Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MARYLAND 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.

Gloria L. Jarmon
Deputy Inspector General

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A-03-12-00200

Office of Inspector General

https://oig.hhs.gov

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EXECUTIVE SUMMARY

Maryland claimed $3.5 million in Federal reimbursement that was unallowable and $2.3 million that may be 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. 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 Maryland's Department of Health and Mental Hygiene (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 amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs. To collect these rebates, States submit to the manufacturers 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 Maryland, the State agency is responsible for billing and collecting Medicaid drug rebates for physician-administered drugs. The State agency contracts with two contractors to bill for rebates. The State agency forwards its claim utilization data for physician-administered drugs to the contractors, who bill the manufacturers quarterly and 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 properly billed for rebates for $1,178,222 of electronic claims in our judgmental sample. However, the State agency paid $9,377,373 for claims received on paper forms but billed for rebates on only $34,932. The State agency did not capture the NDCs and submit the utilization data to collect rebates for claim lines totaling $5,785,472: $5,646,233 for claim lines that we identified for

single-source drugs and $139,239 for claim lines that we identified for top-20 multiple-source drugs. Because the State agency did not capture the NDCs and bill the manufacturers for these rebates, it improperly claimed reimbursement for the $3,488,705 Federal share of the $5,785,472 for these claim lines.

We were unable to determine the portion of an additional $3,556,969 ($2,303,377 Federal share) for which the State agency may have improperly claimed reimbursement. This amount included claim lines for drugs for which there was insufficient information to determine whether they were eligible for rebates. The amount also included claim lines for drugs that were not top-20 multiple-source for which the contractors collected rebates on electronic claims but not paper claims.

The State agency said that it did not create a data field to enter the NDCs from the paper claims in the State's Medicaid Management Information System (MMIS) or implement edits to deny these paper claims for payment because of higher priority demands on its resources. As a result, the MMIS did not capture the NDCs for these claims, and the State agency did not report the drug utilization to the contractors to bill for rebates.

WHAT WE RECOMMEND

We recommend that the State agency:

- refund $3,488,705 (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 portion of the $2,303,377 (Federal share) for other outpatient physician-administered drug claims that was 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;

- update its MMIS edits to require NDCs for payment on all drug claims; and

- establish and implement processes to ensure that all physician-administered drug claims, including claims submitted on paper forms, are processed for rebates.

STATE AGENCY COMMENTS AND OUR RESPONSE

In written comments on our draft report, the State agency concurred with our recommendations and 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 has taken.

We did not audit the State agency's actions because they were outside our audit period; therefore, we did not modify 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 Maryland's Department of Health and Mental Hygiene (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.

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 National Drug Code (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 on the Medicaid Drug Rebate Schedule. This 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.

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

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.

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 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. Providers may submit claim forms electronically or in paper form. In Maryland, both claim forms contain a field for the NDC. During our audit period, the State agency paid $38,408,124 for electronic and paper claims submitted for physician-administered drugs.

The State agency contracts with ACS State Healthcare, LLC,[2] and Provider Synergies, LLC (the contractors), to manage its drug rebate program.[3] The State agency provides the contractors with claim lines with NDCs for drug utilization.[4] Using this data, the contractors identify the rebatable units, calculate the rebates due based on CMS's unit rebate amount, and bill the manufacturers by NDC for rebates on single-source and all multiple-source drugs.[5] The manufacturers pay the rebates directly to the State agency. The State agency forwards copies of the payment information to the contractors, who reconcile the invoiced amount to the paid amounts. The contractors maintain accounts receivable information and work with manufacturers to resolve any unpaid rebates.[6]

For the quarter ended March 2008, the State agency forwarded to the contractors utilization data for both electronic and paper claims, and the contractors identified NDCs that did not appear on

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

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

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

[5] Although the Medicaid drug rebate law relating to multiple-source drugs specifically addresses only rebates for the 20 drugs with the highest dollar volume dispensed (top 20 multiple-source drugs), Maryland officials stated that the contractors billed for rebates on all multiple-source drugs.

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

the claim lines. After March 2008, the State agency forwarded utilization data only for electronically processed claims, which captured NDCs on the claim lines, and did not forward data for the paper claims, which did not capture the NDCs.

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 drugs administered by physicians in outpatient hospital settings. Accordingly, CMS granted a 6-month extension through June 30, 2008, for hospital outpatient claims.

HOW WE CONDUCTED THIS REVIEW

Our audit covered $38,408,124 that the State agency claimed for physician-administered drugs: $29,030,751 that providers claimed electronically and $9,377,373 that providers claimed on paper forms. The claims were for drugs administered in a physician's office and paid between January 1, 2008, and December 31, 2010, and drugs administered by a physician in a hospital outpatient setting and paid between July 1, 2008, and December 31, 2010 (audit period).[7]

Using the summary drug utilization information for the fourth quarter of calendar year 2010, we judgmentally selected 34 NDCs associated with 16 manufacturers ($1,178,222 in total) that represented drugs with high utilization. When we determined that none of the summary drug utilization information provided for the fourth quarter of 2010 included NDCs for claims submitted on paper, we requested and reviewed detail information for 57,285 claim lines associated with the paper claims.

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 properly billed for rebates for $1,178,222 of electronic claims in our judgmental sample. However, the State agency paid $9,377,373 for claims received on paper forms but billed for rebates on only $34,932. The State agency did not capture the NDCs and submit the utilization data to collect rebates for claim lines totaling $5,785,472: $5,646,233 for claim lines that we identified for single-source drugs and $139,239 for claim lines that we identified for top-20 multiple-source drugs. Because the State agency did not capture the NDCs and bill the manufacturers for these

[7] 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. We also excluded outpatient hospital claims paid during the audit period for services provided on or before June 30, 2008, when the State agency's waiver expired.

rebates, it improperly claimed reimbursement for the $3,488,705 Federal share of the $5,785,472 for these claim lines.

We were unable to determine the portion of an additional $3,556,969 ($2,303,377 Federal share) for which the State agency may have improperly claimed reimbursement. This amount included claim lines for drugs for which there was insufficient information to determine whether they were eligible for rebates. The amount also included claim lines for drugs that were not top-20 multiple-source for which the contractors collected rebates on electronic claims but not paper claims.

The State agency said that it did not create a data field to enter the NDCs from the paper claims in the State's Medicaid Management Information System (MMIS) or implement edits to deny these paper claims for payment because of higher priority demands on its resources. As a result, the MMIS did not capture the NDCs for these claims, and the State agency did not report the drug utilization to the contractors to bill for rebates.

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 Maryland a waiver through June 30, 2008, for physician-administered claims in an outpatient hospital setting.

The Code of Maryland Regulations (COMAR) 10.09.02.07(B) states that claims that are not properly completed may be returned to providers for completion before they are paid. Through its provider transmittals, the State agency notified providers that it 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 DRUGS

The State agency improperly claimed Federal reimbursement of $5,785,472 ($3,488,705 Federal share) for 11,718 claim lines for which it did not collect rebates. The claim lines were submitted by physicians in an office setting using paper forms that included a field for the NDC. However, the State agency did not capture the NDCs, and the State agency did not provide to the contractors any utilization data on these claims.

The claim lines for the paper claims that the State agency supplied to us identified the drugs by HCPCS. We used CMS's Medicare Part B crosswalk to match the HCPCS codes to NDCs listed in the CMS Medicaid Drug File.[8] We determined that the State agency paid:

- $5,646,233 ($3,404,316 Federal share) for 6,141 claim lines for single-source drugs administered by physicians and

- $139,239 ($84,389 Federal share) for 5,577 claim lines for top-20 multiple-source drugs administered by physicians.

Because the State agency did not submit to its contractors drug utilization data, including NDCs, and did not bill for rebates on these physician-administered drugs, the claims are not eligible for Federal reimbursement.

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

We were unable to determine whether the State agency improperly claimed Federal reimbursement for $3,556,969 ($2,303,377 Federal share) for 45,465 claim lines paid for physician-administered drugs. Providers submitted these claims on paper forms that included a field for the NDC. However, the State agency did not capture the NDCs and did not provide to the contractors any utilization data on these claims. As a result, the contractors did not bill the manufacturers for rebates on the State agency's behalf. The State agency paid:

- $2,370,009 ($1,450,046 Federal share) for 31,833 claim lines submitted for outpatient hospital physician-administered drugs for which the claim lines contained revenue codes that did not provide sufficient information to identify the NDC and

- $666,384 ($541,847 Federal share) for 4,013 claim lines submitted 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 did not include an NDC that appeared on the Medicaid Drug File.

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.

We identified an additional $520,576 ($311,484 Federal share) for 9,619 claim lines submitted for drugs administered by a physician in an office setting. These claim lines 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

[8] 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. We also used this crosswalk to match the HCPCS codes to NDCs listed in the CMS Medicaid Drug File.

top-20 multiple-source drugs, State agency officials advised us that the contractors billed for rebates on non-top-20 multiple-source drugs claimed on electronic forms. Because the State agency required providers to submit NDCs on all drug claims and billed manufacturers for all NDCs it captured, it should have captured the NDCs and directed its contractors to bill manufacturers for rebates on non-top-20 drug claims submitted on paper forms as well.

Accordingly, we set aside $3,556,969 ($2,303,377 Federal share) for CMS's adjudication.

THE STATE AGENCY DID NOT CAPTURE NATIONAL DRUG CODES AND BILL FOR REBATES ASSOCIATED WITH DRUGS CLAIMED ON PAPER FORMS

The State agency required providers to include the NDC on physician office and hospital outpatient claims submitted electronically or on paper. However, the State agency said that it did not create a data field to capture the NDCs from the paper claims in the State's MMIS or implement edits to deny these paper claims for payment because of higher priority demands on its resources. As a result, the State agency did not submit drug utilization data to contractors, 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 $3,488,705 (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 portion of the $2,303,377 (Federal share) for other outpatient physician-administered drug claims that was 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;
- update its MMIS edits to require NDCs for payment on all drug claims; and
- establish and implement processes to ensure that all physician-administered drug claims, including claims submitted on paper forms, are processed for rebates.

STATE AGENCY COMMENTS AND OUR RESPONSE

In written comments on our draft report, the State agency concurred with our recommendations in principle but requested that we reduce the unallowable amount to take into account the actions it has taken. The State agency also requested that we modify our report to indicate that it did not capture the NDCs from the paper claims because of higher priority demands on its resources. The State agency described corrective actions it has taken or plans to take.

We did not audit the State agency's actions because they were outside our audit period; therefore, we did not modify our recommendations. However, we modified our report to reflect the State agency's explanation.

The State agency's comments are included in their entirety as Appendix D.

OTHER MATTERS

The State agency reported negative beginning and ending accounts receivable balances for rebates on its Medicaid Drug Rebate Schedule. Specifically, the December 31, 2010, accounts receivable balance for rebates (for both pharmacy and physician-administered drugs) totaled approximately negative $103 million.[9] The accounts receivable rebate balance indicates the amount of outstanding rebates due from drug manufacturers and generally should be a positive balance.

Because the accounts receivable balances included rebates for drugs dispensed through pharmacies, which were outside the scope of our audit, we were unable to reconcile the balance and determine the extent to which Federal reimbursement was affected.

[9] We did not review pharmacy-dispensed drugs in this review; however, State agency officials agreed with our observations.

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
Medicaid Rebates for Physician-Administered Drugs	OEI-03-02-00660	4/2004
States' Collection of Medicaid Rebates for Physician-Administered Drugs	OEI-03-09-00410	6/2011
Nationwide Rollup Report for Medicaid Drug Rebate Collections	A-06-10-00011	8/2011

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered $38,408,124 that the State agency claimed for physician-administered drugs: $29,030,751 claimed electronically and $9,377,373 claimed on paper forms. The claims were for drugs administered in a physician's office and paid between January 1, 2008, and December 31, 2010, and drugs administered by a physician in a hospital outpatient setting and paid between July 1, 2008, and December 31, 2010.[10]

Our audit objective did not require an understanding or assessment of the complete internal 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 Baltimore, Maryland, from October through December 2011.

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 drug rebate process for physician-administered drugs;
- tested the billing and collection of rebates by:
    - obtaining from the State agency the calendar year 2010 fourth-quarter summary drug utilization information submitted to the contractors for physician-

[10] 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. We also excluded outpatient hospital claims paid during the audit period for services provided prior to July 1, 2008.

administered drugs ($2,566,232 for drugs administered in an outpatient hospital setting and $242,630 for drugs administered by a physician in an office);

- judgmentally selecting, from the quarter, summary drug utilization information for 34 NDCs associated with 16 manufacturers that represented drugs with high utilization ($969,065 outpatient hospital claims and $209,157 physician office claims); 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 NDCs;

- determined that the information provided did not account for all of the drug utilization for the sampled calendar quarter;

- obtained from the State agency information that paper claims had not been submitted to the contractors because the MMIS system had not captured the NDCs;

- obtained claim details for 57,285 claim lines that the State agency had not submitted to the contractors to bill for rebates and:

  - identified drug utilization based on 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; and

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

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).[11]

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

STATE REGULATIONS AND GUIDANCE

The Code of Maryland Regulations (COMAR) 10.09.02.07(B) states that the State agency reserves the right to return to the provider, before payment, all claims not properly signed, completed, and accompanied by properly completed forms.

Maryland General Provider Transmittal No. 64 states that, beginning January 1, 2008, Maryland will not reimburse physicians' offices for drugs unless the claim form reports a valid 11-digit NDC and quantity dispensed.

Maryland Dialysis Transmittal No. 1 and General Provider Transmittal No. 67 state that, effective September 1, 2008 (for claims for drugs administered on or after July 1, 2008), outpatient hospital providers who bill using the hospital claim form must include a valid 11-digit NDC.

APPENDIX D: STATE AGENCY COMMENTS

APPENDIX D: STATE AGENCY COMMENTS

STATE OF MARYLAND
DHMH
Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201
Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

September 20, 2013

Mr. Stephen Virbitsky
Regional Inspector General for Audit Services
United States Department of Health and Human Services
Public Ledger Building, Room 316
150 S. Independence Mall West
Philadelphia, PA 19106

Report Number: A-03-12-00200

Dear Mr. Virbitsky.

This letter is in response to a draft report from the Department of Health and Human Services' Office of the Inspector General entitled *Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs.* The Department of Health and Mental Hygiene (Department) has reviewed the report and our comments are attached.

We appreciate the opportunity to review the draft report and submit our comments. If you have any additional questions for the Department, please contact me or Thomas V. Russell, Inspector General, at (410) 767-5862.

Sincerely,

[redacted]

Joshua M. Sharfstein, M.D.
Secretary

Attachments

cc: Charles Milligan, Deputy Secretary, Health Care Financing Administration, DHMH
Keith Sewell, Executive Director, Office of Systems, Operations and Pharmacy, DHMH
Athos Alexandrou, Director. Pharmacy Services, DHMH
Thomas V. Russell, Inspector General, DHMH
Ellwood Hall Jr., Assistant Inspector General, DHMH
Nicole Freda, Audit Manager, DHHS, OIG

Toll Free: 1-877-4MD-DHMH—TTY/Maryland Relay Service 1-800-735-2258
Web Site: www.dhmh.maryland.gov

Maryland Department of Health and Mental Hygiene
Response to HHS OIG Draft Audit Report
Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs
Report Number: A-03-12-00200

Auditor's Recommendation:
We recommend that the State agency refund $3,488,705 (Federal share) for single-source and top-20 multiple source physician-administered drug claims that were ineligible for Federal reimbursement.

Department's Response:
The Department concurs with the recommendation that the State agency refund the Federal share for single-source and top-20 multiple source physician administered drug claims that were ineligible for Federal reimbursement. However, we do not concur that the refund amount should be $3,488,705. Since the Exit Conference, the Department has been able to identify those claims with single-source drugs for which there is a unique respective NDC and therefore, will invoice the respective drug manufacturers for rebates. The reimbursement amount for these claims is $1,511,662 ($934,758 Federal share). Therefore, the refund amount in the report should be reduced to $2,553,947 (Federal share).

Auditor's Recommendation:
We recommend that the State agency work with CMS to determine the portion of the $2,303.377 (Federal share) for other outpatient physician-administered drug claims that was ineligible for Federal reimbursement and refund that amount.

Department's Response:
The Department concurs with the recommendation and will work with CMS to determine the portion of the $2,303,377 (Federal share) for other outpatient physician-administered drug claims that was ineligible for Federal reimbursement and refund that amount.

Auditor's Recommendation:
We recommend that the State agency work with CMS to determine and refund the unallowable Federal reimbursement for physician-administered drugs claimed without NDCs after January 1, 2011.

Department's Response:
The Department concurs with the recommendation and we are in the process of gathering and analyzing data for claims paid after January 1, 2011. Once the analysis is complete we will work with CMS to determine any unallowable Federal reimbursement for physician-administered drugs claimed without NDCs after January 1, 2011, and refund accordingly.

Auditor's Recommendation:
We recommend that the State agency update its MMIS edits to require NDCs for payment on all drug claims.

Department's Response:
The Department concurs with the recommendation. The MMIS edits to require NDCs for payment on all drug claims were updated on July 15, 2013

Auditor's Recommendation:
We recommend that the State agency establish and implement processes to ensure that all physician-administered drug claims, including claims submitted on paper forms, are processed for rebates.

Maryland Department of Health and Mental Hygiene
Response to HHS OIG Draft Audit Report
Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs
Report Number: A-03-12-00200

Department's Response:
The Department concurs with the recommendation and has already updated the MMIS edits to require NDCs for payment on all drug claims. In addition, we will create a process to ensure and reconcile that all physician administered drug claims, including claims submitted on paper forms, are identified, provided to our rebates contractor and processed for rebates.

DHMH Other Comments

The Department has reviewed the HHS OIG draft audit report and finds further clarification is necessary to the portion of the report where it is stated that "the State agency said that it did not have time to create a data field to enter the NDCs from the paper claims in the State's Medicaid Management Information System (MMIS) or to implement edits to deny these paper claims for payment" (Executive Summary Section, page ii and Findings section, pages 4 and 6).

In order to comply with the constantly changing Federal Healthcare laws and programs, as well as State legislative mandates, the Department has to prioritize its programming resources based upon the monetary impact to the Department. The Department did implement in a timely manner the necessary steps to capture the NDCs for the electronic claims which represent the majority of the physician-administered drugs. Because of higher priority demands, the remaining requirements for implementing edits requiring the inclusion of an NDC on the paper claims and for creating a data field in MMIS to capture the NDCs could not be implemented until July 15, 2013.

Additionally, the Department would like to provide clarification to the portion of the report where it is stated that "the State agency reported negative beginning and ending accounts receivable balances for rebates on its Medicaid Drug Rebate Schedule" (Other Matters Section, page 6).

The Medicaid Drug Rebate Schedule reflected a negative balance of $103 million due to the delayed receipt from CMS of the Unit Rebate Amount (URA) information in 2010. As required by federal regulations, States must submit to each manufacturer utilization data on a quarterly basis based on their records, but it remains the responsibility of the labeler to correctly calculate the rebate amount due. Therefore, all of the 2010 quarters were invoiced utilization data only to the manufacturers with zero amounts due shown on the invoices. Each labeler remitted their payments as required by the federal regulations, and the payments were reflected on the CMS 64.9R for each applicable quarter.

Upon receipt of the URA information from CMS, a re-calculation of the 2010 quarters was performed and an adjusted entry was submitted on the report for quarter ended September 30, 2011.

The Federal reimbursement was not affected by the negative balance because it is drawn based upon the following lines on the Form CMS 64.9R:

- Line 2 – Adjustments to Previously Reported Rebates from Drug Labelers Included in Line 1.
- Line 5 – Rebates Reported on This Expenditure Report.

The Balance as of the End of the Quarter, Line 6, is not taken into consideration to determine the federal reimbursement amount.

The Department is also requesting that the name of the Point of Sale (POS) Contractor be changed from ACS State Healthcare, LLC to Xerox State Healthcare, LLC (Introduction Section, page 2).

Finally, there is a correction that must be made under the Executive Summary Section, page ii, first paragraph: the reimbursement amount should change from $5,785,475 to $5,785,472.