Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

IOWA 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.

Patrick J. Cogley
Regional Inspector General
for Audit Services

July 2015
A-07-14-06049

Office of Inspector General

http://oig.hhs.gov/

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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EXECUTIVE SUMMARY

Iowa claimed $174,000 over 3 years in Federal reimbursement that was unallowable and $111,000 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, and States generally must 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, recent Office of Inspector General reviews found that States did not always invoice and collect all rebates due for drugs administered by physicians. For this audit, we reviewed the Iowa Department of Human Services, Iowa Medicaid Enterprise (State agency), invoicing for rebates for physician-administered drugs for the period January 1, 2010, through December 31, 2012.

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

BACKGROUND

The Medicaid drug rebate program became effective in 1991 (the Social Security Act, § 1927). For a covered outpatient drug to be eligible for Federal reimbursement under the program, the manufacturer must enter into a rebate agreement with 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. To execute this responsibility, the State agency contracted with Goold Health Systems to operate the State's drug rebate program. 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 $256,905 ($173,889 Federal share) in physician-administered drugs. Of this amount, $228,958 ($155,296 Federal share) was for single-source drugs, and $27,947 ($18,593 Federal share) was for top-20 multiple-source drugs. Because the State agency 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.

Further, the State agency did not submit the utilization data necessary to collect rebates for all other physician-administered drugs. We were unable to determine whether the State agency improperly claimed Federal reimbursement for an additional $176,044 ($111,485 Federal share) for other physician-administered drug claims that were not for single-source drugs or top-20 multiple-source drugs. We set aside the $176,044 ($111,485 Federal share) and are recommending that the State agency work with CMS to determine the unallowable portion of these claims.

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's internal controls did not always ensure that it invoiced manufacturers for rebates for all eligible physician-administered drugs.

WHAT WE RECOMMEND

We recommend that the State agency:

- refund to the Federal Government $155,296 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement,

- refund to the Federal Government $18,593 (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 $111,485 (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 that were not invoiced for rebates after December 31, 2012, and

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

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency concurred with all of our recommendations and described corrective actions that it had taken or planned to take.

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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 invoice 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 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 Iowa Department of Human Services, Iowa Medicaid Enterprise (State agency), invoicing for rebates for physician-administered drugs for the period January 1, 2010, through December 31, 2012.

OBJECTIVE

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

BACKGROUND

Medicaid Drug Rebate Program

The Medicaid drug rebate program became effective in 1991 (the Social Security Act (the Act), § 1927). For a covered outpatient drug to be eligible for Federal reimbursement under the program, the drug's manufacturer must enter into a rebate agreement 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 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 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. 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. 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'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. To execute this responsibility, the State agency contracted with Goold Health Systems to operate the State's drug rebate program. 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 to the State agency.

HOW WE CONDUCTED THIS REVIEW

The State agency claimed $55,909,332 ($36,369,485 Federal share) for physician-administered drugs paid between January 1, 2010, and December 31, 2012.

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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).

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.[5] 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 $256,905 ($173,889 Federal share) in physician-administered drugs. Of this amount, $228,958 ($155,296 Federal share) was for single-source drugs, and $27,947 ($18,593 Federal share) was for top-20 multiple-source drugs. Because the State agency 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.

Further, the State agency did not submit the utilization data necessary to collect rebates for all other physician-administered drugs. We were unable to determine whether the State agency improperly claimed Federal reimbursement for an additional $176,044 ($111,485 Federal share) for other physician-administered drug claims that were not for single-source drugs or top-20 multiple-source drugs. We set aside the $176,044 ($111,485 Federal share) and are recommending that the State agency work with CMS to determine the unallowable portion of these claims.

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.

[5] 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.

However, the State agency's internal controls did not always ensure that it invoiced manufacturers for rebates for all eligible physician-administered drugs.[6]

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).

CMS Medicaid Drug Rebate Program Release No. 54, dated May 7, 2002, informs participating drug manufacturers that "… [i]f a state Medicaid agency paid any portion of a drug claim to the provider, for purposes of the drug rebate agreement, the manufacturer is liable for the payment of rebates for those units of the drug." (Emphasis in original.)

The Iowa DHS [Department of Human Services] Policies and Procedures Manual states: "DHS is responsible for developing and providing policy to the Pharmacy POS [Point of Sale] contractor on the drug rebate program." DHS also sets performance standards for timeliness, accuracy and funds recovery under the rebate function.

Through the Iowa Informational Letter No. 693, dated March 19, 2008, the State agency notified providers that, "[f]or all J-code claims filed to Medicaid, the claim must include the NDC code, and must be on the CMS rebatable list."

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 $228,958 ($155,296 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 collect rebates, the State agency improperly claimed Federal reimbursement for these single-source physician-administered drugs.

[6] Although the State agency was submitting most of its physician-administered drug claims for rebate before we initiated this audit, it began submitting additional drug claims while we were performing our audit work. Most of these additional drug claims 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). The additional drug claims that the State agency began submitting for rebate during the course of our audit included single-source, top-20 multiple-source, and other physician-administered drugs. These additional drug claims are not part of our findings. See also our discussion of "Methodology" in Appendix B.

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 $27,947 ($18,593 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's system edits did not always reject these claims, nor did the State agency submit the utilization data to the drug manufacturers for rebate purposes.

Because the State agency did not submit utilization data to the manufacturers to collect 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 the State agency improperly claimed Federal reimbursement for an additional $176,044 ($111,485 Federal share) for other physician-administered drug claims that were not for single-source or top-20 multiple-source physician-administered drugs.

Although the State agency generally collected the drug utilization data necessary to invoice the manufacturers for rebates associated with these claims, the State agency did not submit the utilization data to the drug manufacturers to collect rebates. Therefore, the State agency could not determine whether manufacturers paid rebates for all of the required physician-administered drugs.

Accordingly, we set aside the $176,044 ($111,485 Federal share) and are recommending that the State agency work with CMS to determine the unallowable portion of these claims.

RECOMMENDATIONS

We recommend that the State agency:

- refund to the Federal Government $155,296 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement,

- refund to the Federal Government $18,593 (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 $111,485 (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 that were not billed for rebates after December 31, 2012, and

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

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency concurred with all of our recommendations and described corrective actions that it had taken or planned to take. The State agency's comments are included in their entirety as Appendix D.

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
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	04/13/15
Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-09-13-02037	03/04/15
Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs	A-06-14-00031	02/10/15
The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-03-12-00205	08/21/14
Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-13-06040	08/07/14
Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs	A-09-12-02079	04/30/14
Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs	A-09-12-02080	04/24/14
Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-03-12-00200	11/26/13
Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs	A-06-12-00059	09/19/13
Nationwide Rollup Report for Medicaid Drug Rebate Collections	A-06-10-00011	08/12/11
States' Collection of Medicaid Rebates for Physician-Administered Drugs	OEI-03-09-00410	June 2011

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

The State agency claimed $55,909,332 ($36,369,485 Federal share) for physician-administered drugs paid between January 1, 2010, and December 31, 2012.

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

We conducted our audit work, which included visiting and contacting the State agency in Des Moines, Iowa, from October 2013 through December 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 invoicing instructions for physician-administered drugs.

- We reviewed State agency policies and procedures for rebates for physician-administered drugs.

- We interviewed State agency personnel to gain an understanding of the administration of and controls over the Medicaid invoicing and rebate process for physician-administered drugs.

- We obtained listings of the CMS top-20 multiple-source physician-administered drugs, the Medicare Part B crosswalk, and the CMS Medicaid Drug File for our audit period.

- We obtained claim details from the State agency for all drug claims, including physician-administered drugs, for the period January 1, 2010, through December 31, 2012.

- We obtained the listing of 340B entities from the State agency.[7]

- We removed drug claims totaling $42,959,728 ($27,952,370 Federal share) that either were not eligible for a drug rebate or contained an NDC and were invoiced for rebate.

- We reviewed the remaining drug claims totaling $12,949,604 ($8,417,114 Federal share) to determine whether the State agency complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. Specifically:

    - We identified single-source drugs by matching the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk to identify, if possible, the NDCs associated with each HCPCS code listed on claims from providers. We used the CMS Medicaid Drug File to determine whether these NDCs were classified as single-source drugs. (At the start of our audit, the State agency had not invoiced manufacturers for rebates for single-source physician-administered drug claims totaling $9,627,307. As of December 31, 2014, the State agency had invoiced manufacturers for $9,398,349 of these drug claims (of which $8,947,839 was for crossover drug claims and $450,510 was not). The remaining $228,958 ($155,296 Federal share) of the $9,627,307 not invoiced at the start of our audit is the amount conveyed in our finding on single-source physician-administered drugs.)

    - We identified the top 20 multiple-source drugs by matching the HCPCS code on the drug claim to the HCPCS code on CMS's top-20 multiple-source drug listing. (At the start of our audit, the State agency had not invoiced manufacturers for rebates for top-20 multiple-source physician-administered drug claims totaling $292,447. As of December 31, 2014, the State agency had invoiced manufacturers for $264,500 of these drug claims (of which $182,239 was for crossover drug claims and $82,261 was not). The remaining $27,947 ($18,593 Federal share) of the $292,447 not invoiced at the start of our audit is the amount conveyed in our finding on top-20 multiple-source physician-administered drugs.)

    - 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. (At the start of our audit, the State agency had not invoiced manufacturers for rebates for these other physician-administered drug claims totaling $3,029,850. As of December 31, 2014, the State agency had invoiced manufacturers for $2,853,806 of these drug claims (of which $2,794,427 was for crossover drug claims and $59,379 was not). The remaining $176,044 ($111,485 Federal share) of the $3,029,850 not invoiced at the start of our audit is the

[7] 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.

amount conveyed in our finding on other physician-administered drugs and set aside for CMS's adjudication.)

- We discussed the results of our review with State agency officials, and provided detailed support for the drug costs we are questioning and setting aside, on October 28, 2014, December 16, 2014, and April 21, 2015.

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

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

FEDERAL LAWS

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

Section 6002 of the DRA added section 1927(a)(7) to the Act to require that States capture information necessary to secure rebates from manufacturers for certain covered outpatient drugs administered by a physician. In addition, section 6002 of the DRA amended section 1903(i)(10) of the Act to prohibit a Medicaid Federal share for covered outpatient drugs administered by a physician unless the States 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 invoice 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).[8]

[8] 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 AGENCY REQUIREMENTS AND GUIDANCE

The State agency publishes bulletins, called Iowa Informational Releases or Iowa Informational Letters, to clarify and explain new and existing programs and policies for providers and other stakeholders.

Iowa Informational Release No. 593, dated March 28, 2007, announced that the State agency would be implementing changes involving the reporting of physician-administered drugs to comply with CMS requirements implemented in response to the DRA. This guidance also states:

> **Effective May 1, 2007, all claims for dates of service on or after May 1, 2007 for drug products administered in an office/clinic or other outpatient setting which are reported with a "J" (or HCPCS) code must also include the corresponding National Drug Code (NDC) number. In addition, only those NDCs that are rebatable will be payable by [the State agency].**
>
> **The NDC number** serves as a universal product identified for drug products. An NDC is 11 digits and can be located on a drug's packaging or by contacting the manufacturer. [All emphasis (bolding and underlining) in original.]

Iowa Informational Release No. 647, dated October 26, 2007, clarifies the guidance in Release No. 593 and states:

> **The NDC requirement states** that all claims for drug products administered in an office/clinic or other outpatient setting that are reported with a HCPCS "J" code must also include the corresponding National Drug Code (NDC) number. In addition, only those NDCs that are rebatable will be payable by [the State agency].
>
> **Documentation Standards:** providers must ensure that the NDC number of the administered drug is noted in the patient's file. The NDC must match the drug administered and not the number from another manufacturer's product, even if the chemical name is the same. [All emphasis (bolding and underlining) in original.]

APPENDIX D: STATE AGENCY COMMENTS

Iowa Department of Human Services

Terry E. Branstad, Governor | Kim Reynolds, Lt. Governor | Charles M. Palmer, Director

MAY 20 2015

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

RE: *Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs,* Draft Report, A-07-14-06049

Dear Mr. Cogley:

Enclosed please find comments from the Iowa Department of Human Services (DHS) on the April 24, 2015, draft report concerning Office of Inspector General's (OIG) review of the drug rebate claims processed by DHS.

DHS appreciates the opportunity to respond to the draft report and provide additional comments to be included in the final report. DHS strives to administer the program in compliance with applicable Federal and State law, regulations, and other policies. DHS is committed to working with CMS to resolve the issues identified in this audit review and are appreciative of the hard work your staff has undertaken relative to this audit.

Questions about the enclosed response can be addressed to:

Jody Lane-Molnari, Executive Officer II
Division of Fiscal Management
Iowa Department of Human Services
Hoover State Office Building, 1st Floor SW
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Sincerely,

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Director

enclosure

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IOWA DEPARTMENT OF HUMAN SERVICES
RESPONSE TO OIG DRAFT REPORT:

Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs
Draft Report, A-07-14-06049

Background

The Medicaid drug rebate program became effective in 1991. For a covered outpatient drug to be eligible for Federal reimbursement under the program, the manufacturer must enter into a rebate agreement with CMS and pay quarterly rebates to 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 (DHS) 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, the Department of Human Services (DHS), is responsible for paying claims, submitting invoices to manufacturers, and collecting Medicaid drug rebates for physician-administered drugs. To execute this responsibility, DHS contracted with Goold Health Systems to operate the state's drug rebate program. DHS 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.

For this audit, OIG reviewed the Department of Human Services invoicing for rebates for physician-administered drugs for the period January 1, 2010, through December 31, 2012.

OIG Findings and Recommendations

Iowa DHS did not always comply with Federal Medicaid requirements for invoicing manufactured for rebates for physician-administered drugs. DHS did not invoice manufacturers for rebated associated with $256,905 ($173,889 Federal share) in physician-administered drugs. Of this amount, $228,958 ($155,296 Federal share) was for single-source drugs, and $27,947 ($18,593 Federal share) was for top-20 multiple-source drugs. Because DHS did not submit utilization data to the manufacturers to collect rebates, DHS improperly claimed Federal reimbursement for these single-source and top-20 multiple-source drugs.

Further, DHS did not submit the utilization data necessary to collect rebates for all other physician-administered drugs. OIG was unable to determine when DHS improperly claimed Federal reimbursement for an additional $176,044 ($111,485 Federal share) for other physician-administered drug claims that were not for single-source or top-20 multiple-source drugs. OIG set aside this finding and are recommending that DHS work with CMS to determine the unallowable portion of these claims.

DHS required providers to include NDCs on all physician-administered drug claims, and DHS notified providers that it would deny claims that did not include NDCs. However, DHS's internal controls did not always ensure that it invoiced manufacturers for rebates for all eligible physician-administered drugs.

OIG recommends that DHS:

- Refund $155,296 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement,
- Refund $18,593 (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 $111,485 (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 that were not invoiced for rebated after December 31, 2012, and
- Strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.

DHS Response

OIG Recommendation #1 – Refund $155,296 for single-source physician-administered drugs that were ineligible for Federal reimbursement.

DHS concurs with this recommendation. A corrective action has been implemented which has updated the NDC requirement of J-codes that were not previously set in the MMIS to require the NDC. Additional corrective actions are noted under the response to OIG Recommendation #5, which is part of our comprehensive overall project plan to improve drug rebate policy under the physician administered drug program.

OIG Recommendation #2 – Refund $18,593 for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement.

DHS concurs with this recommendation. DHS/IME is researching an appropriate corrective action to resolve the multiple source drug issue and is considering enforcing the requirement that all drugs billed to and paid by the IME must be rebatable. This requirement currently only applies to the top 20 physician administered multiple source drugs that have the highest dollar volume as published by CMS. This change is being considered in light of the fact that the "top 20 multiple-source list" is no longer maintained by CMS. Additional corrective actions are noted under the response to OIG Recommendation #5, which is part of our comprehensive overall project plan to improve drug rebate policy under the physician-administered drug program.

OIG Recommendation #3 – Work with CMS to determine the unallowable portion of the $111,485 (Federal share) for other claims for outpatient physician-administered drugs that were ineligible for Federal reimbursement and refund that amount.

DHS concurs with this recommendation and will work with CMS to determine the unallowable portion related to claims for outpatient physician-administered drugs that were ineligible for federal reimbursement; corrective actions are noted under the response to OIG Recommendation #5.

OIG Recommendation #4 – Work with CMS to determine and refund the unallowable Federal reimbursement for physician-administered drugs that were not invoiced for rebated after December 31, 2012.

DHS concurs with this recommendation and will work with CMS to determine the unallowable federal reimbursement for physician-administered drugs which were not invoiced for rebate after December 31, 2012. Corrective actions are noted under the response to OIG Recommendation #5.

OIG Recommendation #5 – Strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.

DHS concurs with this recommendation. In light of this audit, DHS/IME has implemented the following internal controls to ensure that all submitted physician-administered drugs include valid NDCs and are invoiced for rebate:

1. DHS/IME implemented the quarterly Medicare (Part B) "J code/NDC" cross-walk and will also utilize, as needed, a monthly cross-walk in between issuance of the monthly CMS cross-walk.
   a. This measure will better assure that the physician-administered drug claims will only be paid where the correct NDC is listed with the J code being billed and where the NDC being billed is for a drug that is indeed rebatable;
   b. This will also provide greater integrity and certainty in the information passed to GHS for invoicing/processing of rebates.

2. Strengthened interaction between the IME Core Unit and the IME Pharmacy contractor (Goold Health Systems – GHS) to assure that GHS has all necessary information for submitting rebate invoices to manufacturers, including Medicare crossover claims.

3. Other internal control modifications include the following:
   a. Relative to findings related to NDCs not being on claims that were paid and where claims were paid where an incorrect NDC (i.e., not 11-digit NDC) was included on the claim, additional internal controls have now been implemented to address these issues. Beyond use of the crosswalks discussed immediately above, other modifications/controls include:

i. Enforcing the NDC requirement on J-codes which were previously excluded from the NDC requirement (e.g., Rhogam and Aloxi);
ii. Implementing/enforcing the requirement that ALL NDCs billed with J codes must be rebatable, or the claim will deny;
iii. Implementation of enhanced/detailed reporting of invoicing for each quarterly invoice period;
iv. NDC digit (count) checks, to assure that only proper 11-digit NDCs are allowed for payment of rebatable physician-administered drugs; and
v. Better controls for validating 340B provider status, based on providers using the "UD" modifier signifying that they are a 340B provider, which will address non-340B providers incorrectly appending the "UD" modifier to their J-code claims.