drugs, implemented as part of the DRA, had created "significant administrative and financial" difficulties for hospitals in Missouri.

DSS stated that as a result of these difficulties, it requested and CMS granted a hardship extension to give DSS additional time to comply with the NDC reporting requirements. DSS also said that, on the basis of CMS guidance, it understood that it could use the Medicare Part B crosswalk to link the submitted Healthcare Common Procedure Coding System (HCPCS) codes to the appropriate NDCs for single-source drug claims.

On the basis of these statements, DSS disagreed with our first four recommendations. Regarding our second recommendation, DSS said that it currently collects rebates from the drugs identified on the most recently published list of the top 20 multiple-source physician-administered drugs and that it believes that it has collected rebates for all such drugs. With respect to our first, third, and fourth recommendations, DSS said that it would like to work with CMS and us to extend the State's hardship exemption and to devise a timeframe within which Missouri hospitals could comply with a requirement to submit NDCs. DSS said that it was taking our fifth recommendation under advisement.

After reviewing DSS's comments, we maintain that our findings and recommendations remain valid. The State agency applied to CMS for a waiver (the "hardship extension" referred to in DSS's comments) in early 2008; CMS granted the waiver. In so doing, CMS noted that DSS had sufficient time to prepare providers to submit physician-administered drug claims with NDCs. CMS granted the extension for hospital provider claims only and stated that Federal reimbursement would remain available for these claims until June 30, 2008, which was 6 months before our audit period began. In fact, the waiver expired more than 6 years ago, but DSS has not taken the steps necessary to ensure that providers submit NDCs with physician-administered drug claims in keeping with the NDC requirements of the DRA. By contrast, our audits of the Medicaid drug rebate program in other States have determined that some other States are requiring providers to submit NDCs for physician-administered drugs and have instituted edits to deny claims that are submitted without NDCs.

With respect to our second recommendation, our audit work identified specific claims that had HCPCS codes that were on CMS's published list of top-20 multiple-source physician-administered drugs. During our audit, we provided the State agency officials this detailed claim listing. The State agency reviewed this listing and identified these claims as not having been submitted for rebate. Therefore, we maintain that the State agency did not submit for rebate all top-20 multiple-source physician-administered drugs during the audit period.

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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, and States generally must offset their Federal share of these rebates against their Medicaid expenditures. States bill the manufacturers for rebates to reduce the cost of drugs to the program. However, recent Office of Inspector General reviews found that States did not always bill 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 Missouri Department of Social Services (DSS), MO HealthNet Division's (State agency's), billing for rebates for physician-administered drugs for the period January 1, 2009, through December 31, 2011.

OBJECTIVE

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

BACKGROUND

Medicaid Drug Rebate Program

The Medicaid drug rebate program became effective in 1991 (the Social Security Act (the Act), § 1927). For a covered outpatient drug to be eligible for Federal reimbursement under the program, the drug's manufacturer must enter into a rebate agreement with the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. 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 billing manufacturers for rebates as described in section 1927 of the Act. To bill 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.

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[1] *States' Collection of Medicaid Rebates for Physician-Administered Drugs* (OEI-03-09-00410), issued June 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 billed to the Medicaid program on a claim form using Healthcare Common Procedure Coding System (HCPCS) codes. For purposes of the Medicaid drug rebate program, physician-administered drugs are classified as either single-source or multiple-source.[3]

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.[4] 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 so that rebates can be collected.

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 "… exact NDC that appears on the product dispensed or administered."[5] The State agency uses its claim utilization data for physician-administered drugs, which it derives from claims submitted by providers, to bill 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 $104,500,744 ($72,598,217 Federal share) for physician-administered drugs between January 1, 2009, and December 31, 2011. Of this, we reviewed $69,120,321

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[3] As specified in CMS's *Medicare Claims Processing Manual*, chapter 17, section 20.1.2, a single-source drug is a drug for which there is not another therapeutically equivalent drug listed in the most recent Food and Drug Administration (FDA) Orange Book. Multiple-source drugs, by contrast, are drugs for which there are two or more drug products that are rated as therapeutically equivalent in the most recent FDA Orange Book.

[4] 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).

[5] *Missouri Provider Bulletin*, volume 30, number 29, dated January 8, 2008.

($48,063,108 Federal share) that the State agency claimed for physician-administered drugs that were submitted with a HCPCS code but without an NDC.

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 billing manufacturers for rebates for physician-administered drugs. The State agency did not collect the NDCs (from claims submitted by providers) that were required for it to invoice manufacturers for rebates associated with $49,954,190 ($34,837,957 Federal share) in physician-administered drugs. Of this amount, $48,993,427 ($34,181,807 Federal share) was for single-source drugs, and $960,763 ($656,150 Federal share) was for top-20 multiple-source drugs. Because the State agency did not obtain NDC-level detail on the claims and did not submit utilization data to the manufacturers to collect rebates, the State agency improperly claimed Federal reimbursement for these single-source drugs and top-20 multiple-source drugs.

The State agency did not capture utilization and coding data necessary to collect rebates for all physician-administered drugs. Without the NDCs, we were unable to determine whether the State agency improperly claimed Federal reimbursement for an additional $19,166,132 ($13,225,151 Federal share) for other physician-administered drug claims that may have included single-source drugs.

The State agency required providers to include NDCs on physician-administered drug claims, and the State agency notified providers that it would deny claims that did not include NDCs. However, the State agency did not have a system edit in place to reject all of the claims submitted without NDCs. As a result, the State agency did not collect the drug utilization data

[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.

necessary to bill the manufacturers for rebates associated with these physician-administered drug claims, and the claims were therefore ineligible for Federal reimbursement.

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)). Federal regulations prohibit Federal reimbursement for physician-administered drugs unless the States submit to manufacturers drug utilization data containing the NDCs (42 CFR § 447.520).

The Missouri Code of State Regulations (CSR) states that filing instructions for claims are provided in provider manuals and provider bulletins.[7] Through the *Missouri Provider Bulletin*, volume 30, number 29, dated January 8, 2008, the State agency notified providers that it would "… require the NDC(s), for all medications administered in the clinic or outpatient hospital setting." In addition, "[c]laims submitted with J-Codes only, without the corresponding NDC, will be denied."[8]

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

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

The State agency improperly claimed Federal reimbursement of $48,993,427 ($34,181,807 Federal share) for single-source physician-administered drug claims for which it did not bill manufacturers for rebates. Providers submitted these claims to the State agency without NDCs, and therefore, the State agency did not provide utilization data to the manufacturers to collect the drug rebates.

Because the State agency did not bill for rebates for all single-source physician-administered drugs, these claims were not eligible for Federal reimbursement.

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

The State agency improperly claimed Federal reimbursement of $960,763 ($656,150 Federal share) for top-20 multiple-source physician-administered drug claims for which it did not collect rebates. Providers submitted these claims to the State agency without NDCs and, therefore, the State agency did not provide utilization data to the manufacturers to collect rebates.

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[7] Missouri Code of State Regulations, division 70, chapter 3, 13 CSR 70-3.100.

[8] The HCPCS codes associated with physician-administered drugs generally begin with a "J" and are commonly referred to as J-Codes. These physician-administered drugs include injectable drugs that ordinarily cannot be self-administered, chemotherapy drugs, immunosuppressive drugs and inhalation solutions, and some orally administered drugs.

During our audit period, CMS provided the State agency, on a yearly basis, with a listing of top-20 multiple-source HCPCS codes and their respective NDCs. The State agency said that it had configured its automated system to automatically reject any top-20 multiple-source drug claims that had been submitted without corresponding NDCs. However, the State agency's system edits did not always reject these claims.

Because the State agency did not bill for rebates for all top-20 multiple-source physician-administered drugs, the claims that were not billed for rebates were not eligible for Federal reimbursement.

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

The State agency did not capture the utilization and coding data necessary to collect rebates for all physician-administered drugs. Without the NDCs, we were unable to determine whether the State agency improperly claimed Federal reimbursement for an additional $19,166,132 ($13,225,151 Federal share) for other physician-administered drug claims that may have included single-source drugs.[9]

The State agency required providers to include NDCs on all physician-administered drug claims. However, the State agency did not have an edit in place to reject all of the claims that were submitted without NDCs. As a result, the State agency did not collect the drug utilization data necessary to bill the manufacturers for rebates associated with these claims and was unable to determine whether manufacturers paid rebates for all of the required physician-administered drugs.

Accordingly, we set aside the $19,166,132 ($13,225,151 Federal share) for CMS's adjudication.

RECOMMENDATIONS

We recommend that the State agency:

- refund to the Federal Government $34,181,807 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement,

- refund to the Federal Government $656,150 (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 the $13,225,151 (Federal share) for other claims for outpatient physician-administered drugs that were ineligible for Federal reimbursement and refund that amount,

[9] HCPCS codes for drugs that are included in this finding have both single-source and multiple-source NDCs associated with them.

- work with CMS to determine and refund the unallowable Federal reimbursement for physician-administered drugs claimed without NDCs and not billed for rebates after December 31, 2011, and

- update its system edits to reject claims for all physician-administered drugs that do not include NDCs in order to improve the State's ability to ensure that all such drugs eligible for drug rebates are invoiced.

DEPARTMENT OF SOCIAL SERVICES COMMENTS

In written comments on our draft report, DSS did not concur with any of our recommendations. DSS said that the requirements for the collection of rebates on physician-administered drugs, implemented as part of the DRA, had created "significant administrative and financial" difficulties for hospitals in Missouri. DSS added that the denial of large numbers of claims for physician-administered drugs "… created an enormous access problem for Missouri Medicaid enrollees. At the time, there was no bigger problem facing the [*sic*] Missouri's Medicaid program."

DSS stated that as a result of these difficulties, it requested and CMS granted a hardship extension (also referred to in DSS's comments as a "hardship exemption" and as a "hardship waiver") to give DSS additional time to comply with the NDC reporting requirements. DSS said that it later announced that, effective November 3, 2008, (1) hospitals could submit claims for single-source physician-administered drugs using only a HCPCS code and did not have to include the corresponding NDC, but (2) hospitals were still required to provide NDCs for claims for the top 20 multiple-source physician-administered drugs.

DSS also said that, on the basis of CMS guidance, it understood that it could use the Medicare Part B crosswalk to link the submitted HCPCS codes to the appropriate NDCs for single-source drug claims. DSS stated: "While not a perfect system, use of the crosswalk to link HCPCS and NDC codes was the only feasible way for MO HealthNet to implement the requirement to collect rebates for physician-administered single source drugs." DSS said that the State agency expected that the use of the crosswalk would allow it to determine the appropriate NDCs and to seek rebates for "most" single-source physician-administered drugs. DSS added that when more than one NDC was associated with a single HCPCS code, the State agency could not identify "… the specific NDC for the drug administered and therefore could not (in general) seek a Medicaid rebate for the drug."

On the basis of these statements, DSS disagreed with our first four recommendations. DSS asked that we reconsider the recommended refund in our first recommendation. DSS also disagreed with our second recommendation and said that it currently collects rebates from the drugs identified on the most recently published list of the top 20 multiple-source physician-administered drugs and that it believes that it has collected rebates for all such drugs. With respect to our first, third, and fourth recommendations, DSS said that it would like to work with CMS and us to extend the State's hardship exemption and to devise a timeframe within which Missouri hospitals could comply with a requirement to submit NDCs. DSS said that it was taking our fifth recommendation, to update its system edits, under advisement and was

(1) evaluating the system changes that would be necessary to implement this recommendation and (2) reaching out to hospitals "… to determine whether or not and how such providers could submit NDC information."

DSS's comments appear in their entirety as Appendix D.

OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing DSS's comments, we maintain that our findings and recommendations remain valid. The State agency applied to CMS for a waiver (the "hardship extension" or "hardship exemption" referred to in DSS's comments) in early 2008; CMS granted the waiver. In its written communication granting this waiver to the State agency, CMS stated:

> We appreciate the problems your providers have had with the implementation of the physician-administered drug provision. While you requested an extension for both professional and institutional provider claims, we believe that you have had sufficient time to prepare your professional providers to submit claims with NDCs. CMS grants you the requested six-month extension for hospital provider claims only. FFP [Federal financial participation; also known as Federal reimbursement] will remain available to you for these claims until June 30, 2008.

Our audit period began on January 1, 2009, which was 6 months after the expiration of the waiver. In fact, this waiver expired more than 6 years ago, but DSS has not taken the steps necessary to ensure that providers submit NDCs with physician-administered drug claims in keeping with the NDC requirements of the DRA. By contrast, our audits of the Medicaid drug rebate program in other States (Appendix A) have determined that some other States are requiring providers to submit NDCs for physician-administered drugs and have instituted edits to deny claims that are submitted without NDCs.

With respect to our second recommendation, our audit work identified specific claims that had HCPCS codes that were on CMS's published list of top-20 multiple-source physician-administered drugs. During our audit, we provided the State agency officials this detailed claim listing. The State agency reviewed this listing and identified these claims as not having been submitted for rebate. Therefore, we maintain that the State agency did not submit for rebate all top-20 multiple-source physician-administered drugs during the audit period.

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-03-12-00205	August 2014
Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-13-06040	August 2014
Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs	A-09-12-02079	April 2014
Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs	A-09-12-02080	April 2014
Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-03-12-00200	November 2013
Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs	A-06-12-00059	September 2013
Nationwide Rollup Report for Medicaid Drug Rebate Collections	A-06-10-00011	August 2011
States' Collection of Medicaid Rebates for Physician-Administered Drugs	OEI-03-09-00410	June 2011
Follow-Up Audit of the Medicaid Drug Rebate Program in Oregon	A-09-07-00052	March 2008
Medicaid Rebates for Physician-Administered Drugs	OEI-03-02-00660	April 2004

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

The State agency claimed $104,500,744 ($72,598,217 Federal share) for physician-administered drugs between January 1, 2009, and December 31, 2011. Of this, we reviewed $69,120,321 ($48,063,108 Federal share) that the State agency claimed for physician-administered drugs that were submitted with a HCPCS code but without an NDC.

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 visiting and contacting the State agency in Jefferson City, Missouri, from June 2012 through July 2014.

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 billing 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 billing 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, 2009, through December 31, 2011.

- We obtained the single-source drug listing from the State agency that was used, according to State agency officials, to identify the NDCs of single-source drugs by HCPCS code.

- We obtained the listing of 340B entities from the State agency.[10]

- We removed drug claims totaling $35,380,422 ($24,535,109 Federal share) that were not eligible for a drug rebate (including the drug claims submitted by 340B entities), contained an NDC (which according to State agency officials would already have been rebated), were identified by the State agency as having already been rebated, or were credits.

- We reviewed the remaining drug claims totaling $69,120,321 ($48,063,108 Federal share) to determine whether the State agency complied with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs. Specifically:

    - We identified single-source drugs by matching the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk to identify, if possible, the NDCs associated with each HCPCS code listed on claims from providers. We used the CMS Medicaid Drug File to determine whether these NDCs were classified as single-source drugs. (Because there were often multiple NDCs associated with a single HCPCS code, we were not always able to identify the specific NDC that should have been submitted to the drug manufacturer for rebate purposes.)

    - 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 on the basis of the date of service.

    - We classified the remaining drugs (ones that were not identified as single-source or as top-20 multiple-source drugs) as other outpatient physician-administered drugs.

- We discussed the results of our review with State agency officials on July 7, 2014.

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.

[10] Under the 340B drug pricing program (set forth in 42 U.S.C. § 256b), a 340B entity may purchase reduced-price covered outpatient drugs from manufacturers; examples of 340B entities are Medicare/Medicaid disproportionate share hospitals, which generally serve large numbers of low-income and/or uninsured patients, and State AIDS drug assistance programs.

APPENDIX C: FEDERAL AND STATE REQUIREMENTS AND GUIDANCE RELATED TO PHYSICIAN-ADMINISTERED DRUGS

FEDERAL LAWS

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

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

Section 1927(a)(7) of the Act requires that States capture utilization and coding data necessary to secure rebates for all single-source physician-administered drugs effective January 1, 2006, and for the top 20 multiple-source drugs effective January 1, 2008. Section 1927(a)(7)(C) of the Act stated that, effective January 1, 2007, the utilization data must be submitted using the NDC.

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 bill a manufacturer for rebates (42 CFR § 447.520).

Federal regulations defined a brand-name drug as a single-source or innovator multiple-source drug and, in relevant part, a multiple-source drug as a covered outpatient drug for which there is at least one other drug product that is rated as therapeutically equivalent (42 CFR § 447.502).[11]

[11] On November 15, 2010, CMS amended 42 CFR § 447.502 to remove the definition of multiple-source drug (75 Fed. Reg. 69591, 69592 (November 15, 2010)).

STATE REGULATIONS AND GUIDANCE

The CSR, division 70, chapter 3, 13 CSR 70-3.100, states that filing instructions for claims are provided in provider manuals and provider bulletins.

Through the *Missouri Provider Bulletin*, volume 30, number 29, dated January 8, 2008, the State agency notified providers that:

> [t]he Deficit Reduction Act of 2005 (DRA) requires states to collect rebates for certain physician-administered drugs. As a result, state agencies must now collect the 11-digit National Drug Codes (NDC) on all outpatient drug claims submitted to the MO HealthNet program from all providers for rebate purposes. To comply with the DRA, effective for dates of service on or after February 1, 2008, MO HealthNet will require the NDC(s), for all medications administered in the clinic or outpatient hospital setting. Providers will be required to submit their claims with the exact NDC that appears on the product dispensed or administered. The NDC is found on the medication's packaging and must be submitted in the 5 digits-4 digits-2 digits format. If the NDC does not appear in the 5-4-2 digit format on the packaging, a zero(s) (0) may be entered in front of the section that does not have the required number of digits.

The *Missouri Provider Bulletin*, volume 30, number 29, also specifies that, for providers submitting drug information on an electronic claim transaction or manually entering a claim:

> in addition to the NDC, the claim must include the J-code that best represents the NDC being billed. Claims submitted with J-codes only, without the corresponding NDC, will be denied. The system will automatically generate a separate claim for the NDC to process as a Pharmacy claim and will appear as a separate claim on your Remittance Advice. The corresponding J-code will be dropped from the claim unless an NDC is not provided, then it will remain to report the denied line.

APPENDIX D: DEPARTMENT OF SOCIAL SERVICES COMMENTS

Missouri Department of
SOCIAL SERVICES
Your Potential. Our Support.

JEREMIAH W. (JAY) NIXON, GOVERNOR • BRIAN KINKADE, DIRECTOR

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November 19, 2014

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

Dear Mr. Cogley:

This letter is in response to the Office of Inspector General's (OIG) draft report entitled "Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician – Administered Drugs", Report Number A-07-14-06051. The Department of Social Services' (DSS) responses are below.

The DSS is the single state agency charged with administering the Missouri Medicaid program. The DSS oversees the provision of Medicaid health care coverage to approximately one million Missourians through roughly 600 enrolled hospitals (147 located in Missouri) and 20,500 physicians.

Pursuant to federal law, DSS collects Medicaid rebates for physician-administered single source drugs and for the drugs listed on the "Top 20 multiple source physician-administered drugs" list (last published on the Medicaid.gov website in 2011). Effective February 1, 2008, in response to changes enacted as part of the Deficit Reduction Act (DRA) of 2005, DSS required clinics and hospital outpatient departments to submit claims for physician-administered single source and top 20 multiple source drugs using both National Drug Codes (NDCs) and procedure codes (such as Healthcare Common Procedure Coding System (HCPCS) codes, also sometimes called "J Codes"). *See* MO. DEP'T SOC. SERVS., MOHEALTHNET PROVIDER BULLETIN, Vol. 30, No. 29 (Jan. 8, 2008), *available at* http://dss.mo.gov/mhd/providers/pdf/bulletin30-29_2008jan08.pdf. After February 1, 2008, any claims submitted without the relevant NDC were automatically denied. *Id.*

Missouri hospitals encountered significant administrative and financial barriers in attempting to comply with the new NDC submission requirement. In the months following implementation of the requirement, Missouri denied over 77,000 claims for physician-administered drugs due to hospitals' inability to identify and provide the required NDCs. The denial of such a large volume of claims created an enormous access problem for Missouri Medicaid enrollees. At the time, there was no bigger problem facing the Missouri's Medicaid program.

In order to address the access to pharmacy services crisis, the DSS sought and the Centers for Medicare & Medicaid Services (CMS) granted a hardship extension to give the DSS additional time to comply with the NDC reporting requirements. *See* MO. DEP'T SOC. SERVS., MOHEALTHNET PROVIDER BULLETIN, Vol. 30, No. 42 (Feb. 20, 2008), *available at* http://dss.mo.gov/mhd/providers/pdf/bulletin30-42_2008feb20.pdf (noting request for hardship waiver). DSS later announced that, effective November 3, 2008, hospitals could submit claim for single source drugs using only a HCPCS code and did not have to include the corresponding NDC code; hospitals were still required to provide NDC codes for claims for the Top 20 multiple-source drugs.

Based on CMS guidance, DSS understood that it could use the Medicare Part B crosswalk to link the submitted HCPCS codes to the appropriate NDC codes for single source drug claims. In a 2006 State Medicaid Director Letter, CMS had noted that many states were using crosswalks in their rebate collection efforts to link HCPCS to NDC numbers. Letter to State Medicaid Dir., from Dennis G. Smith, Dir., CMS Ctr. for Medicaid and State Operations (July 11, 2006) ("SMDL 06-016"), *available at* http://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SMD071106.pdf. Similarly, in the Final Rule implementing the NDC reporting provisions, CMS noted that "[f]or States not currently billing manufacturers for rebates on single source drugs, [CMS] believed that the Medicare Part B crosswalk may be helpful to crosswalk HCPCS codes to NDC numbers." Final Rule, CMS, *Medicaid Program; Prescription Drugs*, 72 Fed. Reg. 39142, 39156–57 (July 17, 2007) ("If States collect HCPCS codes for single source drugs, they can crosswalk these codes to NDC numbers. . . ."); *see also* OIG DRAFT REPORT 3 n.6 ("CMS instructed States that they could use the Medicare Part B crosswalk as a reference . . . .").

While not a perfect system, use of the crosswalk to link HCPCS and NDC codes was the only feasible way for MO HealthNet to implement the requirement to collect rebates for physician-administered single source drugs. When a submitted HCPCS code was traceable to one single-source NDC code, DSS considered the claimed drug to be a "single source" drug and sought a rebate from the appropriate manufacturer. Because HCPCS codes generally map to one NDC, MO HealthNet expected that use of the HCPCS crosswalk would allow it to determine the appropriate NDC codes and to seek rebates for "most" single source drugs. *See id.* at 39156 ("[M]ost HCPCS codes for single source drugs include only one NDC in order to collect rebates.").

However, as both the OIG and CMS have acknowledged, when multiple NDCs were associated with a single HCPCS code, MO HealthNet could not identify the specific NDC for the drug administered and therefore could not (in general) seek a Medicaid rebate for the drug. By way of example, HCPCS code J1610 is associated with NDCs 00002-8031-01 (glucagon hydrochloride, manufactured by Eli Lilly) and with 55390-0004-01 and 55390-0004-10 (glucagon hydrochloride, manufactured by Bedford Laboratories). When a provider files a claim using HCPCS code J1610, MO HealthNet cannot determine if the Eli Lilly or Bedford Laboratories product was dispensed and thus cannot claim the rebate. In such cases, MO HealthNet considered the drug administered to be a multiple-source drug not included on the Top 20 list, and DSS did not seek a rebate for the drug.

MO HealthNet devised a reasonable approach for dealing with the access to pharmacy services crisis that resulted when MO HealthNet attempted to require the submission of NDCs for physician-administered single source drugs. Because Missouri hospitals were unable to implement the systems required to submit NDCs, MO HealthNet appropriately sought to link submitted HCPCS codes with the corresponding NDCs using a crosswalk. Although MO HealthNet could not identify the relevant physician-administered NDCs for certain claims identified by the OIG, DSS disagrees with OIG's recommendation that DSS repay up to $48 million in Federal Financial Participation for the audit period alone.

If the OIG nevertheless believes that DSS has failed to comply with the NDC reporting provisions of the DRA, DSS requests an opportunity to meet with OIG and CMS to discuss an extension of the hardship exemption under 42 C.F.R. § 447.520(c) and a reasonable time frame for Missouri hospitals to come into compliance with the NDC reporting requirements. Requiring DSS to refund up to $48 million for the 2009–2011 period alone (plus additional amounts for the period beginning January 2012) would impose an enormous hardship on the State. DSS asks that it be permitted discuss a resolution of this matter that addresses OIG's and CMS's concerns, while not unduly penalizing the State or its Medicaid providers or participants.

DSS Responses to OIG Recommendations:

OIG Recommendation: The OIG recommends that the State agency refund to the Federal Government $34,181,807 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement.

DSS Response (Nonconcurrence): DSS disagrees with this recommendation. As discussed above, DSS implemented the most feasible strategy to address hospitals' inability to submit NDC claims for single source drugs. DSS expected the majority of claims for such drugs would be traceable to particular NDC codes and thus, that DSS could claim rebates for these drugs. With respect to claims with which multiple NDCs were associated, DSS could not identify a single NDC number or claim associated rebates. DSS asks that the OIG reconsider its recommendation that DSS repay approximately $34 million for single source claims. DSS would like to work with CMS and OIG to extend the State's hardship exemption and to devise a time frame within which Missouri hospitals could comply with a requirement to submit NDCs.

OIG Recommendation: The OIG recommends that the State agency refund to the Federal Government $656,150 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement.

DSS Response (Nonconcurrence): DSS currently collects rebates from the drugs identified on the most recently published list of the Top 20 multiple source drugs. The OIG has not identified drugs on this list for which DSS failed to claim a rebate. DSS believes that it has collected rebates for all such drugs and DSS disagrees with this recommendation.

OIG Recommendation: The OIG recommends that the state agency work with CMS to determine the unallowable portion of the $13,225,151 (Federal share) for other claims for

outpatient physician-administered drugs that were ineligible for Federal reimbursement and refund that amount.

DSS Response (Nonconcurrence): Again, to the extent that a given HCPCS code is associated with more than one NDC, it was not possible for DSS to claim a rebate for the drug administered. However, DSS would like to work with the OIG and CMS to extend the State's hardship exemption and to devise a time frame within which Missouri hospitals could comply with a requirement to submit NDCs.

OIG Recommendation: The OIG recommends that the state agency work with CMS to determine and refund the unallowable Federal reimbursement for physician-administered drugs claimed without NDCs and not billed for rebates after December 31, 2011.

DSS Response (Nonconcurrence): DSS is willing to work with CMS to identify the physician-administered drugs claimed without NDCs and not billed for rebates after December 31, 2011. However, as DSS has explained, DSS did not require hospitals to submit NDCs for single-source drugs because the Department's attempt to implement this requirement in 2008 led the Department to deny over 77,000 claims and had created significant access problems for Medicaid beneficiaries. Again, DSS would like to work with CMS and OIG to extend the State's hardship exemption and to devise a time frame within which Missouri hospitals could comply with a requirement to submit NDCs.

OIG Recommendation: The OIG recommends that the state agency update its system edits to reject claims for all physician-administered drugs that do not include NDCs in order improve the State's ability to ensure that all such drugs eligible for drug rebates are invoiced.

DSS Response: DSS is taking this recommendation under advisement. The agency is evaluating the system changes that would be necessary to implement such a change and is reaching out to hospitals that would be significantly impacted by the change to determine whether or not and how such providers could submit NDC information.

Please contact Patrick Luebbering, Director, Division of Finance and Administrative Services at (573) 751-7533 if you have further questions.

Sincerely,

Brian Kinkade
Director

BDK:PL:bsb