Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

THE DISTRICT OF COLUMBIA CLAIMED UNALLOWABLE FEDERAL REIMBURSEMENT FOR SOME MEDICAID PHYSICIAN-ADMINISTERED DRUGS

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Office of Inspector General

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EXECUTIVE SUMMARY

The District of Columbia claimed $2.4 million in Federal reimbursement that was unallowable and $983,000 that may be unallowable over nearly 3 years 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. States bill the manufacturers for the rebates to reduce the cost of the 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 in an office or hospital outpatient facility.

Our objective was to determine whether the District of Columbia's Department of Health Care Finance (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 drug's 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 essentially amended section 1927 of the Act to address the collection of rebates on physician-administered drugs. To collect these rebates, States submit to the manufacturers utilization data containing the national drug codes (NDCs) for all single-source and 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 data to bill and collect rebates.

In the District of Columbia, the State agency is responsible for billing and collecting Medicaid drug rebates for physician-administered drugs. The State agency contracts with a contractor to process its Medicaid claims and manage its drug rebate program. The contractor maintains claim utilization, which includes claim lines with NDCs, in the State agency's Medicaid Management Information System (MMIS); enters the drug claims into its drug rebate system; bills the manufacturers quarterly; and maintains a record of rebate accounts receivable due from the manufacturers. From April 1, 2008, through December 31, 2010 (audit period), the State agency paid $15,076,565 for claims submitted for physician-administered drugs.

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 properly billed for

rebates for claim lines totaling $2,221,478 in our judgmental sample. However, the State agency did not bill for rebates for claim lines totaling $4,347,029 during our audit period. Of this amount, we identified $3,082,971 ($2,392,539 Federal share) for which the State agency should have billed for rebates on claim lines for single-source and top-20 multiple-source drugs. Because the State agency did not capture NDCs or did not bill the manufacturers for rebates, it improperly claimed Federal reimbursement for these claim lines.

We were unable to determine the portion of the remaining $1,264,058 ($983,125 Federal share) for which the State agency may have improperly claimed reimbursement. This amount included claim lines for drugs that were not top-20 multiple-source and claim lines for which there was insufficient information to determine whether the drugs were eligible for rebates.

The State agency said that it did not capture NDCs or submit these claims for rebates because of many issues with its MMIS and rebate system. The State agency did not require that providers include NDCs on physician-administered drug claims until June 2008 and did not begin to bill for rebates until 2010.

WHAT WE RECOMMEND

We recommend that the State agency:

- refund to the Federal Government $2,392,539 (Federal share) for single-source and top-20 multiple-source physician-administered drug claims that were ineligible for Federal reimbursement,

- work with CMS to determine the unallowable portion of the $983,125 (Federal share) for other physician-administered drug claims 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 after January 1, 2011,

- ensure that its MMIS edits require valid NDCs for payment on all drug claims, and

- improve its rebate processes to ensure that all physician-administered drug claims are submitted for rebates.

STATE AGENCY COMMENTS AND OUR RESPONSE

In written comments on our draft report, the State agency partially concurred with our first two recommendations and fully concurred with our remaining recommendations. The State agency described some of the corrective actions it has taken or plans to take. The State agency requested that we reduce the unallowable amount to take into account the actions it described. We did not audit the State agency's actions because they were after our audit; therefore, we have not modified our recommendations.

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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. States bill the manufacturers for the rebates to reduce the cost of the 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 in an office or hospital outpatient facility. (Appendix A lists previous reviews.)

OBJECTIVE

Our objective was to determine whether the District of Columbia's Department of Health Care Finance (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.[1] 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 fields for the 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 must capture drug utilization data that identifies, by NDC, the number of units of each drug for which the States reimbursed Medicaid providers and must 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.

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

[1] Section 1927(b) of the Act and section II of the Medicaid rebate agreement.

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 in an office setting are typically billed to the Medicaid program on a claim form using Healthcare Common Procedure Coding System (HCPCS) codes. Drugs administered by a physician in an outpatient hospital setting are typically billed on a claim form using a revenue code to identify the type of service. For purposes of the Medicaid drug rebate program, physician-administered drugs are classified as either single-source or multiple-source.[2]

Before the Deficit Reduction Act of 2005, many States did not collect rebates on physician-administered drugs if the drug claims did not contain NDCs. The Deficit Reduction Act essentially amended section 1927 of the Act to require States to capture the necessary information, including NDCs, to bill manufacturers for rebates on such drugs. However, section 1927(a)(7) of the Act allowed CMS to delay some collection and submission requirements for States that demonstrated a need for additional time for implementation.

The State Agency's Medicaid Drug Rebate Program

The State agency is responsible for paying claims and collecting Medicaid drug rebates for physician-administered drugs. In the District of Columbia, claim forms contain a field for the NDC. From April 1, 2008, through December 31, 2010 (audit period), the State agency paid $15,076,565 for claims submitted for physician-administered drugs.

The State agency contracts with ACS State Healthcare, LLC (contractor),[3] to process its Medicaid claims and manage its drug rebate program.[4] The contractor maintains the State agency's Medicaid Management Information System (MMIS)[5] and also maintains a separate drug rebate system for billing rebates. On a monthly basis, the contractor collects the claim lines[6] with NDCs for covered drugs and enters the information into its drug rebate system. The drug rebate system identifies the rebatable units, calculates the rebates due based on CMS's unit rebate amount, and bills the manufacturers by NDC for rebates on single-source and all multiple-

[2] 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.

[3] On September 28, 2009, Xerox Corporation acquired ACS State Healthcare.

[4] The contractor also manages the State agency's pharmacy drug rebate processes; however, this review does not cover the pharmacy claiming and rebating processes.

[5] The MMIS is a mechanized claims payment and information retrieval system.

[6] A claim line represents one physician-administered drug service. Claims may include more than one claim line.

source drugs.[7] The manufacturers pay the rebates directly to the contractor. The contractor reconciles the invoiced amounts to the paid amounts and forwards the checks to the State agency. The contractor maintains accounts receivable information and works with manufacturers to resolve any unpaid rebates.[8]

As allowed by section 1927(a)(7) of the Act, the State agency requested a waiver from CMS to meet the requirement of the Deficit Reduction Act related to capturing NDCs for physician-administered drugs.[9] Accordingly, CMS granted a 3-month extension through March 31, 2008, for these claims. The State agency began collecting NDCs in June 2008. However, the State agency did not begin billing for rebates for physician-administered drugs until the second quarter of 2010, when it updated its MMIS system and included edits to check for valid NDCs.[10]

HOW WE CONDUCTED THIS REVIEW

Our audit covered $15,076,565 that the State agency claimed for physician-administered drugs. The claims were for drugs administered in a physician's office or in a hospital outpatient setting and paid during our audit period.[11]

For the $15,076,565 of physician-administered drug claims, the State agency provided and we reviewed 66,962 claim lines totaling $4,347,029 that it said had not been billed for rebates. Of the remaining claim lines, totaling $10,729,536, we judgmentally selected and tested 33 NDCs (14,333 claim lines) associated with 16 manufacturers ($2,221,478 in total) for the third quarter of 2010 to ensure that the claims were properly invoiced.

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.

[7] Although the section of the Medicaid drug rebate law relating to physician-administered multiple-source drugs specifically addresses only rebates for the 20 drugs with the highest dollar volume dispensed (top-20 multiple-source drugs), State agency officials stated that the contractor billed for rebates on all multiple-source drugs.

[8] The invoices and accounts receivable identify drugs by NDC and do not distinguish between pharmacy and physician-administered drugs.

[9] At the time the waiver was requested, the State agency was the Medical Assistance Administration. In February of 2008, the Department of Health Care Finance assumed responsibility as State agency.

[10] Subsequently, the State agency began billing retroactively for some rebates.

[11] Our scope was limited to Medicaid fee-for-service drug claims. We did not include the drug utilization of managed care organizations in this review.

FINDINGS

The State agency did not always comply with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs. The State agency properly billed for rebates for claim lines totaling $2,221,478 in our judgmental sample. However, the State agency did not bill for rebates for claim lines totaling $4,347,029 during our audit period. Of this amount, we identified $3,082,971 ($2,392,539 Federal share) for which the State agency should have billed for rebates on claim lines for single-source and top-20 multiple-source drugs. Because the State agency did not capture NDCs or did not bill the manufacturers for rebates, it improperly claimed Federal reimbursement for these claim lines.

We were unable to determine the portion of the remaining $1,264,058 ($983,125 Federal share) for which the State agency may have improperly claimed reimbursement. This amount included claim lines for drugs that were not top-20 multiple-source and claim lines for which there was insufficient information to determine whether the drugs were eligible for rebates.

The State agency said that it did not capture NDCs or submit these claims for rebates because of many issues with its MMIS and rebate system. The State agency did not require that providers include NDCs on physician-administered drug claims until June 2008 and did not begin to bill for rebates until 2010.

FEDERAL AND STATE REQUIREMENTS AND GUIDANCE

The Deficit Reduction Act 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)(A)). Federal regulations prohibit Federal reimbursement for physician-administered drugs unless the States submit utilization data containing the NDCs (42 CFR § 447.520). CMS granted temporary waivers to certain States that needed additional time to implement these requirements. CMS granted the District of Columbia a waiver through March, 31, 2008, for all physician-administered claims.

The State agency provided guidance that providers would be required to include NDCs on their claims, and that the State agency would not reimburse providers for drugs unless a valid NDC was reported on the applicable claim form.

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

THE STATE AGENCY DID NOT BILL MANUFACTURERS FOR REBATES AS REQUIRED FOR FEDERAL REIMBURSEMENT ON SOME PHYSICIAN-ADMINISTERED DRUG CLAIMS

The State agency improperly claimed Federal reimbursement of $3,082,971 ($2,392,539 Federal share) for 39,911 claim lines for physician-administered drugs for which it did not collect rebates. To determine whether the State agency was required to bill for rebates for these claim lines, we matched the NDCs to the CMS Medicaid Drug File.

Claim Lines That Included National Drug Codes

The State agency captured the NDCs for $1,814,909 ($1,436,187 Federal share) for 23,825 claim lines but did not bill the claim lines for rebates.[12] We determined that the State agency paid:

- $1,737,797 ($1,375,059 Federal share) for 22,115 claim lines for single-source drugs administered by physicians and

- $77,112 ($61,128 Federal share) for 1,710 claim lines for top-20 multiple-source drugs administered by physicians.

Claim Lines That Did Not Include National Drug Codes

The State agency did not capture valid NDCs for the remaining $1,268,062 ($956,352 Federal share) for 16,086 claim lines. The claim lines without valid NDCs identified the drugs by HCPCS code. Therefore, we used CMS's Medicare Part B crosswalk to match the HCPCS codes to the NDCs.[13] We determined that the State agency paid:

- $1,002,977 ($754,679 Federal share) for 9,921 claim lines for single-source drugs administered by physicians and

- $265,085 ($201,673 Federal share) for 6,165 claim lines for top-20 multiple-source drugs administered by physicians.

Rebates Were Required for Federal Reimbursement

For these claim lines totaling $3,082,971 ($2,740,774 for single-source drugs and $342,197 for top-20 multiple-source drugs) the State agency did not bill for rebates as required. As a result, the State agency improperly claimed reimbursement of $2,392,539 (Federal share).

THE STATE AGENCY DID NOT BILL MANUFACTURERS FOR REBATES THAT MAY HAVE BEEN REQUIRED FOR FEDERAL REIMBURSEMENT ON OTHER PHYSICIAN-ADMINISTERED DRUG CLAIMS

We were unable to determine whether the State agency improperly claimed Federal reimbursement for $1,264,058 ($983,125) for 27,051 claim lines paid for physician-administered drugs.

[12] The State agency said that it intended to submit these claim lines for rebates but had not done so by the end of our fieldwork.

[13] CMS instructed States that they could use the Medicare Part B crosswalk as a reference because HCPCS codes and NDCs are standardized codes used across programs. Therefore, we used this crosswalk to match the HCPCS codes to NDCs listed in the CMS Medicaid Drug File.

Claim Lines for Non-Top-20 Multiple-Source Drugs

We identified $1,121,918 ($872,650 Federal share) for 24,646 claim lines for which the State agency paid:

- $685,402 ($542,351 Federal share) for 10,628 claim lines that contained valid NDCs for non-top-20 multiple-source drugs and

- $436,516 ($330,299 Federal share) for 14,018 claim lines that contained HCPCS codes that CMS's Part B crosswalk matched to NDCs in the Medicaid Drug File that were for non-top-20 multiple-source drugs.

Although the law specifically addresses rebates only on top-20 multiple-source drugs administered by physicians, State agency officials advised us that the contractor billed for rebates on all multiple-source drugs. Because the State agency required providers to submit NDCs on all drug claims and billed manufacturers for any NDCs it captured, it should have captured the NDCs and directed the contractor to bill manufacturers for rebates on these non-top-20 drug claims as well.

Claims for Which the National Drug Code Could Not Be Identified

We identified $142,140 ($110,475 Federal share) for 2,405 claim lines for which the State agency did not capture the coding data necessary to collect rebates. These claims did not contain a valid NDC or provide sufficient information to identify the specific NDCs for the drugs administered. The State agency paid:

- $74,079 ($56,597 Federal share) for 1,913 claim lines for drugs administered by a physician in an office setting for which the HCPCS codes did not appear on CMS's Part B crosswalk or that included an NDC that did not appear on the Medicaid Drug File and

- $68,061 ($53,878 Federal share) for 492 claim lines that did not contain sufficient information to identify the NDC.

Because the claim lines did not provide sufficient information to identify the specific NDCs for the drugs administered, we were unable to determine whether they were single-source drugs or top-20 multiple-source drugs for which the State agency was required to bill for rebates.

Rebates May Have Been Required for Federal Reimbursement

We were unable to determine the amount of these claims that should have been billed for rebates. Accordingly, we set aside $1,264,058 ($983,125 Federal share) for CMS's adjudication.

THE STATE AGENCY DID NOT CAPTURE NATIONAL DRUG CODES AND BILL FOR REBATES ASSOCIATED WITH SOME PHYSICIAN-ADMINISTERED DRUG CLAIMS

The State agency said that it had a number of technical issues with its MMIS and rebate systems. Also, the State agency did not require providers to include the NDC on all physician-administered claims until June 2008 and did not bill for rebates or update the edits in its MMIS to deny claim lines without valid NDCs until the second quarter of 2010. After the second quarter of 2010, the State agency's MMIS edits continued to pay claims that did not include valid NDCs, primarily because of delays in loading CMS's status updates for changes in NDC codes. As a result of these issues, the contractors did not bill for rebates associated with these claims, and the claims were therefore ineligible for Federal reimbursement.

RECOMMENDATIONS

We recommend that the State agency:

- refund to the Federal Government $2,392,539 (Federal share) for single-source and top-20 multiple-source physician-administered drug claims that were ineligible for Federal reimbursement,
- work with CMS to determine the unallowable portion of the $983,125 (Federal share) for other physician-administered drug claims 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 after January 1, 2011,
- ensure that its MMIS edits require valid NDCs for payment on all drug claims, and
- improve its rebate processes to ensure that all physician-administered drug claims are submitted for rebates.

STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the State agency partially concurred with our first two recommendations and fully concurred with our remaining recommendations. The State agency described corrective actions it has taken or plans to take. The State agency requested that we reduce the unallowable amount to take into account the actions it described.

We did not adjust our calculations because the State agency's actions were after our audit; therefore, we have not modified our recommendations.

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

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered $15,076,565 that the State agency claimed for physician-administered drugs: $10,729,536 that the State agency said it billed for rebates and $4,347,029 that it said had not been billed for rebates. The claims were for drugs administered in a physician's office or in a hospital outpatient setting and paid from April 1, 2008, through December 31, 2010 (audit period).[14]

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 and controls over billing for Medicaid rebates for physician-administered drugs.

We performed fieldwork at the State agency and its contractors in the District of Columbia in July 2012 and May 2013.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance pertaining to the Medicaid drug rebate program and physician-administered drugs;
- interviewed CMS officials about the Federal requirements and guidance governing physician-administered drugs under the Medicaid drug rebate program;
- reviewed State agency regulations and guidance to providers, including billing instructions for physician-administered drugs;
- reviewed State agency policies and procedures for physician-administered drug rebates;
- interviewed State agency and rebate contractor personnel to gain an understanding of the administration of and controls over the Medicaid rebate billing process for physician-administered drugs;
- obtained from the State agency 227,232 physician-administered claim lines totaling $15,076,565 paid during the audit period;
- tested the billing and collection of rebates for claim lines that the State agency said had been billed for rebates by:

[14] Our scope was limited to Medicaid fee-for-service drug claims. We did not include the drug utilization of managed care organizations in this review.

- judgmentally selecting the third quarter of 2010 because it reflected high payments compared with other quarters and because it was the first quarter for which the rebate process was in effect;

- from the third-quarter claims, selecting claim lines totaling $2,221,478 for 33 NDCs associated with 16 manufacturers that represented drugs with high utilization; and

- reviewing copies of rebate invoices submitted to the 16 manufacturers and the resultant remittances to verify the billing of rebates by NDC and receipt of rebates for the sampled claim lines;

- reviewed the remaining 66,962 claim lines, totaling $4,347,029, that the State agency said had not been billed for rebates and:

  - identified 34,453 claim lines that contained valid NDCs and used the NDC and the CMS Medicaid Drug File to identify whether the drugs were single- or multiple-source;

  - identified 32,509 claim lines that did not contain a valid NDC and:

    - identified drug utilization on the basis of the HCPCS codes on the claim lines;

    - matched the HCPCS code on each claim line to the HCPCS code in the Medicare Part B crosswalk, which CMS instructed States that they could use as a reference, to identify the NDCs associated with each HCPCS code;

    - mapped the resultant NDCs to CMS's Medicaid Drug File to identify whether the drugs were single- or multiple-source;

    - identified claims for which we could not determine a drug category; and

- discussed the results of our review with State agency officials on February 18, 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.

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 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 Deficit Reduction Act of 2005 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 Deficit Reduction Act 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 mandated that, effective January 1, 2007, the utilization data must be submitted using the NDC.

Section 1927(a)(7)(D) of the Act allowed the Secretary 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 specifically state 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 in effect during most of the audit period 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).[15]

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

STATE GUIDANCE

In its February 20, 2008, Medical Assistance Program Action Transmittal #08-07, *System Modifications Affecting Claims Processing*, the Medical Assistance Administration described upcoming changes in its MMIS system, including the rebate program for physician-administered drugs. The transmittal said:

> The J-Code [HCPCS Code] Rebate initiative is a Centers for Medicare and Medicaid Services' mandate for Medicaid programs to capture NDCs on submitted J-codes for the purpose of collecting manufacturer rebates on the drugs. J-codes are used by providers to bill Medicaid programs for injectable prescription drugs, including cancer drugs. Because the Medicaid Drug Rebate Program is an NDC driven program, the specific NDC dispensed is necessary for states to bill manufacturers for rebates.

The transmittal did not require that providers submit NDCs on claim forms, but advised providers that the rebate initiative would be implemented in June 2008. It further stated that "[a]dditional details will be provided for each project as the modifications are completed."

The State agency's *Medicaid Bulletin*, volume 2, issue 4 (2008), reminded providers that "Due to the Deficit Reduction Act of 2005, the National Drug Code is required when billing for physician administered drugs provided in other than an inpatient setting." The *Medicaid Bulletin* provided a list of relevant HCPCS codes. In a brief Frequently Asked Questions section, the bulletin further emphasized that the District of Columbia would not reimburse providers for physician-administered drugs unless the claim contained a valid NDC.

APPENDIX D: STATE AGENCY COMMENTS

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Department of Health Care Finance

Office of Health Care Operations Administration

June 27, 2014

Mr. Stephen Virbitsky
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Public Ledger Building, Suite 316
150 S. Independence Mall West
Philadelphia, PA 19106

Re: Report Number: A-03-00205

Dear Mr. Virbitsky,

Enclosed is the D.C. Department of Health Care Finance's response to Audit Report #A-03-12-0020, which was received from the U.S. Department of Health and Human Services, Office of the Inspector General (OIG), on May 20, 2014. We understand that the OIG report is a draft and not a final document, and our response pertains only to findings contained therein. Per your request, we have indicated whether we concur, do not concur, or partially concur with each finding and corresponding recommendation, and propose or describe corrective actions where necessary.

The Department of Health Care Finance is prepared for on-going communication with the OIG until each audit finding is resolved. After you have received our response, please inform us of next steps. If you have any questions, I can be reached by phone at 202-698-2007, and email at donald.shearer@dc.gov.

Sincerely

[redacted]

Donald Shearer
Director, Health Care Operations Administrator
Department of Health Care Finance
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Suite 900s
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GOVERNMENT OF THE DISTRICT OF COLUMBIA

Department of Health Care Finance

Office of Health Care Operations Administration

June 27, 2014

Mr. Donald Shearer, Director of Health Care Operations
D.C. Department of Health Care Finance
Response to HHS OIG Report #A-03-12-00205

OIG Recommendation #1:

Refund to the federal Government 2.392.539 (Federal share) for single-source and top-20 multiple-source physician-administered drug claims that were ineligible for Federal reimbursement.

DHCF Response:

DHCF partially concurs with the recommendation. The $2,392,539 number for Federal share includes $754,679 single source claims and $201,673 multi-source claims where DHCF does not have a valid NDC, and should therefore reimburse the stated amount ($956,352) to CMS.

However, the remaining claims where and NDC was submitted as part of the claim, but was not selected by MMIS to be submitted for rebate, have been identified and DHCF is in the process of submitting these claims for rebate. Accordingly, the $1,375,059 in single-source drugs and $61,128 in multi-source drugs will be filed for rebate not later than September 30, 2014 and should be excluded from this recommendation.

OIG Recommendation #2:

Work with CMS to determine the unallowable portion of the $983,125 (Federal share) for other physician-administered drug claims that were ineligible for Federal reimbursement and refund that amount.

DHCF Response:

DHCF partially concurs with this recommendation. The $685,402 ($542,351 Federal share) identified that contained valid NDCs are being submitted for rebate, along with the claims mentioned under the first recommendation. These should not be subject to reimbursement.

DHCF concurs that insufficient data was collected on 2,405 claims in the amount of $142,140 ($110,475 Federal share) to determine if a rebate was due because of invalid NDC's and/ or missing procedure codes. The federal share related to these claims should be reimbursed.

The remaining $436,516 ($330,299 Federal share) that is associated with drug codes not specifically addressed by the law should not be subject to penalties since the6y were not required to be submitted for rebate.

OIG Recommendation #3:

Work with CMS to determine and refund the unallowable Federal reimbursement for physician-administered drugs claimed without NDC's after January 1, 2011.

DHCF Response:

DHCF concurs with this recommendation, and this has been included in our overall project plan for improving the overall drug rebate process.

OIG Recommendation #4:

Ensure that its MMIS edits require valid NDCs for payment on all drug claims, and

DHCF Response:

DHCF concurs with the recommendation. Although edits were not in place for all of the time period covered by the audit, edits have been subsequently added to MMIS to ensure that valid NDC codes are collected and that the services are files for rebate.

OIG Recommendation #5:

Improve its rebate processes to ensure that all physician-administered drug claims are submitted for rebate.

DHCF Response:

DHCF concurs with the recommendation. Programming issues have been identified and corrected that caused some eligible drug claims to be skipped when the MMIS prepared data for transmission to DRAMS for rebate. We are monitoring the production environment to determine if any additional instances of incorrect data are occurring. At the end of this evaluation period (July 15, 2014), we will begin the process of data clean-up and submission of claims to DRAMS for rebate. This process will span the next 4 to 6 weeks, and when completed, invoices for drug rebates that were not submitted previously will be current.

As a separate additional step, we are working with the DRAMS group to determine the best approach to account reconciliation should it be needed in the future.